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DESMITIFICANDO PROTOCOLOS ADESIVOS E RESTAURADORES: RESINA COMPOSTA PRÉ-AQUECIDA APRESENTA MELHOR DESEMPENHO CLÍNICO EM LESÕES CERVICAIS NÃO CARIOSAS?

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Tese apresentada ao Programa de Pós-graduação Stricto sensu em Odontologia da Universidade Estadual de Ponta Grossa, como requisito parcial à obtenção do título de Doutor em Odontologia, área de concentração em Dentística Restauradora, linha de pesquisa de Pesquisa Clínica em Odontologia.

Ponta Grossa, 26 de abril de 2024.

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A vida é uma mistura de circunstâncias favoráveis e desfavoráveis, mas essa dualidade é essencial para o nosso crescimento. Devemos estar abertos para aprender com nossos erros e acertos, pois são experiências únicas que só nós podemos vivenciar. Enquanto pode parecer complicado, a vida também é surpreendentemente simples quando aprendemos a aproveitar o que está a nosso favor e a conviver com o que não está. Eventualmente, alcançaremos nosso potencial máximo e apreciaremos a jornada, reconhecendo que as coisas são como devem ser.

RESUMO

Favoreto, M. W. **Desmitificando protocolos adesivos e restauradores: Resina composta pré-aquecida apresenta melhor desempenho clínico em lesões cervicais não cariosas?** Orientadora: Alessandra Reis. Ponta Grossa, 2024. Tese (Doutorado em Odontologia – Área de Concentração - Dentística Restauradora), Universidade Estadual de Ponta Grossa, Ponta Grossa, 2024.

As investigações laboratoriais desempenham um papel fundamental no avanço da ciência. No entanto, para validar suas descobertas, é crucial conduzir estudos clínicos, onde uma infinidade de variáveis, conhecidas e desconhecidas, bem como mecanismos complexos, estão presentes. Basear recomendações clínicas apenas em conclusões de estudos laboratoriais pode resultar em "verdades" generalizadas, muitas vezes infundadas, ou até mesmo em mitos, em qualquer campo do conhecimento. Esses equívocos podem acarretar custos financeiros e tempo, ou até mesmo em danos, como efeitos colaterais indesejados, uma vez que o protocolo ou conduta atual já foi submetido a uma avaliação mais ampla e complexa em ambiente clínico. Ao longo desta tese, serão explorados alguns mitos relacionados à união adesiva à dentina, os quais podem influenciar as decisões clínicas. Para isso, serão aplicados princípios de prática baseada em evidências, permitindo uma análise criteriosa das descobertas presentes na literatura. Na odontologia adesiva e restauradora, diversos mitos permeiam a prática, como o aquecimento da resina composta para restaurações diretas. Por mais que os resultados laboratoriais sejam positivos em relação ao aquecimento, poucos são os estudos clínicos disponíveis na literatura que confirma a prática. Com o objetivo de desmistificar esta prática, dois ensaios clínicos randomizados, duplo-cegos e de boca dividida, acompanhados por 24 meses, foram conduzidos para avaliar as taxas de fratura e retenção em lesões cervicais não cariosas. O primeiro comparou uma resina composta termoviscosa pré-aquecida com outra não aquecida, enquanto o segundo investigou o método mais eficaz de aquecimento da resina composta, utilizando um dispositivo dispensador para cápsulas unidose associado ao dispositivo de pré-aquecimento ou um dispensador e aquecedor de cápsulas unidose. Independentemente do método de aquecimento ou da presença ou não do aquecimento, ambos os estudos demonstraram altas taxas de retenção após o período de 24 meses. Por mais que o aquecimento demonstre resultados promissores in vitro, as avaliações clínicas até 24 meses não demonstram nenhum benefício clinicamente importante da técnica.

Palavras-chave: Adesivos Dentinários; Odontologia Baseada em Evidências; Prática Clínica Baseada em Evidências; Ensaio Clínico Controlado Aleatório; Resinas Compostas; Temperatura; Viscosidade.

ABSTRACT

Favoreto, M. W. **Demystifying adhesive and restorative protocols: Does preheated composite resin exhibit better clinical performance in non-carious cervical lesions?** Advisor: Alessandra Reis. Ponta Grossa, 2024. Thesis (Doctorate in Dentistry - Concentration Area: Restorative Dentistry), State University of Ponta Grossa, Ponta Grossa, 2024.

Laboratory investigations play a fundamental role in advancing science. However, to validate their findings, it is crucial to conduct clinical studies, where a multitude of variables, known and unknown, as well as complex mechanisms, are present. Relying solely on conclusions drawn from laboratory studies to make clinical recommendations can result in generalized "truths," often unfounded, or even myths, in any field of knowledge. These misconceptions can lead to financial and time costs, or even to harm, such as unwanted side effects since the current protocol or practice have already undergone a broader and more comprehensive evaluation in a clinical setting. Throughout this thesis, some myths related to dentin bonding, which can influence clinical decisions, will be explored. For this purpose, principles of evidence-based practice will be applied, allowing for a thorough analysis of the findings present in the literature. In adhesive and restorative dentistry, various myths pervade practice, such as the preheating of composite resin for direct restorations. Despite positive laboratory results regarding preheating, few clinical studies are available in the literature. To debunk this practice, two randomized, double-blind, split-mouth clinical trials, with a 24-month follow-up, were conducted to assess retention fracture rates in non-carious cervical lesions. The first compared a preheated thermoviscous composite resin with one that was not preheated, while the second investigated the most effective method of preheating the composite resin, using a Caps dispenser device associated with the Caps Warmer or a VisCalor Caps Dispenser/Warmer. Regardless of the preheating method or the presence of heating, both studies demonstrated high retention rates after the 24-month period. Even though heating demonstrates promising results in vitro, clinical evaluations up to 24 months do not demonstrate any clinically important benefit of the technique.

Keywords: Dentin Bonding Agents; Evidence-Based dentistry; Evidence-Based Practice; Randomized Controlled Trial; Composite Resins; Temperature; Viscosity.

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LISTA DE ABREVIATURAS E SIGLAS

10-MDP	10-methacryloyloxydecyl dihydrogen phosphate
BS	Bonding strength
REBEC	Brazilian Clinical Trials Registry
CD	Caps Warmer
CHX	Chlorhexidine
CI	Confidence interval
CNPq	Conselho Nacional de Desenvolvimento Científico e Tecnológico
CAPES	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior
EBP	Evidence-based practice
HRs	Hazard ratios
NCCLs	Non-carious cervical lesions
NHT	Non-heating; Non-heated composite resin
ASA I	Normal healthy patient
NNT	Number needed to treat
ASA II	Patients with mild systemic disease without substantial functional limitations
POS	Post-operative sensitivity
PHT	Preheating; Preheated thermoviscous composite resin
RCTs	Randomized controlled trials
RoB	Risk of bias
OHI-S	Simplified Oral Hygiene Index
SRs	Systematic reviews
VD	VisCalor Caps dispenser/warmer
FDI	World Federation criteria

LISTA DE SÍMBOLOS

=	Igual
±	Mais ou menos
<	Menor
>	Maior
%	Porcentagem
p	Valor da significância estatística
®	Marca Registrada

SUMÁRIO

1 INTRODUÇÃO

A prática da odontologia evoluiu significativamente nos últimos anos. A eficácia superior dos sistemas adesivos atuais possibilitou o desenvolvimento de procedimentos restauradores minimamente invasivos e estéticos, aumentando o papel da odontologia na saúde e autoestima dos pacientes [1].

Apesar da melhoria desses sistemas adesivos, estudos in vitro relataram quedas significativas na resistência de união após o armazenamento de curto e longo prazo [2; 3; 4]. Também, têm sido observados diversos problemas clínicos, tais como a queda e fratura das restaurações, a sensibilidade pós-operatória e a descoloração marginal [5]. Esses desafios têm direcionado a atenção dos pesquisadores para a avaliação dos mecanismos de envelhecimento da interface adesiva entre os materiais e a estrutura dental. Além disso, tem-se dedicado esforços aos estudos laboratoriais com o objetivo de explorar protocolos e materiais que possam diminuir a degradação da camada híbrida [6].

As investigações laboratoriais desempenham um papel fundamental na pesquisa odontológica, impulsionando o progresso científico. Estes estudos representam o estágio inicial da pesquisa, fundamental para avançar o conhecimento e expandir as fronteiras científicas. No entanto, é crucial reconhecer que qualquer avanço obtido em ambiente laboratorial deve ser validado em um contexto clínico mais complexo. Isso se deve ao fato de que inúmeras variáveis, conhecidas e desconhecidas, podem influenciar a eficácia e longevidade das restaurações.

A utilização de pesquisas laboratoriais para embasar protocolos é comum, em parte, devido à rapidez com que os resultados podem ser obtidos, em questão de semanas e com um número maior de amostras. Em contraste, a obtenção de achados clínicos confiáveis demanda anos de estudo e enfrenta uma série de dificuldades adicionais, como desistências de pacientes, custos de pesquisa e potenciais mudanças na composição dos materiais ao longo do estudo.

Infelizmente, é comum observar renomados professores oferecendo recomendações clínicas com base exclusivamente em estudos laboratoriais, propagando inconscientemente protocolos que não são confirmados em ensaios clínicos, tornando-se mitos [7; 8]. Embora nosso senso comum rotineiramente relacione “mito” a contos ou parábolas, nas ciências da saúde, um mito pode ser descrito como

um fato que geralmente não tem origens claras e retrata uma crença em um fenômeno biológico ou protocolo de saúde sem evidências clínicas.

Esses mitos persistem ao longo do tempo sem uma base de evidências substantivas, particularmente quando aumentados pela autoridade ou proclamados a partir da opinião de especialistas [7; 9; 10]. Os mitos são confundidos com evidências quando compartilhados rotineiramente e ritualisticamente, ganhando credibilidade com repetição e reiteração. E isso se materializa com bastante frequência nos livros didáticos odontológicos e, mais recentemente, nas mídias sociais. Geralmente há uma explicação coerente e plausível por trás de qualquer mito.

A aceitação de mitos pode resultar em consequências adversas significativas, incluindo aumento dos custos (em termos de efeitos colaterais, impactos financeiros, tempo, entre outros) e potencialmente danos aos pacientes, como a redução da durabilidade das restaurações e perda de substrato dental. Estes problemas poderiam ser evitados se os materiais fossem submetidos a avaliações rigorosas em ensaios clínicos randomizados.

Essa explicação sobre nossa propensão a acreditar em mitos é embasada pela teoria descrita no livro "Thinking, Fast and Slow" de Daniel Kahneman [11], que delineia os dois sistemas de julgamento e escolha que guiam nossas decisões. O "sistema 1" opera de forma automática e rápida, baseando-se em intuições e emoções, enquanto o "sistema 2" envolve processos de pensamento mais deliberados, lógicos e analíticos, mas também mais lentos. Embora esses sistemas não tenham fronteiras entre si, o sistema 1 tende a predominar em situações em que a rapidez e a eficiência são prioritárias, muitas vezes levando-nos a aceitar mitos ou informações não verificadas sem questionamento.

A maioria das nossas decisões e impressões são formadas de maneira involuntária e emergem inconscientemente através do sistema 1. Esse processo permite lidar de forma precisa com uma grande quantidade de informações em um curto espaço de tempo, sendo essencial para a nossa sobrevivência em situações do dia a dia [11]. No entanto, o sistema 1 carece da capacidade de pensamento crítico. O ceticismo necessário na ciência é uma habilidade que somente o sistema 2 pode fornecer. Portanto, é fundamental questionar constantemente a veracidade de qualquer declaração ou crença presente na literatura, perguntando-se: "Isso é

realmente verdade?". Este exercício de avaliação crítica é fundamental para discernir informações confiáveis e fundamentadas.

Aplicar o pensamento cético de forma eficaz requer o esforço mental do sistema 2. É mais fácil e menos exigente utilizar as associações automáticas endossadas pelo sistema 1 do que mobilizar a atenção do sistema consciente, que é mais lento e consome mais recursos cognitivos. Essa é a razão pela qual somos naturalmente propensos a acreditar em mitos e informações não verificadas, pois é mais cômodo seguir o caminho do pensamento automático e intuitivo do sistema 1. No entanto, ao cultivar a consciência crítica e questionadora, podemos desenvolver a capacidade de ativar o sistema 2 de forma mais deliberada e discernir com mais acuidade a veracidade das informações que encontramos.

Existem diversos protocolos na odontologia restauradora e adesiva que são propagados com base em resultados positivos de estudos laboratoriais que não foram confirmados dentro de estudos clínicos, um deles é pré-aquecimento da resina composta para restaurações diretas. Essa técnica in vitro demostrou o aumento do grau de conversão e das propriedades mecânicas da resina composta, enquanto torna o composto regular ou de alta viscosidade mais fluido durante a aplicação [12; 13; 14]. Vários dispositivos estão disponíveis no mercado odontológico para esse fim, como o aquecedor Calset (AdDent Inc., Danbury, CT, EUA), aquecedor ENA HEAT (Micerium, Avegno GE, Itália) e o Caps Warmer (Voco GmbH, Cuxhaven, Alemanha), sendo algumas das opções mais comuns. Esses dispositivos oferecem temperaturas operacionais que variam de 37°C a 68°C [12; 13; 14].

Recentemente, foi introduzido um novo material bulk-fill termovisco chamado VisCalor bulk (Voco GmbH em Cuxhaven, Alemanha). Esse material permite o pré-aquecimento de até 68°C utilizando o dispositivo Caps Warmer (Voco GmbH em Cuxhaven, Alemanha). O pré-aquecimento demonstrou ser vantajoso em estudos in vitro, facilitando a inserção do material sem qualquer ativação térmica que causasse polimerização prematura[15; 16]. Além disso, o pré-aquecimento demonstrou reduzir a ocorrência de bolhas internas quando comparado a outras técnicas [15; 16; 17; 18]. Essa abordagem garante um alto grau de conversão e, como resultado, propriedades mecânicas elevadas em comparação com outros materiais não pré-aquecidos [19; 20]. Em essência, o preenchimento da VisCalor combina a fluidez de uma resina composta de baixa viscosidade durante a aplicação quando aquecido com a característica de

manuseio da resina composta de alta viscosidade, permitindo a inserção e escultura em incrementos de até 4 mm [21].

Apesar dos resultados de estudos in vitro promissores para resinas compostas pré-aquecidas [15; 16], um exame mais detalhado dos estudos clínicos que avaliaram o impacto do pré-aquecimento em resinas compostas revela resultados conflitantes [22; 23; 24; 25; 26; 27]. Enquanto alguns estudos observam resultados semelhantes em termos de adaptação marginal e descoloração marginal, outros demonstram um benefício quando a resina composta é submetida ao aquecimento. É importante destacar que esses estudos se concentram nas cavidades posteriores [22; 23; 24; 25; 26; 27]. No entanto, até onde os autores sabem, nenhum estudo clínico ainda foi realizado para comparar o desempenho clínico desta nova resina composta termoviscosa em contraste com a resina composta não aquecida.

Além disso, está resina é apresentada na forma de cápsula e oferece diversas opções de aquecimento. Os dispositivos de bancada geralmente exigem um longo período de pré-aquecimento, em torno de 20 minutos, além de mais 3 minutos para pré-aquecer a resina [28; 29; 30]. Esse tempo prolongado vai contra o objetivo de simplificar os procedimentos odontológicos, comprometendo a eficiência dos protocolos clínicos. O desenvolvimento de um aquecedor dispensador (VisCalor dispenser, Voco GmbH, Cuxhaven, Alemanha) une o aquecimento e o manuseio, torna o procedimento mais rápido, pois não requer tempo de pré-aquecimento do aparelhp e permite que a resina composta atinja a temperatura adequada para colocação na cavidade em até 30 segundos [22; 25; 26; 30].

Apesar dos resultados promissores observados em laboratório em relação a diferentes formas de pré-aquecimento da resina composta [31], as recomendações clínicas devem basear-se principalmente em evidências coletadas de estudos clínicos [8]. Até o momento, um número limitado de investigações clínicas controladas explorou os efeitos do pré-aquecimento de resinas compostas, com uma lacuna notável na literatura em relação a comparações entre diferentes métodos de pré-aquecimento (aquecedor de bancada vs. aquecedor dispensador) para resina composta termoviscosa bulk-fill [8]. Portanto, até onde se sabe, faltam estudos comparando o desempenho clínico dessas novas resinas compostas bulk-fill termoviscosas utilizando os diferentes métodos de pré-aquecimento mencionados acima.

2 PROPOSIÇÃO

2.1 PROPOSIÇÃO GERAL

Desmistificar alguns protocolos adesivos e restauradores através da avaliação crítica dos achados da literatura e trazer respostas clínicas através de estudos clínicos randomizados sobre a influência do aquecimento de resina composta para restaurações diretas em lesões cervicais não cariosas.

2.2 PROPOSIÇÕES ESPECÍFICAS

Revisar alguns mitos na união adesiva a dentina que podem influenciar a tomada de decisão clínica, trazendo alguns princípios da prática baseada em evidências para permitir uma avaliação mais crítica dos achados da literatura.

Comparar o desempenho clínico (fratura e retenção) de uma resina composta pré-aquecida comparada a uma resina composta não aquecida em lesões cervicais não cariosas através de um ensaio clínico randomizado de equivalência, duplo-cego, boca dividida, por 6, 12, 18 e 24 meses.

Comparar o desempenho clínico (fratura e retenção) de uma resina composta termoviscosa bulk-fill pré-aquecida colocadas em lesões cervicais não cariosas utilizando dois métodos de aquecimento distintos: aquecedor de bancada (Caps warmer device com Caps dispenser) versus um aquecedor dispenser (VisCalor dispenser) através de um ensaio clínico randomizado de equivalência, duplo-cego e de boca dividida, durante um período de acompanhamento de 24 meses.

3 MATERIAIS E MÉTODO

A descrição abrangente dos materiais e método utilizados em cada artigo pode ser encontrada na próxima seção de cada artigo individual, oferecendo aos leitores uma compreensão detalhada da metodologia empregada em cada estudo.

4 ARTIGO 1 - SOME MYTHS IN DENTIN BONDING: AN EVIDENCE-BASED PERSPECTIVE

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Abstract

Laboratory investigations are essential models responsible for science development. However, laboratory discoveries must be confirmed in a clinical environment where many known and unknown variables and complex mechanisms are involved. Using conclusions from laboratory studies to make clinical recommendations can lead to widespread “unreliable truths” or so-called myths in any field of knowledge. These myths may increase the costs (financial and time) or even cause harm (side effects) that would be unnecessary, given that the current protocol or conduct was previously evaluated in a more complex and complete clinical setting. This article will discuss certain myths in dentin bonding that may influence clinical decision-making, bringing some principles of evidence-based practice to allow a more critical evaluation of the literature findings.

Introduction

The practice of dentistry has evolved significantly over the past years. The superior efficacy of the current adhesives developed minimally invasive and esthetic

restorative procedures, enhancing the role of dentistry in patients' health and self-esteem (Van Meerbeek et al. 2020).

Despite the adhesives' improvements, significant drops in bonding strength (BS) after short- and long-term storage have been reported (Carvalho et al. 2012; Perdigão et al. 2013; Breschi et al. 2018). In addition, restoration debonding, postoperative sensitivity, and marginal discoloration have been some observable clinical issues (Mahn et al. 2015). These problems shifted researchers' focus to evaluating the aging mechanisms of the resin-bonded interface and conducting laboratory studies to explore protocols and materials to lessen the degradation of the hybrid layer (Reis et al. 2013).

Laboratory investigations are essential in dental research as they initiate scientific progress. However, any laboratory breakthrough should be validated in a clinical environment as many other known and unknown variables can make the one investigated trivial or irrelevant for restoration longevity. It is common to see renowned lecturers making clinical recommendations based on laboratory studies, unconsciously spreading protocols that eventually are not confirmed in clinical trials, becoming myths. This uncritical acceptance of myths may increase the costs (side effects, financial, time, etc.) and even cause harm to patients (decreased durability, increased loss of tooth substance) that could be avoided with controlled trials.

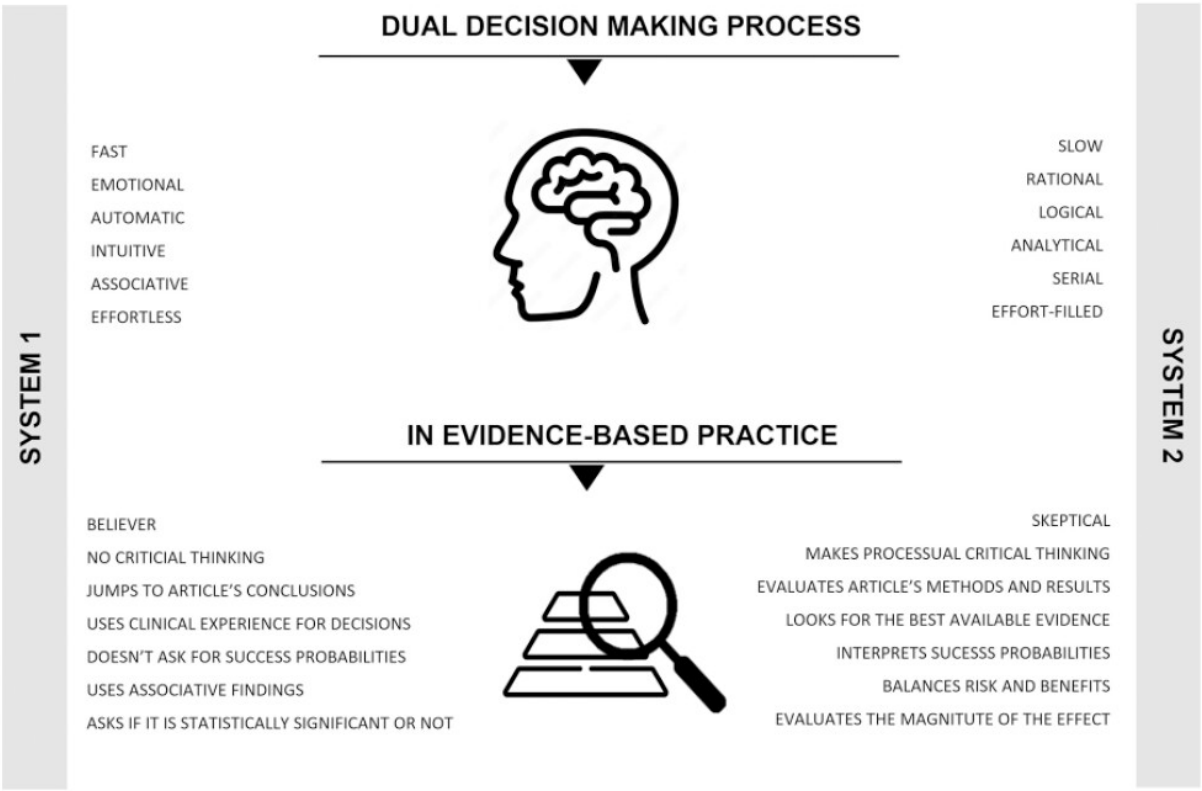
The use of laboratory research to support protocols is probably done because results can be gathered within weeks, while trustworthy clinical findings take years to collect, apart from other difficulties such as patient dropouts, research costs, and changes in materials composition during the study. This article discusses why we are so prone to believe in myths and presents some dentin-bonding myths that influence clinical restorative procedures from the perspective of evidence-based practice (EBP) principles.

Why Are We So Prone to Believe in Myths?

In his book *Thinking, Fast and Slow*, Kahneman (Kahneman and Egan 2011) describes our 2-system approach to judgment and choice. The automatic functions of "system 1" and the controlled functions of "system 2" are the core of decision-making processes in all our activities. While there are no absolute borders between the 2

systems, we can think of system 1 as rapid, automatic, effortless, and emotional. In contrast, system 2 is conscious, logical, and analytical but much slower (Figure 1).

Figure 1 - Characteristics of the dual decision-making processes involving system 1 and system 2 and their influence on critical thinking in evidence-based practice.



Most of our decisions and impressions are involuntary and arise unconsciously knowing how they got there (system 1). This thought process allows us to accurately deal with much information from any scene in milliseconds (Kahneman and Egan 2011). However, system 1 is incapable of critical thinking. The sense of skepticism required in science is an ability only system 2 can deal with. The question “Is this really true?” should be asked by evaluating any statement or belief published in the literature.

Applying this skeptical thinking requires mental effort from system 2. It is easier and more effortless to use associations endorsed by system 1 than to mobilize the attention of the conscious, relatively slow, and resource-intensive system 2 and thus the reason why we are prone to believe in myths.

An approach to making system 2 oversee the decision-making process is to use the null hypothesis principle to guide EBP. We should assume that a potential treatment does not exist until the evidence shows otherwise. The burden of the proof

should always be on treatment efficacy. The Evidence-Based Medicine Working Group (1992) reported that “the practice of an EBP should de-emphasize intuition, clinical expertise, and pathophysiologic rationale ... focusing on evidence from clinical research.”

Where Do Laboratory Studies Stand on the Scientific Evidence Hierarchy?

Laboratory testing is the earliest research stage to advance knowledge and expand science borders. Researchers can perform extensive tests with more samples than would be possibly done in human trials. However, laboratory testing cannot replicate the complex conditions inside a living organism, where far more biological variables are in play. Laboratory models account for some but not all interactions between materials and the challenging conditions inside the buccal cavity.

Thus, we should interpret laboratory data with caution, as results do not necessarily predict the clinical performance of any material/protocol. Clinical trials should be conducted to explore whether the effect of the variable is relevant in a clinical setting.

