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Clinical Evaluation of a Novel Nanostructural Calcium Silicate–Hydroxyapatite Cement for Pulp Capping

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Abstract

Background: Vital pulp therapy (VPT) is a conservative approach aimed at preserving pulp vitality in compromised teeth, contributing to long-term tooth survival. This study evaluated the clinical and radiographic outcomes of a novel hydroxyapatite-calcium silicate material (ALBO-MPCA) compared with commercially available mineral trioxide aggregate (MTA) in pulp-capping procedures, focusing on tertiary dentin formation.
Methods and Results: Twenty permanent teeth were treated with ALBO-MPCA (n = 15) or MTA (n = 5), and evaluated clinically and radiographically at baseline and after 6 months using cone-beam computed tomography (CBCT). The primary outcome was the thickness of tertiary dentin (μm), while secondary outcomes included pulp vitality, postoperative pain, and adverse events. Tertiary dentin formation was observed in all treated teeth in both groups. The mean thickness of newly formed tertiary dentin was higher in the MTA group compared to the ALBO-MPCA group (220 μm and 196 μm, respectively), with no statistically significant difference between the groups (p = 0.519). Pulp vitality was preserved in all cases. No adverse or serious adverse events were recorded, and only one patient in the MTA group reported mild postoperative pain.
Conclusion: ALBO-MPCA demonstrated clinical and radiographic performance comparable to MTA in vital pulp therapy. (**International Journal of Biomedicine. 2026;16(4):505-512.**)

Keywords: tertiary dentin • vital pulp therapy • mineral trioxide aggregate • cone-beam computed tomography

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Introduction

Vital pulp treatment (VPT) procedures are biologic and conservative treatment modalities, including direct or indirect pulp capping, aimed at maintaining the vitality of the dental pulp in teeth compromised by deep carious lesions, tooth wear, or trauma, thereby extending tooth longevity. Preservation of pulp vitality through minimally invasive approaches remains a key determinant of long-term tooth survival in contemporary restorative dentistry.

Traditionally, calcium hydroxide (CH) pulp-capping agents have been considered the gold standard of care for these procedures [1,2] because of their antibacterial properties and ability to promote healing and repair; however, their poor sealing ability and the formation of less homogeneous tertiary dentin compared with primary dentin represent notable limitations.[3] As a result, new generations of materials for VPT, namely calcium silicate cements, were subsequently introduced.[4,5]

One of the most widely investigated calcium silicate-based materials is mineral trioxide aggregate (MTA) due to its biocompatibility, bioactivity, and hard-tissue-inductive properties,[6-8] as well as favorable physical characteristics.[9] Hence, the indications for the use of MTA have expanded considerably beyond its original application, and it has become a widely accepted alternative to CH in several clinical

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procedures, including direct [1,4] and indirect[7] pulp capping, root and furcation perforation repair,[10] apexification,[11] etc. Despite the considerable clinical advantages and expanded indications, MTA cements show several drawbacks. The major limitations include a prolonged setting time,[12] difficult handling, discoloration of the remaining tooth structure,[13] and the presence of heavy metals (arsenic, lead, and chromium) in the powder.[14] Therefore, researchers in this field have focused on synthesizing new materials to overcome the limitations of MTA cements.

In this context, an experimental material based on hydroxyapatite and calcium silicates, named ALBO-MPCA, has recently been synthesized.[15] The ALBO-MPCA material combines the advantages of hydroxyapatite, demonstrating excellent biocompatibility and bioactivity, along with similarity to the inorganic phases of biomineralized tissues. It also has the advantages of calcium silicates, whose progressive hydration enables the continuous transition of a hydrating cement paste from a fluid to a rigid material.[16] Several studies have evaluated the biocompatibility of the tested cement under both *in vitro* and *in vivo* conditions and compared it with MTA;[16-22] nevertheless, further clinical studies are required to assess its biocompatibility, effectiveness in tertiary dentin formation, and overall treatment outcomes.

Thus, the purpose of this *in vivo* study was to assess the clinical performance of the tested ALBO-MPCA cement for direct and indirect pulp capping and to compare it with MTA, focusing on clinical outcomes, including the occurrence of adverse events and the thickness of tertiary dentin.

