RANDOMIZED CONTROL TRIAL

Calcium Hydroxide Paste, Mineral Trioxide Aggregate, and Formocresol as Direct Pulp Capping Agents in Primary Molars: A Randomized Controlled Clinical Trial

Ahmed ElSebaai, PhD, PhD[1] • Ahmed Hamdy Wahba, PhD[2] • Mohammed E. Grawish, PhD[3] • Ibrahim Hassan Elkalla, PhD[4]

Abstract: ***Purpose:*** *The purpose of this study was to evaluate the clinical and radiographic outcomes of direct pulp capping (DPC) using calcium hydroxide (CH), mineral trioxide aggregate (MTA), and premedicated DPC with formocresol (FC) in primary teeth.* ***Methods:*** *Sixty primary mandibular second molars with pulp exposures in children aged four to eight years old were treated using DPC. The molars were randomly divided into three groups (n equals 20 per group). Pulp exposures in the CH and MTA groups were capped directly using CH and MTA pastes, respectively, while those in the FC group were premedicated with FC and then capped with zinc oxide eugenol (ZOE) cement. All teeth were finally restored with stainless steel crowns, and clinical and radiographic evaluations were carried out at baseline and three, six, and 12 months after restoration. Fisher's exact test was performed to define the significance between the groups and follow-up periods.* ***Results:*** *The clinical and radiographic findings showed no significant difference between the three groups. The overall success in the CH, MTA, and FC groups were 88.2 percent, 100 percent, and 73.3 percent, respectively. However, these differences were not statistically significant (P>0.05).* ***Conclusion:*** *All three materials examined in this study exhibited clinical and radiographical efficacy when used as direct pulp capping materials.* *(Pediatr Dent 2022;44(6):411-5. E14-E15) Received March 11, 2022 / Last Revision September 22, 2022 / Accepted September 27, 2022*

KEYWORDS: PRIMARY TEETH; CALCIUM HYDROXIDE; MINERAL TRIOXIDE AGGREGATE (MTA); FORMOCRESOL; DIRECT PULP CAPPING

The structural and physiological characteristics of the dentin-pulp complex of primary teeth are very similar to that of permanent teeth. Previous studies examining primary teeth have highlighted the protective abilities of odontoblasts and odontoblast-like cells in the treatment of reversible inflammatory diseases of the pulp.[1,2] The majority of pulp therapies aim to maintain vitality through stimulation of the regenerative and reparative processes. Vital pulp therapy in primary teeth can be classified into indirect pulp therapy, direct pulp capping (**DPC**), and pulpotomy, based on the clinical approaches used.[3]

Cases of vital pulp exposure can be treated using DPC or pulpotomy. The former is a more conservative approach involving the application of medication, dressing, or dental material to the exposed pulp in an attempt to preserve pulp vitality by initiating reparative tertiary dentin formation at the exposure site. According to the American Academy of Pediatric Dentistry (**AAPD**),[4] DPC is best indicated for the treatment of primary teeth with a small exposure of normal pulp measuring one millimeter or less, provided conditions are optimal for a favorable response.

However, some studies have reported poor outcomes and an increased risk of internal resorption associated with DPC,[5,6] which can be attributed to the presence of undifferentiated cells in the primary pulp that later form odontoclasts, leading to internal resorption.[7]

Historically, calcium hydroxide (**CH**) has been considered the gold standard for DPC due to its antibacterial effects and ability to stimulate tertiary dentin formation.[8,9] Mineral trioxide aggregate (**MTA**), a potential substitute for CH, has also been recommended for use in pulpotomies of primary molars.[10,11] However, to date, a limited number of studies have examined the use of MTA as a DPC agent for primary molars.

