

Original Article

Coronal microleakage of two intraorifice bioceramic barriers in single-rooted premolars: *In vitro* study

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ABSTRACT

Background: Coronal microleakage compromises the longevity of root-filled teeth. Intra-orifice barriers are used to reduce coronal ingress, but comparative performance among bioceramics remains uncertain. This study aimed to evaluate the coronal microleakage of two bioceramic materials, NeoPutty and mineral trioxide aggregate (MTA) Plus, used as intraorifice barriers in extracted human single-rooted premolars.

Materials and Methods: This randomized controlled *in vitro* experimental study included 50 extracted human single-rooted premolars, which were randomly allocated into four groups: two experimental groups (NeoPutty and MTA Plus; $n = 20$ each) and two control groups (positive and negative controls; $n = 5$ each). Following root canal preparation and obturation, intraorifice barriers were placed, and the samples were immersed in Rhodamine B dye for 48 h. The teeth were then sectioned buccolingually, and dye penetration was observed under a stereomicroscope ($\times 16$). Data were analyzed using an independent samples *t*-test with a significance level of $P < 0.05$.

Results: The mean dye penetration with standard deviation (SD) was 5.49 (1.72) mm for NeoPutty and 5.21 (1.11) mm for MTA Plus; the difference was not statistically significant (NeoPutty – MTA Plus = 0.275 mm; 95% confidence interval [CI], -0.651–1.201; $t = 0.60$; $P = 0.55$).

Conclusion: Both NeoPutty and MTA Plus showed similar coronal sealing effectiveness as intraorifice barriers in premolars. These results support the use of either material to enhance the coronal seal. Further studies incorporating aging protocols and alternative leakage models are recommended.

Key Words: Bioceramics, endodontics, microleakage, mineral trioxide aggregate, root canal therapy

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INTRODUCTION

Preservation of natural teeth is a key goal of dentistry. Root canal treatment aims to eliminate infection and prevent reinfection^[1,2] However, treatment failure may occur because of microleakage, defined as the

passage of fluids, bacteria, or contaminants through the material-tooth interface^[3] Coronal leakage is considered particularly important because it can permit bacterial recontamination of the root canal system and adversely affect long-term prognosis.^[4,5] Defective

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restorations, delayed final restoration, marginal defects, and the complex anatomy of the pulp chamber may all contribute to this process.^[5-8]

Intraorifice barrier materials have been introduced to improve coronal sealing after root canal obturation^[9,10] Among these, calcium silicate-based bioceramics have attracted attention because of their favorable sealing properties and bioactivity^[9] Mineral trioxide aggregate (MTA) has shown favorable sealing performance, and bioceramic materials in general have demonstrated reduced microleakage in endodontic applications^[9,11-15] NeoPutty and MTA Plus are two calcium silicate-based materials with different handling characteristics and formulations.^[4,16] However, the existing evidence has largely focused on apical leakage or other endodontic sealing applications, whereas direct comparative evidence regarding the performance of NeoPutty and MTA Plus as intraorifice barriers against coronal microleakage remains limited.^[9,17] Therefore, the present study directly compared NeoPutty and MTA Plus as intra-orifice barrier materials under standardized *in vitro* conditions, thereby providing comparative evidence relevant to coronal sealing after root canal obturation.

MATERIALS AND METHODS

Study design and sample selection

This randomized, controlled *in vitro* experimental study was approved by the Institutional Review Board of the College of Dentistry, Gulf Medical University, Ajman, United Arab Emirates (Ref. no. IRB-COD-STD-124-JUNE-2023). The objective of this study was to compare coronal microleakage between NeoPutty and MTA Plus when used as intra-orifice barriers in extracted human single-rooted premolars. Fifty extracted human single-rooted premolars with fully developed roots were obtained from patients treated at Thumbay Dental Hospital, Ajman, United Arab Emirates, a member of the Gulf Medical University Academic Health System, following extraction for orthodontic reasons. Teeth with root resorption, calcification, fractures, or anatomical variations were excluded based on periapical radiographic examination. After extraction, the specimens were stored in 0.1% thymol solution at 4°C and rehydrated in distilled water for 24 h before use.

Sample allocation and randomization

The sample size was estimated *a priori* using G*Power version 3.1.9.2, (Heinrich Heine University Düsseldorf,

Düsseldorf, North Rhine-Westphalia, Germany) based on a previous study.^[18] Assuming a medium-to-large effect size (Cohen's $d = 0.57$), an alpha level of 0.05, and a desired statistical power of 0.95, 40 experimental teeth were determined to be sufficient to detect significant differences in coronal microleakage between NeoPutty and MTA Plus (20 per group). An additional 10 teeth were included as positive and negative controls to validate the experimental model, resulting in a total study sample of 50 teeth.