Methods

Preparation of the Test Material

The experimental material (ALBO-MPCA) consists of 40% hydroxyapatite, 20% calcium silicates, 20% gypsum, and 20% barium sulfate ($BaSO_4$) as a radiopaque agent. Synthesis methods of hydroxyapatite and calcium silicates have been described in previous investigations.[16-22] Gypsum dihydrate and $BaSO_4$ were purchased from Whip Mix Corporation (USA) and Merck (Germany), respectively. Detailed physicochemical characterization of the material has also been reported in previous references.[16-22]

Study Design and Participants

This prospective clinical study was approved by the Ethics Committee of the Health Centre Foča, Bosnia and Herzegovina (Approval No. 01-78/2023). All participants provided written informed consent prior to inclusion, and the study was conducted in accordance with the Declaration of Helsinki.

The sample consisted of six females and fourteen males (n = 20), aged between 19 and 41 years. Eligible participants were adults (≥18 years) who provided written informed consent and presented with previously untreated Class II or Class IV carious lesions in permanent teeth. The distribution of participants by gender and age, treatment type, treated teeth, and pulp-capping material (ALBO-MPCA or MTA) is presented in Table 1.

Table 1.

Distribution of participants according to gender, age, type of treatment, treated teeth, and pulp-capping material used (ALBO-MPCA or MTA).

Patient No.	Gender	Age	Pulp capping	Tooth FDI notation	Smoker (Yes/No)	Pulp-capping material
P1	M	25	Direct	46	No	ALBO-MPCA
P2	M	19	Direct	37	No	ALBO-MPCA
P3	M	20	Direct	48	No	ALBO-MPCA
P4	M	22	Direct	25	No	ALBO-MPCA
P5	M	20	Indirect	16	No	ALBO-MPCA
P6	F	23	Indirect	17	No	ALBO-MPCA
P7	F	20	Indirect	27	No	ALBO-MPCA
P8	M	20	Indirect	24	No	ALBO-MPCA
P9	F	24	Direct	25	Yes	ALBO-MPCA
P10	M	29	Indirect	25	No	ALBO-MPCA
P11	M	20	Direct	14	No	ALBO-MPCA
P12	M	23	Direct	12	No	MTA
P13	M	22	Direct	24	No	ALBO-MPCA
P14	M	22	Indirect	15	No	ALBO-MPCA
P15	M	23	Indirect	25	Yes	ALBO-MPCA
P16	F	19	Direct	36	No	MTA
P17	M	19	Direct	25	No	MTA
P18	M	25	Direct	46	No	ALBO-MPCA
P19	F	41	Direct	44	Yes	MTA
P20	F	23	Direct	15	No	MTA

Abbreviations: *FDI, Fédération Dentaire Internationale; MTA, mineral trioxide aggregate; ALBO-MPCA, Calcium Silicate–Hydroxyapatite Cement for Pulp Capping*

Inclusion and Exclusion Criteria

Included participants were adults aged 18 years or older who provided written informed consent. Only carious teeth without prior restorative treatment were included. Eligible teeth presented with a pulpal diagnosis compatible with normal, healthy pulp and were asymptomatic, with accidental vital pulp exposure where present. Only symptomless vital teeth without clinical signs of pulp degeneration, such as spontaneous pain, tenderness to percussion, swelling, sinus tract formation, pathological mobility, or excessive pulpal bleeding, were included. All selected teeth were considered restorable. Radiographic inclusion criteria required the absence of internal or external resorption, interradicular and/or periapical bone destruction, and pulp stones.

Exclusion criteria comprised pregnancy or lactation within 6 months before or during the study period, a history of irreversible pulpal pain, immature teeth, non-restorable teeth, and teeth with active periodontal disease. Patients with systemic diseases, significant renal or hepatic impairment, or a life expectancy of less than 6 months were excluded. Subjects receiving concurrent systemic therapy with steroids, antibiotics, analgesics, immunomodulatory drugs, or cytostatics were not eligible for participation. Additionally, non-compliant patients, individuals with inadequate oral hygiene or unacceptable occlusal interferences, and participants enrolled in another clinical trial involving an investigational product within the previous 12 weeks were excluded. Any other condition that, in the opinion of the investigators, could compromise patient safety, influence study outcomes, or affect participation also constituted an exclusion criterion.

Clinical screening included thermal pulp testing using a cotton pellet sprayed with Endo-Frost cold spray (-50°C) (Coltene/Whaledent®, Altstatten, Switzerland), as well as percussion and palpation tests, and a standardized radiographic examination performed using the parallel cone technique with a Rinn holder (Dentsply Rinn®, Elgin, IL, USA) to exclude teeth with periradicular pathology.