The high success of pulpotomies in primary dentition endorsed the concept of using formocresol for DPC in this population,[12] with the rationale for this proposed modality being that pulpal inflammation is often confined to the exposure site in the coronal pulp and a modified, less invasive method of pulpotomy may be sufficient. This form of therapy, also known as "micro-pulpotomy," substitutes zinc oxide eugenol (**ZOE**) dressing for CH cement, which is thought to be the root cause of DPC failure.[13] Moreover, when the pulp is medicated with formocresol at the exposure site, there is no actual contact between the capping material and the vital pulp due to the presence of a superficial layer of fixed necrotic tissue.[14]

DPC and its indication for the treatment of reversible pulpitis in the primary dentition are debatable, highlighting the need for further research in this area. Therefore, the purpose of the current study was to determine the efficacy of the most commonly used pulp treatment materials for direct pulp capping in pediatric dentistry.

[1]*Dr. ElSebaai is a lecturer, Pediatric Dentistry Department, Faculty of Oral and Dental Medicine, Delta University for Science and Technology, Gamsa;* [2]*Dr. Wahba is lecturer, Pediatric Dentistry Department, Mansoura University, Mansoura;* [3]*Dr. Grawish is a professor, in the Oral Biology Department, Faculty of Dentistry, Mansoura University, Mansoura; and a professor in the Oral Biology Department, Faculty of Oral and Dental Medicine, Delta University for Science and Technology, Gamsa; and* [4]*Dr. Elkalla is a professor, Department of Pediatric Dentistry, Mansoura University, Mansoura, all in Egypt.*

Correspond with Dr. ElSebaii at Ahmed.elsebaai@students.mans.edu.eg

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Methods

All clinical procedures were carried out per the study protocol approved by the Ethical Committee of Research, Mansoura University, Mansoura, Egypt (code no: 05030718). Informed consent was collected from the guardians of all participants, and the study was executed following CONSORT Statement 2010 guidelines. It was also registered on the ClinicalTrials.gov Protocol Registration and Results System (PRS; ID: NCT 05222243).

Study sample. Using the Sampsize application (https://app.sampsize.org.uk) at 80 percent power, a significance level of 0.05, an anticipated response on treatment with MTA of 98 percent,[15] and an anticipated response on treatment with CH of 57 percent,[13] a total sample size of 32 was considered adequate. An anticipated attrition rate of 10 percent increased this to 36 (18 patients per group). Therefore, the total sample size for the three study groups was 54.

This randomized, parallel, active-controlled clinical trial included 60 primary teeth, with an allocation ratio of one to one, resulting in 20 teeth in each group. The patients, aged four to eight years old, were recruited from the pediatric dental clinics of Mansoura University.

Selection criteria. The following selection criteria were used to select patients: cooperative patients; absence of chronic systemic diseases; absence of drug, anesthetic, or environmental allergies; restorable teeth with deep carious lesions; teeth with signs of reversible pulpitis, no spontaneous pain, and absence of edema, fistula, pathological mobility, or sensitivity to percussion; true pinpoint exposure (small exposure surrounded by sound dentin with normal bleeding that is easily controlled); teeth with the absence of pathological root resorption or peri-radicular or furcal radiolucency; and teeth with less than one-third physiological root resorption (no resorption or one-fourth resorption of the root).

Patient allocation. Each child was assigned an identification (ID) number at the first visit and was identified using this throughout this study. Computer-generated random numbers (https://randomnumbergenerator.org) were used to randomly allocate patients to one of three treatment groups (CH, MTA, and FC; N equals 20 each).

Clinical procedures. Preoperative intraoral periapical radiographs were taken to confirm the absence of periapical pathosis in the event of a clinical examination revealing the presence of deep caries. Local anesthesia was administered, and teeth were isolated using a rubber dam. All peripheral caries were removed along with the overhanging enamel using high-speed round burs. Deep caries were removed using carbide low-speed round burs. Only teeth with a true pinpoint exposure surrounded by sound dentin were included in the study (Figure 1). The exposure site was irrigated with saline to wash away debris and then dried using a sterile cotton pellet.

After achieving hemostasis, the capping materials were applied (Figure 1) according to the manufacturers' instructions. Dycal® (Dentsply Sirona, Charlotte, N.C., USA) was mixed and applied to the exposure site using a burnisher in the CH group, while the MTA group received MTA (CERKAMED, Kwiatkowskiego, Stalowa Wola, Poland) that was mixed according to the manufacturers' instructions and applied onto the exposure site using moist cotton. In the FC group, the exposure site was first blotted using a cotton wool pellet moistened with FC (Prevest Denpro®, Bari Brahmana, Jammu, India) for five minutes and then capped with ZOE (Prevest Denpro®) mix packed with a moist cotton pellet.

