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CLINICAL AND RADIOGRAPHIC EVALUATION OF DIRECT PULP CAPPING IN PRIMARY MOLARS WITH TWO DIFFERENT MEDICAMENTS: A RANDOMIZED CONTROLLED TRIAL

Dentistry

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ABSTRACT

Background: Preservation of pulp vitality is essential for the maintenance of normal dental functions, particularly in the primary dentition. Direct pulp capping (DPC) offers a conservative alternative to traditional pulpotomy in cases of pulp exposure. Advances in bioactive materials such as Mineral Trioxide Aggregate (MTA) and TheraCal LC have enhanced the potential for successful outcomes in primary teeth. **Aim:** To clinically and radiographically evaluate the efficacy of direct pulp capping in primary molars using MTA and TheraCal LC. **Materials and Methods:** An in vivo randomized controlled study was conducted on 44 primary molars in children aged 6–10 years. The teeth were divided into two groups: Group A (MTA) and Group B (TheraCal LC). Carious lesions were excavated, pinpoint pulp exposures were capped with assigned materials, and teeth were restored with stainless steel crowns. Clinical and radiographic evaluations were performed at 3, 6, and 9 months. Success criteria included absence of pain, swelling, mobility, and periapical or internal/external resorption. **Results:** At 9 months, the overall success rate for DPC was 84.1%. TheraCal LC showed higher clinical and radiographic success rates (95.4%) compared to MTA (72.7%) at 9 months, with the difference being statistically significant ($p<0.05$). **Conclusion:** Direct pulp capping using bioactive materials like MTA and TheraCal LC is a viable treatment for deep carious primary molars. TheraCal LC demonstrated superior clinical outcomes and handling properties, suggesting its preference over MTA. Long-term studies are recommended to validate these findings.

KEYWORDS

Pulp Capping, Dental Pulp, MTA Cement, Calcium, Cavity Liner

INTRODUCTION

The preservation of pulp vitality stands as a cornerstone of pediatric dental care. The dental pulp plays a vital role not only in dentin formation but also in protecting against bacterial invasion and transmitting sensory signals. By maintaining healthy pulp tissue through conservative treatments, clinicians can help avoid invasive procedures and support the natural exfoliation process of primary teeth.

Traditionally, pulpotomy has been the treatment of choice for primary molars with pulp exposure, largely due to concerns about the risk of internal resorption following direct pulp capping (DPC)[1]. Although early materials such as calcium hydroxide initially showed promise, their high solubility, poor long-term sealing ability, and inconsistent formation of reparative dentin limited their success[2].

However, recent advances in material science have introduced more biocompatible options like Mineral Trioxide Aggregate (MTA) and resin-modified calcium silicate cements such as TheraCal LC. These newer materials offer enhanced sealing properties, promote the formation of reparative dentin, and demonstrate excellent biological compatibility[3].

While earlier guidelines from the American Academy of Pediatric Dentistry (AAPD) advised caution against using DPC for carious exposures in primary teeth, emerging evidence suggests that when combined with careful case selection, strict aseptic protocols, and appropriate material choice, DPC can be a reliable and successful treatment modality[4,5].

The present study was designed to evaluate and compare the clinical and radiographic success of DPC in primary molars using MTA and TheraCal LC over a nine-month follow-up period.

MATERIALS AND METHODS

Study Design

The study included children aged 6–10 years who required restorative treatment for deep carious lesions. Ethical approval (institutional ethical committee no. 09) was obtained for the study and the accompanying parents or guardians received a comprehensive explanation of the study objectives, method and associated risks and benefits. Written consent were obtained from parents and and assent from children over 8 years of age.

Inclusion Criteria

- Deep occlusal dentin caries in primary first or second molars with radiolucency upto inner third of dentin (ICDAS RB4-RC5 criteria).
- Pulp exposure (≤1 mm) during excavation with surrounding sound dentin.
- Tooth with at least two-third root present due to physiological resorption.

Exclusion Criteria

- History of nocturnal/spontaneous pain
- Swelling, fistulae, tenderness to percussion/palpation, pathological mobility
- Evidence of pathological, internal/external root resorption, or periradicular/ furcation radiolucency

Sample Size Determination

Sample size was calculated using nMaster ® software (Version 2) (Copyright © Department of Biostatistics, CMC, Vellore, Tamil Nadu, India). Minimum total sample size of 44 teeth (22 per group) was determined to be sufficient at precision of 5% and desired confidence level of 95%. A sample size of 50 children with a 10% expected loss was taken.

Randomization

In this study, the patients were divided into two groups using a randomized allocation technique using the enveloped drawing method. To ensure homogeneity between the groups, strict measures were taken, each group being distinguished by two different color codes: blue for Group A (MTA) and red for Group B (TheraCal LC). These color-coded assignments were printed and sealed in the envelopes and presented to the children. When the selected envelope was opened, the independent researcher determined the group allocation for each patient. The selection of pulp capping medicament depended on the color selected by the parents of the children. Blinding protocols were meticulously maintained throughout the study for both evaluator and patient. Both the groups had 22 participants each.