The first and earliest principle of EBP indicated that a hierarchy of evidence exists (Graves 2002). Although the study design is insufficient to rate the certainty of the evidence, well-conducted designs can roughly be seen as a pyramid with weaker study designs (more prone to bias) at the bottom (case series), followed by case-control, cohort studies, and, above all, randomized controlled trials (RCTs). Well-conducted and appropriately discussed systematic literature reviews can be seen as a lens that critically appraises and summarizes clinical studies (Murad et al. 2016).

This hierarchy of evidence does not contemplate laboratory studies, as only RCTs can provide clinicians with probabilities of success and failure of any given protocol. The trade-offs between the benefits and risks, costs, patients’ values, preferences, and clinical expertise are the core of EBP.

Unfortunately, in dental materials, laboratory findings may be believed to be prematurely true without clinical evidence support. A classic example in dentistry was the gallium amalgam (Okamoto and Horibe 1991). In the early 1990s, many researchers studied the mechanical properties, microstructure, toxicity, and handling characteristics of gallium alloys to replace silver amalgam (McComb 1998). One alloy

was approved by the American Dental Association, Food and Drug Administration, and Nordic Institute of Dental Materials.

Although some properties of gallium-based dental alloys equaled those of silver amalgam in vitro, their clinical behavior significantly differed. Corrosion, discoloration, rough surface, expansion, postoperative sensitivity, and fractures were serious problems that RCTs identified at a later moment (Osborne and Summitt 1999; Kiremitci and Bolay 2003; Dunne et al. 2005).

Some Myths about Dentin Bonding

Although our common sense routinely relates “myth” to tales or parables, in health sciences, a myth can be described as a fact that usually does not have clear origins and depicts a belief in a biological phenomenon or health care protocol without clinical evidence.

These myths persist over time without a substantive evidence base, particularly when augmented by authority or proclaimed from expert opinion (Milgram 1963). Myths become mistaken for evidence when shared routinely and ritualistically, gaining credence with repetition and reiteration. And this materializes quite often in dental textbooks and, more recently, on social media. There is usually a coherent and plausible explanation behind any myth, making it easy for system 1 to endorse them.

Although it seems almost counterintuitive that myths persist in this era of EBP, they do in dentistry and other health care areas. We can debunk myths by applying a skeptical questioning of assumptions and searching for the best evidence.

In the sequence, some widespread protocols in dentin bonding will be revisited through the lens of the best available evidence. This article intends to cover only some dentin bonding myths. We selected the myths that would allow us to discuss some essential principles of EBP. Some other myths are summarized in Appendix Table 1.

The Etch-and-Rinse Adhesives Should Be Applied with the Wet-Bonding Protocol

The wet-bonding protocol is a good example of a procedure that became extensively used clinically, based on laboratory findings. Kanca (1992) was the first to reported higher resin-dentin BS values for adhesives applied to conditioned-wet dentin

(Kanca 1992). This protocol was reinforced by microscopy findings revealing the collapse of the demineralized collagen after air drying, which prevented resin infiltration into the entire depth of demineralization (Tay et al. 1996).

Promising laboratory findings and a reasonable and coherent theoretical basis allowed system 1 to endorse the wet-bonding procedure. Not long after, manufacturers of etch-and-rinse adhesives recommended adhesive application onto moist dentin. However, this short path from basic studies to clinical recommendations is far beyond the practice of EBP.

EBP should be grounded on skepticism. A skeptical attitude is not a view that promotes the disbelief of every truth or claim but an investigatory approach that reduces the possibility of adopting a valid claim that may not be true. The position of a skeptical thinker, in line with EBP, is to assess the evidence's validity before making a decision.

Then, we should ask whether dentin moisture is essential in a complex clinical scenario where many different variables (adhesive application, the composite resin used, light curing process, contamination, patient occlusion, etc.) play a role in restoration durability. Only RCTs, the top research design for clinical recommendations, can answer this research question.

The few RCTs that evaluated dentin moisture on restoration longevity did not report that this technique was superior to the dry bonding in cervical lesions (Perdigão et al. 2005; Zander-Grande et al. 2011) or posterior restorations (Castro et al. 2022) (Appendix Table 2). In other words, we lack high-level evidence to support this clinical recommendation, and thus we should stay with the null hypothesis that dry and wet bonding do not differ. By stating this, clinicians are given the option to choose whether they apply the wet-bonding protocol with etch-and-rinse adhesives. Other aspects, such as technical difficulties, treatment duration time, risks of making mistakes, and so on, must be balanced during the decision.

Chlorhexidine Should Be Applied to Enhance Restoration Longevity

Uncountable laboratory publications presented promising chlorhexidine (CHX) results in reducing the degradation of the BS (Pashley et al. 2004; Montagner et al. 2014). CHX is a potent inhibitor of endogenous enzymes that degrade the nonencapsulated collagen within the hybrid layer (Pashley et al. 2004).

Stable BS values were observed with CHX either applied as a separate bonding step or incorporated in conditioners (Stanislawczuk et al. 2011; Loguercio et al. 2017) and adhesive formulations with up to 5 to 10 y of water storage (Loguercio et al. 2016; Breschi et al. 2020). In an ex vivo study (Carrilho et al. 2007), restorations were performed in a clinical scenario with or without CHX application on etched dentin, but the outcomes were assessed through BS and morphology tests (Hebling et al. 2005; Carrilho et al. 2007). The authors showed that the CHX application prevented BS reductions of restorations significantly (Carrilho et al. 2007).

Some authors considered this ex vivo methodology as clinical proof of CHX efficacy in producing longer-lasting restorations. However, this methodology did not evaluate any clinically relevant outcome, which is a result that directly measures tangible patient benefits (Pannuti et al. 2020). Earlier attempts to associate BS data with clinically relevant outcomes (Van Meerbeek et al. 2010; Heintze et al. 2015) failed to establish cause and effect.

In restorative dentistry, restoration debonding, secondary caries lesions, and tooth loss are clinically relevant outcomes. Some RCTs that compared restoration debonding with and without CHX did not report clinically important differences in follow-ups up to 3 y (Araújo et al. 2015; Favetti et al. 2017) (Appendix Table 2). Without more credible and long-term evidence, we should continue with the null hypothesis that bonding with and without CHX is not different from one another (Josic et al. 2021).

Rubber Dam Isolation Is Essential to Have Long-Lasting Restorations

Contamination by moisture, saliva, and blood during adhesive protocols can jeopardize bonding. Therefore, isolation of the dental cavity before treatment implementation is essential.

Several dental schools recommend rubber dam isolation for restorative procedures (Lynch et al. 2010, 2011) due to superior saliva isolation, protection of the oral soft tissues, and prevention of instrument aspiration (Susini et al. 2007). In addition, it reduces the risk of cross-infection by decreasing the microbial content of air turbine aerosols produced during treatments (Harrel and Molinari 2004). Some systematic reviews with low-quality evidence recommended rubber dam for restoration longevity (Appendix Table 3).

Even with these advantages, we cannot simply state that successful restorations are only obtained using rubber dam isolation. All the potential benefits of rubber dam isolation are pertinent, but they are surrogate outcomes, not validated to predict restoration longevity.

A surrogate outcome is information obtained in a complementary examination and used as a substitute for clinically relevant patient outcomes. Using surrogate end points might be problematic since they are not always good representatives of tangible clinical outcomes (Fleming and DeMets 1996).

A systematic review of the literature (Miao et al. 2021) found with low certainty of evidence that rubber dam has a lower failure rate of the restorations compared with cotton roll usage after 6 months. The evidence is even more uncertain at more prolonged and relevant time points. From a clinical perspective, this means that the effect of the rubber dam on the restoration's longevity of permanent teeth remains undefinable. This was also reported in a recent RCT in deciduous teeth (Olegário et al. 2022).

In addition, we should consider the trade-offs over benefits and harms before deciding on the isolation method. The patient's acceptance may be low, mainly for mouth breathers, and there is the inconvenience of gingival tissue damage caused by clamps (Loguercio et al. 2015). Clinicians usually require more chairside time for application and spend more on materials and equipment. Other less common yet possible side effects include latex allergy to rubber dam and chipping of thin restoration margins by the metallic clamps (Miao et al. 2021).

By no means are the authors of the current review contraindicating the use of rubber dam. We are just calling the readers' attention to the lack of high-level evidence to state that rubber dam is associated with higher restoration longevity, as other factors may be pondered when choosing the isolation method for restorative protocols.

OptiBond FL and Clearfil SE Are "Gold-Standard" Adhesives

Among the 3-step etch-and-rinse and 2-step self-etch adhesives, the brands OptiBond FL (Kerr Corp.) and the Clearfil SE Bond (Kuraray) have been considered the gold-standard materials by many researchers and clinicians (Van Meerbeek et al. 2020).

Although this belief has been in the literature for more than 20 years, it became more widespread after the publication of a meta-analytical review of parameters of the BS values (De Munck et al. 2012). The authors (De Munck et al. 2012) concluded that the 2 best-performing adhesives in terms of BS were the OptiBond FL and Clearfil SE Bond.

BS tests provide laboratory results and not clinically meaningful outcomes. Ideally, EBP should use patient-oriented evidence (i.e., outcomes of importance to patients, such as restoration retention, pain, and quality of life) rather than basic results or disease-oriented evidence (e.g., biofilm accumulation, surface texture) when making clinical decisions. Thus, the endorsement of the adhesives as gold standards can only be performed if RCTs confirm.

A systematic literature review of RCTs comparing the retention rates of restorations placed with these so-called gold standards and other competitive materials (Dreweck, et al. 2021) showed that OptiBond FL was not better than other materials at short- and long-term follow-ups, and the same trend was observed for Clearfil SE Bond (Dreweck, et al. 2021) (Appendix Table 3). Although these 2 materials have excellent clinical performance (Van Dijken and Pallesen 2008; Peumans et al. 2015), they cannot be claimed as gold standards based on the evidence available.

In some countries, these 2 materials may cost at least double the price of other good-performing materials. Assuming they are gold standards, they increase the costs of restorative procedures in private and public dental care systems. In public systems, fewer restorations can be done using the same costly resources. However, this may not be a problem in countries where the price difference is insignificant.

While we should keep up with the null hypothesis principle until we get robust evidence to acclaim OptiBond FL and Clearfil SE Bond as gold-standard materials, we must also be open-minded to new literature findings.

Roughening Sclerotic Dentin May Improve Restoration Longevity

It is the function of our human mind, especially our system 1, to make coherent cause–effect connections. Due to the remarkable accuracy of the associative system 1 thinking system, we routinely apply this thinking process in our daily decisions by following what seems plausible. The problem arises when we extrapolate this thinking to more complex scenarios.

There are some situations where biological plausibility prevails, but there are numerous complex situations where plausibility is different from reality. In complex systems, like the human body system, any outcome results from a diversity of causes, which interact with one another, making it impossible to predict it just with plausibility. To clarify, we could think of the inflammatory system's complexity, where several cell types and cytokines are involved in the process.

In dentistry, let's consider bonding to sclerotic dentin. We know dentinal tubules from sclerotic dentin have partial or complete obliteration with minerals and have an acid-resistant hypermineralized layer that challenges adhesive infiltration (Tay and Pashley 2004; Perdigão 2010). Consequently, bonding to sclerotic dentin with current adhesive systems results in a lower resin-dentin BS (Tay and Pashley 2004).

As excess minerals prevent adhesive infiltration, it is plausible that its removal would make adhesive penetration easier, improving bonding. This is what we call biological plausibility, a heuristic used too often in our clinical decisions. This biological plausibility was reinforced by laboratory studies (Tay and Pashley 2004; Perdigão 2010) and non-RCTs (van Dijken 2000) indicating that sclerotic dentin removal could increase bonding. Although noncontrolled trials are at a higher level of evidence than laboratory studies, this research design cannot control for known and unknown prognostic factors. Without randomization, other factors not balanced at baseline may play a role in the differences observed.

Thus, we investigated this research question in an RCT (Loguercio et al. 2018) (Appendix Table 2). After randomizing cervical lesions to have the sclerotic dentin removed or not, we did not gather any evidence to support that sclerotic dentin removal would improve the retention rates of restorations.

In the health care field, the final word should not be biological plausibility. Plausibility serves to create hypotheses, which must be experimentally tested before application. Without scientific proof, everything remains in the field of speculation, and the null hypothesis must prevail.

The Clinical Performance of the Adhesive Can Be Predicted by Its Bonding Strategy/Number of Steps

This is another myth based on biological plausibility. Etch-and-rinse adhesives remove the smear layer and open dentin tubules, increasing dentin permeability and

demineralizing dentin further than resin monomers can infiltrate (Carvalho et al. 2012; Perdigão et al. 2013). Laboratory studies show that this nonimpregnated collagen zone is more susceptible to degradation by endogenous metalloproteases making the adhesive interface weaker over time (Breschi et al. 2018). Conversely, self-etch adhesives do not remove the smear layer; for most of them, demineralization can also occur with resin infiltration (Van Meerbeek et al. 2020). This led some authors to believe that self-etch systems are less prone to degradation and capable of producing long-lasting restorations (Carvalho et al. 2012; Perdigão et al. 2013; Breschi et al. 2018).

Although there is biological plausibility behind this belief, anyone could come up with opposite theoretical explanations. For instance, other authors may hypothesize that as self-etch adhesives do not remove but incorporate the smear layer in the bonding interface, they produce weaker interfaces, leading to more restoration debonding.

Indeed, both theories may happen clinically, as multiple factors with unknown weights act together. Without clinical evidence, the discussion remains at the hypothesis level. This makes the outcome unexpected and requires clinical trials to solve this uncertainty. Therefore, attempts to characterize adhesive efficacy by its bonding strategy/number of steps is a very simplistic analysis of the complex chemistry of the adhesive systems.

A network meta-analysis that included 66 RCTs did not show any superiority of 1 bonding strategy/number of steps over the others (Dreweck, et al. 2021b), also confirmed by another systematic review (Chee et al. 2012). Although other systematic reviews reached different conclusions, they were rated as critically low evidence (Appendix Table 3). These high-quality evidence-based findings prevent us from stating that adhesive strategy predicts restoration longevity.

When Laboratory and Clinical Trials Match: What Should We Look At?

Several laboratory studies showed reductions in BS after specimen storage (Carvalho et al. 2012). Then, laboratory investigations evaluated modified protocols to obtain adhesive interfaces with higher resistance to degradation (Reis et al. 2013).

One of these approaches was the vigorous rubbing adhesive application. Laboratory studies demonstrated increased resin-dentin BS of adhesives under

vigorous application compared to the slight or passive application (Reis et al. 2007; Loguercio et al. 2011). The authors claimed that resin monomers applied under pressure could compress the demineralized and mineralized dentin substrate, pulling the adhesive into the underlying tissue once pressure was relieved.

This was endorsed by some RCTs (Zander-Grande et al. 2014; Hass et al. 2022). The vigorous manual application (Zander-Grande et al. 2014) and sonic application (Hass et al. 2022) improved an important clinical outcome: the retention rates of non-carious cervical restorations. Thus, for this protocol, one of the pillars of EBP, the use of the best available evidence, was contemplated.

However, our analysis should not stop by establishing whether the protocol is statistically significant or not. We need to move forward and analyze the magnitude of the effect observed. Looking at the figures of 1 RCT (Zander-Grande et al. 2014), we observed that the overall retention rates for the vigorous and passive application methods were 96.8% and 83.9%, respectively. The absolute risk difference between the application modes was approximately 13%. This figure allows us to calculate the number needed to treat (NNT = 7.6), which is the ratio between 100 and the absolute risk difference.

The NNT inserts into the health care area the nondeterministic notion of the treatment. Treating or not treating is not the only determinant of the outcome. We need to quantify the benefit to improve our skills in decision-making. The ideal is an NNT of 1, which means that every treated patient benefits from the therapy. However, NNTs usually differ from 1. For the vigorous adhesive application, an NNT of 7.6 means that around 8 patients need to have vigorous application so that one can benefit from having a long-lasting restoration.

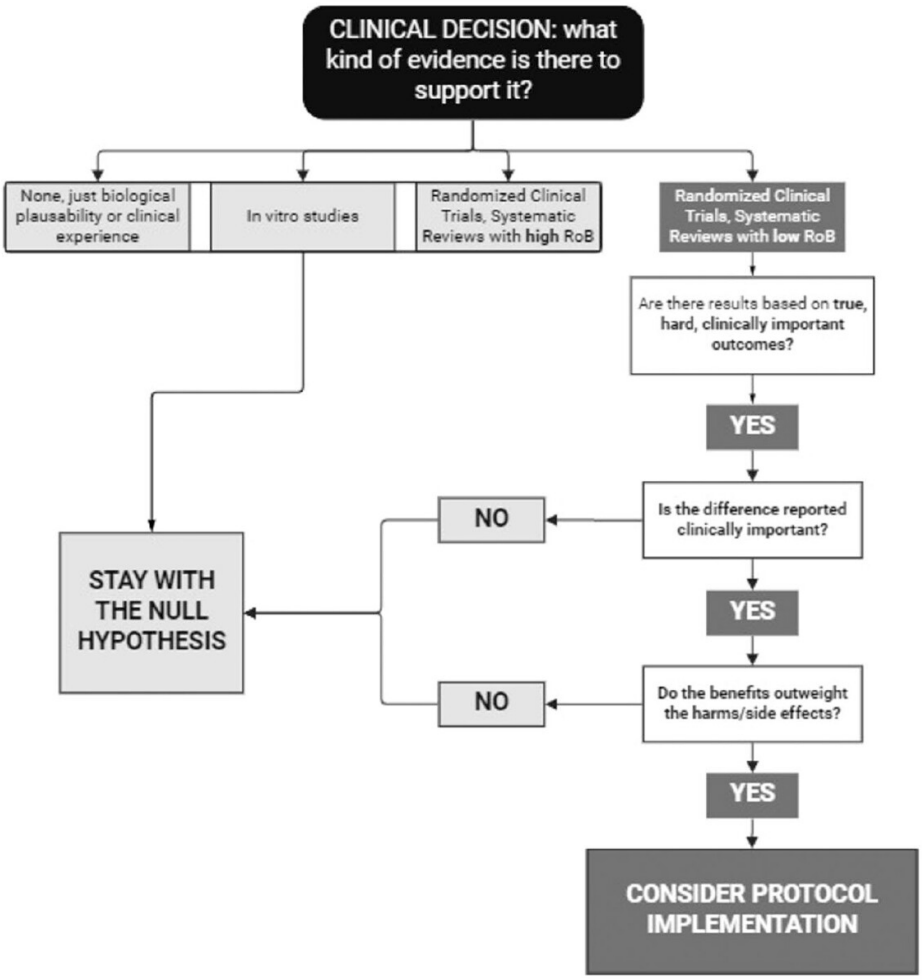
The NNT makes us aware that our decisions are limited in efficacy. An implemented treatment does not guarantee benefits. It is impossible to predict which patient will benefit from it accurately. We will always need to treat many patients in the hope that some will benefit from the protocol.

Unfortunately, there is no rule of thumb for interpreting NNT figures. It depends on the clinical scenario, outcome, treatment robustness, costs, risks, side effects, and patients' and caregivers' perceptions. So, an exceptionally good NNT in some situations may be neglectable in other scenarios.

Final Considerations

Health care providers, researchers, and professors are always in a position of authority when making clinical decisions. That is why we should avoid using our clinical experience as proof of efficacy. Our clinical experience is blind to the benefits of protocols that improve prognostic outcomes (Figure 2). In addition, our clinical ecosystem is a naturally believing and biased environment highly prone to confirmation bias.

Figure 2 - Basic flowchart to aid clinicians and caregivers in decision-making processes when exposed to new protocols or treatments in dental materials science. RoB, risk of bias.



The foundation of critical thinking must be on system 2, which is analytical and skeptical enough to allow us to ignore the relatively easy-to-measure numbers of questionable significance when making clinical decisions. We need to move away from the dichotomization of procedures as simply being statistically significant or not and

start discussing the magnitude of the benefit, risks, and harms without disregarding the patients' values and preferences.

Putting system 2 into work in scientific activities is a daunting task. We are prone to making quick decisions based on heuristics and shallow associations of system 1 rather than formulating a conclusion based on a long chain of reproducible and scientifically verified facts.

Evidence suggests that many published research findings in biomedical research are misleading, are not as robust as they claim, or cannot be reproduced (Ioannidis 2016). This is even more pronounced in basic and laboratory studies as most of them do not survive the death valley (Butler 2008) during their translation to clinical protocols.

Acknowledging these limitations in dental bonding is essential for a shift toward more EBP focusing on clinically relevant outcomes that can make a difference in patients' lives.

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Appendix file

A short description of other myths in the dentin bonding field can be seen in Table 1.

Table 1 – Overview of some other myths in the dentin bonding field.

Myth in dentin bonding	The rationale behind the myth	What do laboratory studies report?	What do randomized clinical trials (RCTs) or systematic reviews (SRs) report?
Self-etch adhesives cause less post-operative sensitivity (POS)	Based on the hydrodynamic theory of Brännström, the smear layer removal by acid etching before application of etch-and-rinse adhesives opens dentinal tubules, and increases dentinal fluid movement, thus causing POS. This fact does would not occur for self-etch adhesives as they only interact and do not remove the smear layer (Perdigão 2020; Van Meerbeek et al. 2020)	° Increased dentin permeability of the dentin substrate after acid etching conditioning (Reis et al. 2015; Schroeder et al. 2017). ° Scanning electron microscopy images showing open dentinal tubules and demineralization of intertubular dentin (Perdigão et al. 2021; Rosales-Leal et al. 2007).	° Two SRs of RCTs in posterior teeth and non-carious cervical lesions (NCCLs) (Reis et al. 2015; Schroeder et al. 2017) did not report any significant and clinically important differences between the two bonding strategies (etch-and-rinse or self-etch) for the clinically relevant outcome of POS.
Desensitizers applied before adhesive helps to prevent POS	Due to the presence of POS in composite restorations, mainly in posterior teeth, several desensitizers have been recommended for application before dental adhesives. One of the most used is the glutaraldehyde-based desensitizing agent (Cunha-Cruz et al. 2010), which blocks tubular flow, due to its inherent biological fixative property (Bergenholtz et al. 1993).	° Studies showed that glutaraldehyde-based desensitizing agent obliterate dentinal tubules (Arrais et al. 2004; Schüpbach et al. 1997) ° This tubular occlusion decreases the dentin permeability (Ishihata et al. 2012).	° Two RCTs showed that the application of glutaraldehyde-based desensitizing did not reduce spontaneous or stimulated-POS of posterior composite restorations up to 12 months of clinical evaluation (Chermont et al. 2010; de Oliveira et al. 2022; Sobral et al. 2005).
Application of flowable resin as a base for restorations in the so-called elastic bonding concept	The occurrence of NCCLs has been explained by the continuing tooth flexure at the cervical area during mastication. Thus, materials with low elastic modulus such as flowable composites should be used instead of regular viscosity composites that have higher elastic modulus (Baroudi and Rodrigues 2015; Bayne et al. 1998). It is believed that flowable resins can absorb the stresses from the	° Flowable composites showed inferior mechanical properties when compared to the high or regular viscosity composite (Ilie and Hickel 2009; Labella et al. 1999). ° Improved marginal integrity of in vitro restorations using flowable composites as a base (Haak et al. 2003). ° Less microleakage was observed in the class V margins when flowable composite	° A SR of RCTs (Szesz et al. 2017) did not report any benefit in retention rates of composite resin restorations placed in NCCLs up to 3 years of follow-up.

	polymerization shrinkage of composites and the compression produced by the mechanical loading on restorations during function (Kemp-Scholte and Davidson 1990; Van Meerbeek et al. 1993).	was used (Kubo et al. 2004; Nie et al. 2018).	
Immediate dentin sealing (IDS) for luting procedures improves the longevity of indirect restorations	Also referred to as "resin coating technique," this protocol requires the application of dentin adhesives before the provisional phase of indirect restorations. It is especially indicated to protect the pulp after preparation of vital teeth for indirect restoration, since dental preparation opens dentinal tubules, which connects the pulp with the external buccal surface (Josic et al. 2021a; Magne 2005; Nikaido et al. 2003).	◦ Superior immediate and long term bond strength values were observed with the immediate dentin sealing (Magne et al. 2005). ◦ The marginal integrity of indirect ceramic restorations bonded with the immediate dentin sealing technique was improved (Elbishari et al. 2021). ◦ Reduced microleakage was observed in restorations performed with the immediate dentin sealing protocol (Kitayama et al. 2011). ◦ Superior fracture resistance was observed in indirect restorations cemented by IDS (Elbishari et al. 2021; Kolanko and Bonsor 2022).	◦ A SR of RCTs (Josic et al. 2021a) did not report reduced POS of indirect restorations when IDS was used in comparison with the traditional luting procedure (without IDS). ◦ Additionally, no significant improvement in other clinical parameters like fracture or retention of the indirect restorations were observed when IDS was used (van den Breemer et al. 2019b).
Cross-linking agents can improve restoration longevity.	Usually, when etch-and-rinse adhesives are used, an area of demineralized dentin is not properly infiltrated by adhesive systems. This area of exposed collagen fibrils in the hybrid layer are susceptible to degradation (Perdigão 2020; Van Meerbeek et al. 2020). The rationale behind the use of cross-linking agents is reinforce collagen fibrils by additional cross-linking between fibrils. The	◦ A significant increase in the stiffness of demineralized dentin was observed (Bedran-Russo et al. 2008; Vidal et al. 2014). ◦ Both agents were effective as inhibitors of metaloproteases and cysteine cathepsins (Seseogullari-Dirihan et al. 2016; Seseogullari-Dirihan et al. 2015; Vidal et al. 2014), similar to what was described for	◦ Three RCTs showed that the application of proanthocyanins or epigallocatechin-3-gallate before adhesive or its incorporation in an adhesive formulation did not improve the retention rates of non-carious cervical restorations (Souza et al. 2019; Souza et al., 2020; Costa et al., 2020). ◦ Similarly, no improvement in the retention rates of NCCLs or POS in

	most evaluated agents were proanthocyanins, epigallocatechin-3-gallate, and glutaraldehyde (Bedran-Russo et al. 2014; Liu et al. 2011).	chlorhexidine in the body of the article. ° Less degradation of collagen matrix was observed (Castellan and Bedran-Russo 2020) and consequently, less degradation of the adhesive interface was observed in vitro (Leme et al. 2015; Neri et al. 2016; Santiago et al. 2013).	posterior cavities were observed for a glutaraldehyde-containing adhesive (Ritter et al. 2008; Van Meerbeek et al. 1994).
Dentin deproteinization for improved restoration quality	Taking in account the same problem described for the cross-linking agents, some authors suggested the removal of all exposed collagen fibrils, after acid etching, using a deproteinizing agent like sodium hypochlorite (Delgado et al. 2022).	° A 15-second application of sodium hypochlorite removed partially the collagen fibrils increasing the space among the remaining ones (Perdigão et al. 2000). ° Improved long-term bond strength values were reported with dentin deproteinization (Cecchin et al. 2012; Pucci et al. 2016). ° Additionally, reduced microleakage was observed after 12 months when sodium hypochloride was applied (Torres et al. 2004).	° Three RCTs showed that sodium hypochloride after acid etching and before adhesive application did not improve significantly the clinical performance of NCCLs, even after 5 year follow-up (Saboia et al. 2006; Torres et al. 2004) (Favetti et al. 2022).

