

Effect of Pre-endodontic Sealing on the Microleakage of Temporary Restorative Materials After Endodontic Treatment: An *In Vitro* Study

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ABSTRACT

Objective: This study aimed to investigate the effectiveness of various commercial temporary restorative materials in preventing microleakage when used in conjunction with a pre-endodontic sealing technique (PES).

Methods: Ninety-six human single-rooted premolars were prepared for endodontic access and randomly allocated to five groups according to the material to restore the cavity (n=16): CON: Control group, Tetric N-bulk, Ivoclar; COL: Coltosol, Coltene; KET: Ketac Molar, 3M; FUJ: Gold Label Fuji II, GC; CLI: Clip F; and two experimental conditions (n=8): COT: conventional technique and PES technique. Methylene blue dye penetration was measured in mm. Two-way ANOVA and Bonferroni post-hoc were used (p<0.05).

Results: For most materials, PES exhibited statistically significantly lower values of dye penetration (p<0.001), except for KET and COL. The highest dye penetration was found in FUJ using the COT technique.

Conclusion: The PES technique was more effective in preventing microleakage when polymer-based materials were used.

Keywords: Endodontics, microleakage, pre-endodontic, temporary restorations

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- A pre-endodontic sealing technique minimizes microleakage in temporary restorative materials applied between appointments.
- Utilizing polymer-based temporary materials for interim restorations is recommended, accompanied by a preceding adhesive resin coating.
- Contamination between appointments should be carefully evaluated in a conventional endodontic treatment.

INTRODUCTION

Accurate prognosis of nonsurgical endodontic treatment depends on proper mechanical cleaning and chemical preparation of the root canal space (1). In root canal treatment, it's common that the permanent restoration of the tooth cannot be completed in the same visit as the root canal filling; thus, a temporary restoration is essential to protect the tooth's condition until the subsequent appointment (2). Furthermore, temporary sealing of the access cavity is vital for maintaining the effectiveness of the intracanal treatment against

bacteria and sealing the cavity from oral fluids and contaminants (3).

Temporary restorative materials must adequately seal the access cavity to avoid marginal leakage (4), withstand masticatory forces (5), display acceptable aesthetic properties, and maintain chemical and physical stability while being easy to handle. To ensure this, temporary restorative materials, such as calcium sulfate-based, glass ionomer, and resin-based materials, are currently used either individually or in various combinations for temporary sealing (6).

Several studies have explored the marginal sealing effectiveness of temporary endodontic sealing materials (7–13). Most of these thorough studies have evaluated the sealing performance of such materials under conditions aligned with the four-step scoring criteria established by Lee et al. (14). The majority of evidence suggests that temporary restorations may not be effective in sealing the cavity until the final restoration is completely completed (6, 15).

Pre-endodontic sealing (PES) was described by Pashley et al. in 1992 (16). This approach requires sealing freshly exposed dentin surfaces using an adhesive system to achieve optimal bonding (17). PES is derived from immediate dentin sealing (IDS) and resin coating techniques, which involve applying the dentin bonding agent and/or a resin coating immediately after dentin preparation (18, 19). Additionally, the application of this hydrophobic coating (especially in simplified adhesive systems) and a resin composite build-up is increasingly favored to bolster the adhesive qualities of the final restoration, maintain the integrity of dentin and its smear layer against endodontic irrigation, simplify the process of rubber dam isolation, avert fractures in compromised teeth, and enhance the aesthetic appearance during treatment (20, 21).

On the other hand, when PES is performed, a marginal gap could persist between the temporary restoration and restorative material (adhesive or composite). Some studies have assessed the sealing capability of temporary restorations, but there is limited evidence evaluating the impact of PES on the marginal sealing of temporary restorations (22).

Thus, this study aimed to investigate the ability to achieve marginal sealing between different commercial temporary restorative materials in exposed dentin or PES. The null hypotheses tested in this research are: first, that there are no differences in microleakage between cavities with exposed dentin and those treated with the PES technique; and second, among temporary restorative materials.

MATERIALS AND METHODS

Specimen Preparation

The Local Ethics Committee of Universidad los Hemisferios approved this study. (159.125, date: January 06, 2024). The study was conducted in accordance with the declaration of Helsinki.

The PRILE Laboratory Study Guidelines (23) were used (Fig. 1).

The sample size was determined based on a previous study (24), using an online statistical tool (https:/clincalc.com/stats/samplesize.aspx). With an α value of 0.05 and a power of 80%, the required sample size was 8 for each experimental group, resulting in an effect size of 2.4, which confirms the adequacy of the sample size.