All teeth were filled with glass ionomer cement and restored using prefabricated stainless steel crowns (Kids Crowns™, Shinhung, Korea; Krishna Township, Gujarat India Figure 1).

Evaluation. All patients attended postoperative recall visits three, six, and 12 months after restoration where overall success was assessed via evaluation of clinical symptoms (spontaneous pain; sensitivity on percussion or palpation; change of color; the presence of edema or fistula in the soft tissue; pathologic mobility; and lymphadenopathy of the related region) and radiographical outcomes (radiolucency at the periapical or furcation areas; pathological internal or external root resorption; widening of the periodontal space; and calcification of the pulp canal).[16]

Clinical and radiographic results were both used to assess overall success. The operator coded the patient data to be assessed by two evaluators who were blinded to the generation and implementation of the treatment assignment. Evaluators responsible for clinical and radiographic examinations were blinded to the treatment protocol. Each evaluator analyzed the data separately more than once to ensure inter-examiner and intra-examiner reliability of 85 percent. Treatment failure was defined as the observation of any of the clinical or radiographical outcomes mentioned previously at the follow-up intervals. Any disagreements between the evaluators were resolved through discussion with a third more experienced evaluator until a consensus was reached.

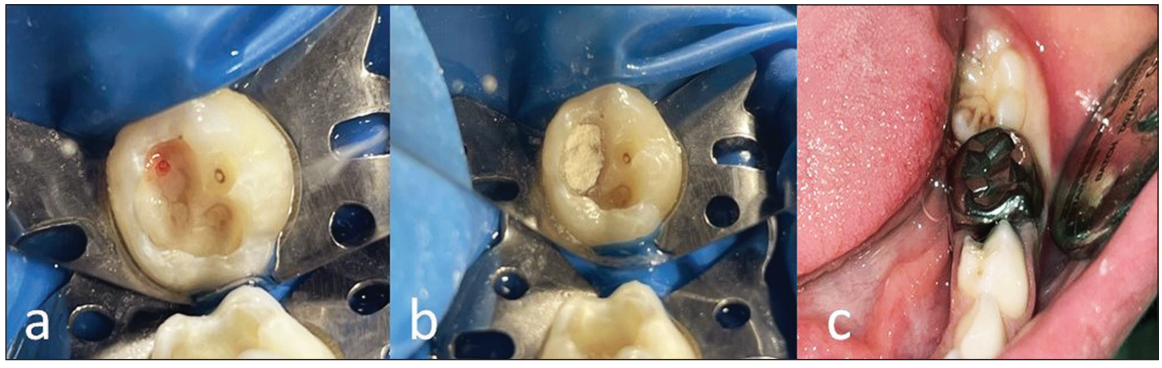

Figure 1. Representative photographic pictures showing clinical steps of direct pulp capping procedures: (a) Pinpoint pulpal exposure with controlled bleeding after caries removal; (b) pulp capping of the exposure site with mineral trioxide aggregate; and (c) final restoration with stainless steel crown immediately after capping.