Additional notes and References

We added additional references whenever possible to improve the scientific support of all myths. We also critically evaluated the RCTs and SRs of the literature cited in the body of this article. For the RCTs, we evaluated the risk of bias using the Risk of Bias tool version 1.0 from the Cochrane Collaboration (Higgins et al. 2011) (Table 2). For the SRs, we used the AMSTAR 2 tool (Shea et al. 2017) (Table 3). The additional references (not previously cited) are identified in italics in Tables 2 and 3 below.

A critical issue to be addressed is that any widespread procedure, conduct, or treatment can be considered a myth due to a **lack of evidence** to support them or the **presence of evidence at high risk of bias,** which means it is not reliable. When we

lack high-quality evidence, we should keep up with the null hypothesis, meaning that any treatment should be considered null until low risk of bias evidence is produced. When we have evidence, but it is low-quality (whether showing efficacy or not), the reliability of the article is low and again it should not be used to drive any change in practice recommendations.

Table 2 - Overall risk of bias of previously cited and additional clinical trials referenced in the myths described in the article. The dentin bonding myths not listed in this table were supported by SRs and they are presented in Table 3.

Dentin bonding myth	**Clinical trial**	**Overall risk of bias 1.0 (Higgins et al. 2011)**	**Additional comments**
The etch-and-rinse adhesives should be applied with wet-bonding protocol	(Perdigão et al. 2005)	Unclear	° The RCTs that evaluated dentin moisture on restoration longevity did not report that this technique was superior to the dry bonding in NCCLs or posterior restorations. Although some RCTs are of unclear risk of bias, additional low risk of bias studies conducted with universal adhesives show the same trend.
	(Zander-Grande et al. 2011)	Unclear	
	(de Paris Matos et al. 2020)	Low	
	(de Albuquerque et al. 2022)	Low	
	(Barceleiro et al. 2022) 2022	Low	
	(Castro et al. 2020)	Low	
	(Castro et al. 2022)	Low	
Chlorhexidine (CHX) should be applied to enhance restoration longevity	*(Dutra-Correa et al. 2013)*	Unclear	° RCTs that compared restorations with and without CHX associated with the adhesive procedure did not report clinically important differences in follow-ups up to three years.
	(Sartori et al. 2013)	Unclear	
	(Araújo et al. 2015)	Low	
	(Favetti et al. 2017)	Low	
Roughening sclerotic dentin may improve restoration longevity	(van Dijken 2000)	-- Non-RCT	° No additional reference was found in the literature for this myth. Van Dijken et al. (2000) is a non-RCT (low level of evidence than RCTs) and reported a benefit for dental roughening.
	(Loguercio et al. 2018)	Low	° The only low risk of bias RCT conducted on this subject (Loguercio et al. 2018) did not gather evidence to reject the null hypothesis that roughening sclerotic dentin is better than no roughening.

Desensitizers applied before adhesive helps to prevent POS	(Sobral et al. 2005)	Unclear	◦ No additional reference was found for this myth. Both clinical studies (although one is of unclear risk) did not find any superiority of the use of desensitizers associated to adhesives in the prevention of POS.
	(de Oliveira et al. 2022)	Low	
Cross-linking agents can improve restoration longevity.	(Van Meerbeek et al. 1994)	Unclear	◦ The additional references found for this myth did not find evidence to reject the null hypothesis that cross linking agents are superior to the application of adhesive without cross linking.
	(Ritter et al. 2008)	Unclear	
	(Chermont et al. 2010)	Unclear	
	(de Souza et al. 2019)	Low	
	(Costa et al. 2020)	Unclear	
	(de Souza et al. 2020)	Low	
Dentin deproteinization for an improved restoration quality	(Saboia et al. 2006)	Unclear	◦ The additional references for this myth agrees with the ones cited in body of the manuscript that there is no clinical support to indicate the use of dentin deproteinization.
	(Torres et al. 2004)	Low	
	(Favetti et al. 2022)	Low	
Immediate dentin sealing (IDS) for luting procedures improves the longevity of indirect restorations	*(Josic et al. 2021a)*	See table 3	
	(Hu and Zhu 2010)	Unclear	◦ Although IDS technique showed lower post-cementation hypersensitivity in one study, no superiority of IDS was observed in terms of survival rates and success in periods ranging from 1 to 3 years of clinical function.
	(van den Breemer et al. 2019a)	Unclear	
	(van den Breemer et al. 2019b)	Unclear	

Table 3 - Appraisal of the cited and additional SRs of the literature referenced in the myths described in the article. The dentin bonding myths not listed in this table were supported by RCTs in Table 2.

Myth in dentin bonding	Systematic review	Some important methodological flaws	Overall confidence according to AMSTAR 2 (Shea et al. 2017)	Study conclusion
Rubber dam isolation is essential to have long-lasting restorations	(Miao et al. 2021)	--	High	◦ This study did not gather evidence to support that rubber dam isolation can improve longevity of restoration in

				medium short term. However, few low risk of bias studies were included.
	(Heintze and Rousson 2012)	This SR did not evaluate the risk of bias of the eligible studies; there were no comprehensive literature search, non-appropriate meta-analytical approach and authors did not grade the certainty of evidence	Critically low	◦ The study reported significant reduction of fractures in Class II composite restorations with rubber-dam isolation.
	(Cajazeira et al. 2014)	This SR incorrectly classified non-RCT as RCTs and did not grade the certainty of the evidence	Critically low	◦ The authors concluded that rubber dam did not influence the longevity of restorations.
	(Heintze et al. 2015)	This SR did not evaluate the risk of bias of the eligible studies; there were no comprehensive literature search, non-appropriate meta-analytical approach and authors did not grade the certainty of evidence	Critically low	◦ The authors concluded that rubber dam isolation may not be needed for longevity of anterior restorations if adequate relative isolation (cotton roll/saliva ejector) was ensured.
	(Mahn et al. 2015)	This SR did not evaluate the risk of bias of the eligible studies; there were no comprehensive literature search, non-appropriate meta-analytical approach and authors did not grade the certainty of evidence	Critically low	◦ Rubber dam found significantly better composite restoration retention rates in NCCLs.
	Final remark: The additional SRs that we included in this myth present more than one critical flaw and should not be relied on to provide an accurate and comprehensive summary of the available studies (Shea et al. 2017), regardless of their conclusions.			

Optibond FL and Clearfil SE are "gold-standard" adhesives	(Dreweck et al. 2021a)	--	High	◦ None of these adhesives was found to be superior to other competitive brands
	Final remark: We have not found any other additional SR to add for this specific myth.			
The clinical performance of the adhesive can be predicted by its bonding strategy/number of steps	(Dreweck et al. 2021b)	--	High	◦ The authors did not find any superiority of one adhesive strategy over the other
	(Dreweck et al. 2021c)	--	High	◦ The authors did not find any superiority of 3-step etch-and-rinse adhesives in comparison with 1-step self-etch adhesives in NCCLs.
	Heintze et al. 2010	This SR did not evaluate the risk of bias of the eligible studies; there were no comprehensive literature search, non-appropriate meta-analytical approach and authors did not grade the certainty of evidence.	Critically low	◦ The authors concluded that 2-step self-etch adhesives or 3-step etch-and-rinse adhesives perform better than other adhesive categories.
	(Krithikadatta 2010)	This study has several methodological flaws that goes from the search strategy up to the statistical analysis.	Critically low	◦ The clinical effectiveness of etch-and-rinse adhesives, 2-step self-etch and 1-step self-etch adhesive were considered similar in terms of retention rates.
	(Chee et al. 2012)	No protocol registration.	Low	◦ The authors reported that there was insufficient evidence to make firm recommendations for the use of one adhesive system or bonding strategy over another.
	(Santos et al. 2014)	No protocol registration.	Low	◦ The 3-step etch-and-rinse

				adhesives showed a lower risk of loss of a NCCL restoration compared to a two-step etch-and-rinse adhesive. ° The 2-step self-etch adhesive system has a lower risk of loss of a NCCL restoration compared to a two-step etch-and-rinse adhesive system.
	(Peumans et al. 2014)	No protocol registration. The risk of bias of the eligible studies was not evaluated. The authors did not used appropriate meta-analytical statistical methods	Critically low	° The 3-step etch-and-rinse adhesive, 2-step and 1-step self-etch mild ph showed better clinical performance in NCCLs when compared to 2-step etch-and-rinse adhesive, 2-step and 1-step self-etch acidic ph.
	(Mahn et al. 2015)	This SRs did not evaluate the risk of bias of the eligible studies; there were no comprehensive literature search, non-appropriate meta-analytical approach and authors did not grade the certainty of evidence.	Critically low	° The clinical performance is significantly influenced by the type of adhesive system and/or the adhesive class to which the system belongs.
	Final remark: Most of earlier SRs and meta-analyses that reported the clinical effectiveness of different types of adhesives had important methodological flaws and should not be relied on to provide an accurate and comprehensive summary of the available studies (Shea et al. 2017), regardless of their conclusions. In most of them, no appraisal of the risk of bias of the eligible studies was performed and the authors failed to choose an appropriate statistical analysis for data management.			
Application of flowable resin as a base for restorations in the so-called elastic bonding concept	(Szesz et al. 2017)	--	High	° The authors have reported moderate confidence that the resin composite viscosity does not influence the

				retention rates at 3 years.
	(Peumans et al. 2014)	No protocol registration. The risk of bias of the eligible studies was not evaluated. The authors did not used appropriate meta-analytical statistical methods	Critically low	° The restorative material did not influence the clinical performance in NCCLs.
	(Shaalan et al. 2017)	No protocol registration. Inadequacy of the search strategy. The authors did not used appropriate meta-analytical statistical methods.	Critically low	° Flowable composites had similar clinical performance when compared to conventional composite in both carious and NCCLs.
	Final remarks: Regardless of the additional references included and their confidence there seems that no study gathered evidence to support that the use of flowable resin is superior to the sole use of conventional viscosity resins.			
Immediate dentin sealing (IDS) for luting procedures improves the longevity of indirect restorations	*(Josic et al. 2021a)*	--	High	° The authors concluded that IDS do not reduce POS in teeth restored with indirect restorations with low certainty of evidence
	(Hu and Zhu 2010)	See table 2	--	--
	(van den Breemer et al. 2019a)	See table 2	--	--
	(van den Breemer et al. 2019b)	See table 2	--	--
	Final remark: From the body of evidence, most of the RCTs and SRs did not gather evidence to support that IDS improve the longevity of the indirect restorations.			
Self-etch adhesives cause less POS	(Reis et al. 2015)	The authors did not grade the certainty of the evidence	High	° The authors did not report any difference in spontaneous or induced POS between self-etch and etch-and-rinse adhesives in posterior restorations
	(Schroeder et al. 2017)	The authors did not grade the	High	° The authors did not report any difference in

		certainty of the evidence		spontaneous or induced POS between self-etch and etch-and-rinse adhesives in NCCLs
	(Josic et al. 2021b)	--	High	° The authors reported reduced induced POS for the self-etch systems, but they did not report reduced spontaneous POS.
	Final remark: There is no evidence to support the fact that self-etch adhesives produce less spontaneous POS than etch-and-rinse adhesives			

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5 ARTIGO 2 - A NEW PREHEATING THERMOVISCOUS COMPOSITE FOR RESTORATION OF NON-CARIOUS CERVICAL LESIONS: A 6-MONTH RANDOMIZED CLINICAL TRIAL

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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 (α = 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.

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.comA 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 3A) were cleaned through prophylaxis using pumice and water using a brush (Figure 3B), 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 4).

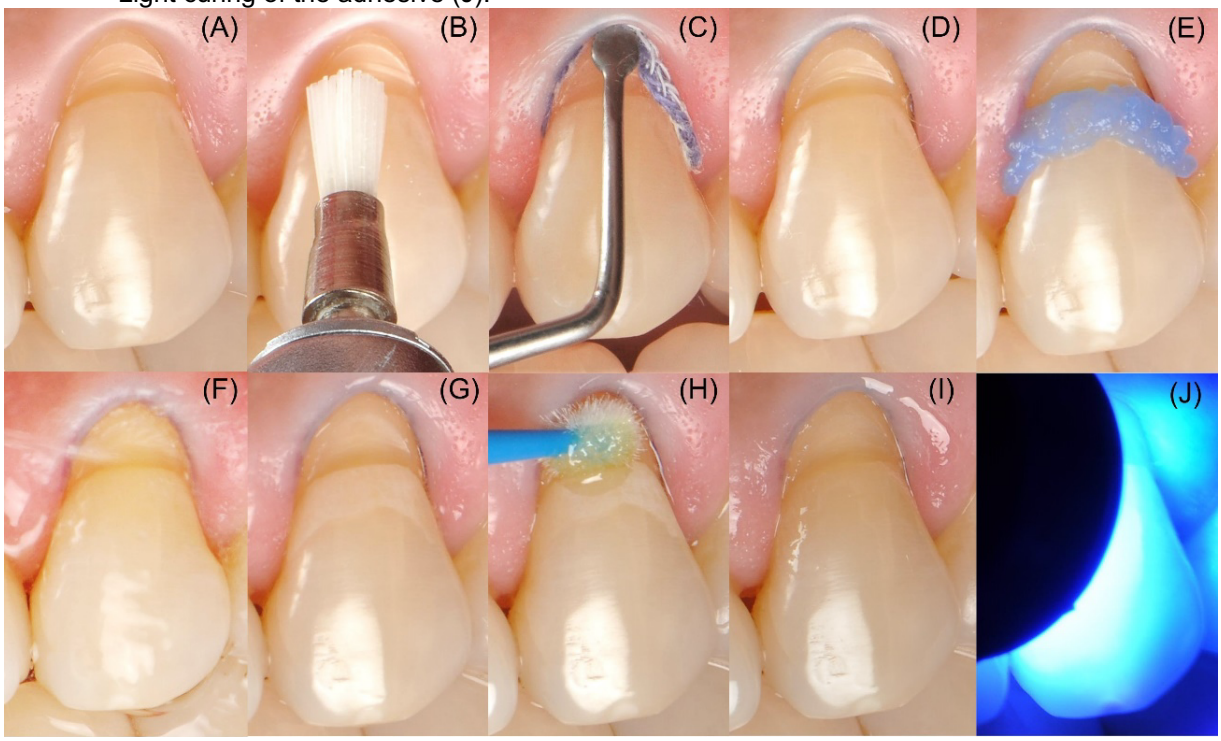
Table 4 - Manufacture information of investigated composites.

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

(*) Abbreviations: NI: not defined by the manufacturer

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 3C and 3D), associated to cotton rolls. No hemostatic liquids were necessary during this study. Selective enamel conditioning (Vococid, Voco GmbH, Cuxhaven, Germany) (Figure 3E), followed by rinsing (Figure 3F) and drying (Figure 3G). 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 3H) followed drying by an air jet for 10 seconds (Figure 3I). 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/cm^2 (Valo, Ultradent, South Jordan, UT, USA) for 20 seconds (Figure 3J). Then, the cavities were restored with one of the two compounds described below:

Figure 3 - 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).



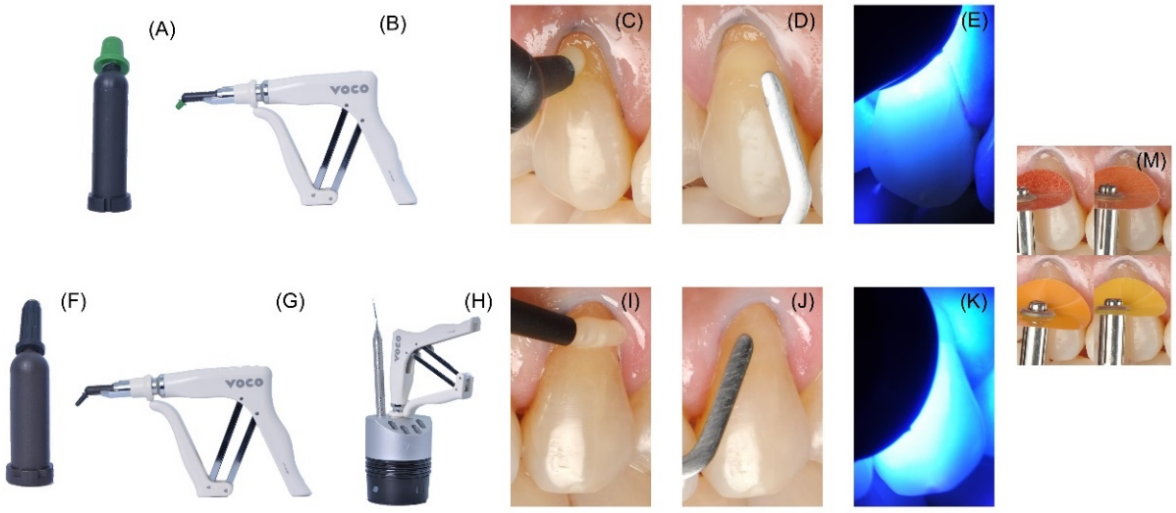
NHT group: in this group non-heating, a one dose composite resin Admira Fusion (Voco GmbH, Cuxhaven, Germany) (Figure 4A) was applied. The restorative

material was placed in the Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany) (Figure 4B) and inserted in 2 mm increments (Figure 4C). After the correct accommodation of the composite in the cavity (Figure 4D), the light curing of each increment was carried out with an irradiance of 1200 mW/cm^2 (Valo, Ultradent, South Jordan, UT, USA) for 20 seconds (Figure 4E).

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

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 4M).

Figure 4 - 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 (M).



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 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

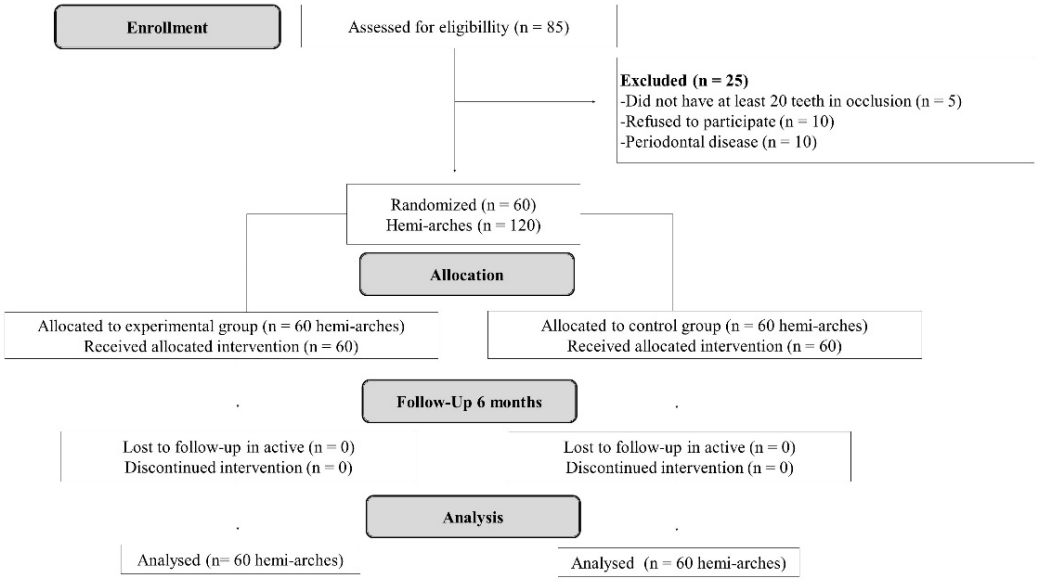
Twenty-five out of 85 patients examined for eligibility were not enrolled in the study because they did not fulfill the inclusion criteria (Figure 5). Thus, a total of 60 subjects (30 male and 30 female) were selected. One hundred and twenty restorations were placed: 60 for each group (Figure 5). All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 5. 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.

Table 5 - 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

Figure 5 - CONSORT 2010 Flow Diagram.



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 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 6). 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 6), 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 6), 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 6, after 6 months of clinical performance.

Figure 6 - Clinical follow-up of restorations in different groups and times.

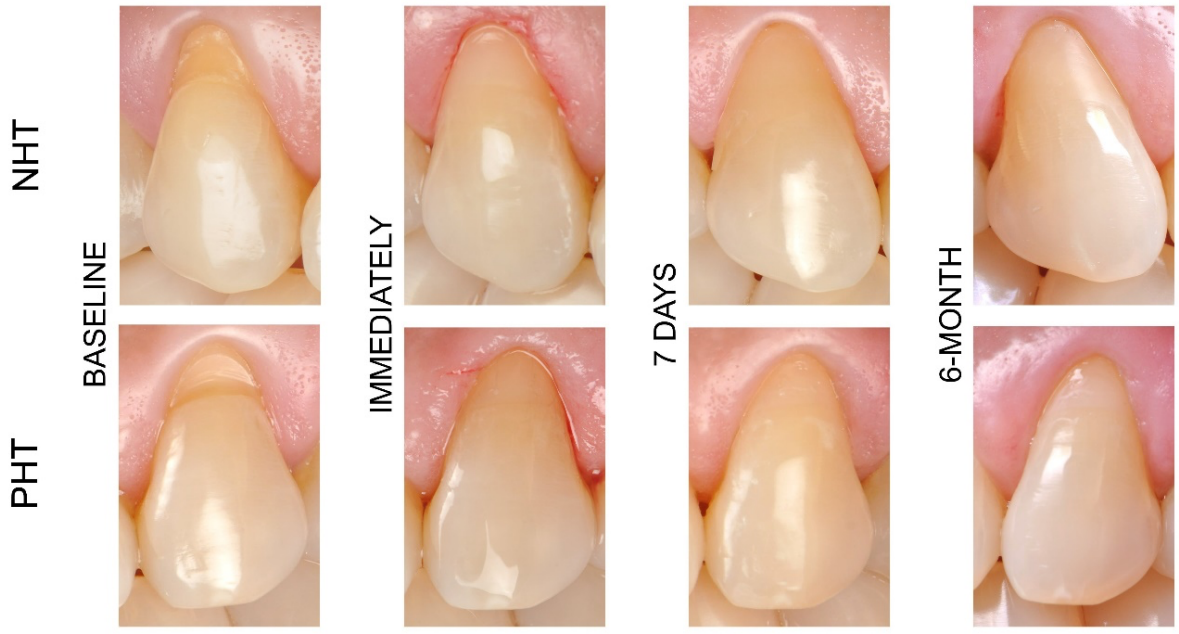


Table 6 - Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria.

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.

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 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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6 ARTIGO 3 - CLINICAL PERFORMANCE OF PREHEATING THERMOVISCOUS COMPOSITE RESIN FOR NON-CARIOUS CERVICAL LESIONS RESTORATION: A 24-MONTH RANDOMIZED CLINICAL TRIAL

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Abstract

Objectives: This 24-month, double-blind, split-mouth randomized clinical trial aimed to compare the retention rates of a preheated thermoviscous composite resin (PHT) compared to a non-heated composite resin (NHT) in non-carious cervical lesions (NCCLs).

Methods: A total of 120 restorations were restored on NCCLs using a preheated (VisCalor bulk, Voco GmbH) and a non-heated (Admira Fusion, Voco GmbH) composite resins with 60 restorations per group. A universal adhesive in the selective enamel conditioning was applied. In the PHT group, composite was heated at 68 °C for using a bench heater. In the NHT group, no heating was employed. Both restorative materials were dispensed into caps and inserted into the NCCLs. The restorations were evaluated at baseline, 6, 12, 18, and after 24 months of clinical service using the

FDI criteria. Statistical analysis was performed with Kaplan–Meier estimation analysis for retention/fracture rate and Chi-square test for the other FDI parameters (α=0.05).
Results: After 24 months 108 restorations were assessed. Seven restorations were lost (two for PHT group and five for NHT group), and the retention rates (95 % confidence interval [CI]) were 96.7 % (81.5–99.9) for PHT group and 90.8 % (81.1–96.0) for NHT group, with no statistical differences between them ($p > 0.05$). The hazard ratio (95 % CI) was 0.52 (0.27 to 1.01), with no significant difference within groups. In terms of all other FDI parameters that were assessed, all restorations were deemed clinically acceptable.
Conclusions: Both composites showed high rates of retention rates after 24 months.
Clinical significance: The clinical performance of the new preheated thermoviscous was found to be as good as the non-heated composite after 24-month of clinical evaluation in non-carious cervical lesions.
Registration of clinical trials: RBR-6d6gxxz

Introduction

Composite resins are versatile materials suitable for anterior teeth and posterior teeth because of their excellent esthetic properties and good mechanical characteristics [1]. Nonetheless, the techniques used for inserting composite into cavity preparations are challenging. The viscosity and stickiness of composite resins can make the material placement [2], and achievement of proper adaptation to the preparation walls difficult. This occasionally turns the procedure into a source of stress for both the operator and the patient [3].