Ninety-six human single-rooted premolars extracted for orthodontic reasons were used. All teeth with clinical signs of caries, root resorption, cracks, or fractures were excluded.

Standard endodontic access preparations were performed on the occlusal surfaces of the teeth using a calibrated spherical diamond bur (3.5 mm - Jota AG, Switzerland). Access was achieved using a high-speed air turbine handpiece with water coolant, and a diamond cylindrical, rounded-tip bur (Ø2 x 5mm, Jota AG, Switzerland) was employed to shape the preparation walls and pulp chamber. A periodontal probe measured the depth of the opening, ensuring that it could accommodate at least 4 mm of the temporal restoration. The same operator conducted all access preparations.

Study Design

The teeth were randomly divided using an online tool (Sealed Envelope Ltd. 2024 [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 2 March 2024]), creating a blocked randomization list to match into five groups (four experimental and a control group n=16), according to the material used: CON: Control group, bulk-fill composite resin (Tetric N-bulk, Ivoclar, Shaan, Liechtenstein); COL: Zinc Oxide/Calcium Sulphate material (Coltosol, Coltene, Alstatten, Switzerland); KET: conventional glass ionomer material (Ketac Molar, 3M, Minnesota, USA); FUJ: resin-reinforced, light-cured glass ionomer (Gold Label Fuji II, GC, Tokio, Japan); CLI: Polymer-based material (Clip F, Voco, Cuxhaven, Germany). Materials used in the study are summarized in Table 1.

From each group, specimens were randomly allocated to the experimental conditions (n=8): 1) Exposed dentin - conventional technique (COT): An endodontic treatment was performed after cavity delimitation, followed by the insertion of a cotton pellet on the pulp chamber floor and the temporary restoration, and 2) Pre-endodontic sealing technique (PES): Before endodontic treatment, the PES was performed. A Universal adhesive (Tetric-N Universal; Ivoclar Vivadent, Schaan, Liechtenstein) was used in total-etch mode with 37% phosphoric acid (Total Etch; Ivoclar Vivadent, Schaan, Liechtenstein) for 5 s, followed by rinsing and drying for 15 s. Then, active application of the adhesive was performed using a micro-applicator (Microbrush International, Wisconsin, USA) for 20 s, gentle air-drying for 15 s for solvent evaporation, and light polymerization for 20 s using an LED curing unit with an intensity of 2000 MW/cm2 (Bluephase NG4, Ivoclar Vivadent, Schaan, Liechtenstein). A thin layer of flowable composite resin was placed on all cavity walls and light-cured for 20 s.

Endodontic Treatment

Pulp tissue was removed with endodontic instruments (K-type files, Dentsply Maillefer, Oklahoma, USA). Root canal irrigation was performed using a 1% sodium hypochlorite solution (Na-OCI), and the apical preparation was completed up to file #40. Afterward, the root canal was washed with 2 mL of distilled water using a disposable syringe (Terumo, Tokyo, Japan). Next, the root canal was filled with an 18% EDTA solution (Ultradent EDTA 18%, Ultradent Products, South Jordan, UT, USA) for 1 minute and then washed with 2 mL of distilled water. After suctioning the remaining water, the root canals were dried with #40 absorbent paper tips (JM paper point, J. Morita, Tokyo, Japan). The apical portion of the root was sealed with gutta-percha cones (Dentsply Maillefer, Oklahoma, USA) using the step-back technique and obturated with an epoxy resin-based sealer (AH Plus, Dentsply Sirona, Charlotte, USA).