Baseline Assessment

Before dental pulp capping, a baseline assessment was performed and included a detailed medical history, explanation and signing of the informed consent form, and a comprehensive oral clinical examination. Baseline pain assessment was conducted using a visual analogue scale (VAS). Pulp vitality was evaluated using thermal testing, and periapical status was assessed radiographically using standardized intraoral periapical radiographs obtained with the paralleling technique.

Clinical Procedure

All clinical procedures were performed under local anesthesia (4% articaine with adrenaline 1:100.000, Septanest®, Septodont, Saint-Maur-des-Fossés, France) and rubber dam isolation. The clinical crown was disinfected with 0.12% chlorhexidine (Hibideks®, Galenika, Belgrade, Serbia) before caries removal. Enamel was removed using round diamond burs in a high-speed handpiece with copious water spray, while carious dentin was removed using carbide burs in a low-speed handpiece under air-water spray. Complete caries excavation was performed from the peripheral to the central area using slow-speed round burs and hand instruments, with magnification (dental loupe).

In cases where caries removal resulted in a thin layer of remaining dentin without pulp exposure, indirect pulp capping was performed. When accidental pulp exposure occurred during caries excavation, the cavity was irrigated with sterile saline, and hemostasis was achieved using cotton pellets moistened with sodium hypochlorite or saline.

Following caries removal and, when present, pulp exposure management, a calcium silicate-based cement (ALBO-MPCA or MTA) was applied over the exposed pulp tissue or over the remaining dentin. The experimental material ALBO-MPCA was mixed with distilled water at a powder-to-liquid ratio of 2:1.[18] The control material MTA (MTA+®, Cerkamed, Poland) was prepared according to the manufacturer's instructions. To prevent displacement of the pulp-capping material during cavity sealing, a hard-setting protective glass-ionomer layer (GC Fuji IX GP®, GC Corporation, Tokyo, Japan) was applied. Subsequently, the cavity was gently rinsed with water to minimize potential adverse effects of disinfecting solutions on adhesive bonding (G-BOND®, GC Corporation, Tokyo, Japan), and the tooth was permanently restored using a resin composite restoration (Gradia Direct®, GC Corporation, Tokyo, Japan) during the same visit.

Clinical and Radiographic Evaluation

Clinical and radiographic evaluation was performed to assess the efficacy and clinical outcomes of the pulp-capping materials. The primary outcome measure was the formation and depth of tertiary dentin following direct or indirect pulp capping. Secondary outcome measures included changes in pulpal volume, presence of pulpal calcifications, postoperative pain, swelling or flare-up, analgesic consumption, sinus tract or fistula formation, and the occurrence of any adverse events.

Clinical follow-up examinations were conducted at 7 days, 3 months, and 6 months after treatment. Postoperative pain was assessed using a visual analogue scale (VAS). Pulp vitality was evaluated using thermal and electric sensitivity tests (Analytical Technologies®, Redmond, WA). Clinical assessment also included evaluation of tenderness to percussion and palpation, swelling, sinus tract formation, and pathological mobility.

Radiographic evaluation was performed using cone-beam computed tomography (CBCT) scans obtained at the 6-month follow-up. All CBCT scans were performed using a Romexis® 3D X-ray unit (Planmeca®, Helsinki, Finland) with standardized exposure parameters (90 kVp, 14 mA, voxel size 0.1 mm^3) to ensure consistency and comparability of radiographic measurements. A small field of view (5 × 5 cm) was used, and image reconstruction was performed with a matrix size of 1024 × 1024 pixels. CBCT data were analyzed using axial and coronal sections to identify tertiary dentin formation. The thickness of the newly formed tertiary dentin was measured in micrometers (μm) using a digital linear measurement tool at the narrowest point of the hard tissue formation. Coronal slices were used for occlusal locations, while axial slices were used for mesial and distal locations.

Radiographic analysis also included assessment of changes in pulpal chamber volume, presence of pulpal calcifications, and evaluation of periapical status and pathological root resorption. All measurements were independently performed by three examiners, and the mean value was used for statistical analysis to minimize potential measurement bias.

Adverse events were recorded during the follow-up period and included postoperative pain, analgesic use, swelling, flare-up, sinus tract formation, and any other procedure-related complications.

Statistical Analysis

Statistical analysis was performed to evaluate the primary outcome measure, defined as the thickness of tertiary dentin formed after pulp capping, and to compare the performance of the two pulp-capping materials (ALBO MPCA and MTA). Data distribution was assessed using the Shapiro-Wilk test.