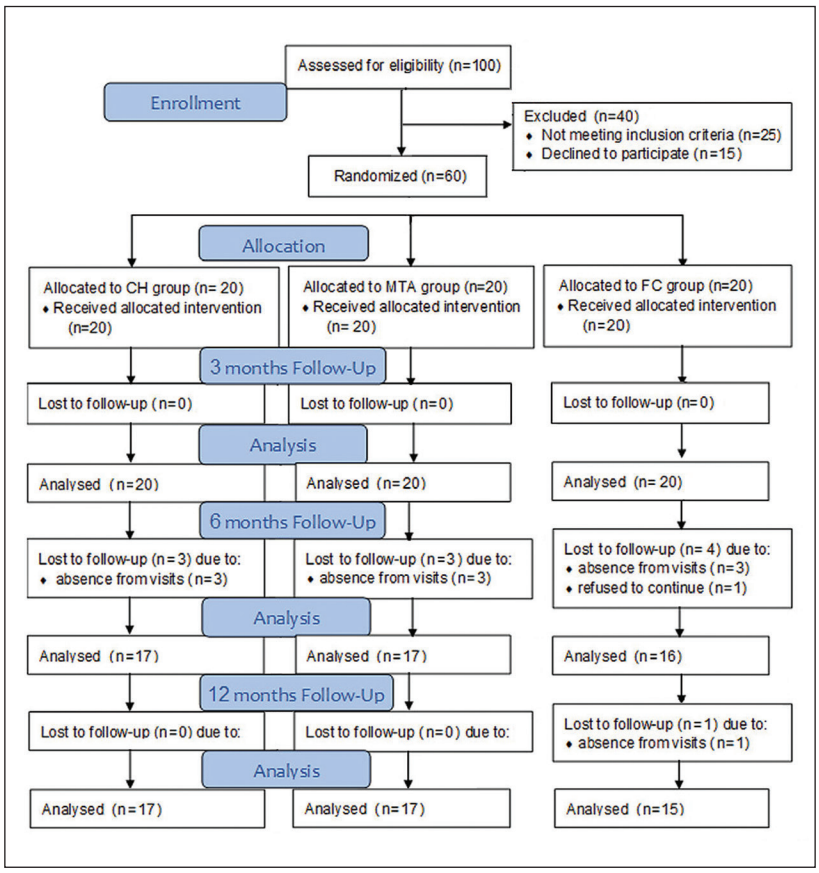

Figure 2. Participant CONSORT Statement flow diagram.

Table 1. CLINICAL SUCCESS OF THE DIFFERENT GROUPS*

	Followed for 3 months			Followed for 6 months			Followed for 12 months		
	Success	Failure	Total	Success	Failure	Total	Success	Failure	Total
CH	20	0	20	17	0	17	16	1	17
MTA	20	0	20	17	0	17	17	0	17
FC	19	1	20	15	1	16	13	2	15
E (*P*-value)**		1.851 (1.000)			1.941 (0.320)			2.223 (0.292)	

* Abbreviations used in this table: CH=calcium hydroxide; MTA=mineral trioxide aggregate; FC=formocresol.

** E=Fisher's exact test, significant at $P<0.05$.

Table 2. RADIOGRAPHIC SUCCESS OF THE DIFFERENT GROUPS*

	Followed for 3 months			Followed for 6 months			Followed for 12 months		
	Success	Failure	Total	Success	Failure	Total	Success	Failure	Total
CH	20	0	20	16	1	17	15	2	17
MTA	20	0	20	17	0	17	17	0	17
FC	20	0	20	16	0	16	13	2	15
E (*P*-value)**		_			1.819 (1.000)			2.417 (0.442)	

* Abbreviations used in this table: CH=calcium hydroxide; MTA=mineral trioxide aggregate; FC=formocresol.

** E=Fisher's exact test, significant at $P<0.05$.

Statistical analysis. Different parameters were recorded at each follow-up period, and participants were classified as exhibiting treatment success or failure. Fisher's exact test was used to examine differences between the groups and follow-up periods, and all statistical analyses were performed using SPSS® 23 software (IBM Corp, Armonk, N.Y., USA). The level of significance was set at $P=0.05$, and inter- and intra-examiner reliability was assessed using Kappa statistics.

Results

Sixty primary mandibular molars in 50 children (median age equals six years; range equals four to eight years) were treated using DPC. Ten patients dropped out of the study after six months, and one additional patient dropped out after 12 months, resulting in a final sample size of 49 patients (Figure 2). The clinical and radiographic success of the three groups by follow-up periods and the comparisons between the groups and follow-up periods are shown in Tables 1 and 2. No significant differences were observed between the groups and between follow-up periods within the same group (two-sided exact significance test). Supplemental figures (see **Supplemental Electronic Data—sFigures 1–5**) show the success and failure of selected cases from the three groups by follow-up period.

Table 3 shows the overall success by treatment group at different follow-up time points. DPC with MTA resulted in the highest success (100 percent) as no signs of clinical or radiographic failure were observed in this group throughout the study period.