Viscosity primarily depends on the chemical composition of the composite resin, specifically, the size, type, and concentration of filler particles, and the nature of the organic matrix [4,5]. All other factors being equal, an increase in filler loading content and the molecular weight of the monomers directly correlates with elevated viscosity in the composite resin, as well as enhanced mechanical properties [4,5].

While highly viscous composites boast superior mechanical properties [6], they can sometimes struggle to achieve optimal adaptation within the cavity preparation, resulting in compromised marginal integrity and gap formation [6], [7], [8]. In response to these issues, flowable composite resins have emerged. These materials are

characterized by their low viscosity compared to traditional composite resins, featuring reduced filler content and less viscous resin composition [9]. Unfortunately, flowable composites fall short in terms of providing adequate mechanical properties for use in areas subjected to substantial masticatory stresses [8,[10], [11], [12]].

Ideally, composite resin should exhibit flowable properties during application, ensuring superior adaptability to all cavity walls. However, once the application phase concludes, its viscosity should increase to prevent seepage from the cavity, making it suitable for carving and contouring [2]. Striking a balance between higher mechanical properties and user-friendly handling characteristics is paramount for the success of composite resin restorations [9].

Manufacturers have developed various alternatives in the way to achieve this equilibrium. One of them is the SonicFill system by Kerr (Orange, CA, USA). This system employs a highly viscous composite resin that can have its viscosity temporarily reduced during application by utilizing ultrasonic energy. Once the energy source is deactivated, the material promptly reverts to its original viscosity. While this feature may appear advantageous for clinicians, it's important to note that the use of sonic energy can potentially lead to an increased occurrence of voids in composite resin restorations [13,14].

Another approach involves preheating the composite resin [15], [16], [17]. Preheating enhances the degree of conversion and mechanical properties of the composite resin, while simultaneously rendering regular or high-viscosity composite more fluid during application [17]. Various devices are available in the dental market for this purpose, with the Calset heater (AdDent Inc., Danbury, CT, USA) and ENA heat (Micerium, Avegno GE, Italy) being among the most common options, offering operating temperatures ranging from 37 °C to 68 °C [18,19].

Recently, a novel thermo-viscous bulk fill material, VisCalor bulk by Voco (GmbH, Cuxhaven, Germany), has been introduced. This innovative material allows preheating up to 68 °C using the Caps Warmer device (Voco GmbH in Cuxhaven, Germany), prior to application. Preheating has proven advantageous for facilitating placement without causing any premature polymerization-related issues [20,21]. Furthermore, it has been shown to reduce the occurrence of internal voids when compared to other techniques [22,23]. This approach ensures a high degree of conversion and, as a result, elevated mechanical properties in comparison to other

composite materials [24,25]. In essence, VisCalor bulk-fill combines the flowability of a flowable composite during application when heated with the sculptability characteristic of bulk-fill composite, allowing for placement in increments of up to 4 mm [26].

Despite the promising in vitro results for pre-heated composite resins [18,19], a more in-depth examination of clinical studies that have assessed the impact of preheating on composite resins reveals conflicting outcomes [27], [28], [29], [30], [31], [32]. While some studies note similar outcomes in terms of marginal adaptation and marginal discoloration, others demonstrate a benefit when composite resin is subjected to heating. It is important to emphasize that these studies focus on posterior cavities [27], [28], [29], [30], [31], [32]. However, to the best of the authors' knowledge, no clinical study has yet been undertaken to compare the clinical performance of this new thermoviscous composite resin in contrast to non-heated composite resin in non-carious cervical lesions (NCCLs). Therefore, the objective of this double-blind, split-mouth randomized controlled trial was to compare the retention rates of a preheated thermoviscous composite resin, employing the Caps heating device, and a non-heated composite resin for the restoration of NCCLs over a 24-month follow-up period.

Material and methods

Ethics approval and protocol registration

The clinical investigation received approval (4.656.880) from both the Scientific Review Committee and the Committee for the Protection of Human Participants at the State University of Ponta Grossa. The trial was registered in the Clinical Trials Registry under the identification number RBR-6d6gxxz. The present clinical study was described in accordance with the CONSORT guidelines [33], with specific extensions for paired designs [34].

Trial design, settings, locations of data collection and recruitment

This study was conducted as a double-blind, split-mouth, equivalence, randomized controlled trial. The research took place over a brief period, from October

2021 to November 2021, and the 24-month data collection occurred between October 2023 and November 2023. The authors opted to create a convenience sample, refraining from any recruitment advertising efforts.

Patients visiting the private clinic for various reasons were approached when they were identified as potential candidates for the study. Once these patients were informed about the ongoing research at the clinic and had a clear understanding of the study's objectives, they were invited to participate in the trial and asked to sign an informed consent form.

Eligibility criteria

All participants underwent thorough examination by two well-trained operators to ensure their eligibility based on the inclusion and exclusion criteria of the study. These assessments were conducted using standard dental instruments, including a mouth mirror, an explorer, and a periodontal probe.

Participants were required to meet the following criteria for inclusion: Good general health status according to the American Society of Anesthesiologists (ASA) Physical Status Classification System, falling into either ASA I (normal healthy patient) or ASA II (patients with mild systemic disease without substantial functional limitations) categories [35]. A minimum age of 18 years and an acceptable level of oral hygiene as determined by the Simplified Oral Hygiene Index (OHI-S) [36]. A minimum of 20 teeth in occlusion and, in these teeth, the presence of at least two comparable NCCLs in terms of size, shape, dimensions, and color which required restorative procedure. These lesions needed to be non-retentive, deeper than 0.5 mm, and involve both enamel and dentin in vital teeth without periodontal mobility.

Exclusion criteria encompassed participants with a cavosuperficial margin involving over 50% of enamel. Additionally, patients with extremely poor oral hygiene (OHI-S score exceeding 3) [36], those using orthodontic devices, individuals suffering from severe or chronic periodontitis (teeth with probing pocket depths exceeding 4 mm with bleeding on probing and clinical attachment loss surpassing 3 mm in more than four teeth) [37], and individuals exhibiting heavy bruxism (severe masticatory muscle pain, temporomandibular joint pain, or extensive tooth wear) [38] were excluded from the study, as they necessitated other dental treatments before restorative intervention.

Participants with known allergies to resin-based materials or any other substances employed in this study, pregnant or lactating women, and those in chronic use of anti-inflammatories, analgesics, or psychotropics were not included in the present study.

Sample size calculation

The retention rate for composite resin after three years of clinical service was shown to be around 80% [39]. Given the absence of a discernible difference between the standard and experimental treatments, a sample size of 112 patients (56 per group) guarantees 90% confidence that the two-sided 90% confidence interval will not encompass a difference exceeding 25% between the groups. To account for any potential losses, 60 restorations were performed in each group, thereby ensuring a robust and reliable dataset for analysis.

Randomization and allocation concealment

Randomization in this study was conducted on an interindividual basis, with each participant receiving two restorations. The randomization schemes were generated using tools available on the website www.sealedenvelope.com. To maintain the allocation concealment of the study, a researcher not involved in the research protocol oversaw the randomization process. Each participant was randomized at the time of their intervention. To achieve this, the operator sent a message via a social communication network (WhatsApp, LLC) to the researcher 15 min prior to commencing the intervention. The researcher then disclosed the patient randomization scheme and promptly communicated the allocation to the operator. This approach maintains the concealment of the random sequence. In all cases, the tooth with the highest numerical identifier according to the FDI numbering system received the first described treatment, while the tooth with the subsequent number in sequence received the second treatment.

Blinding

The evaluators and participants were unaware of the allocation assignment in a double-blind study. In a pilot test, we assessed whether patients could detect differences between heated and non-heated composites. During this preliminary study, participants were asked if they felt any temperature difference during the restorative procedure for the two teeth. None reported sensing any distinction between the restorative procedures, confirming that heating did not compromise participant blinding. Due to material differences during restoration placement, blinding the operators conducting the procedures was not feasible.

Interventions: restorative procedure

All participants who met the inclusion and exclusion criteria had their NCCLs preliminarily assessed in terms of the degree of sclerotic dentin, a measurement performed in accordance with the criteria outlined by Swift et al. [40]. The dimensions of the cavities, including height, width, and depth, were meticulously measured using a millimeter probe. Additionally, the cavity geometry was evaluated by means of profile photography, and these profiles were categorized into angles of <45°, 45°−90°, 90° <135°, and >135° [41].

The presence of an antagonist and the identification of friction facets were also recorded. Preoperative sensitivity was assessed by applying an air-dry for 10 s using a dental syringe, placed 2 cm from the tooth surface, and by employing an explorer. The presence of biofilm was also evaluated by moving the millimeter probe along the entire cervical region. These characteristics were documented to facilitate the comparison of baseline cavity characteristics between the experimental groups.

To ensure consistency in the restorative procedures, the study coordinator carried out a restoration for each group, comprehensively detailing all the steps of the restorative technique. Subsequently, the other three operators, all of whom were in the post-graduation course of the School of Dentistry with more than five years of clinical experience, placed independently four restorations in a clinical setting, under the supervision and guidance of the study coordinator. The study coordinator could identify failures in the procedure and correct the operators in the standardized procedure. From this point on, the operators were considered properly calibrated for the execution of all restorative procedures of the present clinical trial.

Before the restorative procedure, all NCCLs were cleaned through prophylaxis, with pumice and water in low-speed handpiece mounted with a rotary brush. This cleaning process was followed by rinsing and thorough drying. The color of the dental structure was evaluated using the color guide provided in the composite kit (Admira Fusion, Voco GmbH, Cuxhaven, Germany). Based on this initial color selection, the corresponding color was employed for the other group (VisCalor bulk, Voco GmbH, Cuxhaven, Germany; Table 7).

Table 7 - Composition, application mode and batch number of the composite resins used.

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

The operators administered local anesthesia to the teeth scheduled for restoration, using a 3 % solution of articaine hydrochloride (Articaine, Nova DFL, Rio de Janeiro, RJ, Brazil) and they placed a lip and cheek retractor (Lip Retractor with Rod, Morelli, Sorocaba, São Paulo, Brazil) in the patients' mouth. The operators placed a retraction cord (Ultrapak # 0, Ultradent, South Jordan, UT, USA) in the gingival sulcus of the teeth to be restored using an insertion spatula. Cotton rolls and saliva ejectors was used to keep the operative field dry. No hemostatic liquids were required during this study.

The universal adhesive system (Futurabond U, Voco GmbH, Cuxhaven, Germany) was applied in the selective enamel mode, following the manufacturer's instructions for all cavities. Initially, the enamel was conditioning using Vococid (Voco GmbH, Cuxhaven, Germany) for 30 s, followed by rinsing and slightly drying. Subsequently, a single coat of the universal adhesive system (Futurabond U, Voco GmbH, Cuxhaven, Germany) was applied in enamel and dentin using a microbrush (Single Tim, Voco GmbH, Cuxhaven, Germany) with vigorous agitation, followed by air-drying for 10 s. Afterward, a second coat was applied similar to the first, and the adhesive was light-cured at 1200 mW/cm^2 (Valo, Ultradent, South Jordan, UT, USA) for 20 s. Following these preparatory steps, the cavities were restored using one of the two compounds as described below:

-Preheated thermoviscous composite resin group (PHT): A single-dose thermo-viscous bulk-fill composite resin, VisCalor bulk (Voco GmbH, Germany) was used. The restorative material was preheated to 68 °C in a bench heater (Caps Warmer, Voco GmbH, Cuxhaven, Germany) for 3 min. After preheating, the composite was inserted into the cavity in a single increment using the Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany) and, allowing inserted into the cavities for up to 4 mm. The composite resin was shaped with a spatula within the cavity within 20 s after insertion. After 20 s, the composite resin got rigid preventing any sculpturing. Light curing was carried out with an irradiance of 1200 mW/cm^2 (Valo, Ultradent, South Jordan, UT, USA) for 40 s. After filling the cavity, the restorations were adjusted and polished with a sequence of polishing discs (Solf-lex, 3 M Oral Care, St. Paul, MN, USA).

-Non-heated composite resin group (NHT): a single dose of the composite resin Admira Fusion (Voco GmbH, Cuxhaven, Germany) was employed. The restorative material was dispensed using a Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany) and inserted into the cavities in 2 mm increments. Once the composite was adequately positioned in the cavity, each increment was subjected to light curing with at an irradiance of 1200 mW/cm^2 (Valo, Ultradent, South Jordan, UT, USA) for 20 s. After filling the cavity, the restorations were adjusted and polished with a sequence of polishing discs (Solf-lex, 3 M Oral Care, St. Paul, MN, USA).

2.8. Calibration procedures for clinical evaluation

To ensure consistent and reliable assessments, two experienced, blind, and calibrated examiners underwent a training process. During this training, they observed 10 representative photographs of each score from both evaluation criteria. Subsequently, these examiners assessed 10 to 15 patients each over the course of two consecutive days. It is important to note that these patients had restorations in NCCLs but were not part of the study sample. Before commencing the assessment of the study participants, it was necessary to establish an inter-examiner agreement level of at least 85 % between the examiners [42].

Clinical evaluation

The evaluation of the restorations was performed at baseline and after 6 [43], 12, 18 and 24 months was conducted using the World Federation criteria (FDI) [44,45]. The primary outcome of interest was the retention/fracture of the restorations. Other secondary outcomes were also evaluated: 1. Surface gloss/luster and roughness; 2. Surface and marginal staining; 3. Marginal adaptation; 4. Color match; 5. Aesthetic anatomical form; 6. Recurrence of initial pathology; 7. Tooth cracks and fractures; 8. The effect of the restoration on the periodontium; 9. Postoperative sensitivity; 10. Recurrence of caries; 11. Tooth integrity; 12. Periodontal response; 13. Oral health.

Throughout the follow-up recalls, the examiners remained unaware of earlier evaluations scores to maintain blinding. At different time points, namely seven days, 6, 12, 18, and 24 months after the restorative procedure, spontaneous postoperative sensitivity was assessed. Patients were asked whether they experienced any pain during the initial seven days following the 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) [44,45]. 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 [33]. Descriptive statistics were used to describe the distribution of the scores of the FDI criteria. A statistical analysis was performed with Kaplan–Meier estimation analysis for retention/fracture rate, estimating the hazard ratios (HRs) and 95 % confidence intervals (CIs). The log-rank test was used to compare the survival distributions of these restorations (pre-set at 5 %). The Chi-square test was used to compare the changes across different time points within each restorative material for the secondary outcomes. 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 7). Thus, a total of 60 subjects (30 male and 30 female) were selected. A total of 120 restorations were placed, with 60 in each group (Figure 7). The restorative procedures were performed according to the protocol without any modification. Table 8 presents the baseline participant details and the characteristics of the treated lesions.

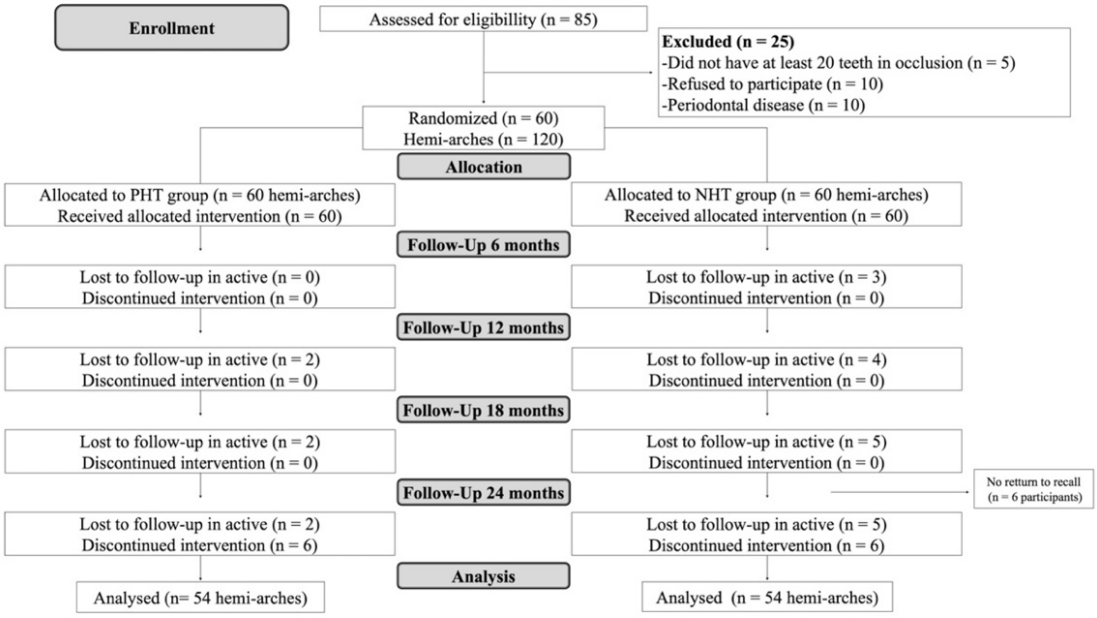
Table 8 - Characteristics of the Research Subjects and the Noncarious Cervical Lesions (NCCLs) per Group. PHT = preheated thermoviscous composite resin; NHT = non-heated composite resin.

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**	
	PHT	NHT
Shape (degree of angle)		
<45	0	0

45-90	13	15
90-135	25	26
>135	22	19
Cervico-incisal height (mm)		
<1.5	5	7
1.5-2.5	28	19
2.5-4.0	23	30
>4.0	4	4
Cervico-incisal height (mm)		
<1.5	6	7
1.5-2.5	21	19
2.5-4.0	29	30
>4.0	4	4
Degree of sclerotic dentin		
1	10	11
2	22	24
3	20	16
4	8	9
Presence of antagonist		
Yes	60	60
No	0	0
Attrition facet		
Yes	20	16
No	41	44
Pre-operative sensitivity (spontaneous)		
Yes	12	9
No	48	51
Pre-operative sensitivity (air dry)		
Yes	26	28
No	34	32
Pre-operative sensitivity (touch)		
Yes	13	14
No	47	46
Tooth distribution		
Anterior		
Incisor	1	2
Canines	12	10
Posterior		
Premolar	29	36
Molar	18	12
Arch distribution		
Maxillary	40	37

Mandibular	20	23
Presence of biofilm		
0	52	48
1	6	7
2	2	3
3	0	2

Figure 7 - CONSORT 2010 Flow Diagram.



The overall Cohen's kappa statistics demonstrated a high level of agreement among the examiners at the 6-month (0.94), 12-month (0.92), 18-month (0.92), and 24-month (0.92) follow-ups. All research subjects were assessed at baseline and during the 6- [43], 12-, and 18-month follow-up visits, with a recall rate of 100 %. However, six subjects could not be evaluated during the 24-month follow-up (recall rate of 90 %) because they either moved to another city or changed their phone number, which prevented us from having contact with them.

Retention/Fracture

Seven restorations were lost or fractured after 24 months (Table 9). The retention rates (95 % confidence interval) at 24 months were 96.3 % (81.5 - 99.9) for the PHT group and 90.8 % (81.1 - 96.0) for the NHT group representing a risk ratio of 0.4 (0.1 – 2.0). The Kaplan–Meier curves showed no significant differences (Log-rank

test, p = 0.06) between the cumulative probability of retention/fracture (Figure 8). Table 10 depicts the paired comparisons among the two resin composites as the hazard ratios. No significant differences were observed between groups (HR = 0.52; 95 % CI 0.27 to 1.01, p = 0.06).

Table 9 - Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria.

FDI Criteria	Scores*	Baseline		6 months		12 months		18 months		24 months	
		PHT	NHT	PHT	NHT	PHT	NHT	PHT	NHT	PHT	NHT
Fractures and retention	A	60	60	57	56	55	55	55	54	49	48
	B	0	0	2	1	2	1	2	1	2	1
	C	0	0	1	0	1	0	1	0	1	0
	D	0	0	0	1	0	1	0	2	0	2
	E	0	0	0	2	2	3	2	3	2	3
Surface gloss/lustre and roughness	A	60	60	58	55	56	54	56	53	50	47
	B	0	0	2	2	2	2	2	2	2	2
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Surface and marginal staining	A	60	60	59	56	56	53	56	52	50	46
	B	0	0	1	1	2	3	2	3	2	3
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Marginal adaptation	A	60	60	46	50	42	49	41	47	35	40
	B	0	0	14	7	16	7	17	8	17	9
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Color match	A	60	60	52	50	50	48	49	48	43	42
	B	0	0	6	6	6	7	7	7	7	7
	C	0	0	2	1	2	1	2	0	2	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Esthetic anatomical form	A	60	60	60	57	58	56	58	55	52	49

	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Recurrence of initial pathology	A	60	60	60	57	58	56	58	55	52	49
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Tooth cracks and fractures	A	60	60	60	57	58	56	58	55	52	49
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Effect of the restoration on the periodontium	A	60	60	60	57	58	56	58	55	52	49
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Postoperative sensitivity	A	60	60	60	57	58	56	58	55	52	49
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Recurrence of caries	A	60	60	60	57	58	56	58	55	52	49
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0

	E	0	0	0	0	0	0	0	0	0	0
Tooth Integrity	A	60	60	60	57	58	56	58	55	52	49
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Periodontal response	A	60	60	60	57	58	56	58	55	52	49
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Oral health	A	60	60	44	45	42	46	42	41	38	36
	B	6	7	15	9	13	7	12	12	10	12
	C	2	3	1	3	3	3	4	2	4	1
	D	0	2	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0

(*) A = Clinically very good; B = Clinically good; C = Clinically sufficient / satisfactory; D = Clinically unsatisfactory; E = Clinically poor. PHT = preheated thermoviscous composite resin and NHT = non-heated composite resin.

Figure 8 - Survival Kaplan-Meier curse for both groups. PHT = preheated thermoviscous composite resin and NHT = non-heated composite resin.

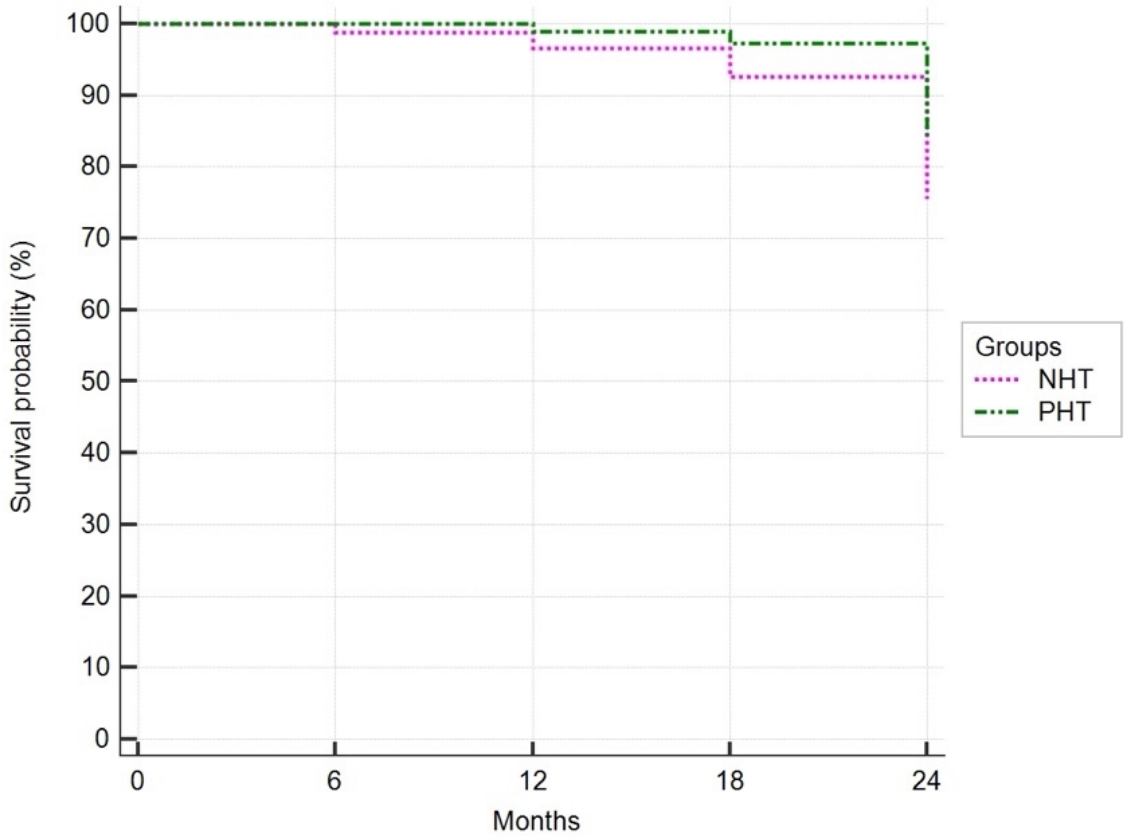


Table 10 - Absolute risk (95% CI), risk ratio (95% CI), and hazard ratio (95% CI) for outcome fracture/retention for the two groups after 24 months of clinical evaluation. PHT = preheated thermoviscous composite resin and NHT = non-heated composite resin.