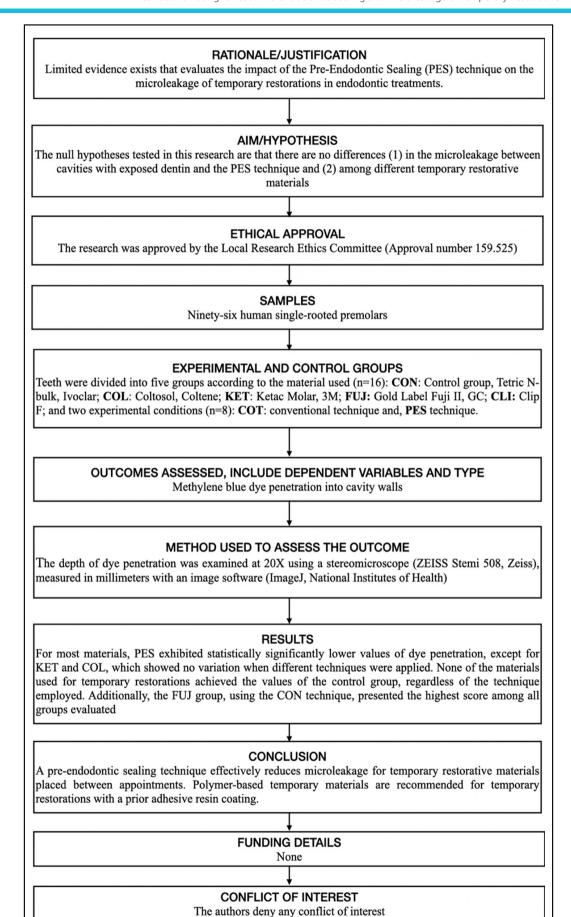


Figure 1. PRILE 2021 flow chart

TABLE 1. Means±standard deviation (mm) for dye penetration with both performed techniques.

Material	Technique	
	Conventional exposed dentin	Pre-endodontic sealing
CON	0.00±0.0 Aa	0.00±0.0 Aa
COL	1.89±0.3 Ca	1.55±0.4 Ca
KET	1.38±0.3 Ba	1.36±0.1 Ca
FUJ	2.79±0.8 Da	0.53±0.2 Bb
CLI	1.46±0.2 Ba	0.66±0.3 Bb

Similar letters (upper case letters within the column; lower case letters within the row) indicate that means are not significantly different (pre-set alpha of 0.05). CON: Control group, bulk-fill composite resin, COL: Zinc Oxide/Calcium Sulphate material, KET: Conventional glass ionomer material, FUJ: Resin-reinforced, light-cured glass ionomer, CLI: Polymer-based temporary material

Cavities were filled with provisional restoration materials, which were mixed and manipulated according to the manufacturer's instructions and were carefully placed to achieve maximum adaptation into the cavity walls.

Microleakage Procedures

After the tested materials were placed in the preparations, the apex samples were sealed with adhesive bonding material at the apical part to ensure a seal. After polymerization, the samples were stored in a 37°C incubator at 100% humidity for 24 hours. Then, they were thermocycled for 500 cycles in distilled water at 5°C and 55°C, with a dwell time of 30 seconds in each water bath. The thermocycler specimens were then immersed in 37°C water for an additional 24 hours.

After thermal cycling, the samples were air-dried and sealed with nail varnish, except for a 1 mm area around the tooth-restoration interface. All samples were then placed in a 2% methylene blue neutral solution (pH 7.0) in an incubator at 37 °C and 70% humidity for 7 days (UF260-Memmert GmbH Co., Schwabach, Germany). Subsequently, they were removed from the staining solution, washed with running tap water, and air-dried.

After the prescribed period had passed, the specimen's surface was cut perpendicular to its long axis using a precision cutter and a low-speed diamond disc (ISOMET 1000, Buehler, USA).

Measurement of Linear Dye Penetration

The depth of dye penetration was examined at 20X using a stereomicroscope (ZEISS Stemi 508, Zeiss, Oberkochen, Germany), measured in millimeters with an image software (ImageJ, National Institutes of Health, Bethesda, MD, USA), and classified according to the dye parameters of the four-step scoring criteria described by Lee et al. (14): [0] no visible dye penetration at the tooth/temporary filling interface, [1] dye penetration limited to the dentin–enamel junction, [2] dye penetration of up to half of the pulp chamber, and [3] dye penetration of over half of the pulp chamber (Fig. 2).

The maximum depth of dye penetration was recorded as the final value for each specimen. If the methylene blue dye pen-

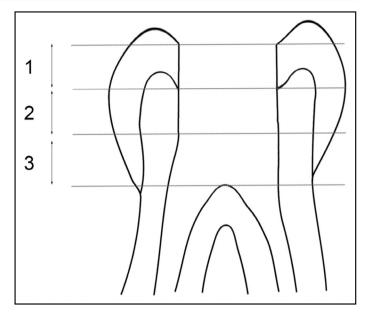


Figure 2. Scores of dye penetration: O, no dye penetration; 1, dye penetration within DEJ dentin-enamel junction; 2, dye penetration within half of the pulp chamber; and 3, dye penetration over half of the pulp chamber

etrated beyond the bottom of the temporary restoration, the penetration depth was determined as 4 mm. The same operator performed all the measures of dye penetration.

Means of dye penetration (mm) were analyzed using a two-way analysis of variance (ANOVA) with the following independent variables: material and technique. After performing the homogeneity test of variances and the Shapiro-Wilk normality test, both parameters passed. Bonferroni's post hoc test was then applied for multiple comparisons. All statistical testing and post hoc power analysis were performed at a pre-set α of 0.05 with commercial statistical software (Statistics 19, SPSS Inc., IBM Company, USA).