Discussion

The indications for use of DPC in primary teeth have evolved, with AAPD guidelines[17] published in 2014 recommending DPC for mechanical or traumatic pulp exposures but not for carious pulp exposures. However, with recent evidence[13,18] reporting high treatment success, AAPD guidelines,[4] published in 2017, were modified to include carious pulp exposures that were one mm or less in size as an indication. The guidelines also suggested that clinicians should choose the medicament based on individual preferences. Currently, there is limited evidence of DPC's efficacy in primary teeth. Therefore, the current study investigated the clinical and radiographic outcomes of DPC in primary teeth using different materials.

The 60 children included in this study were aged between four and eight years, and this age range was chosen to allow efficient treatment in children capable of cooperative behavior to avoid aging of the dental pulp, avoid impairment of cell differentiation, and include teeth that had been subjected to minimal exfoliation resorption. Children with any systemic diseases or on medications were excluded from the study to minimize bias.

Table 3. OVERALL SUCCESS OF THE DIFFERENT GROUPS*

	Followed for 3 months			Followed for 6 months			Followed for 12 months		
	Success	Failure	Total	Success	Failure	Total	Success	Failure	Total
CH	20	0	20	16	1	17	15	2	17
MTA	20	0	20	17	0	17	17	0	17
FC	19	1	20	15	1	16	11	4	15
E (*P*-value)**		1.851 (1.000)			1.326 (0.764)			4.947 (0.064)	

* Abbreviations used in this table: CH=calcium hydroxide; MTA=mineral trioxide aggregate; FC=formocresol.

** E=Fisher's exact test, significant at $P<0.05$.

Only primary mandibular second molars were included in the present study to facilitate standardization of factors such as pulp size, innervation, blood supply, masticatory forces, and ease of restoration. This also aided obtaining clear radiographs devoid of superimposing structures were obained, making them easier to interpret during follow-up periods. Mandibular first molars were excluded due to their apparently smaller size which could affect pulp healing and complicate restorative procedures. Exposures from the occlusal surface only were included in the study, while axial exposures were excluded to prevent observation of failure related to the site of exposure.

Rubber dams were used in all patients to ensure maximum isolation and prevent contamination. After the occurrence of pulpal exposure and achievement of hemostasis, the cavities were washed with saline to remove debris. Failure to achieve hemostasis may result in the exudation of plasma, contamination of the surrounding surfaces, and disruption of the artificial basement membrane to which cells adhere and express odontoblastic activity.[19] Stainless steel crowns were used immediately after restoration to provide a hermetic seal as any bacterial leakage through the restoration can cause critical contamination during the clinical process.[20]

In the present study, exposures were carefully inspected for evidence of bleeding and to allow measurement of the size of the exposure. Teeth were excluded upon observation of excessive bleeding that was dark in color as this may indicate further inflammation. Garcia-Godoy[21] stated that the nature of pain, findings upon examination, and characteristics of bleeding observed can influence the success of capping treatments.

The overall success of DPC treatment in the three groups were 98.3 percent, 96 percent, and 87.7 percent three, six, and 12 months after restoration, respectively. These results were in accordance with Erfamárast et al.[22] and Vafaei et al.,[23] who reported comparable findings confirming the efficacy of DPC treatment in primary teeth. These findings encourage the use of this treatment measure in primary teeth as it can save time and effort and is associated with less pain when compared to pulpotomies. Therefore, it appears that pulpal healing in primary teeth can be attained without the need for more invasive procedures.

Only one tooth treated with CH in the present study showed root resorption after 12 months of follow-up. Previous studies[7,24,25] have reported internal and external root resorption as the most common limitation of DPC in primary teeth. The CH groups resulted in overall success of 90 percent after 12 months of follow-up, and this was in agreement with Garrocho-Rangel et al.,[26] who recommended the use of CH in DPC. Also, Tuna and Ölmez[15] reported 100 percent success upon using CH and MTA cements as DPC materials in primary teeth, suggesting that treatment failure could be attributed to the techniques used and the underlying diagnoses instead of the materials selected.