	PHT	NHT
Absolute risk 95% CI)	96.3 (87.5 – 98.9)	90.7 (80.1 – 95.9)
Risk ratio (95% CI)	0.4 (0.1 – 2.0)	
Hazard ratio (95% CI)	0.52 (0.27 to 1.01)	

Secondary outcomes at the 24-month follow-up

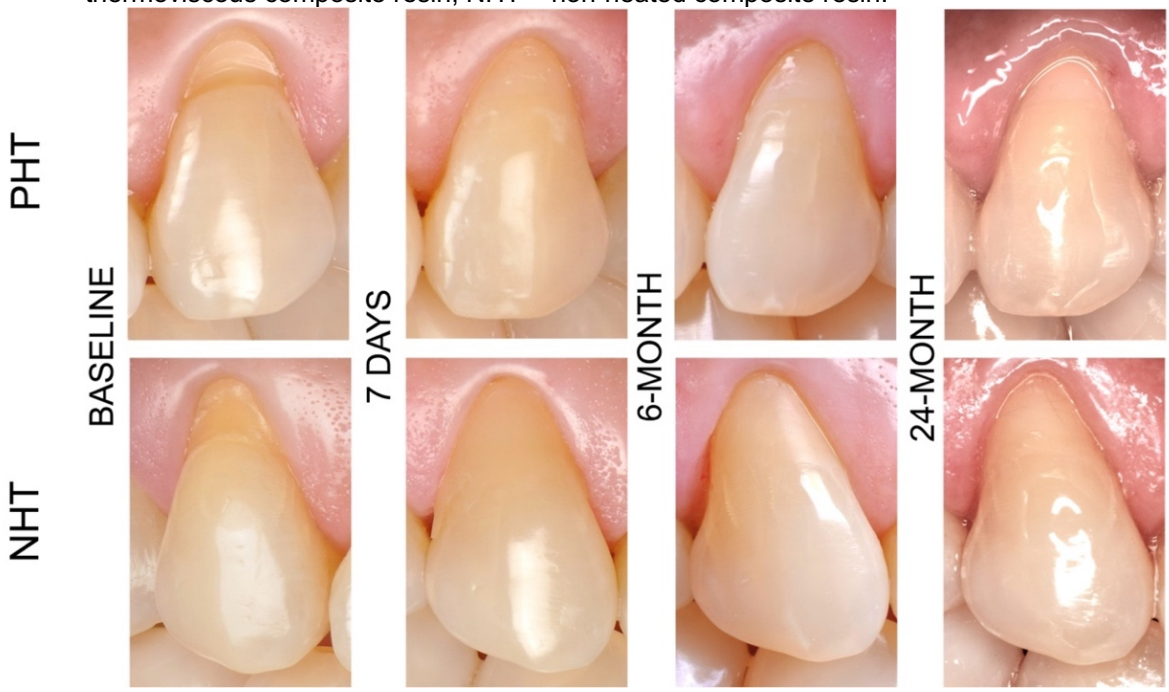
Three restorations (2 for PHT and 1 for NHT) showed some loss of gloss/luster (Table 9; p = 0.59). Five restorations (2 for PHT and 3 for NHT) showed marginal staining (Table 9, p = 0.58). Sixteen restorations (9 for PHT and 7 for NHT) showed color mismatch (Table 9; p = 0.71). Twenty-five restorations were considered to have small discrepancies in marginal adaptation (17 for PHT and 8 for NHT; Table 9; p = 0.06). Twenty-seven restorations were found to have biofilm retention (14 for PHT

and13 for NHT; Table 9, p = 0.96). In none of these cases statistically significant differences were detected.

Other parameters

No restorations had postoperative sensitivity throughout the study period. Additionally, no restoration showed any clinically important discrepancy in the other FDI parameters at the 24-month evaluation. In general, the restorations showed a very good clinical performance after 24 months, which can be seen in Figure 9.

Figure 9 - Clinical follow-up of restorations in different groups and times. PHT = preheated thermoviscous composite resin; NHT = non-heated composite resin.



Discussion

Preheating of composite resins is not a novel technique [15,16], and there is a substantial body of laboratory studies demonstrating enhanced properties for preheated composite resins compared to non-heated composites [18,19]. While in vitro studies can isolate variables and examine them in a controlled environment, they merely generate hypotheses that need confirmation in a clinical setting. The impact of these variables within the intricate clinical scenario, where numerous known and unknown prognostic factors may overshadow the benefits observed in vitro, needs to

be clinically assessed. Additionally, potential harms not previously investigated may come to light [46]. So far there are only short-term clinical studies that compared these techniques and evaluated restorations in class I and II [27], [28], [29], [30], [31], [32].

To the best of the authors' knowledge, this study is the first study designed to assess the impact of preheating on the clinical performance of composite resin restorations in NCCLs [43]. Given the proximity of NCCLs to the gingival margin and pulp chamber [47,48] this study design enables the assessment of the effects of composite heating on these dental tissues. So, concerns that preheating can potentially harm pulp tissue, leading to an increased risk of postoperative sensitivity [49], was not confirmed in the present investigation aligning with previous studies that compared post-operative sensitivity of preheated and non-preheated composites in posterior restorations [27], [28], [29], [30], [31], [32]. Moreover, while we might influence the gingival tissues surrounding the NCCLs, the FDI criteria for periodontal response did not reveal any discernible difference between the groups. Additionally, none of the participants from this study noticed a difference between the temperatures used in both groups, which underscores the safety and feasibility of preheating in this context.

In terms of retention/fracture, the results of the present study showed a small number of fractured restorations (3 for the PHT group and 1 for NHT group), as well as high retention rates for both groups, with 96.3 % for the PHT group and 90.8 % for the NHT group. The excellent clinical performance of both composites can be attributed to the good mechanical properties of the composite resins employed. Several in vitro studies have demonstrated that VisCalor, preheated or without preheating, achieves a degree of conversion and mechanical properties as high as those reported for other good comparable composite resins available in the market [20,21,49,50]. It is worth mentioning that VisCalor was applied as a bulk-fill composite, while, on the other hand, Admira Fusion was applied using an incremental filling approach. Consequently, to some extent, it involves a comparison between a bulk-fill technique (VisCalor) and a layered application method (Admira Fusion). A thorough review of the literature revealed that there was no significant difference in the retention rate observed after 12, 18, and 30 months of clinical evaluation when both techniques were compared [51], [52], [53], [54].

Contributing to high retention rates is the effective adhesive protocol with Futurabond U, a universal adhesive with a mild pH of 2.3. Adhesives with a mild pH

enhance interaction with dental tissues, preventing excessive demineralization and collagen fiber collapse [55], ultimately improving monomer penetration and bond strength [55]. Recent studies identified the presence of the functional monomer as 10-MDP in its composition. These salts, known for their high hydrolytic stability, form a strong chemical bond with dental substrates, not only protecting collagen fibers but also enhancing adhesive etching potential compared to other functional monomers [56], [57], [58], [59]. Speculation also exists about a potential reaction between MDP and organic molecules in dentin, particularly collagen [60,61].

In line with these findings, prior studies employing Futurabond U for the restoration of NCCLs demonstrate retention/fracture rates like those reported in the current investigation [62,63]. For example, Matos et al. [62] reported a success rate of approximately 95 % after 24 months of clinical evaluation, while de Albuquerque et al. [63] found that around 94 % of restorations were successful after 36 months. Considering that marginal discoloration relates to bonding performance, the reduced rates of marginal discoloration observed in this study and previous clinical trials [62,63,[69], [70], [71]] serve as additional evidence of the adhesive's excellent performance.

Although both materials exhibited excellent retention rates, the probability of the null hypothesis being true (i.e., groups being statistically similar) was borderline ($p = 0.06$), indicating a trend towards the preheated composite potentially demonstrating superior performance in terms of retention/fracture. Hordones Ribeiro et al. [50] demonstrated that preheating, compared to non-preheating, significantly reduced shrinkage stress at 10 min for various composites. This reduction can potentially decrease stress concentration at the adhesive interface and increase the fracture toughness of the adhesive layer, enhancing resistance against debonding [64,65]. Long-term follow-ups in this study could confirm if the observed trend at 24 months persists.

We anticipated improved marginal adaptation between the preheated composite and the cavity walls, as demonstrated by in vitro studies [23,66,67] and clinical studies [29], [30], [31], due to the enhanced flowability during placement. However, despite not detecting a significant difference between the groups, we observed a contrary trend with a borderline p-value of 0.06. Specifically, the preheated

composite demonstrated a higher rate of inferior marginal adaptation (33 % for the PHT group and 16 % for the NHT group).

The brief handling time associated with the preheated composite using the benchtop heater may have contributed to the observed higher rates of lack of ideal marginal adaptation. Initially, the composite resin and manipulation gun were placed in a benchtop heater, and a waiting period of 20–30 min were required for the heater to reach a temperature of 68 °C. Subsequently, the material and device were removed, and approximately 3 min were needed for the material to attain sufficient fluidity for extrusion from the capsule. However, the handling time is limited to 20 s, as the resin becomes more viscous with the loss of heat, diminishing its sculptability [20]. This underscores the sensitivity of the insertion procedure, requiring a highly skilled and calibrated operator. It is likely that results less favorable than those presented herein could have been observed if performed by students or inexperienced clinicians. Once again, when a composite inserted as a bulk-fill material was compared to the composite inserted by incremental technique, no significant differences in marginal adaptation were observed in the short-term (12–18 months) and mid-term (30 months) randomized clinical trials [51], [52], [53], [54].

Important to highlight that the contrast of the above findings with the laboratory investigations can also be attributed to methodological differences. Most of them control the temperature during the handling/insertion time [23,66,67] allowing the composite to retain the temperature for a longer period in a way that is not replicable in a clinical situation. In a clinical situation there is a significant heat loss that occurs when the material is removed from the benchtop heater and taken to where the material was inserted [16,50,66].

An alternative to enhance the handling of this material has been introduced by the manufacturer which developed a dedicated heater in the form of a pistol. This device not only rapidly heats the material but also maintains a constant temperature during handling and insertion into the cavity, extending the working time up to 3 min [68]. However, there is limited amount of research available on this equipment, either in vitro or in vivo [50]. More clinical studies evaluating this new device should be encouraged to evaluate this hypothesis.

The limitation of this randomized controlled trials should be mentioned. We have only evaluated one preheated composite resin. Another limitation is that we

conducted non-direct comparisons between a bulk-fill material (single increment) and a conventional material (several increments). It's essential to emphasize that the experimental composite resin used in the present study is a resin that cannot be manipulated without heating, and this constitutes a partial consideration of the last limitation. This in an interim analysis of 24 months and therefore long-term clinical follow-up studies are necessary to determine whether preheating composite resin restorations truly enhances their clinical performance in NCCLs. Exploring this area further will provide valuable insights into the long-term implications of preheating techniques and their potential benefits for patients with NCCLs.

Conclusions

The new preheated thermoviscous composite heated with a benchtop device and the non-heated resin placed in non-carious cervical lesions, showed high retention rates after 24 months of clinical service.

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7 ARTIGO 4 - VARIOUS WAYS OF PRE-HEATING A BULK-FILL THERMOVISCOUS COMPOSITE IN RESTORATION IN NON-CARIOUS CERVICAL LESIONS: 12-MONTH RANDOMIZED CLINICAL TRIAL

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Abstract

Objective: The objective of the study is to evaluate through a randomized clinical trial the best method to preheat a composite resin, if using a Caps dispenser device associated with Caps Warmer (CD) or with a VisCalor Caps dispenser/warmer (VD) for restorations in non-carious cervical lesions (NCCLs).

Material and Methods: One hundred and twenty restorations were distributed to two groups (n = 60) according to the pre-heating way of thermoviscous bulk-fill composite resin. For the CD group, pre-heating was carried at 68 °C using a heating bench for 3 min. For the VD group, pre-heating was performed at 68 °C using a heating gun for 30 s. After that, pre-heated bulk-fill composites were directly inserted in the NCCLs. The total working time was recorded. The restorations were evaluated after 6 and 12 months of clinical performance according to the FDI criteria. Statistical analysis was

performed using the Student's t test for unpaired samples for working time, and the Chi-square test for restoration clinical performance ($\alpha = 0.05$).

Results: Working time was shorter for VD with a statistically significant difference compared to CD ($p = 0.01$). Few restorations were lost or fractured after 12 months of clinical evaluation ($p > 0.05$). The retention rates were 96.7% (CI 95 %: 88.6–99.1%) for CD and 98.3% (CI 95 %: 91.1–99.7%) for VD. The other FDI parameters were considered clinically acceptable.

Conclusions: The different pre-heating ways did not influence the clinical performance of thermoviscous bulk-fill composite restorations in NCCLs after 12 months.

Clinical relevance: Regardless of the bulk-fill thermoviscous composite resin pre-heating ways, the restorations are clinically acceptable after 12 months.

Introduction

Due to the decreasing use of amalgam and more requests by patients for esthetic restorations, composite resins have become the first choice for direct anterior and posterior restorations [1,2,3]. Some advantages of composite resins are related to the match to natural tooth color, minimal cavity preparation when associated with the use of adhesive systems [4], and the low cost of composites compared to that of ceramic materials [1, 5].

Despite several differences in composition and viscosity, high-filled and regular/highly viscous composites are usually considered universal materials, mainly because these composites maintain their esthetic properties for use on anterior teeth and, at the same time, show better mechanical properties for use on posterior teeth [1].

However, the insertion of composite resin into tooth cavities could be considered a stressful experience [6] because their higher viscosity and stickiness make them difficult to handle and manipulate [7,8,9]. Consequently, regular/highly viscous composites can fail to adapt well to the cavity preparation walls, leading to a deficient marginal adaptation [10]. In contrast, flowable composites have a lower filler load and less viscous monomer content, which is favorable in terms of flowability and, consequently, improved marginal adaptation [9, 11]. It should be noted that the majority of flowable composites available in the market show low mechanical properties

compared to regular/highly viscous composites, hindering their use in areas of masticatory force [11].

An alternative should be to pre-heat regular/highly viscous composites. Pre-heating improves the degree of conversion, therefore all the composite's mechanical properties [12, 13]. At the same time, it makes the regular/highly viscous composite more fluid, improving manipulability during application [12, 13]. The idea of preheating composite resins is not new since evidence of its benefits has been reported in vitro studies for more than two decades [14,15,16,17,18]. However, recently, a tendency has arisen of growing, not only in composites but also in adhesives and luting cements for veneers [19,20,21,22,23,24,25,26].

Recently, a thermoviscous resin composite (VisCalor bulk, Voco GmbH, Cuxhaven, Germany) was launched in the market. This composite is dispensed from the capsule only when it is heated. After being inserted into the cavity, the composite lost temperature, gaining consistency to become sculptable without flowing out of the cavity, until being light-cured [27,28,29,30,31,32,33,34,35].

In the dental market, some heated 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 to 68 °C [12, 13]. However, a long pre-heating time is usually necessary, approximately 30 min of preheating added to the 3 min of resin preheating [36]. From a clinical point of view, this is against the necessity of simplification, mainly because it is an unacceptable long time into the clinical routine. In this sense, the manufacturer developed a self-preheating gun that only requires 30 s of preheating to reach the working temperature of 68 °C [35, 37].

Recently, researchers evaluated different forms of preheating and those did not affect the composite mechanical properties [35]. Moreover, the VisCalor bulk presented favorable mechanical properties and low contraction stress [35]. However, in vitro studies did not demonstrate clinical responses [38], and only a few clinical studies were conducted to evaluate the effects of preheating composite resins [36, 39,40,41]. Therefore, to the best of our knowledge, there is a lack of studies comparing the clinical performance of this new thermoviscous bulk-fill composite resins used with the different preheating methods mentioned above.

Thus, the aim of this double-blind, split-mouth, randomized clinical trial was to compare the clinical behavior of a preheating bulk-fill composite resin using the Caps dispenser device associated with Caps Warmer vs. the Caps dispenser/warmer device in restorations of non-carious cervical lesions (NCCLs). The null hypotheses tested were that (1) the use of different preheating methods will not influence the retention/fracture rates of restorations in NCCLs; (2) the use of different preheating methods will not influence in all the other FDI criteria parameters, and (3) there will not be a difference in the working time regardless of the preheating method.

Material and methods

Ethics approval and protocol registration

This clinical study was approved by the Scientific Review Committee and by the Committee for the Protection of Human Participants of the university, and it was registered in the Clinical Trials Registry. The study was conducted and described according to the CONSORT statements [42] with extension for projects within pairs [43]. Readers can find the explanatory document about these CONSORT extensions (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 in the clinics of the State University of Ponta Grossa, PR, Brazil between November 2021 and December 2021. The 12-month data was collected from November 2022 to December 2022. No advertisement was made for recruiting participants. Patients sought treatment for different reasons at the private clinic, making a convenience sample. When identified, participants were informed about the research nature and objectives and signed a voluntary informed consent before being 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 (ASA I, a normal healthy patient; and ASA II, a patient with mild systemic disease without substantive functional limitations) [44], at least 18 years old, have an acceptable level of oral hygiene level according to the Simplified Oral Hygiene Index (OHI-S) [45] 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 enamel were excluded. Patients with extremely poor oral hygiene (OHI-S more than 3) [45], or using orthodontic devices, severe or chronic periodontitis (teeth with probing pocket depth more than 4 mm with bleed on probing and clinical attachment loss more than 3 mm in more than 4 teeth) [46], or heavy bruxism (severe masticatory muscle pain, temporomandibular joint pain, or extreme tooth wear) [47] 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, or 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% [48]. With an 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 realized the randomization for the patient and immediately sent it to the 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 examiners were not involved with the restorative procedures and, therefore, were blinded to evaluating groups. As heating was used in both restorative groups, the patient was also considered blinded to the group's assignment, characterizing the double-blind study. Due to the significant difference between the equipment to be used and evaluated, it was not possible to blind the operators.

Baseline characteristics of the selected teeth

The characteristics of each tooth intended for restoration were evaluated and recorded before the placement of the restorations to allow a comparison between experimental groups. Three trained and calibrated operators who were involved in the participants' selection and carried out the restorative procedures evaluated all the features.

The degree of sclerotic dentin of the NCCLs was measured according to the criteria described by Swift et al. (2001) [49] as follows: (1) no sclerosis present; dentin is light yellowish or whitish, with little discoloration; dentin is opaque, with little translucency or transparency; (2) more sclerosis than in category 1 but less than halfway between categories 1 and 4; (3) less sclerosis than in category 4 but more than halfway between categories 1 and 4; and (4) significant sclerosis present; dentin

is dark yellow or even discolored (brownish); glassy appearance, with significant translucency or transparency evident.

The dimensions of the cavities (height, width, and depth) were measured with a millimeter probe. Geometry of the cavity was also evaluated by a profile photography and labeled at < 45°, 45°–90°, 90° < 135°, and > 135°) [50]. 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 s 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 area.

Interventions: restorative procedure

In order to calibrate the restorative procedures, the study director performed a restoration of each group to identify all the steps involved in the restorative technique. Then, the other three operators, residing in the school of dentistry and with more than 5 years of clinical experience, placed the four restorations in a clinical setting, two from each group, under the supervision of the study director. 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 10A) were cleaned through prophylaxis using pumice and water using a brush (Figure 10B), followed by rinsing and drying. Before the restorative procedures, the operators performed anesthesia on the corresponding teeth to be restored with a 3% solution of articaine hydrochloride (Articaine, Nova DFL, Rio de Janeiro, RJ, Brazil). 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 10C; 10D), associated to cotton rolls. No hemostatic liquids were necessary during this study. Selective enamel conditioning was Applied for 30 sec (Vococid, Voco GmbH, Cuxhaven, Germany) (Figure 10E), followed by rinsing and drying (Figure 1F) [51]. The universal adhesive system (Futurabond U, Voco GmbH, Cuxhaven, Germany) was applied in the self-etching mode, according to the manufacturer’s instructions in

all cavities [52,53,54,55,56,57]. The adhesive was manipulated, and the first application was made with a microbrush (Single Tim, Voco GmbH, Cuxhaven, Germany) (Figure 10G) followed drying by an air jet for 10 s. Following, a second coat was applied as the previous one, and at the end, the light curing of the adhesive was carried out with an irradiance of 1200 mW/cm^2 (Valo, Ultradent, South Jordan, UT, USA) for 20 s (Figure 10H). The cavities were restored with (VisCalor bulk, Voco GmbH, Cuxhaven, Germany) (Table 11). The two ways of preheating, one for each group, are described below:

Figure 10 - 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 and Drying (F). Applied universal adhesive system (G); Light curing (H).

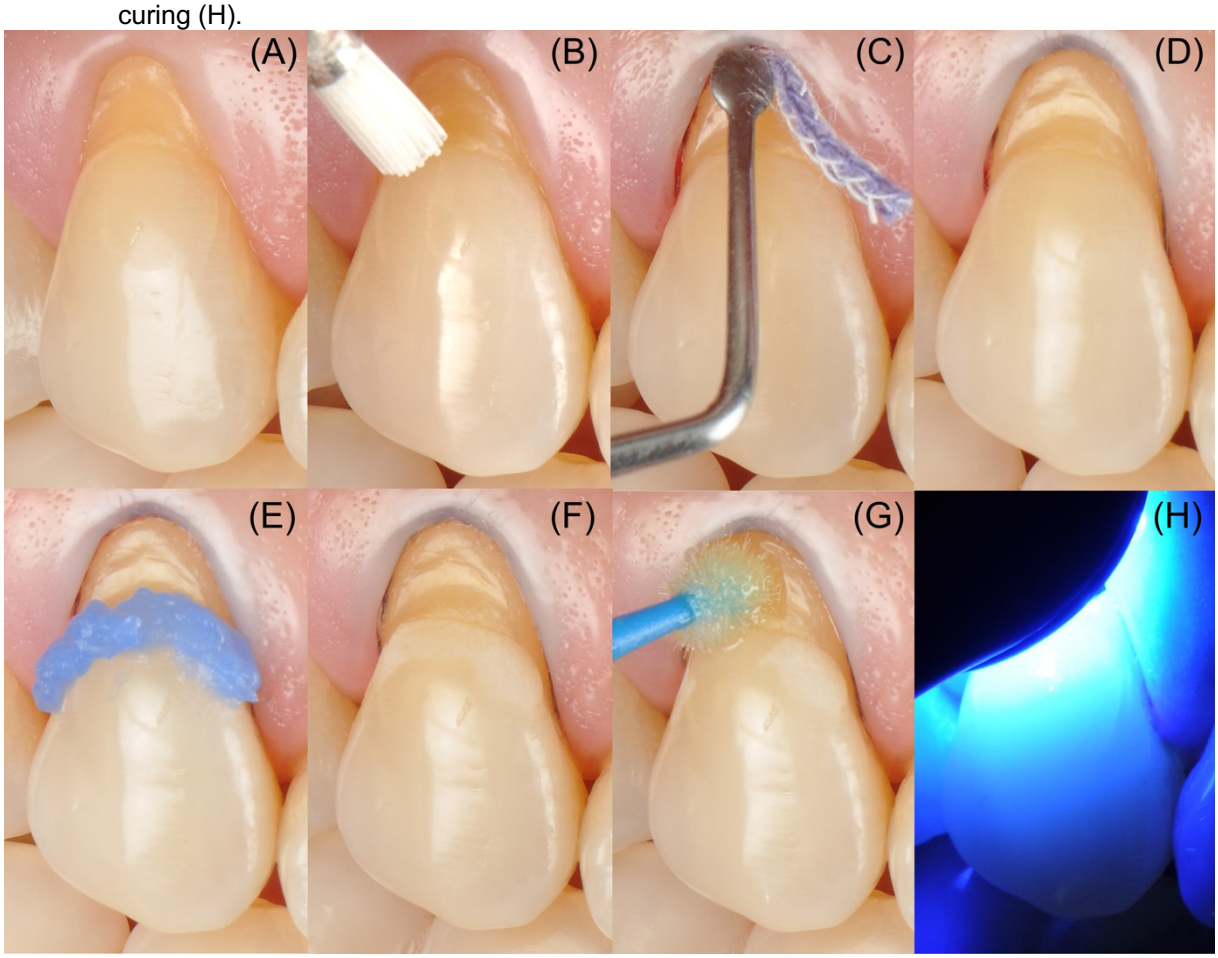


Table 11 - Manufacture information of investigated composites.

Material	Manufacturer	Color/Batch Number	Resin system	Application mode
VisCalor bulk	Voco GmbH, Cuxhaven, Germany	U / 2020095 A1 / 2020153 A2 / 2020239 A3 / 2021097	Resin matrix: Bisphenol-A-glycidyl dimethacrylate, aliphatic dimethacrylate. Inorganic filler: NI. Filler wt. 83%.	**CD group** 7. The capsule is inserted into the Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany). 8. Pre-heated to 68°C using a bench heater (Caps Warmer, Voco GmbH, Cuxhaven, Germany) for 3 minutes. 9. Placed in increments of 4 mm. 10. Light-curing of each increment is performed with an irradiance of 1200 mW/cm^2 for 40 seconds. **VD group** 1. The capsule is inserted into the Caps dispenser/warmer (VisCalor dispenser, Voco GmbH, Cuxhaven, Germany). 2. Pre-heated to 68°C for 30 seconds. 3. Placed in increments of 4 mm. 4. Light-curing of each increment is performed with an irradiance of 1200 mW/cm^2 for 40 seconds.