RESULTS

The means and standard deviations of dye penetration are summarized in Table 1. A two-way ANOVA revealed a significant interaction between the factors (material and technique) (p<0.001). Bonferroni's multiple comparisons revealed significant differences in all groups, as shown in Table 1. For most materials, PES exhibited statistically significantly lower values of dye penetration (p<0.001), except for KET and COL (p=0.889 and p=0.763, respectively), which showed no variation when different techniques were applied. None of the materials used for temporary restorations achieved the values of the control group, regardless of the technique employed. Additionally, the FUJ group, using the CON technique, achieved the highest score among all evaluated groups. Scores of dye penetration are presented in Figure 3.

DISCUSSION

After performing cavity access, the pre-endodontic seal demonstrated less dye penetration compared to the conventional technique, except for KET and COL. Thus, the first hypothesis was partially rejected. Temporary restorations are essential to avoid contamination during the interval

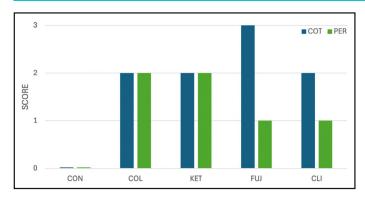


Figure 3. Score classification of dye penetration means for all materials tested

COT: Conventional technique, PER: Pre-endodontic restoration, CON: Control group, bulk-fill composite resin, COL: Zinc Oxide/Calcium Sulphate material, KET: Conventional glass ionomer material, FUJ: Resin-reinforced, light-cured glass ionomer, CLI: Polymer-based temporary material

between treatments; numerous studies have explored the sealing effectiveness of temporary restorative materials (7-9, 25). However, the effect of previous PES remains underexplored. In the conventional technique, there is no dentine sealing and/or regularization of the cavity walls. Without thermal stress, temporary restorative materials can achieve an effective seal, even in the absence of chemical adhesion to the tooth. This capability may primarily arise from the cavity wall's wettability and the interface's robust cohesion (6). Research shows that the effectiveness of seals decreases under thermal stress due to the differing thermal expansion rates of the tooth and temporary materials. Consequently, thermocycling tests are vital for evaluating the marginal sealing capabilities of temporary restorative materials. In this study, we conducted artificial aging for 500 cycles at temperatures ranging from 5°C to 55°C, reflecting the conditions used in previous studies (26).

In the PES technique, an earlier resin coating can help smooth the cavity walls and improve the fit of the temporal restoration at the tooth's margins. This is further supported by the comparable properties of thermal expansion, water absorption, and shrinkage found in these materials, particularly in polymer-based or resin-reinforced types. Additionally, this may assist in the final restoration placement, avoiding over-preparation and preserving the healthy tissue structure as much as possible. Conversely, if no PES technique is applied, it is important to reprepare the dentin. This process eliminates low-quality collagen exposed to endodontic irrigants and the saturated dentin layer. The endodontic sealer can penetrate the dentin to a depth ranging from 0.5 mm to 1 mm, potentially compromising bond strength (27).

Significant differences were found between the temporary materials, independent of the technique employed. Therefore, the second hypothesis was rejected. In the control group treated with bulk-fill composite resin, no dye penetration was observed in any specimens. The bulk-fill technique involves fewer clinical steps, which could reduce the incorporation of air voids, produce a more homogeneous structure, and result in a more predictable treatment (28). *In vitro* and clinical trial

studies (29, 30) have demonstrated that the bulk-fill resin composite (Tetric N, Bulk fill – TB) used in the present investigation is effective in terms of marginal adaptation and gap reduction, owing to the presence of pre-polymerized particles that contribute to lower polymerization shrinkage values. Additionally, a polymerization stress reliever is another unique component of this material that may reduce shrinkage stress and cuspal deflection during the restoration process (31). Additionally, the manufacturer claims that the absence of low-molecular-weight monomers, such as TEGDMA, in the composition of TB may also lower shrinkage stress and contribute to less marginal discoloration and improved fit (29).