Randomization

The specimens were sequentially numbered and randomly allocated to two experimental groups and two control groups using the randomization tool available at randomization.org.

- Group 1: NeoPutty ($n = 20$)
- Group 2: MTA Plus ($n = 20$)
- Group 3 (Negative Control): No intra-orifice barrier, fully coated with nail varnish ($n = 5$)
- Group 4 (Positive Control): No intra-orifice barrier, no nail varnish ($n = 5$).

Blinding

All dye penetration measurements were performed by a single examiner who was blinded to group allocation throughout the assessment process. Before the formal assessment, the examiner was calibrated on a subset of sectioned specimens to standardize the identification of the deepest extent of dye penetration.

Root canal preparation and experimental material placement

All teeth were sectioned at the cemento-enamel junction to standardize access preparation. Working length was determined using a size 10 K-file (Dentsply Maillefer, Ballaigues, Switzerland), and instrumentation was performed using ProTaper Gold rotary files (Dentsply Maillefer, Ballaigues, Switzerland) at 300 rpm and a torque of 2.5 N·cm. Canals were irrigated with 3% NaOCl, and obturation was performed with F2 gutta-percha (Dentsply, Maillefer, Switzerland) and zinc oxide-eugenol sealer (Ariadent, Tehran, Iran). Coronal 3 mm of gutta-percha was removed using # 5 Gates-Glidden drills (Maillefer, Ballaigues, Switzerland). Experimental groups received NeoPutty (NuSmile Ltd., Texas, USA) or MTA Plus (Prevest DenPro Ltd., Jammu, India) to a standardized depth of 3 mm. Root surfaces were coated with two layers of nail varnish, leaving the orifice exposed. The negative control specimens were fully coated, whereas the positive control specimens received no varnish.

All specimen preparation procedures, including canal preparation, obturation, coronal gutta-percha removal, and intra-orifice barrier placement, were performed by a single operator under standardized conditions.

Dye penetration and measurement

Specimens were immersed in 0.2% Rhodamine B dye solution (Vama Dyes, Mumbai, India) at 37°C for 48 h. After immersion, each specimen was rinsed under running distilled water for 5 min to remove surface dye residues. The teeth were then gently blotted dry with absorbent paper and air-dried. The nail varnish coating was carefully removed using a scalpel. Each root was sectioned longitudinally in the buccolingual direction using a diamond disc under copious water irrigation.

The linear dye-penetration depth was measured from the coronal surface of the intraorifice barrier to the deepest point of dye penetration along the canal wall. Measurements were performed using a stereomicroscope at $\times 16$ (Zeiss Stemi; Carl Zeiss Microscopy GmbH, Germany) and recorded in millimeters (mm) using ZEN 3.9 imaging software calibrated to 0.1 μm precision. All measurements were recorded by a single examiner who was blinded to group allocation.

Data analysis

Analyses were performed in IBM SPSS Statistics v26 (IBM Corp., Armonk, NY, USA). Descriptive statistics (mean and standard deviation) were calculated for each group. The normality of data distribution was assessed using the Kolmogorov–Smirnov test. As the data followed a normal distribution ($P > 0.05$), parametric analysis was conducted. An independent-samples *t*-test was used to compare the mean dye penetration depths between the NeoPutty and MTA Plus groups. A significant level of $P < 0.05$ was set for all statistical tests.

RESULTS

Stereomicroscopic examination revealed that all specimens in the positive control group exhibited full dye penetration, confirming the absence of a coronal seal [Figure 1a]. In contrast, the negative control group showed no dye penetration beyond the access cavity [Figure 1b]. Both the NeoPutty [Figure 2a] and MTA Plus [Figure 2b] groups exhibited dye penetration predominantly confined to the coronal third, with occasional lateral spread into the middle third. The minimum dye penetration depth in the

NeoPutty group was 2.71 mm, while the maximum was 10.10 mm. In contrast, the MTA Plus group exhibited a narrower range of dye penetration depths, from 2.83–6.72 mm [Table 1].

Table 2 compares the dye-penetration depths between NeoPutty (mean = 5.49 ± 1.72 mm) and MTA Plus (mean = 5.21 ± 1.11 mm). The mean difference was 0.275 mm. No statistically significant difference in coronal sealing performance was observed between the two materials ($t = 0.60$, 95% CI: $[-0.65, 1.20]$, $P = 0.55$).