Teeth treated with MTA exhibited 100 percent success both clinically and radiographically, indicating the superiority of the material, however in this study was not statistically significantly different from the other groups. Nonetheless, these findings are in agreement with Fallahinejad-Ghajari et al.,[27] who also reported clinical and radiographic success of 90.4 percent and 100 percent, respectively, when using MTA for DPC. MTA exhibits superior biocompatibility and sealing properties, which makes it suitable for use in pulp therapy.[28]

As noted above, no significant differences in success were observed between the groups; this was in contrast to Aminabadi et al.,[13] who reported a significant difference in success between CH used for conventional DPC and FC used for premedicated direct pulp capping. They reported clinical and radiographical success of 61 percent and 53 percent, respectively, in the CH group, and 90 percent and 85 percent, respectively, in the FC group (premedication with FC before DPC with ZOE). They attributed the success of premedicated DPC to the antibacterial and palliative effects exerted upon the fixation of the tissues using ZOE.

In the current study, only one tooth in the FC group exhibited treatment failure after three months, no teeth exhibited failure after six months, and three further teeth exhibited failure after 12 months of follow-up. Failure in these teeth was characterized by the observation of spontaneous pain and widening of the periodontal ligament space. The antibacterial effect of ZOE was related to eugenol leaching, which reduces over time, resulting in failure. The hydroxyl group in eugenol exerts a bacteriostatic effect as it alters the permeability of the cell membrane, causing leakage of its content and leading to damage.[29,30]

The overall clinical and radiographic success of DPC treatment in all three groups were 93.8 percent and 91.8 percent, respectively. Of the six teeth exhibiting failure, one presented clinical failure only, three teeth showed radiographic failure only, and two teeth exhibited both clinical and radiographic failures. Although radiographic examination is more accurate when defining failure, it must be supplemented with clinical examination to ensure a true assessment of treatment success.

Limitations of this study included a low number of events and a lack of independence as some subjects received more than one treatment (FC and ZOE). Future clinical trials with longer follow-up periods and larger sample sizes are needed before the provision of definitive clinical practice recommendations regarding the use of the materials examined in this study in primary molars.

Conclusions

Based on this study's results, the following conclusions can be made:

1. Direct pulp capping is a successful treatment technique for primary teeth.
2. Although there was no significant difference between the groups, the use of mineral trioxide aggregate as the material of choice is strongly recommended since calcium hydroxide and formocresol had some failures but MTA had a 100 percent success.
3. Additional larger scale clinical trials may be required to demonstrate differences between the three treatment modalities compared in this study.