For normally distributed data, comparisons between groups were performed using the independent *t*-test. For non-normally distributed data, the Mann-Whitney *U* test was applied. Effect size was calculated using Cohen's *d*. Categorical variables were analyzed using Cochran's test, where appropriate.

Statistical analyses were performed using standard statistical software, and the level of statistical significance was set at $p < 0.05$.

Results

During the study period, adverse events or serious adverse events were not recorded in either the ALBO-MPCA or MTA group. Clinical follow-up revealed no signs of postoperative infection, swelling, flare-up, sinus tract formation, pathological mobility, or tenderness to percussion or palpation.

Pulp vitality was preserved in all treated teeth in both groups throughout the follow-up period. Thermal and electric pulp tests showed normal responses in all treated teeth with ALBO-MPCA and MTA at all evaluation time points, while in the MTA group (patient No. 17), one tooth showed mild thermal sensitivity at the 3-month follow-up, which resolved by the 6-month examination.

No additional complications or adverse events related to direct or indirect pulp-capping procedures were observed, and VAS scores indicated the absence of postoperative pain (score 0) in all patients, except for a single case in the MTA group (patient No. 17), who reported mild pain.

Radiographic analysis performed using CBCT demonstrated tertiary dentin formation in all treated teeth in both groups. The mean tertiary dentin thickness was 196 ± 72 µm in the ALBO-MPCA group and 220 ± 57 µm in the MTA group. An independent *t*-test showed no significant difference in tertiary dentin thickness (µm) between the two materials ($p > 0.05$) (Table 2).

Representative original CBCT images demonstrating reparative dentin formation after direct pulp capping with ALBO-MPCA are shown in Figure 1.

Table 2.

Comparison of tertiary dentin thickness between ALBO-MPCA and MTA.

Group	n	Mean ± SD (µm)	*p*-value
ALBO-MPCA	14	196 ± 72	0.519
MTA	5	220 ± 57	

Independent t-test; $p > 0.05$.

***Abbreviations**: SD, standard deviation; MTA, mineral trioxide aggregate; n, number of samples.*

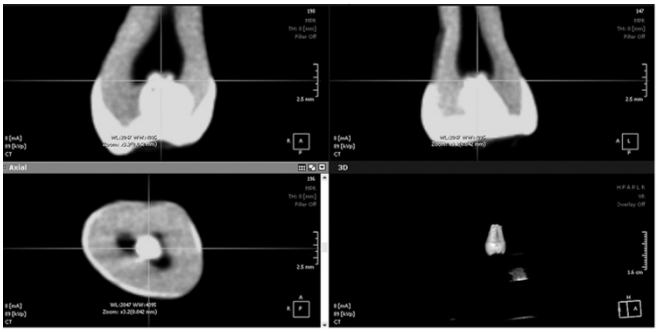


***Figure 1.** Original and multiplanar reconstructed CBCT images demonstrating tertiary dentin formation after pulp capping with ALBO-MPCA*

Discussion

Preservation of dental pulp vitality is essential for maintaining tooth health and long-term functionality. The present clinical study evaluated the performance of the experimental ALBO-MPCA cement compared with MTA in direct and indirect pulp capping procedures.

The clinical performance of the novel ALBO-MPCA material represented the primary endpoint and was assessed through systematic monitoring of adverse events and serious adverse events throughout the entire follow-up period. Special attention was given to potential complications, including postoperative infection, persistent pulp sensitivity, swelling, and sinus tract formation. No adverse or serious adverse events were recorded during the 6-month follow-up in either group. Pulp vitality was preserved in all treated teeth. VAS scores indicated absence of postoperative pain (score 0) in all cases, but only one tooth in the MTA group (patient No. 17) showed mild thermal sensitivity at the 3-month follow-up, which resolved by the 6-month examination. Although this isolated finding does not appear to be clinically significant, the overall results indicate favorable short-term clinical outcomes for both materials. These findings are in accordance with previous studies describing the high biocompatibility and favorable clinical performance of calcium silicate-based materials, particularly MTA, in vital pulp therapy procedures.[23-25] Furthermore, earlier *in vitro* and *in vivo* investigations of ALBO-MPCA have demonstrated promising biocompatibility and favorable biological properties,[16-22] which supports the clinical findings of the present study.