DISCUSSION

The present study evaluated the coronal sealing ability of NeoPutty and MTA Plus when used as standardized 3-mm intra-orifice barriers in extracted human single-rooted premolars. No statistically significant difference in the extent of linear dye penetration was observed between the two materials, indicating

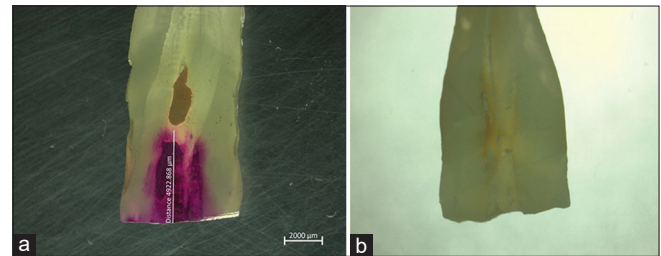


Figure 1: (a) Positive control specimen showing complete dye penetration in the absence of an intraorifice barrier, (b) Negative-control specimen showing no dye penetration, with the root surface fully coated.

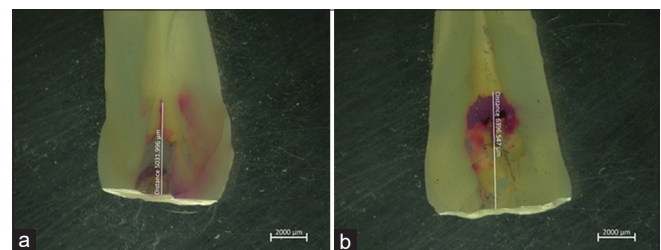


Figure 2: (a) Representative NeoPutty specimen showing dye penetration primarily confined to the coronal third, (b) Representative MTA Plus specimen showing dye penetration primarily confined to the coronal third.

Table 1: Dye penetration (mm) by material

Material	Minimum (mm)	Maximum (mm)	95% CI (mm)	
			Lower	Upper
NeoPutty	2.71	10.10	4.69	6.29
MTA Plus	2.83	6.72	4.69	5.73

CI: Confidence interval; MTA: Mineral trioxide aggregate

Table 2: Comparison of dye penetration between NeoPutty and MTA Plus

Material	n	Mean (mm)	SD (mm)	SEM (mm)	Mean difference (mm)	t	P	95% CI (mm)	
								Lower	Upper
NeoPutty	20	5.49	1.72	0.38	0.275	0.60	0.55	-0.65	1.20
MTA Plus	20	5.21	1.11	0.25					

SD: Standard deviation; SEM: Standard error of the mean; CI: Confidence interval; MTA: Mineral trioxide aggregate

comparable short-term sealing performance under the conditions of this *in vitro* model. This finding should be interpreted as comparable performance rather than proof of equivalence, because no equivalence or non-inferiority analysis was performed.

The observed similarity is biologically plausible. Both NeoPutty and MTA Plus are calcium silicate-based bioceramics and may therefore produce similar sealing outcomes because their sealing behavior depends on hydration, calcium ion release, and the formation of apatite-like interfacial deposits, which may improve marginal adaptation over time.^[19]

Although NeoPutty is supplied as a premixed putty and MTA Plus has different handling characteristics, these formulation differences may not be sufficient to produce a statistically detectable difference in short-term dye penetration under the present experimental conditions.

The similarity in leakage may also reflect the fact that handling properties and setting reaction influence adaptation only indirectly. A premixed putty may facilitate placement, but if both materials achieve adequate adaptation within a 3-mm barrier, the final sealing outcome may remain comparable. In addition, calcium silicate materials set in the presence of moisture, and minor differences in setting rate, washout resistance, or surface integrity may not be sufficient to alter the sealing outcome in a standardized laboratory model.

The present findings are consistent with previous evidence indicating that calcium silicate-based materials generally provide favorable sealing performance and bioactivity in endodontic applications.^[20,21] They are also consistent with studies reporting no significant differences among calcium silicate-based bioceramic materials when leakage was assessed using laboratory models.^[22,23] A systematic review further showed that intraorifice barriers reduce coronal microleakage, although comparative superiority among different materials has not been consistently established because of considerable methodological heterogeneity across studies.^[24]

Several studies have reported favorable outcomes for MTA-based materials,^[25,26] whereas a recent *in vitro* study on furcal perforation repair reported lower dye penetration for NeoPutty than for other calcium silicate-based materials.^[27] These discrepancies are likely related to differences in defect configuration, material thickness, substrate conditions, moisture exposure, leakage model, and observation period, all of which may substantially affect the measured sealing behavior.