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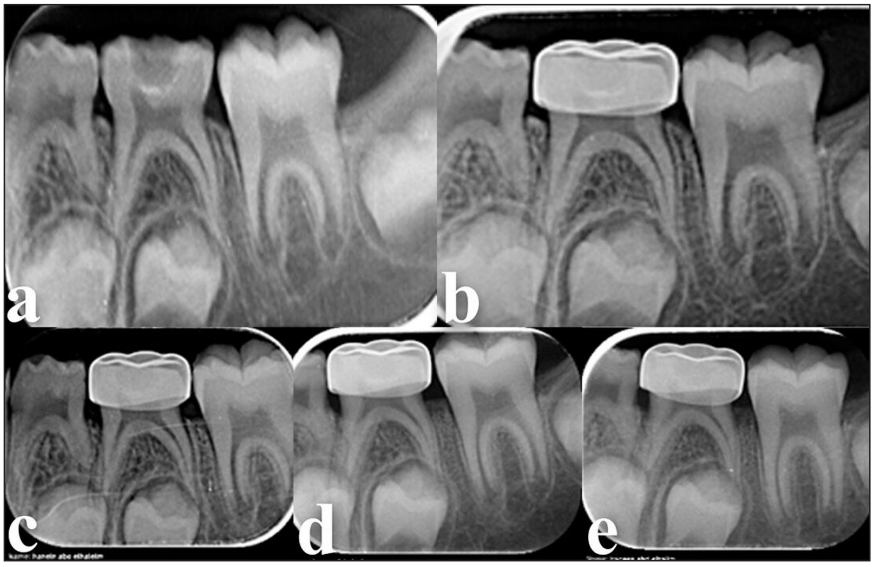
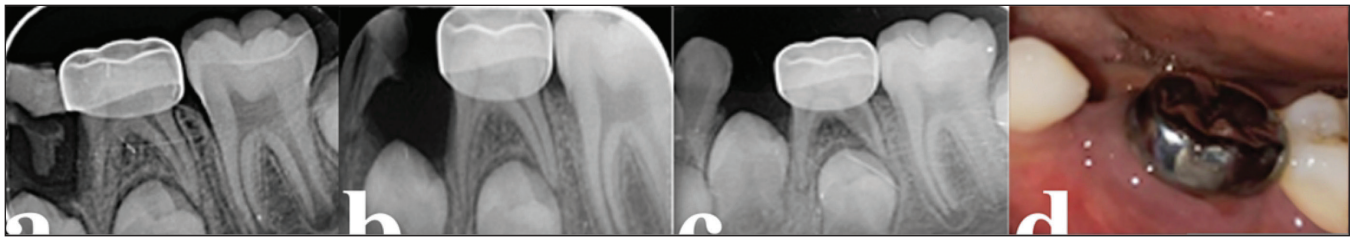
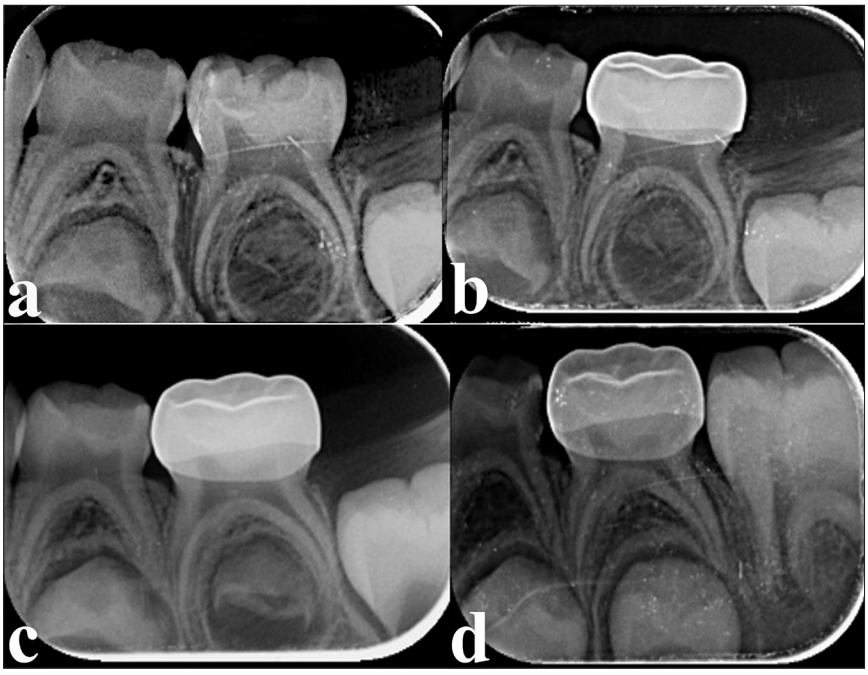
Supplemental Electronic Data—Figures