Conversely, none of the temporary materials tested presented results comparable to those of the control group. The conventional Glass ionomer material did not exhibit any changes in dye penetration between techniques. This material has demonstrated higher water sorption and solubility relative to polymeric materials, including resin composites (32). The premature dissolution of glass ionomer cements (GIC) in water is attributed to two primary factors: first, the release of calcium and aluminum ions that can be lost during the chemical reactions of the newly mixed material, and second, the formation of soluble salts in water, particularly in the presence of sodium content in GIC. Additionally, aluminum ions react gradually with the anions that constitute the matrix and are particularly vulnerable to early water infiltration. GICs, being water-based and curing through the reaction of water-soluble ions, are vulnerable to aqueous solutions until they completely set. Therefore, clinicians usually apply varnishes or petroleum jelly immediately after placement to control ion release, as a strategy to reduce it (33). By doing so, this coating not only retains structure-forming ions within the cement but also strengthens it, preventing these ions from being lost through dissolution in surrounding water (34). Likewise, GICs have demonstrated low tensile bond strength to composite resin, which may explain why KET was not benefiting from the PES technique. Therefore, we recommend avoiding GICs for temporary restorations on teeth that previously underwent composite treatment before endodontic procedures.

Conversely, in the conventional technique, FUJ (Resin-modified glass ionomer cement - RMGIC) was the material that presented the highest dye penetration values. RMGICs typically undergo a two-stage reaction process. This process involves an acid-base reaction between carboxylic acid polymers and glass powder, followed by a free-radical reaction that is activated by visible light curing (32). Water is vital for the effective clinical application of RMGICs, as its composition typically contains 10–20% water as a liquid component. Controlling water levels during the acid-base reaction following initial light curing is crucial for enhancing bond strength. Additionally, RMGICs have the capacity to absorb water (25), which leads to hygroscopic expansion of the material and minimizes shrinkage stress. Dentin and oral fluids may supply moisture to the RMGIC-dentin interface, and factors such as dentin depth can influence the initial moisture content of dentin, which in turn could affect RMGIC shrinkage after

placement (35). In endodontically treated teeth, moisture can be affected during the process, which may explain high stress at the interface and more significant gaps.

RMGIC has been demonstrated to shrink in a manner comparable to resin composite materials. Irie et al. (35) measured the diametral linear shrinkage strain of RMGIC compared to resin composites to assess marginal gap formation. All materials, including Fuji II LC, showed some level of marginal gap development. Additional studies indicate that FUJ exhibits higher shrinkage strain and microleakage (36), approximately 3% without water after 5 minutes of curing, highlighting the essential role of water in sustaining an optimal environment. Conversely, dye penetration values decreased significantly when an adhesive resin coating was applied. We hypothesize that a stronger bond was formed between the polymer composition of RMGIC and the resin coating layer, thereby decreasing gap formation and microleakage as well.

Additionally, CLI is made from a polymer that includes BIS-GMA, silicon dioxide, methacrylate groups, and organic filler particles. The manufacturer states that polymerization shrinkage is minimal and does not affect sealing. However, any slight shrinkage is accompanied by a lack of dentin adhesion, which may lead to marginal leakage (36, 37). This explains the results of the conventional technique and agrees with previous findings (4, 9, 38). Similarly to FUJ, CLI benefited from a prior resin coating application. Finally, COL is a moisture-curing, zinc oxide/zinc sulphate-based temporary material. Similar to KET, no differences were found between the techniques. This may be attributed to the material's high viscosity, which prevents a perfect fit into the cavity walls, thereby promoting voids and spaces at the dentin-material interface. Furthermore, since it lacks a resinous or polymeric component, it does not appear to benefit from a previous adhesive treatment.

The present study evaluated microleakage using the methylene blue dye technique, which has been widely tested (14, 22, 39). Some concerns regarding the reliability, reproducibility, and clinical relevance of dye leakage experiments have been discussed (40). The authors suggest that the small size of dye molecules may lead to false-positive results and an overestimation of leakage (41). However, alternative methods, such as radioisotope leakage techniques, bacterial leakage studies, and fluid infiltration studies, are also recognized. (42). Nevertheless, the methodologies used to assess bacterial colonization for microleakage have their limitations, as these experiments require histological validation (43). Further investigations involving alternative methodological approaches and clinical randomized trials are needed to confirm the findings of the present study.

CONCLUSIONS

Within the limitations of the current *in vitro* study, a pre-endodontic sealing technique effectively reduces microleakage for temporary restorative materials placed between appointments. Flowable composite or polymer-based temporary materials are recommended for temporary restorations with a prior adhesive resin coating.

Disclosures

Ethics Committee Approval: The study was approved by the Universidad de los Hemisferios Ethics Committee (no: 159.125, date: 06/01/2024).

Informed Consent: Informed consent was obtained from all participants. **Conflict of Interest Statement:** The authors have no conflicts of interest to declare.

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