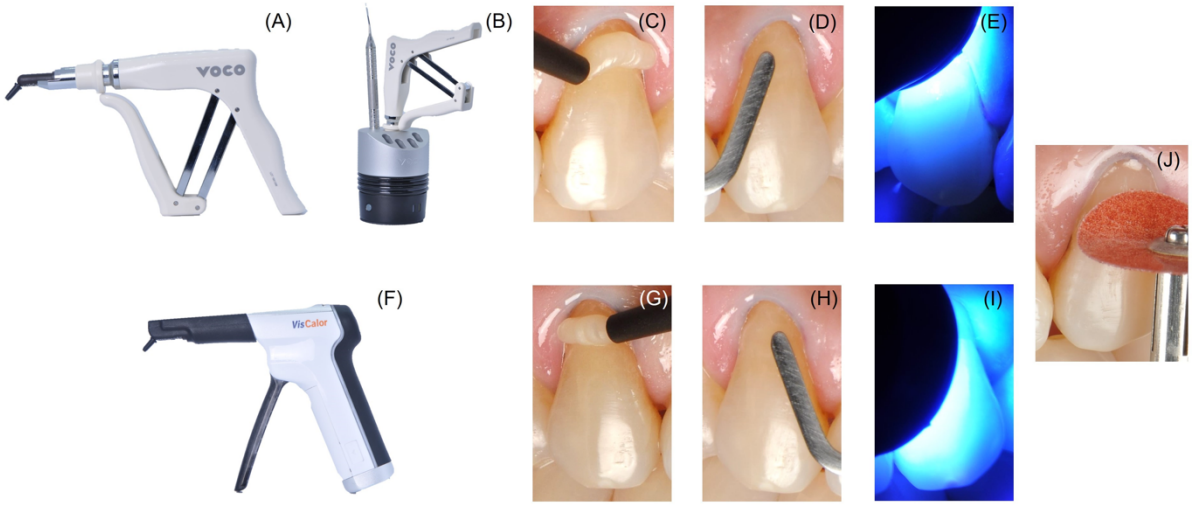
(*) Abbreviations: NI: not defined by the manufacturer

CD group: For the material to be heated, the bench heater (Caps Warmer, Voco GmbH, Cuxhaven, Germany) had to be heated for 20 min to reach the temperature capable of pre-heating the material. The restorative material was placed in the Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany) (Figure 11A) to be heated to 68 °C using a bench heater (Caps Warmer, Voco GmbH, Cuxhaven, Germany) for 3 min (Figure 11B). After heating, the composite was inserted in a single increment (up to 4 mm) in the cavity (Figure 11C) [58, 59]. The composite was inserted in the cavity with the help of a special instrument during up to 20 s, because the composite decreases its viscosity (loss of heat), hindering, from this time on, a better accommodation of the composite resin in the cavity (Figure 11D). The light

curing was carried out with an irradiance of 1200 mW/cm^2 (Valo, Ultradent, South Jordan, UT, USA) for 40 s (Figure 11E).

VD group: The restorative material was placed in the Caps dispenser/warmer (VisCalor dispenser, Voco GmbH, Cuxhaven, Germany) and was heated to 68 °C for 30 s (Figure 11F). After heating, the composite was inserted in a single increment (up to 4 mm) in the cavity (Figure 11G) [58, 59]. The composite was accommodated in the cavity with the help of a special instrument during up to 2.5 min (Figure 11H) for the same reason previously described in the CD group. The light curing was carried out with an irradiance of 1200 mW/cm^2 (Valo, Ultradent, South Jordan, UT, USA) for 40 s (Figure 11I). After filling the cavity, the restorations were immediately adjusted and polished with a sequence of polishing discs (Solf-lex, 3 M Oral Care, St. Paul, MN, USA) (Figure 11J).

Figure 11 - Caps dispenser (A); Heated to 68°C using a bench heater for 3 minutes (B); Inserted in a single increment in the cavity (C); Accommodation of the composite in the cavity (D); Light curing of the composite (E); Caps dispenser/warmer heated to 68°C using a bench heater for 30 seconds (F); Inserted in a single increment in the cavity (G); Accommodation of the composite in the cavity (H); Light curing of the composite (I); Adjusted and polished with a sequence of polishing discs (J).



Calibration procedures and clinical evaluation

For training purposes, two experienced and calibrated examiners observed 10 representative photographs of each score for each criterion. They evaluated 10 to 15 patients each on 2 consecutive days. These subjects had restorations in NCCLs but did not participate in the study sample. An agreement between examiner and inter-examiner of at least 85% was required before the start of the assessment [60].

The restorations at baseline and after 6 months were evaluated by World Federation criteria (FDI) [61, 62]. The primary outcome was 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; and periodontal response and oral health. Examiners were kept blind to earlier evaluations during the follow-up recalls. Seven days, 6 months, and 12 months after the restorative procedure, spontaneous postoperative sensitivity was evaluated. Patients were asked if they experienced any pain during the first 7 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) [61, 62]. 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. The working time with each of the techniques was also evaluated, timing the time of each restoration.

Statistical analysis

The statistical analyses followed the intention-to-treat [42]. Descriptive statistics were used to describe the distributions of the evaluated criteria. A statistical analysis was performed with chi-square test was used to compare the changes across different time points within each restorative material for all outcomes: retention/fracture; 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; and periodontal response and oral health. Cohen’s kappa statistics were used to test inter-examiner agreement. The total working time for each group was statistically evaluated using Student’s t test for unpaired samples. In all statistical tests, the significance level was pre-set at 5%.

Results

Forty-five out of 105 patients examined for eligibility were not enrolled in the study because they did not fulfill the inclusion criteria (Figure 12). Thus, a total of 60 subjects (32 male and 28 female) were selected. One hundred and twenty restorations were placed: 60 for each group (Figure 12). All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 12.

Figure 12 - CONSORT Flow Diagram.

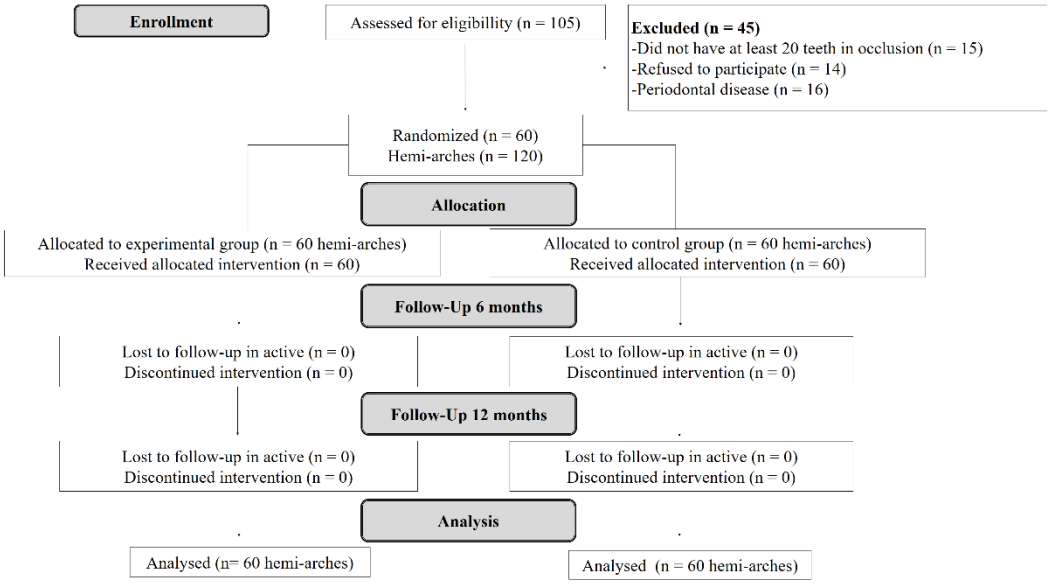


Table 12 - Characteristics of the Research Subjects and the NCCLs per group.

Characteristics of Research Subjects	Number of Subjects	
Gender Distribution		
Male	32	
Female	28	
Age distribution, (Years)		
20-29	1	
30-39	7	
40-49	27	
>49	5	
Characteristics of NCCLs lesions	**Number of Lesions**	
	CV	**VD**
Shape (degree of angle)		
<45	0	0
45-90	12	13
90-135	26	22
>135	22	25

Cervico-incisal height (mm)		
<1.5	5	3
1.5-2.5	28	17
2.5-4.0	22	36
>4.0	5	4
Degree of sclerotic dentin		
1	10	3
2	20	26
3	22	18
4	8	13
Presence of antagonist		
Yes	60	60
No	0	0
Attrition facet		
Yes	18	17
No	42	43
Pre-operative sensitivity (spontaneous)		
Yes	15	18
No	45	43
Pre-operative sensitivity (air dry)		
Yes	26	20
No	34	40
Pre-operative sensitivity (touch)		
Yes	13	12
No	47	48
Tooth distribution		
Anterior		
Incisor	3	4
Canines	12	4
Posterior		
Premolar	29	43
Molar	16	9
Arc distribution		
Maxillary	40	31
Mandibular	20	29
Presence of biofilm		
0	53	57
1	6	7
2	1	1
3	0	1

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. No participant complained about the difference between both restorative procedures. This intervention confirms that the temperature did not compromise the blinding of the participants. Regarding the 12-month clinical follow-up recall, the overall Cohen kappa statistics showed excellent agreement between the examiners in the 6 months (0.96). All research subjects were evaluated at baseline, 6- and 12-month recall. Usually, the restorations showed a very good clinical performance, after 12 months of clinical performance.

Retention/fracture

Few restorations were lost or fractured after 12 months of clinical evaluation for both groups (Table 13). The retention rates (confidential interval 95%) for 12 months were 96.7% (88.6–99.1%) for the CD group and 98.3% (91.1–99.7%) for the VD group, with no statistical difference between both groups ($p = 0.56$). Four restorations were considered as small discrepancies in retention and fracture in the 12-month recall using the FDI criteria (3 for CD and 1 for VD; Table 13).

Surface gloss/luster and roughness

After 12 months of clinical service, no significant difference was detected between groups ($p > 0.05$; Table 13) when the criteria were dichotomized into the two categories: no necessity of intervention or necessity of intervention.

When comparing the satisfactory ranked categories, five restorations were considered small discrepancies in surface gloss/luster and roughness (Figure 13A) in the 12-month recall using FDI criteria (3 for CD and 2 for VD; Table 13), with no statistical difference between them ($p = 0.63$).

Surface and marginal staining

According to the FDI criteria, after 12-month recall, no significant difference was detected between groups ($p > 0.05$; Tables 3) when the criteria were dichotomized into the two categories: no necessity of intervention or necessity of intervention.

When comparing the satisfactory ranked categories, two restorations were considered small discrepancies in surface and marginal staining in the 12-month recall using FDI criteria (1 for CD and 1 for VD; Table 13), with no statistical difference between them ($p = 0.99$).

Marginal adaptation

After a 12-month evaluation, no significant difference was detected between groups according to the FDI criteria ($p > 0.05$; Tables 3) when data were dichotomized into the two categories: no necessity of intervention or necessity of intervention.

When comparing the satisfactory ranked categories, fifteen restorations were considered small discrepancies in marginal adaptation (Figure 13B) in the 12-month recall using FDI criteria (10 for CD and 5 for VD; Table 13), with no statistical difference between them ($p = 0.16$).

Color match

According to the FDI criteria, no significant difference in the color match was detected between groups at the 12-month recall ($p > 0.05$; Tables 3) when the criteria were dichotomized into the two categories: no necessity of intervention or necessity of intervention.

When comparing the satisfactory ranked categories, eight restorations were considered small discrepancies in color match. in the 12-month recall using FDI criteria (8 for CD and 2 for VD; Table 13). Also, two restorations were considered small discrepancies in color match (Figure 13C) in the 12-month recall using FDI criteria. On overal, there are a significant statistical difference between them ($p = 0.04$).

Oral health

After 12 months of clinical evaluation, no significant difference in oral health was detected between groups according to the FDI criteria ($p > 0.05$; Tables 3) when data were dichotomized into the two categories: no necessity of intervention or necessity of intervention. When comparing the satisfactory ranked categories, thirty-four restorations were found to have biofilm retention (Figure 13D) in the 12-month recall using FDI criteria (16 for CD and 18 for VD; Table 13), with no statistical difference ($p = 0.73$).

Figure 13 - Different situations were found during the 12-month follow-up. (A) Surface roughness of restoration performed with CD; (B) Restoration performed with VD showed marginal adaptation deficiency (explorer); (C) Restorations performed with VD showed poor color match; and (D) Restorations performed with CD with the presence of biofilm.

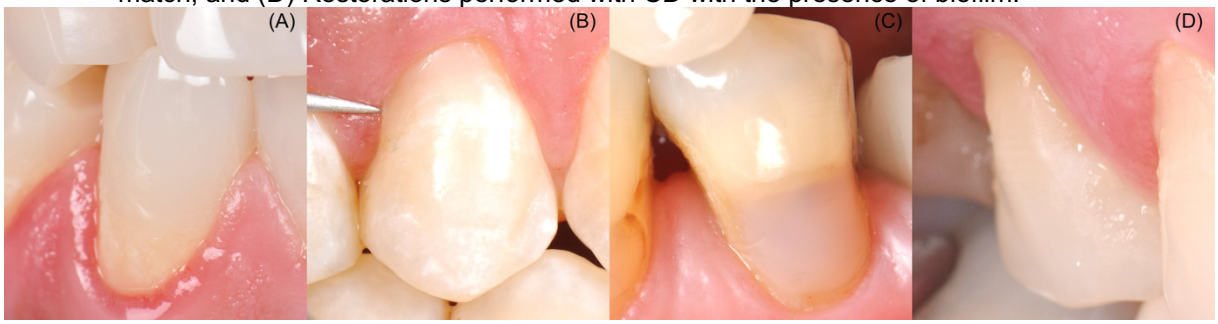


Table 13 - Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria.

FDI Criteria	(*)	Baseline		6 months		12 months	
		VD	**CV**	**VD**	**CV**	**VD**	**CV**
Fractures and retention	A	60	60	60	59	59	57
	B	0	0	0	0	0	0
	C	0	0	0	1	0	1
	D	0	0	0	0	1	2
	E	0	0	0	0	0	0
Surface gloss/lustre and roughness	A	60	60	58	57	57	55
	B	0	0	2	3	2	3
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Surface and Marginal staining	A	60	60	60	60	58	57
	B	0	0	0	0	1	1
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Marginal adaptation	A	60	60	55	50	54	48
	B	0	0	5	10	5	10
	C	0	0	0	0	0	0

	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Color match	A	60	60	58	51	57	50
	B	0	0	0	9	0	8
	C	0	0	2	0	2	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Esthetic anatomical form	A	60	60	60	60	59	58
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Recurrence of initial pathology	A	60	60	60	60	59	58
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Tooth cracks and fractures	A	60	60	60	60	59	58
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Effect of the restoration on the periodontium	A	60	60	60	60	59	58
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Postoperative sensitivity	A	60	60	60	60	59	58
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Recurrence of caries	A	60	60	60	60	59	58
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Tooth Integrity	A	60	60	60	60	59	58
	B	0	0	0	0	0	0
	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Periodontal response	A	60	60	60	60	59	58
	B	0	0	0	0	0	0

	C	0	0	0	0	0	0
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0
Oral health	A	60	60	43	44	41	42
	B	0	0	16	15	17	13
	C	0	0	1	1	1	3
	D	0	0	0	0	0	0
	E	0	0	0	0	0	0

(*) A = Clinically very good; B = Clinically good; C = Clinically sufficient / satisfactory; D = Clinically unsatisfactory; E = Clinically poor. VD = VisCalor Caps dispenser/warmer; CW = Caps dispenser device with Caps Warmer.

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 12 months of clinical evaluation.

Total working time

The total working time was around 36.5 min (± 2.5) for CD and around 14.3 min (± 2.3) for VD. This difference was statistically significant and favorable to VD group ($p = 0.01$).

Discussion

Only one material on the market was specifically developed for use in pre-heating form VisCalor bulk, and it was used in the present study. Because its form of presentation is a capsule, it can be heated with different method [35]. This seems the best study to determine which is the most effective form of pre-heating in the maintenance of restorations in the mouth with this thermoheated composite resin, mainly because there is not enough clinical evidence on the subject to support the use of this type of restorative technique in terms of restorations' quality and durability [36, 39,40,41].

The preheating of composite resins has become increasingly popular in dental practice even though they are not new in dentistry [15, 16]. Despite in vitro benefits, such as decreased viscosity, the increased degree of conversion, improved marginal

adaptation, and less bubble incorporation [12, 13], they cannot be designed to correlate with the clinical performance of restorations [38]. This is the academy's great concern regarding the indication of preheating restorations: preheating could be responsible for some post-operative sensitivity [15, 17]. However, in the present study, no post-operative sensitivity was observed in the baseline or even after 12 months of clinical evaluation, independently of the warming device used, in agreement with previous clinical studies in which researchers evaluated the clinical performance of VD preheating in NCCLs [36] and CD preheating in class I and II restorations [39,40,41].

In addition, steps previous to the insertion of the composite resin, such as the conditioning and rinsing of the dental structures, have been shown to cause a drop in the dentin's and enamel's temperature [4, 17]. Because the tooth structure arrives at a lower temperature than the preheated composite, the tooth acts as a heat sink, rapidly decreasing the temperature of the composite [17]. This decrease generates a temperature gradient between the cooled dentin walls and the pulp, so the cooled dentin acts as a heat sink that not only reduces pulp temperature but also absorbs part of the heat generated during exposure to the light-cure [4]. Additionally, due to the use of a single increment, increasing the thickness of the composite resin layer resulted in a smaller temperature increase in the pulp chamber [59]. The authors attributed these findings to the greater insulating effect provided by thicker resin layers. Therefore, based on current findings, the ability of thicker composite resin layers to act as insulators and reduce pulp-temperature increase is greater than the influence of exothermic polymerization heat on pulp temperature values.

In a pioneer study, the authors evaluated the pulp temperature using preheated resins and found a difference of 31.1 °C between the room temperature (23.6 °C) and the measured composite temperature (54.7 °C) when it is stored in a device unit similar to VD [17]. However, when the preheated composite was injected into the tooth cavity, the maximum temperature recorded in the top surface of the composite was only 38.4 °C (instead of 54.7 °C), in contrast to the 29.6 °C when the composite was kept at room temperature [17]. In the same way, the temperature measured in the pulpal floor was 36.2 °C using the preheated composite, as opposed to 30.4 °C when the composite was at room temperature [17]. Observe that, despite both resins changed temperature (lower temperature for heated resin and higher temperature for not heated resin), the difference between them (from 36.2 to 30.4 °C)

when measured in the pulpal floor of the cavities is still favorable for the former indicating that better handling characteristics was obtained when the resin was heated [17]. It is to worth to mention that, until the author's knowledge, no previous study evaluated the temperature at which the resin reaches the tooth cavity when heated by VD equipment and future studies need to be done to evaluate these characteristics. However, a recent study showed similar behavior, in terms of loss temperature when CD and VC were compared [35].

Due to our understanding of how pre-heated composite resins behave in response to pulp temperature changes, many types of equipment can be used to pre-heat composite resins [12, 13, 35], but the vast majority of them lose temperature when the equipment is transported to the cavity to be restored [16, 18, 35]. Therefore, this new VD equipment seems interesting because it is possible to transport the heated material to the cavity to be restored [37]. An important difference is that the VD equipment allows for the delivery of the heated resin into the cavity at the indicated preheating temperature, which is why this equipment provides more working time in the mouth.

A previous study demonstrated a 50% drop in temperature within 2 min in composite resin samples after the removal of the CD preheating device [15,16,17]. This temperature drop could compromise the restorations' quality due to the change in the composite's viscosity; the clinician would not have enough time to fit and anatomize the restorations during the restorative procedure. Although no significant difference was observed between the two groups after a 12-month recall, more restorations with CD showed defects in terms of marginal adaptation. The equipment used in this group allowed for only 20 s of work after the material's insertion into the cavity, which may be one of the factors behind this finding. This seems to indirectly indicate that keeping the composite preheated for a longer time, as when it is used with VD, could be an advantage over the CD device. However, none of the restorations were considered clinically unsatisfactory in the present evaluation time, so future long-term studies are necessary to prove this hypothesis.

In terms of retention rate, no restorations were lost during the evaluation period, possibly due to the composition of the universal adhesive used and the application technique. Although several universal adhesives are available in the market, it is usually widely recognized that ultra-mild/mild pH adhesives as well as

universal adhesives containing the acidic functional monomer 10-MDP (10-methacryloyloxydecyl dihydrogen phosphate), such as Futurabond U adhesive, have shown stronger bonding values than other monomers with the same purpose [57]. Usually, adhesives with 10-MDP are less acidic (i.e., mild acidity), thereby allowing chemical binding to surface Ca2+ ions of the substrate, which dissolves the dentin in the nano-extension, resulting in the formation of 10-MDP-Ca salts, which are responsible for a stable bond with dentin [57]. Also, the application of selective enamel etching previously to the application of universal adhesive can improve the marginal adaptation and prevent the marginal discoloration of the restorations [51]. Actually, several clinical studies showed excellent clinical performance of Futurabond U when it is applied in NCCLs, mainly when applied by selective enamel etching [52,53,54,55,56].

It is important to consider that one bulk-fill composite was used instead of a composite in the incremental technique [58]. The use of a bulk-fill resin can be considered easier from an operational point of view [35] because a single layer of up to 4 mm in width is sufficient for the restoration to be completed [58]. Although bulk-fill flow resins are available in the market and this materials have the same objective of improving adaptation to the cavity walls [37]. Bulk-fill flow resins can be considered very difficult to fit in the cavity, with the possibility of an outflow of the cavity, mainly in NCCLs [9]. Therefore, preheating the composite resin is considered interesting, since viscosity decreases, making the resin more flowable and easy to insert into the NCCLs. Working time for both groups also needs to be considered. Professionals seek not only effective materials but also reduced chair time. The CD group had twice the working time to finish the restorations, which shows another benefit of using VD.

In the present study, NCCLs were used to evaluate the clinical performance of restorations due to several reasons. (1) NCCLs show high prevalence, mainly in populations older than 30 years [63], that means NCCLs are widely available; (2) taking in account the advantages of use bulk-fill composites, some authors have suggested bulk-fill materials as alternatives [9, 64,65,66] to restore NCCCLs; and (3) despite NCCLs are shallow in mechanical point of view, all cavities are considerate deep in terms of biological. Therefore, it seems an ideal cavity to evaluate postoperative sensitivity, mainly when two different heated systems were evaluated, as in the present study.

Some limitations need to be mentioned. In the present study, the same material was used in different methods of preheating, so the results could not be generalized for all commercial composite brands. Therefore, researchers must conduct more clinical studies with conventional resins heated in different ways.

Another limitation of this clinical investigation is that 12 months may be a too short period of time to observe substantial changes. Therefore, longer-term interim evaluations may be necessary to assess more thoroughly the effect of various pre-heating methods on the present thermoheated composite resin.

Conclusion

The clinical performance of the different ways of pre-heating the thermoviscous composite resin proved to be safe and showed similar clinical performance in non-carious cervical lesions after 6 months of clinical evaluation.

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8 ARTIGO 5 - EVALUATION OF PREHEATING METHODS FOR BULK-FILL THERMOVISCOUS COMPOSITE IN NON-CARIOUS CERVICAL LESIONS: A 24-MONTH RANDOMIZED CONTROLLED TRIAL

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Abstract

Objective: This 24-month, double-blind, split-mouth randomized equivalence clinical trial compared the retention rates of a bulk-fill thermoviscous composite resin (VisCalor bulk, Voco GmbH) preheated with a dispenser heater (DH, VisCalor Caps dispenser/warmer) or with a bench heater (BH, Caps Warmer) for restoration of non-carious cervical lesions (NCCLs).

Material and Methods: A total of 120 NCCLs were randomized in two groups (n = 60 each): In the BH group, the composite underwent preheating at 68°C using a heating bench for 3 min while in the DH group, the composite was preheated at the same

temperature for 30 s using a dispenser heater. Subsequently, the preheated bulk-fill thermoviscous composite resin was directly applied to the NCCLs. The restorations were evaluated at baseline, 6, 12, 18, and after 24 months of clinical service using the FDI criteria. The total working time was recorded. The study used TOST-P to assess groups equivalence, Kaplan-Meier analysis for retention/fracture rate, log-rank test for secondary outcomes' survival distributions, and paired t-tests for comparing time per clinical step between groups, all at a significance level of 5%.

Results: After 24 months 106 restorations were assessed. Four restorations were lost (two for DH group and two for BH group), yielding equivalent and similar retention rates (96.1%, 95% CI 86.8-98.9 for both groups, $p > 0.05$). The hazard ratio was 0.83 (95% CI 0.26 to 2.72) for both groups ($p > 0.05$). The other FDI parameters assessed were deemed clinically acceptable. The total working time for the BH was statistically higher than that for the DH ($p < 0.001$).

Conclusions: Both preheating protocols employed for the bulk-fill thermoviscous composite resin demonstrated high and equivalent retention rates after 24 months.

Clinical Significance: Clinicians can choose either method for heating the thermoviscous composite resin for restoration of non-carious cervical lesions, as they do not impact important clinical outcomes after 24 months. The total working time for the bench heater is higher than that for the dispenser heater due to the need for preheating of the bench heater.

Keywords: Composite resin; Viscosity; Temperature; Pre-heated composite; Clinical Trial.

Introduction

As the demand for esthetic dental solutions rises along with a reduction in the placement of amalgam restorations, composite resins have emerged as the primary preference for both direct anterior and posterior restorations [1, 2]. Adhesive composite resin restorations offer several advantages, including their ability to seamlessly match the natural tooth color, the potential for minimal cavity preparation, and their cost-effectiveness in contrast to ceramic materials [2, 3].