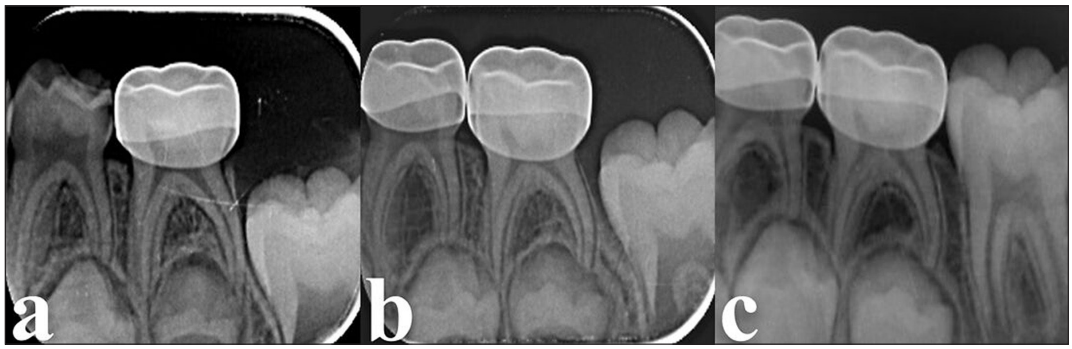
sFigure 1. Representative periapical radiographic images showing a follow-up for a case of direct pulp capping with calcium hydroxide paste illustrating no signs of failure: (a) preoperative; (b) immediate postoperative after capping and stainless steel coverage; (c) after the three-month follow-up period; (d) after the six-month follow-up period; and (e) after the 12-month follow-up period.



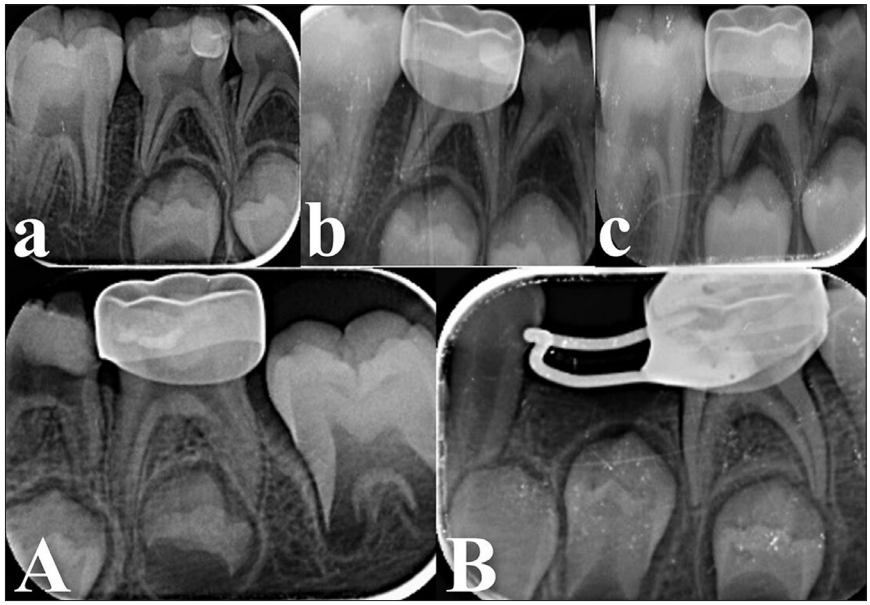
sFigure 2. Representative periapical radiographic images showing a follow-up for a case of direct pulp capping with calcium hydroxide paste illustrating signs of failure: (a) immediate postoperative after capping and stainless steel coverage; (b) after the six-month follow-up period; (c) internal resorption in the distal root as a sign of failure after the 12-month follow-up period; and (d) a clinical picture of swelling and change of color in gingivae after the 12-month follow-up period.



sFigure 3. Representative periapical radiographic images showing a follow-up for a case of direct pulp capping with mineral trioxide aggregate illustrating no signs of failure: (a) after capping with MTA and glass ionomer restoration; (b) immediate postoperative after stainless-steel crown coverage; (c) after the six-month follow-up period; and (d) after the 12-month follow-up period.



sFigure 4. Representative periapical radiographic images showing a follow-up for a case of direct pulp capping with formocresol/zinc oxide eugenol illustrating no signs of failure: (a) immediate postoperative after capping and stainless steel coverage; (b) after the six-month follow-up period; and (c) after the 12-month follow-up period.



sFigure 5. Representative periapical radiographic images showing a follow-up for two cases of direct pulp capping with formocresol and zinc oxide eugenol illustrating signs of failure: (a) after capping with FC/ZOE and glass ionomer restoration; (b) after the six-month follow-up period; and (c) periapical radiolucency as a sign of failure after the 12-month follow-up period; (A) immediate postoperative after capping and stainless steel coverage; and (B) widening of the periodontal ligament space as a sign of failure after 12 months.