The present study is the first clinical study to assess tertiary dentin formation after the application of ALBO-MPCA pulp-capping materials using CBCT imaging. CBCT imaging

enables three-dimensional visualization and qualitative assessment of dentin structures.[26,27]

The CBCT results showed that the control material resulted in a higher tertiary dentin thickness than ALBO-MPCA (220 μm and 196 μm, respectively); however, this difference was not statistically significant. The thickness of tertiary dentin following pulp capping with MTA in the present study is comparable to the values reported by Agrawal et al.[28] and Mohanty et al.,[29] who reported mean thicknesses of 193 μm and 229.81 μm, respectively. These results suggest that the clinical performance of ALBO-MPCA is comparable to MTA and may be explained by the presence of calcium silicate phases in both materials. The reparative and reactive responses of VPT involve molecular activation of odontoblasts and, when necessary, the differentiation of undifferentiated stem cells within the dental pulp into odontoblast-like cells. Calcium silicate cements can stimulate cellular activity and promote the formation of tertiary dentin,[23] which is in accordance with the findings of the present study. This effect is attributed to their ability to release calcium ions during hydration, thereby promoting mineralization and stimulating tertiary dentin formation.[30] In addition, the hydroxyapatite component of ALBO-MPCA may further contribute to its bioactivity. Hydroxyapatite is one of the most commonly used calcium phosphate materials in medicine and dentistry, and its biocompatibility is closely related to its chemical composition, which is similar to that of dental and bone tissues.[31] Likewise, the lower cytotoxicity of the investigated material compared to MTA may be associated with a lower pH and the presence of hydroxyapatite, while the addition of calcium silicate improves mechanical properties.[32] Therefore, the ability of bioactive calcium silicate-based materials to stimulate tertiary dentin formation is considered a key factor in maintaining pulp vitality and promoting long-term tooth preservation.[33]

According to the results of the present *in vivo* study, ALBO-MPCA may represent a promising alternative to MTA for VPT procedures. However, the results should be considered within the limitations of the present study.

First, tertiary dentin formation was evaluated using CBCT imaging. Numerous studies have assessed tertiary dentin formation following indirect and direct pulp capping with different materials using the CBCT technique.[34-36] Nevertheless, for a more precise evaluation of tertiary dentin formation, methods that allow tissue assessment at the cellular level are required.[34] Although radiographic techniques such as CBCT and micro-CT provide valuable three-dimensional information, their resolution may be insufficient for detailed analysis of newly formed dentin. Therefore, histological and molecular techniques, including histologic analysis, immunohistochemical staining, in situ hybridization, and histomorphometric analysis, are considered more accurate for evaluating the structure and quality of tertiary dentin.[33] In the present clinical study, the application of these techniques was not feasible, as such analyses would require extraction of the treated teeth, which would be ethically unacceptable in cases where tooth preservation was the primary treatment goal. Another limitation of the present study is the heterogeneous sample, which included teeth from different tooth groups and both direct and indirect pulp capping procedures. However, this study aimed to evaluate the ability of the novel ALBO-MPCA material to stimulate tertiary dentin formation in comparison with MTA, which is widely accepted as a reference material in VPT procedures.[37-39]

Despite these limitations, the present *in vivo* study provides valuable clinical insight into the efficacy and clinical performance of the novel ALBO-MPCA material in VPT procedures. Both ALBO-MPCA and MTA induced tertiary dentin formation six months after pulp capping, with no significant difference in tertiary dentin thickness between the two materials. These findings suggest that ALBO-MPCA may represent a promising alternative to MTA. However, further clinical studies are needed to confirm the present findings, while long-term evaluation following potential commercialization will provide valuable information regarding the clinical performance and long-term success of ALBO-MPCA in routine clinical practice.

Author Contributions

Marija Lalović: Conceptualization, Data curation, Writing-original draft
Slavoljub Zivković: Investigation, Data curation and interpretation, Formal analysis
Marijana Popović Bajić: Investigation, Data curation, Formal analysis
Vukoman Jokanović: Conceptualization, Data interpretation, Writing-review and editing, Supervision
Vladimir Biočanin: Data curation and interpretation, Investigation, Conceptualization, Writing-review and editing, Supervision.

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Disclosure and Conflicts of Interest

Author Vukoman Jokanovic was employed by the company ALBOS d.o.o., Belgrade, Serbia. He participated in resources, project administration, and funding acquisition in the study. The company's role was to synthesize the experimental mixture (ALBO-MPCA). Vukoman Jokanovic is among the masterminds behind the idea of composition and synthesis of experimental dental materials. The remaining authors declare that the research was conducted without any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary Material

Table S1.