Despite their varying compositions and viscosities, high-filled and regular/highly viscous composites are commonly regarded as universal materials as

they mimic esthetic properties required for anterior teeth while exhibiting high mechanical properties, essential for posterior restorations [2]. Due to the higher viscosity and adhesive nature of these composites, the process of inserting composite resin into dental cavities can be considered a challenging procedure [4-7]. This difficulty in handling often leads to inadequate adaptation of regular/highly viscous composites to the cavity walls, resulting in compromised marginal adaptation [8].

Heating uncured resin composites can improve their handling during restoration [9-11]. By raising the composite's temperature, the movement of radicals and monomers increases, reducing viscosity and enhancing the conversion of monomers to polymers [9-11]. This reduced viscosity leads to improved adhesion to cavity walls, better marginal integrity, and reduced microleakage [9-11]. Moreover, this process enhances various mechanical and physical properties of the composite as reported by in vitro studies over the past two decades [12-16].

A bulk-fill thermoviscous composite resin (VisCalor bulk, Voco GmbH, Cuxhaven, Germany) has been recently introduced in the dental market. This composite is dispensed from the capsule exclusively when it is heated. Upon insertion into the cavity, the composite undergoes a temperature decrease, transitioning to a more manageable consistency, allowing for sculpting without the risk of flowing out of the cavity. This controlled state persists until the composite is ready for light-curing [17-25].

For composite preheating there are some bench devices available in the dental market such as the Calset heater (AdDent Inc., Danbury, CT, USA), ENA heat (Micerium, Avegno GE, Italy), and Caps Warmer (Voco GmbH, Cuxhaven, Germany). They operate between 37°C to 68°C [9-11] but they usually require a lengthy preheating time of around 20 min and an additional 3 min for resin preheating [26-28]. This prolonged duration goes against the aim of simplifying dental procedures, thereby compromising the efficiency of clinical protocols. The development of a dispenser heater (Viscalor dispenser, Voco GmbH, Cuxhaven, Germany) makes the procedure faster as it does not require a preheating time and the composite can take at most 3 min to reach the adequate temperature for placement in the dental cavity [28-31].

Despite promising results observed in laboratory settings regarding composite preheating [9-11], clinical recommendations should primarily rely on evidence gathered from clinical studies [32]. To date, only a limited number of controlled clinical

investigations have explored the effects of preheating composite resins [26-31, 33-37], with a notable gap in the literature concerning comparisons between different preheating methods (bench heater vs. dispenser heater) for thermoviscous bulk-fill composite resin [25].

Besides that, most clinical studies with preheated resins were conducted in posterior restorations [29-31, 33-37]. Clinical trials on non-carious cervical lesions (NCCLs) can offer valuable insights, as these lesions are often closer to the dental pulp, allowing for the assessment of important outcomes such as post-operative sensitivity resulting from the use of heated composite materials [26-28].

Therefore, the objective of this double-blind, split-mouth, randomized equivalence controlled trial (RCT) was to compare the clinical performance of a preheated bulk-fill thermoviscous composite resin placed in NCCLs using two distinct heating methods: the bench heater (Caps warmer device with the Caps dispenser) versus the dispenser heater (VisCalor dispenser) over a follow-up period of 24 months.

Material and methods

Ethics approval and protocol registration

The clinical investigation received approval (4.742.223) from both the Scientific Review Committee and the Committee for the Protection of Human Participants at the local University. The trial was registered in the Clinical Trials Registry under the identification number RBR-889c9qv. The present clinical study was described following the CONSORT guidelines [38, 39].

Trial design, settings, locations of data collection, and recruitment

This study was conducted as a double-blind, split-mouth, equivalence, randomized controlled trial. Restorations were placed from November 2021 to December 2021, and the 24-month data collection occurred between November 2023 to December 2023. The authors opted to create a convenience sample, refraining from any recruitment advertising efforts.

Patients visiting the private clinic for various reasons were approached when

they were identified as potential candidates for the study. Once these patients were informed about the ongoing research at the clinic and had a clear understanding of the study's objectives, they were invited to participate in the trial and asked to sign an informed consent form.

Eligibility criteria

All participants underwent a thorough examination by two well-trained operators to ensure their eligibility. These assessments were conducted using a mouth mirror, an explorer, and a periodontal probe.

Participants should have good general health status according to the American Society of Anesthesiologists (ASA) Physical Status Classification System, falling into either ASA I (normal healthy patient) or ASA II (patients with mild systemic disease without substantial functional limitations) categories [40]. They should be at minimum 18 years old with an acceptable level of oral hygiene as determined by the Simplified Oral Hygiene Index (OHI-S) [41]. They should have a minimum of 20 teeth in occlusion and, in these teeth, the presence of at least two comparable NCCLs in terms of size, shape, dimensions, and color in need of restorative procedure. These lesions needed to be non-retentive, deeper than 0.5 mm, and involve both enamel and dentin in vital teeth without periodontal mobility.

Exclusion criteria encompassed participants with a cavosuperficial margin involving over 50% of enamel. Additionally, patients with extremely poor oral hygiene (OHI-S score exceeding 3) [41], those using orthodontic devices, individuals suffering from severe or chronic periodontitis (teeth with probing pocket depths exceeding 4 mm with bleeding on probing and clinical attachment loss surpassing 3 mm in more than four teeth) [42], and individuals exhibiting heavy bruxism (severe masticatory muscle pain, temporomandibular joint pain, or extensive tooth wear) [43] were excluded from the study, as they necessitated other dental treatments before restorative intervention. Participants with known allergies to resin-based materials or any other substances employed in this study, pregnant or lactating women, and those in chronic use of anti-inflammatories, analgesics, or psychotropics were not included in the present study.

Sample size calculation

The retention rate for composite resin after three years of clinical service was shown to be around 80% [44]. Given the absence of a discernible difference between the standard and experimental treatments, a sample size of 112 patients (56 per group) guarantees 90% confidence that the two-sided 90% confidence interval will not encompass a difference exceeding 25% between the groups. To account for any potential losses, 60 restorations were performed in each group, thereby ensuring a robust and reliable dataset for analysis.

Randomization and allocation concealment

Randomization in this study was conducted on an individual basis, with each participant receiving two restorations, one of each group. The simple randomization scheme was generated using tools available on the website www.sealedenvelope.com. To maintain the allocation concealment of the study, a researcher not involved in the implementation and examination phases performed the randomization process keeping the random list confidential.

At the time of implementation, the operator sent an instant message via WhatsApp (Incorporation Meta, LLC) 15 min before commencing the intervention. The researcher then disclosed the patient randomization scheme and promptly communicated the allocation to the operator. In all cases, the tooth with the highest numerical identifier according to the FDI numbering system received the treatment revealed in the random list, while the tooth with the subsequent number in the sequence received the second treatment.

Blinding

The evaluators were unaware of the allocation assignment, ensuring they were blind during the evaluation. Patients were also kept unaware of the assigned group used in their tooth, thereby characterizing the study as double-blind. Due to substantial differences in the equipment used it was not feasible to blind the operators who placed the restorations.

Baseline characteristics of the selected teeth

A pre-restoration assessment was conducted to ensure groups were comparable at baseline. All participants who met the eligibility criteria had their NCCLs dimensions (height, width, and depth) measured with a millimeter probe. The degree of sclerosis was also evaluated according to Swift et al. [45]. The cavity geometry using profile photography was evaluated and the lesions were categorized into angles of <45º, 45º-90º, 90º<135º, and >135º [45]. The presence of an antagonist, the identification of friction facets, and preoperative sensitivity were also recorded (yes/no). Preoperative sensitivity was assessed by applying a 10-s air-dry stream with a dental syringe at 2 cm from the tooth surface. The lesion was also inspected by an explorer. The presence of biofilm (yes/no) was also evaluated by moving the millimeter probe along the entire cervical region.

Interventions: restorative procedure

To ensure consistency in the restorative procedures, the study coordinator restored each group, detailing all the steps of the restorative technique. Subsequently, the other three operators, all of whom were in the post-graduation course of the School of Dentistry with more than five years of clinical experience, placed independently four restorations in a clinical setting, under the supervision and guidance of the study coordinator. The study coordinator could identify failures in the procedure and correct the operators in the standardized procedure. From this point on, the operators were considered properly calibrated for the execution of all restorative procedures of the present clinical trial.

Before the restorative procedure, all NCCLs were cleaned through prophylaxis, with pumice and water in a low-speed handpiece mounted with a rotary brush. Due to the difficulties in making shade selection with the thermoviscous resin composite (as it would require composite pre-heating, placing a small increment on the dental surface, light cure it and then check color match), we opted to use in most of the cases the universal shade for both groups. Just in cases where significant discrepancies in color match were observed during resin composite placement, other shades were tested for color match (4 1). The operators administered local anesthesia

to the teeth scheduled for restoration, using a 3% solution of articaine hydrochloride (Articaine, Nova DFL, Rio de Janeiro, RJ, Brazil) and they placed a lip and cheek retractor (Lip Retractor with Rod, Morelli, Sorocaba, São Paulo, Brazil) in the patients' mouth. The operators placed a retraction cord (Ultrapak # 0, Ultradent, South Jordan, UT, USA) in the gingival sulcus of the teeth to be restored using an insertion spatula. Cotton rolls and saliva ejectors were used to keep the operative field dry. No hemostatic liquids were required during this study.

Table 14 - Manufacture information of investigated composites.

Material/manufacturer	Color/Batch Number	Composition	Application mode
VisCalor bulk Voco GmbH, Cuxhaven, Germany	U/2020095 A1/2020153 A2/2020239 A3/2021097	Resin matrix: Bisphenol-A-glycidyl dimethacrylate, aliphatic dimethacrylate. Inorganic filler: NR. Filler wt. 83%.	**Dispenser heater group** 1. The capsule is inserted into the Caps dispenser/warmer (VisCalor dispenser, Voco GmbH) 2. Pre-heated to 68°C for 30 s. 3. Placed in increments of 4 mm. 4. Light-curing of each increment is performed with an irradiance of 1,200 mW/cm^2 for 40 s. **Bench heater group** 1. The capsule is inserted into the Caps dispenser (Caps dispenser, Voco GmbH). 2. Pre-heated to 68°C using a bench heater (Caps Warmer, Voco GmbH,) for 3 min. 3. Placed in increments of 4 mm. 4. Light-curing of each increment is performed with an irradiance of 1,200 mW/cm^2 for 40 s.

(*) Abbreviations: NR: not reported by the manufacturer.

The universal adhesive system (Futurabond U, Voco GmbH, Cuxhaven, Germany) was applied in the selective enamel conditioning mode, following the manufacturer's instructions. Initially, the enamel was conditioned using Vococid (Voco GmbH, Cuxhaven, Germany) for 30 s, followed by rinsing and slightly drying. Subsequently, a single coat of the universal adhesive system (Futurabond U, Voco GmbH, Cuxhaven, Germany) was applied in enamel and dentin using a microbrush (Single Tim, Voco GmbH, Cuxhaven, Germany) with vigorous agitation, followed by air-drying for 10 s. Afterwards, a second coat was applied similar to the first, and the adhesive was light-cured at 1,200 mW/cm^2 (Valo, Ultradent, South Jordan, UT, USA) for 20 s. Following these preparatory steps, the cavities were restored using one of the

two compounds as described below:

-Dispenser heater group (DH): In this group, the restorative material was placed in the dispenser heater (VisCalor dispenser, Voco GmbH, Cuxhaven, Germany) and heated to 68°C for 30 s (Figure 1). After heating, the composite was inserted in a single increment (up to 4 mm) into the cavity. Using a composite spatula, the resin composite was accommodated in the cavity for up to 2.5 min. The resin composite was then light cured (1,200 mW/cm^2; Valo, Ultradent, South Jordan, UT, USA) for 40 s. Upon cavity filling, finishing, and polishing of the restorations were performed using a sequence of polishing discs (Solf-lex, 3M Oral Care, St. Paul, MN, USA).

- Bench heater group (BH): To achieve the necessary temperature for preheating the material, the bench heater (Caps Warmer, Voco GmbH, Cuxhaven, Germany) underwent a 20-min warming process. Subsequently, the restorative material cap was placed in the Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany) and heated to 68°C using the bench heater (Caps Warmer, Voco GmbH, Cuxhaven, Germany) for 3 min (Figure 1). Once heated, the composite was inserted in a single increment (up to 4 mm) into the cavity. During the initial 20 s, a resin spatula was used to accommodate the composite. After these 20 s, the resin composite increased viscosity to the point that resin sculpture was not possible. Light curing was then conducted as previously reported for 40 s. Upon cavity filling, finishing and polishing of the restorations were performed using a sequence of polishing discs (Solf-lex, 3M Oral Care, St. Paul, MN, USA).

Figure 14 - Heating devices. **Dispenser heater** (VisCalor dispenser, Voco GmbH, Cuxhaven, Germany) heated to 68°C for 30 s. **Bench heater group** (Caps Warmer, Voco GmbH, Cuxhaven, Germany) underwent a 20 min warming process. Subsequently, the restorative material cap was placed in the Caps dispenser (Caps dispenser, Voco GmbH, Cuxhaven, Germany) and the set heated to 68°C using the bench heater (Caps Warmer, Voco GmbH, Cuxhaven, Germany) for 3 min.

Calibration procedures and clinical evaluation

Two experienced, blind, and calibrated examiners underwent a training process. During this training, they observed 10 representative photographs of each score from the FDI evaluation criteria. Subsequently, these examiners assessed 10 to 15 patients in two consecutive days. It is important to note that these patients had restorations in NCCLs but were not part of the study sample. Before commencing the assessment of the study participants, it was necessary to establish an inter-examiner agreement level of at least 85% between the examiners [46].

Clinical Evaluation

The evaluation of the restorations was performed at baseline and after 6, 12, 18, and 24 months using the World Federation criteria (FDI) [47, 48]. The primary outcome of interest was the retention/fracture of the restorations. Other secondary outcomes were also evaluated: 1. Surface gloss/luster and roughness; 2. Surface and marginal staining; 3. Marginal adaptation; 4. Color match; 5. Aesthetic anatomical form; 6. Recurrence of initial pathology; 7. Tooth cracks and fractures; 8. The effect of the restoration on the periodontium; 9. Postoperative sensitivity; 10. Recurrence of caries; 11. Tooth integrity; 12. Periodontal response; 13. Oral health.

Throughout the follow-up recalls the examiners remained unaware of earlier evaluation scores to maintain blinding. At different time points, namely seven days, 6, 12, 18, and 24 months after the restorative procedure, spontaneous postoperative sensitivity was assessed. Patients were asked whether they experienced any pain during the initial seven days following the 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) [47, 48]. 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.

Working time

The time required for each step of the restorative procedure (preheating of the heater device, anesthesia, and isolation of the operative field, dental cavity preparation, preheating of the composite resin, handling time for composite sculpture, and finishing and polishing procedure) was measured with a digital chronometer. The total working time for resin composite placement was also recorded. The measurement of this outcome was decided during the pilot phase of the study and after the protocol registration.

Statistical Analysis

The statistical analyses followed the modified intention-to-treat analysis [49], including all randomized patients who attended the 24-month recall. For statistical purposes of fracture/retention, the FDI criteria were dichotomized into two categories: no intervention required (clinically very good, clinically good, and clinically sufficient/satisfactory) or intervention required (clinically unsatisfactory but repairable, and clinically poor where replacement is required) [50].

To assess the equivalence of the study groups in terms of retention rates at different assessment points (baseline, 6, 12, 18, and 24 months after restoration) two one-sided t-tests for paired samples (TOST-P) were used. This method employed a right-sided test for the lower margin of the equivalence limit and a left-sided test for the upper margin using one-sided 0.025 significance levels. The overall ‘p-value’ is taken to be the larger of the two ‘p-values’ from the lower and upper tests. The risk differences and 90% confidence interval (CI) were calculated between groups at each time assessment. For the retention rate, if both treatments differ by more than 25% in either direction, then equivalence does not hold.

Additionally, the Kaplan–Meier analysis, estimating the hazard ratios (HRs) and 95% confidence intervals (CIs) for retention/fracture rate was also calculated. All other secondary outcomes from the FDI criteria were tested for superiority using the chi-square test. Cohen’s kappa statistics were used to test inter-examiner agreement. The time required for the accomplishment of every clinical step for both groups was compared with a paired t-test. The mean differences and 95% confidence intervals were calculated. In all statistical tests, the significance level was pre-set at 5%.

Results

Forty-five out of 105 patients examined for eligibility were not enrolled in the study because they did not fulfill the inclusion criteria (Figure 15). Thus, a total of 60 subjects (33 male and 28 female) were selected. A total of 120 restorations were placed, with 60 in each group (Figure 15). The procedures were performed according to the protocol without any modification. Table 15 presents the baseline participant details and the characteristics of the treated lesions. There is an equal distribution of lesion features between groups.

Figure 15 - CONSORT 2010 Flow Diagram.

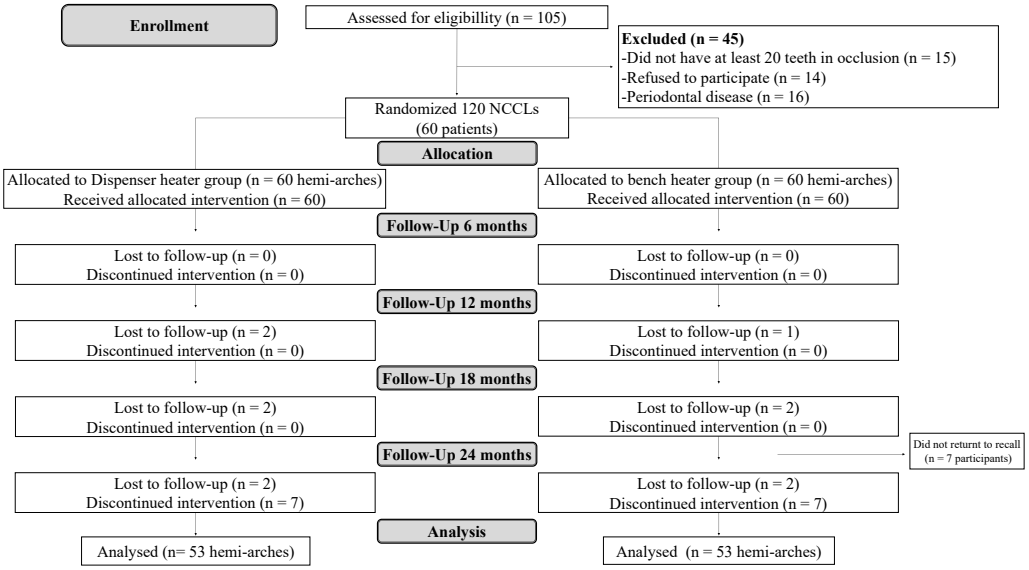

Table 15 - Characteristics of the Research Subjects and the Non-carious Cervical Lesions (NCCLs) per Group.

Characteristics of Research Subjects	**Number of Subjects**	
Gender Distribution		
Male	32	
Female	28	
Age distribution, (Years)		
20-29	1	
30-39	7	
40-49	27	
>49	5	
Characteristics of NCCLs	**Number of Lesions**	
	Dispenser heater	**Bench heater**

Shape (degree of angle)		
<45	0	0
45 - 90	13	12
90 - 135	22	26
> 135	25	22
Cervico-incisal height (mm)		
< 1.5	3	5
1.5 - 2.5	17	28
2.5 - 4.0	36	22
> 4.0	4	5
Mesio-distal width (mm)		
<2.5	4	0
2.5-3.5	22	15
3.5-4.5	18	19
>4.5	16	26
Depth (mm)		
1.0-1.5	55	50
1.5-2.0	4	51
2.0-2.5	2	6
>2.5	1	0
Degree of sclerotic dentin		
1	3	10
2	26	20
3	18	22
4	13	8
Presence of antagonist		
Yes	60	60
No	0	0
Attrition facet		
Yes	17	18
No	43	42
Pre-operative sensitivity (spontaneous)		
Yes	18	15
No	43	45
Pre-operative sensitivity (air dry)		
Yes	20	26
No	40	34
Pre-operative sensitivity (touch)		
Yes	12	13
No	48	47
Tooth distribution		
Anterior		

Incisor	4	3
Canines	4	12
Posterior		
Premolar	43	29
Molar	9	16
Arc distribution		
Maxillary	31	40
Mandibular	29	20
Presence of biofilm		
0	57	53
1	7	6
2	1	1
3	1	0

(*) Dispenser heater = VisCalor Caps dispenser/warmer; Bench heater = Caps dispenser device with Caps Warmer.

The overall Cohen's kappa statistics (0.94%) demonstrated a high level of agreement among the examiners at the 6-month, 12-month, 18-month, and 24-month follow-ups for the main outcome retention/fracture. All research subjects were assessed at baseline and during the 6-, 12-, and 18-month follow-up visits, with a recall rate of 100%. However, seven subjects did not attend the 24-month follow-up, giving an overall 24-month recall rate of 88.3%. The patients did not recall because they either moved to another city or changed their phone number, which prevented us from having contact with them.

Retention/Fracture

Four restorations (dispenser heater = 2, bench heater = 2) were lost or fractured after 24 months (Table 16). Figure 16 presents the risk differences in retention rate for all treatment groups. The TOST-P test demonstrated the equivalence for retention rate ($p < 0.001$). The two-sided 90% CI of the difference of the risk is within the predetermined equivalence margins of -25% and +25%. The p-value reported is the larger of the two p-values from the upper and lower one-sided tests (TOST). Groups were equivalent in all assessment periods (Figure 16, $p < 0.001$).

Figure 16 - Risk differences of retention rate measured with different times (baseline, 6, 12, 18, 24 months) between dispenser heater *vs.* bench heater groups. Horizontal bars indicate two-sided 90% confidence interval (CI) of the risk difference between treatment groups. The zone between the dashed lines indicates the equivalence limit margin.

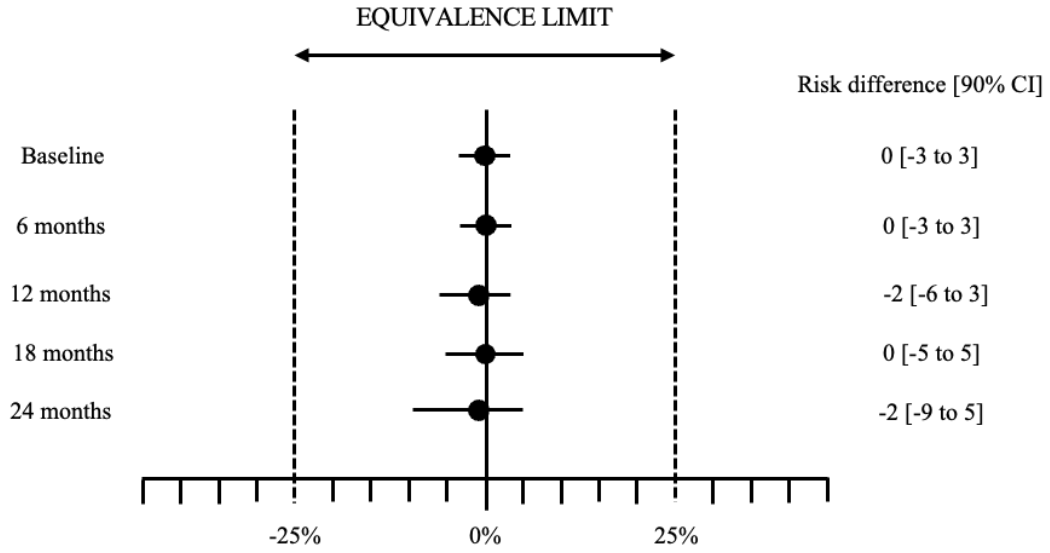

Table 16 - Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria.

FDI Criteria	(*)	Baseline		6 months		12 months		18 months		24 months	
		DH	**BH**	**DH**	**BH**	**DH**	**BH**	**DH**	**BH**	**DH**	**BH**
Fractures and retention	A	60	60	60	59	59	57	55	55	48	48
	B	0	0	0	0	0	0	3	2	3	2
	C	0	0	0	1	0	1	0	1	0	1
	D	0	0	0	0	1	2	0	1	0	1
	E	0	0	0	0	0	0	2	1	2	1
Surface gloss/luster and roughness	A	60	60	58	57	57	55	56	55	49	48
	B	0	0	2	3	2	3	2	3	2	3
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Surface and Marginal staining	A	60	60	60	60	58	57	56	57	49	49
	B	0	0	0	0	1	1	2	1	2	2
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Marginal adaptation	A	60	60	55	50	54	48	51	42	44	35
	B	0	0	5	10	5	10	7	16	7	16
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Color match	A	60	60	58	51	57	50	55	49	48	42
	B	0	0	0	9	0	8	1	7	1	7
	C	0	0	2	0	2	0	2	2	2	2
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0

Esthetic anatomical form	A	60	60	60	60	59	58	58	58	51	51
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Recurrence of initial pathology	A	60	60	60	60	59	58	58	58	51	51
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Tooth cracks and fractures	A	60	60	60	60	59	58	58	58	51	51
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Effect of the restoration on the periodontium	A	60	60	60	60	59	58	58	58	51	51
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Postoperative sensitivity	A	60	60	60	60	59	58	58	58	51	51
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Recurrence of caries	A	60	60	60	60	59	58	58	58	51	51
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0

	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Tooth Integrity	A	60	60	60	60	59	58	58	58	51	51
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Periodontal response	A	60	60	60	60	59	58	58	58	51	51
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Oral health	A	60	60	43	44	41	42	41	43	35	36
	B	0	0	16	15	17	13	14	10	13	11
	C	0	0	1	1	1	3	3	5	3	4
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0

(*) A = Clinically very good; B = Clinically good; C = Clinically sufficient / satisfactory; D = Clinically unsatisfactory; E = Clinically poor. (*) DH - Dispenser heater = VisCalor Caps dispenser/warmer; BH - Bench heater = Caps dispenser device with Caps Warmer.