In the present study, qualitative stereomicroscopic examination revealed broader dye distribution with occasional lateral spread in the NeoPutty group, whereas the MTA Plus group showed a more confined penetration pattern.^[28] However, the between-group mean difference in linear dye penetration was not statistically significant. Therefore, these qualitative differences should be interpreted cautiously and should not be overemphasized in the absence of statistical significance. Under the present experimental conditions, both materials demonstrated comparable sealing ability.

The positive and negative control groups supported the internal validity of the experimental model. All positive-control specimens exhibited complete coronal dye penetration, confirming the absence of an effective coronal seal, whereas the negative-control specimens showed no dye penetration beyond the access cavity, confirming the adequacy of specimen coating and the validity of the leakage assessment method. These findings support the methodological soundness of the model used to compare the two tested intra-orifice barriers.

From a material perspective, MTA has long been recognized for its biocompatibility, sealing properties, and ability to induce hard tissue formation.^[9] Its slight setting expansion may enhance marginal adaptation, although drawbacks such as discoloration potential, handling difficulty, and cost have also been reported.^[29] NeoPutty was developed as a premixed calcium silicate-based alternative with favorable consistency, washout resistance, and bioactive

potential.^[29,30] Although such handling advantages may improve clinical convenience, the present results indicate that these differences did not translate into superior coronal sealing performance in the current model. Thus, material selection should not be based on an assumption of superior sealing efficacy from the present data alone.

Dye penetration was used because it is a simple, widely used, and reproducible method for comparative assessment of microleakage under controlled laboratory conditions.^[30,31] Rhodamine B was selected because of its small molecular size and fluorescent properties, which may allow sensitive detection at low concentrations.^[9,31,32] Nevertheless, dye penetration has recognized limitations. It is a destructive two-dimensional method that may not fully reproduce the complexity of clinical leakage pathways or reflect the three-dimensional interfacial behavior of the tested materials.^[33] More contemporary methods, such as micro-computed tomography, fluid filtration, bacterial leakage, or glucose leakage models may provide complementary structural or functional information. These techniques were not used in the present study because the investigation was designed as an initial controlled *in vitro* comparison using a standardized and accessible leakage model. Accordingly, the present findings should be interpreted as comparative laboratory data rather than definitive evidence of clinical sealing performance.

The clinical relevance of the present findings lies in the observation that both NeoPutty and MTA Plus showed comparable short-term coronal sealing as intra-orifice barriers. Because no statistically significant difference was found, the findings support the potential use of either material when coronal sealing is required after root canal obturation. However, extrapolation to clinical practice should be made cautiously because this was an *in vitro* study performed under static laboratory conditions. Clinical performance may be influenced by additional factors not reproduced here, including thermal stress, occlusal loading, exposure to oral fluids, bacterial challenge, restorative procedures, and long-term aging.

This study has several limitations. It was conducted under static laboratory conditions using a two-dimensional linear dye-penetration model and did not include thermocycling, mechanical loading, bacterial leakage assessment, glucose leakage testing, fluid filtration analysis, or long-term aging. These factors may influence the sealing performance

of intra-orifice barriers under clinical conditions. In addition, the use of zinc oxide-eugenol sealer, which may undergo setting shrinkage, could have affected the degree of coronal leakage observed. Future studies should incorporate thermomechanical aging, complementary leakage models, preferably together with three-dimensional assessment methods, to provide a more comprehensive evaluation of the coronal sealing ability of these materials.

CONCLUSION

Within the limitations of this *in vitro* dye-penetration study, NeoPutty and MTA Plus demonstrated comparable coronal sealing performance when used as 3-mm intra-orifice barriers in single-rooted premolars. No statistically significant difference was observed between NeoPutty and MTA Plus in coronal sealing performance under the conditions of the present model. Both materials may therefore be considered suitable options for use as intraorifice barriers following root canal obturation. Further studies incorporating thermocycling and other aging protocols, bacterial or fluid-filtration leakage models, and long-term clinical follow-up studies are recommended before definitive clinical conclusions can be drawn.

Declaration of generative AI and AI-assisted technologies in the writing process

The authors declare that no generative AI or AI-assisted technologies were used in the writing or preparation of this manuscript.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or non-financial in this article.

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