Clinical follow-up parameters after VPT procedures.

Patient	Thermal sensitivity			Electric sensitivity			Tooth mobility		
	Baseline	3 months	6 months	Baseline	3 months	6 months	Baseline	3 months	6 months
P1	+	-	-	+ (2)	+ (3)	+ (3)	-	-	-
P2	+	-	-	+ (4)	+ (4)	+ (4)	-	-	-
P3	+	-	-	+ (2)	+ (3)	+ (3)	-	-	-
P4	+	-	-	+ (2)	+ (1)	+ (1)	-	-	-
P5	+	-	-	+ (3)	+ (2)	+ (2)	-	-	-
P6	-	-	-	+ (4)	+ (4)	+ (4)	-	-	-
P7	+	-	-	+ (3)	+ (4)	+ (4)	-	-	-
P8	+	-	-	+ (1)	+ (1)	+ (1)	-	-	-
P9	+	-	-	+ (1)	+ (1)	+ (1)	-	-	-
P10	-	-	-	+ (1)	+ (1)	+ (1)	-	-	-
P11	-	-	-	+ (1)	+ (1)	+ (1)	-	-	-
P12	-	-	-	+ (1)	+ (1)	+ (1)	-	-	-
P13	+	-	-	+ (2)	+ (2)	+ (2)	-	-	-
P14	+	-	-	+ (1)	+ (1)	+ (1)	-	-	-
P15	-	-	-	+ (1)	+ (1)	+ (1)	-	-	-
P16	+	-	-	+ (2)	+ (2)	+ (2)	-	-	-
P17	+	-	-	+ (2)	+ (2)	+ (2)	-	-	-
P18	+	-	-	+ (3)	+ (2)	+ (2)	-	-	-
P19	+	-	-	+ (2)	+ (2)	+ (2)	-	-	-
P20	+	-	-	+ (1)	+ (1)	0	-	-	-

Note: *In the "Electric sensitivity" column, the numerical values recorded in parentheses represent the response obtained during electric sensitivity testing, corresponding to the intensity of the tested current on a scale from 0 to 9. +, positive response; –, negative response.*

Table S2.

Types of carious lesions and treated teeth included in the study.

Patient	Type of caries		FDI Tooth notation
	Pit and fissure caries	Smooth-surface caries, class 2 and 4	
P1		+ 2	46
P2	+		37
P3	+		48
P4		+ 2	25
P5	+	+ 2	16
P6		+ 2	17
P7		+ 2	27
P8		+ 2	24
P9		+ 2	25
P10		+ 2	25
P11		+ 2	14
P12		+ 4	12
P13		+ 2	24
P14		+ 2	15
P15		+ 2	25
P16	+		36
P17		+ 2	25
P18	+	+ 2	46
P19		+ 2	44
P20		+ 2	15

Note: *"+" indicates the presence of the lesion. Numbers indicate the Black classification (Class II or Class IV). FDI, Fédération Dentaire Internationale.*

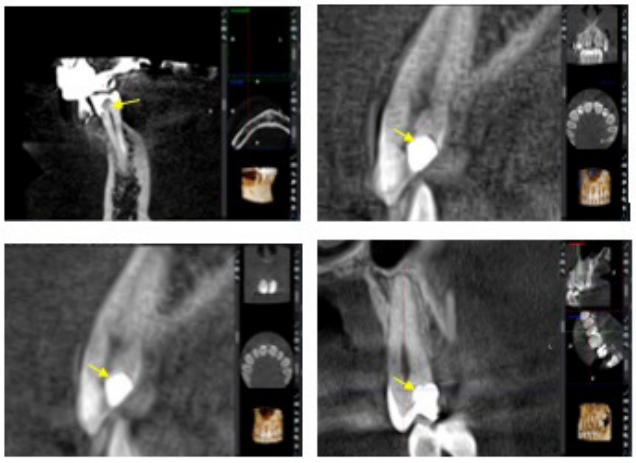


Figure S1.

Representative cone-beam computed tomography (CBCT) images showing a thin, continuous layer of tertiary dentin completely covering the pulp exposure site (yellow arrows). In all cases examined, the newly formed dentin exhibited radiopacity comparable to that of the surrounding dentin, indicating satisfactory mineralization.