The retention rates (95% confidence interval) at 24 months were identical for both groups [96.1% (86.8 – 98.9)], giving a risk ratio of 1.0 (0.1 – 6.8). The Kaplan–Meier curves showed no significant differences (Log-rank test, $p = 0.76$) between the cumulative probability of retention/fracture (Figure 17). Table 17 depicts the paired comparisons of the hazard ratios between the two groups. No significant differences were detected (HR = 0.83; 95% CI 0.26 to 2.72 for both groups).

Figure 17 - Survival Kaplan-Meier curves for both groups.

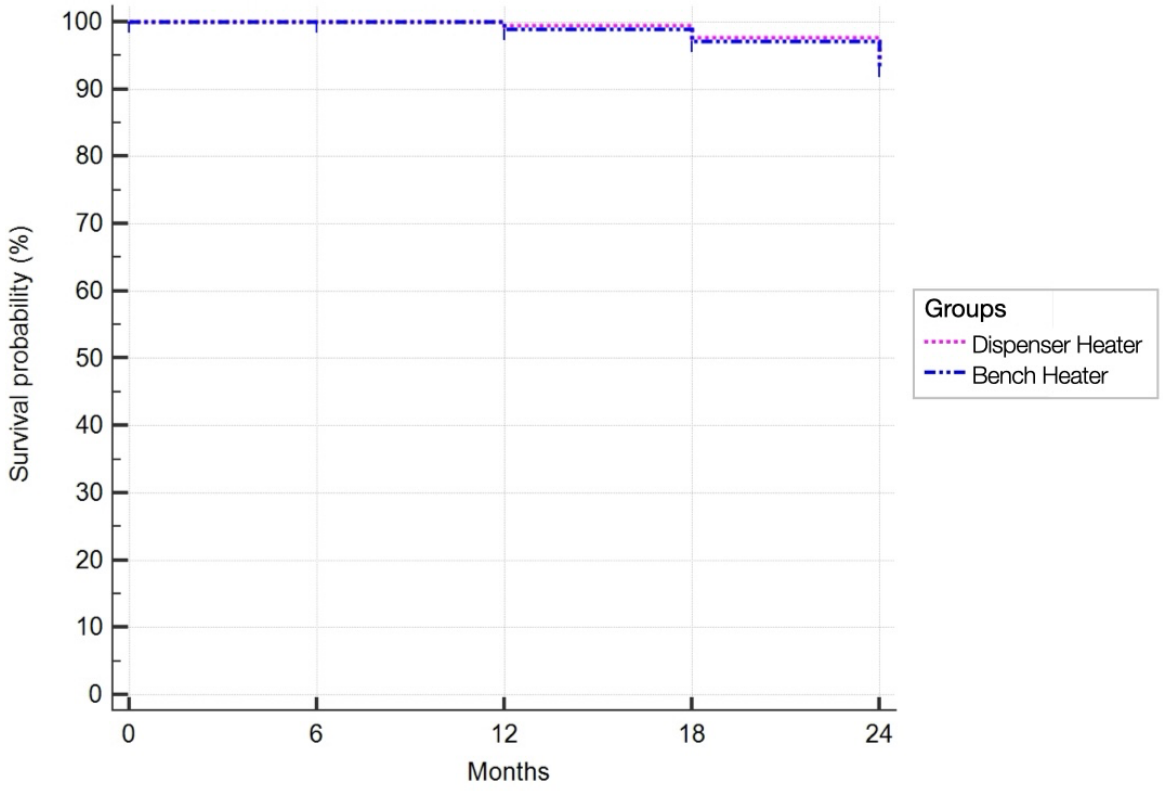

Table 17 - Absolute risk (95% CI), risk ratio (95% CI), and hazard ratio (95% CI) for the outcome fracture/retention for the two groups after 24 months of clinical evaluation.

	Dispenser heater	**Bench heater**
Absolute risk (95% CI)	96.1 (86.8 – 98.9)	96.1 (86.8 – 98.9)
Risk ratio (95% CI)	1 (0.1 – 6.8)	
Hazard ratio (95% CI)	0.83 (0.26 to 2.72)	

Marginal adaptation

A total of 23 restorations (7 for dispenser heater, and 16 for bench heater; Table 16) showed minimal defects in marginal adaptation in the 24-month evaluation,

but none of them required any intervention being categorized as clinically good/acceptable ($p > 0.05$; Table 16).

The comparison of the ranked categories showed that the bench heater group had a higher risk of marginal adaptation defects compared to the dispenser heater ($p = 0.03$ Table 16).

Other clinical secondary outcomes

According to the FDI criteria, after 24 months, 13 restorations (3 for dispenser heater and 9 for bench heater) showed minimal discrepancies in color match. Five restorations (2 for the dispenser heater and 3 for bench heater) showed some loss of gloss/luster. Four restorations (2 for dispenser heater and 2 for bench heater) showed minimal marginal staining, and 31 restorations were found to have biofilm retention (16 for dispenser heater and 15 for bench heater). Nonetheless, no significant difference was detected between groups ($p > 0.05$; Table 16). In all other criteria, no change was detected at the 24-month recall.

Working time

Table 18 depicts the time required for the accomplishment of each operative/restorative step. The total working time for the bench heater is statistically higher than that for the dispenser heater due to the need for preheating of the bench heater. All other steps required similar working times except the one for resin placement/sculpture ($p = 0.010$). The material extruded from the dispenser heater allowed more working time (39.0 s $\pm$ 18.5) for composite placement and sculpture than the material heated in the bench heater (20.0 s $\pm$ 0.0).

Table 18 - Means, standard deviations, and the mean difference for both study groups for the time required (seconds) for each step of the restorative procedure and total working time.

	Groups		Mean difference [95% CI]	p-value*
	Dispenser heater	Bench heater		
Preheating of the heater device	0.0 ± 0.0	1200.0 ± 0.0	-1200.0 [-1200.0 to -1200.0]	<0.001
Anesthesia, and isolation of the operative field	486.0 ± 52.5	492.0 ± 47.3	-6.0 [-19.6 to 7.6]	0.343
Dental cavity preparation	172.0 ± 10.6	174 ± 7.0	-2.0 [-8.8 to 4.8]	0.522
Preheating of the composite resin	30.0 ± 0.0	180.0 ± 0.0	-150.0 [-150.0 to -150.0]	<0.001
Handling time for composite sculpture	39.0 ± 18.5	20.0 ± 0.0	19.0 [5.7 to 32.3]	0.010
Finishing and polishing procedure	132.0 ± 47.3	126.0 ± 44.3	6.0 [-7.6 to 19.6]	0.343
Total working time	859.0 ± 93.6	2186.0 ± 83.6	-1327.0 [-1342.0 to -1312.0]	<0.001

**Paired t-test*

Discussion

Although the bulk-fill thermoviscous composite resin (VisCalor bulk) can be preheated using a bench heater or a dispenser heater, earlier clinical studies have not addressed whether there was any optimal preheating method [26-31, 33-37]. This study stands out as the longest randomized controlled clinical trial that aimed to evaluate these preheating methods on important clinical outcomes.

Overall, all restorations were deemed to be clinically acceptable in all items from the FDI criteria irrespective of the heating method used for the thermoviscous bulk fill composite restoration. Both groups exhibited high and identical retention rates at the 24-month recall (96.1%, 95% CI 86.8 to 98.9), and were equivalent up to the 24-month follow-up. The retention of NCCLs is usually related to the bonding properties of the adhesive system employed for the restoration placement.

The universal Futurabond U adhesive is a universal adhesive that presents acidic monomers. These not only etch and prepare the dental structure but also, due to their lower pH, demineralize the dental substrates. Furthermore, the inclusion of the 10-MDP (10-methacryloyloxydecyl dihydrogen phosphate) monomer in these adhesives ensures stable bonding to hydroxyapatite (10-MDP-Ca salts), thereby enhancing the mechanical resistance of the adhesive and preventing its degradation [51-53]. Several clinical studies with follow-ups ranging from 1 to 5 years showed excellent clinical performance of Futurabond U when used to restore NCCLs, mainly when used in the selective enamel etching mode [26, 27, 54-60].

Although both heating techniques performed well, we noted slight differences in terms of marginal adaptation. These discrepancies were more frequent in the bench heater group, with statistically higher occurrences compared to the dispenser group. A more pronounced marginal adaptation number for this material in the form of bench heating compared to an unheated resin had already been observed in a previous study [26-28]. An important difference between the heating methods was the time available for material placement and sculpture. The dispenser heater group has a prolonged working time in the oral environment (39.0 s $\pm$ 18.5), attributed to the capability of the dispenser heater to maintain the material at an optimal temperature during cavity insertion, which could lead to the minimal marginal adaptation defects observed in this study.

On the other hand, in the bench heater, this working time is significantly lower (20.0 ± 0.0). Once the caps dispenser is removed from the bench heater, the composite's temperature begins to decrease, leading to an increase in viscosity. A previous study documented a 50% decrease in material temperature just 2 min after bench heater removal [12-14]. Consequently, clinicians have approximately 20 s on average for bench hearting group, which is a time approximately 51% lower, to complete the restoration. Even experienced and well-calibrated clinicians may find it challenging to anatomically shape and adapt the restorations within this timeframe. This even seems sufficient when talking about anatomical shape for NCCLs, but when other types of classes can be used such as: class I or class II, the sculpting time of 20 s may not be enough.

Another drawback of using the bench heater is its need for a preheating time of 20 min before heating the resin composite. This demands careful protocol planning or a waiting period of 20 min before using the thermoviscous bulk-fill resin composite. Professionals not only aim for effective materials but also prioritize simplified procedures and reduced chair time, making the preheating requirement a disadvantage.

Although the dispenser heater enabled the composite to remain at an optimal temperature for a longer period compared to the bench heater, the noted variances did not lead to unsatisfactory restorations during the 24-month clinical service period. However, in the long term, these discrepancies may necessitate repairs. Therefore, it is crucial to continue monitoring these restorations over extended periods to assess their durability and performance.

Concerns regarding pulp damage due to preheating arose as it may result in post-operative sensitivity [14]. The outcomes of the present study in NCCLs show that neither the immediate nor 24-month postoperative sensitivity was a clinical problem when using the preheated resin composite. These studies align consistently with earlier studies [26-31, 33-37] that have demonstrated no association between the use of preheated resin and experiencing sensitivity after composite resin placement.

It is essential to note that the composite resin used in this clinical study was a bulk-fill composite rather than an incremental resin composite [61]. Using bulk-fill resin can be considered advantageous operationally because a single layer, up to 4 mm thick, is adequate for restoring NCCLs [61]. Although bulk-fill flow resins are available

to enhance adaptation to cavity walls [62], they can pose technical challenges when fitting into dental cavities, as they tend to flow out of the cavity, especially in NCCLs [7]. Therefore, preheating the composite resin is an interesting approach, since viscosity decreases, making the resin more flowable and easy to insert into the NCCLs, without flowing out the cavity.

We would like to report that we utilize a resin capsule for each restoration procedure. Consequently, there is surplus composite resin contained within the capsule, leading to waste. However, from a practical standpoint, this method effectively minimizes cross-contamination between patients, which is undoubtedly advantageous. Although it's conceivable to utilize the same resin for multiple restorations in the same patient, we remain uncertain about the effects of repeated heating cycles on this composite resin. These uncertainties present areas for future research.

Some limitations of this RCT need to be mentioned. In the present study, the same material was used in different methods of preheating, so the results could not be generalized for all commercial composite brands. Therefore, researchers must conduct more clinical studies with conventional resins heated in different ways. Another limitation of this clinical investigation is that 24 months may be a too short period to observe substantial changes. Therefore, longer-term interim evaluations may be indispensable for a more comprehensive assessment of the impact of different preheating methods on the preheated composite resin used in this study.

Conclusion

The clinical assessment of different methods for preheating thermoviscous composite resin demonstrated comparable and equivalent performance in non-carious cervical lesions over a 24-month evaluation.

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9 DISCUSSÃO

Profissionais da saúde, pesquisadores e professores frequentemente ocupam posições de autoridade ao tomar decisões clínicas. É essencial, portanto, evitar basear a eficácia apenas na experiência clínica. A nossa experiência, por mais vasta que seja, pode não capturar integralmente os benefícios dos protocolos que aprimoram os resultados prognósticos. Além disso, o ambiente clínico em que atuamos tende a ser naturalmente tendencioso e suscetível ao viés de confirmação.

A base do pensamento crítico deve estar no sistema 2 [11], o qual é analítico e cético, que é fundamental para permitir que ignoremos números de significado questionável, ainda que sejam relativamente fáceis de medir, ao tomar decisões clínicas. É crucial afastarmo-nos da simplificação de procedimentos como meramente estatisticamente significativos ou não, e começarmos a discutir a magnitude dos benefícios, riscos e danos, levando em consideração os valores e preferências dos pacientes.

Ativar o Sistema 2 em atividades científicas é uma tarefa desafiadora. Somos naturalmente propensos a tomar decisões rápidas, fundamentadas em heurísticas e associações superficiais do Sistema 1, em vez de basear nossas conclusões em uma extensa cadeia de fatos reprodutíveis e cientificamente verificados.

As evidências indicam que muitas das descobertas de pesquisa publicadas na área biomédica podem ser enganosas, não tão robustas quanto afirmadas ou simplesmente não reproduzíveis [32]. Essa questão é ainda mais acentuada em estudos básicos e laboratoriais, uma vez que a maioria deles não consegue atravessar o chamado “death valley” [33] durante sua transição para protocolos clínicos.

Reconhecer as limitações em procedimentos adesivos em odontologia é fundamental para promover uma mudança em direção a uma prática mais fundamentada em evidências, concentrando-se em resultados clinicamente relevantes que possam realmente impactar positivamente a vida dos pacientes [8].

O pré-aquecimento de resinas compostas não é uma técnica nova [34; 35], e há uma quantidade significativa de estudos laboratoriais que demonstram propriedades aprimoradas para resinas compostas pré-aquecidas em comparação com as não aquecidas [12; 13; 14]. Embora os estudos in vitro possam isolar variáveis e examiná-las em um ambiente controlado, eles apenas geram hipóteses que precisam ser confirmadas em um ambiente clínico [7; 8]. O impacto dessas variáveis dentro do cenário

clínico, onde inúmeros fatores prognósticos conhecidos e desconhecidos podem influenciar os benefícios observados in vitro, precisa ser avaliado clinicamente [16; 30]. Além disso, possíveis danos não investigados anteriormente podem vir à tona [34; 36]. Até o momento, existem apenas estudos clínicos de curto prazo que compararam essas técnicas e avaliaram restaurações nas classes I e II [22; 23; 24; 25; 26; 27].

Até onde os autores sabem, estes são os primeiros estudos projetado para avaliar o impacto do pré-aquecimento no desempenho clínico de restaurações de resina composta em lesões cervicais não cariosas. Dada a proximidade das lesões cervicais não cariosas com a margem gengival e a câmara da polpa [37; 38; 39], estes projetos de estudo permitiram a avaliação dos efeitos do aquecimento composto nesses tecidos dentários. Assim, as preocupações de que o pré-aquecimento possa potencialmente prejudicar o tecido da polpa, levando a um aumento do risco de sensibilidade pós-operatória [40], não foram confirmadas em ambas as investigações, alinhando-se com estudos anteriores que compararam a sensibilidade pós-operatória de resina composta pré-aquecidos e não pré-aquecidos em restaurações posteriores [22; 23; 24; 25; 26; 27]. Além disso, embora possamos intervir aos tecidos gengivais ao redor das lesões cervicais não cariosas, os critérios de FDI para resposta periodontal não revelaram nenhuma diferença entre os grupos. Além disso, nenhum dos participantes notou uma diferença entre as temperaturas, o que ressalta a segurança e a viabilidade do pré-aquecimento neste contexto.

Em termos de retenção/fratura quando comparados o pré-aquecimentos *vs* não aquecimento, os resultados mostraram um pequeno número de restaurações fraturadas (3 para o grupo aquecido e 1 para o grupo não aquecido), bem como altas taxas de retenção para ambos os grupos, com 96,3% para o grupo aquecido e 90,8% para o grupo não aquecido. O excelente desempenho clínico de ambas as resinas composta podem ser atribuídas às boas propriedades mecânicas das resinas compostas empregadas. Vários estudos in vitro demonstraram que a VisCalor pré-aquecida, atinge um grau de conversão e propriedades mecânicas tão altas quanto os relatados para outras boas resinas compostas comparáveis disponíveis no mercado [15; 16; 31; 40]. Vale a pena mencionar que o VisCalor foi aplicado como um incremento único, enquanto, por outro lado, o Admira Fusion foi aplicado usando uma abordagem de preenchimento incremental. Consequentemente, até certo ponto, envolve uma comparação entre uma técnica. Uma revisão completa da literatura

revelou que não existe diferença significativa na taxa de retenção observada após 12, 18 e 30 meses de avaliação clínica quando ambas as técnicas foram comparadas [41; 42; 43; 44].

Contribuindo para altas taxas de retenção é o protocolo adesivo eficaz com Futurabond U, um adesivo universal com um pH leve de 2,3. Adesivos com pH leve aumentam a interação com os tecidos dentários, evitando a desmineralização excessiva e o colapso da fibra de colágeno [45], melhorando a penetração do monômero e a força de ligação [45]. Estudos recentes identificaram a presença do monômero funcional como dihidrogenofosfato de 10-metacriloiloxidecil (10-MDP) em sua composição. Esses sais, conhecidos por sua alta estabilidade hidrolítica, formam uma forte ligação química com substratos dentários, não apenas protegendo as fibras de colágeno, mas também aumentando o potencial do condicionamento dos tecidos em comparação com outros monômeros funcionais [10; 46; 47; 48]. Também existe especulação sobre uma reação potencial entre MDP e moléculas orgânicas na dentina, particularmente colágeno [49; 50].

De acordo com esses achados, estudos anteriores que empregam Futurabond U para a restauração de lesões cervicais não cariosas demonstram taxas de retenção/fratura como as relatadas no presente estudo [51; 52]. Por exemplo, Matos et al. [51] relataram uma taxa de sucesso de aproximadamente 95% após 24 meses de avaliação clínica, enquanto de Albuquerque et al. [52] observou que cerca de 94% das restaurações foram bem-sucedidas após 36 meses. Considerando que a descoloração marginal está relacionada ao desempenho da união adesiva, as taxas reduzidas de descoloração marginal observadas neste estudo e em ensaios clínicos anteriores [51; 52; 53; 54; 55] servem como evidência adicional do excelente desempenho do adesivo.

Embora ambos os materiais tenham exibido excelentes taxas de retenção, a probabilidade de a hipótese nula ser verdadeira (ou seja, grupos serem estatisticamente semelhantes) estão no limite ($p = 0,06$), indicando uma tendência para o composto pré-aquecido potencialmente demonstrando desempenho superior em termos de retenção/fratura. Hordones Ribeiro et al. [31] demonstraram que o pré-aquecimento, em comparação com o não pré-aquecimento, reduziu significativamente a contração de polimerização em 10 minutos para várias resinas compostas. Essa redução pode potencialmente diminuir a concentração de tensão na interface adesiva

e aumentar a tenacidade à fratura da camada adesiva, aumentando a resistência contra a fratura [56; 57]. O acompanhamento de longo prazo neste estudo pode confirmar se a tendência observada aos 24 meses persiste.

Antecipamos uma melhor adaptação marginal entre a resina composta pré-aquecida e as paredes da cavidade, como demonstrado por estudos in vitro [17; 58; 59] e estudos clínicos [25; 26; 27], devido à maior capacidade de fluxo durante a inserção. No entanto, apesar de não detectar uma diferença significativa entre os grupos, observamos uma tendência contrária com um valor p = 0,06. Especificamente, o composto pré-aquecido demonstrou uma maior taxa de desadaptação marginal (33% para o grupo aquecido e 16% para o grupo não aquecido).

O tempo curto de manuseio associado ao composto pré-aquecido usando o aquecedor de bancada pode ter contribuído para as maiores taxas observadas de falta de adaptação marginal ideal. Inicialmente, a resina composta e a pistola de manipulação foram colocadas em um aquecedor de bancada, e um período de espera de 20 minutos foi necessário para que o aquecedor atingisse uma temperatura de 68 °C. Posteriormente, o material e o dispositivo foram removidos, e aproximadamente 3 minutos foram necessários para que o material alcançasse fluidez suficiente para a extrusão da cápsula. No entanto, o tempo de manuseio é limitado a 20 s, à medida que a resina se torna mais viscosa com a perda de calor, diminuindo sua escultura [15]. Isso ressalta a sensibilidade do procedimento de inserção, exigindo um operador altamente qualificado e calibrado. É provável que resultados menos favoráveis do que os apresentados aqui poderiam ter sido observados se realizados por estudantes ou clínicos inexperientes.

É importante destacar que o contraste das descobertas acima com as investigações laboratoriais também pode ser atribuído a diferenças metodológicas. A maioria deles controla a temperatura durante o tempo de manuseio/inserção [17; 58; 59], permitindo que o composto retenha a temperatura por um período mais longo de uma maneira que não seja replicável em uma situação clínica. Em uma situação clínica, há uma perda de calor significativa que ocorre quando o material é removido do aquecedor de bancada e levado para onde o material foi inserido [31; 35; 59].

Uma alternativa para melhorar o manuseio deste material foi introduzida pelo fabricante, que desenvolveu um aquecedor dedicado na forma de uma pistola. Este dispositivo não apenas aquece rapidamente o material, mas também mantém uma

temperatura constante durante o manuseio e a inserção na cavidade, estendendo o tempo de trabalho até 3 min [30]. No entanto, há uma quantidade limitada de pesquisas disponíveis sobre este equipamento, seja in vitro ou vivo [30; 31].

Após o início do nosso estudo clínico, Hordones et al. avaliaram diferentes formas de pré-aquecimento e essas não afetaram as propriedades mecânicas [31]. Além disso, VisCalor apresentou propriedades mecânicas favoráveis e baixa tensão de contração [19]. Este novo equipamento é interessante porque é possível transportar o material aquecido para a cavidade a ser restaurado [30]. Uma diferença importante é que o equipamento permite a entrega da resina aquecida na cavidade na temperatura de pré-aquecimento indicada, e é por isso que este equipamento fornece mais tempo de trabalho na boca.

Embora ambas as técnicas de aquecimento tenham tido um bom desempenho, notamos pequenas diferenças em termos de adaptação marginal. Essas discrepâncias foram mais frequentes no grupo aquecedor de bancada, com ocorrências estatisticamente maiores em comparação ao grupo dispensador. Uma diferença importante entre os métodos de aquecimento foi o tempo disponível para colocação do material e escultura. O grupo aquecedor do dispensador possui um tempo de trabalho prolongado no ambiente bucal (39,0 s ± 18,5), atribuído à capacidade do aquecedor dispensador em manter o material a uma temperatura ideal durante a inserção da cavidade.

Por outro lado, no aquecedor de bancada esse tempo de trabalho é significativamente menor (20,0 s ± 0,0). Uma vez removido o dispensador de capsula do aquecedor de bancada, a temperatura da resina composta começa a diminuir, levando a um aumento na viscosidade. Estudos anteriores relataram uma diminuição de 50% na temperatura do material apenas 2 minutos após a remoção do aquecedor de bancada [34; 35; 39]. Consequentemente, os clínicos têm em média aproximadamente 20 segundos, um tempo aproximadamente 51% menor, para concluir a restauração. Mesmo dentistas experientes e bem calibrados podem achar difícil moldar anatomicamente e adaptar as restaurações dentro deste prazo.

Outra desvantagem do uso do aquecedor de bancada é a necessidade de um tempo de pré-aquecimento de 20 minutos antes de aquecer a resina composta. Isso exige um planejamento cuidadoso do protocolo ou um período de espera de 20 minutos antes de usar a resina composta termoviscosa bulk-fill. Os profissionais não

buscam apenas materiais eficazes, mas também priorizam procedimentos simplificados e redução do tempo de cadeira, tornando a necessidade de pré-aquecimento uma desvantagem.

Embora o aquecedor dispensador tenha permitido que a resina composta permanecesse a uma temperatura ideal por um período mais longo em comparação com o aquecedor de bancada, as variações observadas não levaram a restaurações insatisfatórias durante o período de acompanhamento de 24 meses. No entanto, a longo prazo, estas discrepâncias podem necessitar de reparações. Portanto, é crucial continuar a monitorizar estas restaurações durante longos períodos para avaliar a sua durabilidade e desempenho.

10 CONCLUSÃO

A adoção do pensamento crítico baseado no Sistema 2, caracterizado por sua natureza analítica e cética, é essencial para discernir a verdadeira relevância de dados clinicamente significativos ao tomar decisões. Devemos abandonar a abordagem dicotômica e considerar não apenas a significância estatística, mas também a magnitude dos benefícios, riscos e preferências dos pacientes. Estudos indicam que muitas descobertas de pesquisa são questionáveis ou não reproduzíveis, especialmente em estudos laboratoriais. Reconhecer essas limitações é crucial para uma prática mais fundamentada em evidências, focada em resultados relevantes para os pacientes. No contexto de lesões cervicais não cariosas, resinas compostas pré-aquecidas e não aquecidas demonstraram alta retenção após 24 meses, com desempenho clínico similar, equivalência das diferentes técnicas de pré-aquecimento utilizadas também é observada. Por mais que o aquecimento demonstre resultados promissores in vitro, as avaliações clínicas até 24 meses não demonstram nenhum benefício clinicamente importante da técnica.

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