Methodology

Children aged 6–10 years with deep carious lesion of radiographic ICDAS RB4-RC5 criteria were screened. Participants were selected according to the eligibility criteria and written consent was taken from parents. Local anesthesia (Xicaine, ICPA) was administered followed by rubber dam isolation. Non-selective caries removal was done using a discoid shape spoon excavator. If a pinpoint pulp exposure (<1mm)

was found on complete excavation and surrounded by sound dentin, the exposure site was dried using a sterile cotton pellet. Hemostasis was achieved by applying a sterile cotton pellet soaked with saline on the exposure site. Uncontrolled bleeding for more than 5 min, denoting 'irreversible' pulp damage, was criterion for exclusion. After achieving complete hemostasis, the pulp capping medicaments were applied. For Group A, MTA (Safe Endo, SafeEndo Dental India Pvt. Ltd., Gujarat, India), premixed putty material was used according to the manufacturer's instructions and a small amount was placed directly over the exposed pulp and condensed with a moist cotton pellet and restorative material was placed. In Group B, a thin layer (not exceeding 1 mm) of TheraCal LC (Bisco Inc., Schaumburg, IL, USA) was applied directly over the exposed pulp, then light cured for 20 seconds followed by final restoration. Tooth was restored with composite resin and stainless steel crown. Oral hygiene instructions were given prior to the restoration. The teeth were followed up for clinical and radiographic outcomes.

Clinical and radiographic evaluations were carried out at 3, 6, and 9 months postoperatively as depicted in Figure 1. Clinical success was defined by the absence of pain, tenderness, swelling, sinus tract formation, and pathological mobility. Radiographic success was determined by the absence of internal or external root resorption, furcal radiolucency, periodontal ligament widening, and periapical pathology. Any cases demonstrating clinical or radiographic signs of failure were managed appropriately with either pulpectomy or extraction procedures.

Statistical Analysis

The data for the study were recorded in a Microsoft Excel 2021 and analyzed using SPSS statistical software (version 21.0) IBM Corporation, (Armonk, New York, USA). Descriptive statistics such as frequency and percentage were used. Postoperative parameters were measured in terms of mean and standard deviation. The significance level for the study was set at 5%. To compare ordinal variables between groups, the Chi-square test was used, with $p<0.05$ considered statistically significant. For intragroup comparison of continuous variables, independent t-test was used based on the normality of the data.

RESULTS

Clinical and Radiographic Success

At the 3-month follow-up, both groups demonstrated 100% clinical and radiographic success, with no clinical or radiographic signs of pathology. At the 6-month follow-up, the TheraCal LC group maintained a clinical success rate of 95.4%, while the MTA group showed a slightly reduced clinical success rate of 86.3%. Radiographic assessments revealed 100% success in the TheraCal LC group and 95.4% in the MTA group at this time point. At the 9-month follow-up, the clinical and radiographic success rate for TheraCal LC remained high at 95.4%, while the MTA group exhibited a decline to 72.7%. The difference in success rates between the two groups at 9 months was statistically significant ($p = 0.039$), favoring TheraCal LC. Overall, the study observed an 84.1% success rate for direct pulp capping procedures across both groups (Table 1).

The comparative evaluation and analysis of MTA and TheraCal success according to the post-treatment clinical findings at different time intervals, TheraCal showed better results than MTA but the results indicated no significant differences ($p>0.05$) between the two groups in terms of pain, tenderness on percussion, oedema/fistula and pathological mobility (Table 2). According to the radiographic findings, there were no significant differences ($p>0.05$) between the two groups in terms of internal root resorption and pulp canal calcification. However, statistically significant differences ($p<0.05$) were observed between the two groups regarding pathological resorption ($p = 0.026$) and periodontal ligament (PDL) space widening ($p = 0.009$) at different time intervals (Table 3). TheraCal showed better results than MTA comparatively. These findings underscored the efficacy of both materials, with notably low failure rates, rendering them suitable options for clinical use.

A study of 44 cases using ICDAS radiographic criteria found RB4 had 26 cases and 1 failure with a statistically significant p-value of 0.004, indicating potential effectiveness in caries detection. RB5 showed 18 cases and 6 failures (Table 4). Higher failure was seen in radiographic RC5 criteria which can be attributed to the inflammation of the pulp due to proximity of caries to the pulp.

DISCUSSION

The dental pulp plays a vital role in dentinogenesis, nutrition, defense, and sensation[6]. Preserving pulp vitality is critical for maintaining the tooth's function, especially in primary teeth. If left untreated, both mechanical and carious pulp exposures can lead to irreversible pulp damage. According to the American Academy of Pediatric Dentistry (AAPD), direct pulp capping (DPC) is indicated for primary teeth with small, well-controlled pulp exposures of less than 1 mm under optimal conditions[1]. The goal of DPC is not only the preservation of pulp vitality but also the absence of postoperative symptoms and the stimulation of reparative dentin formation without pathological changes [7].

Historically, the use of calcium hydroxide (CH) as a direct pulp capping medicament in primary teeth was controversial due to internal resorption attributed to odontoclastic differentiation [8]. However, the development of bioactive materials such as Mineral Trioxide Aggregate (MTA) and resin-modified calcium silicate cements like TheraCal LC has revived interest in DPC for primary teeth [9,10,11]. These newer materials offer improved sealing ability, antibacterial effects, and biocompatibility, addressing many limitations associated with earlier agents.

In the current study, DPC was evaluated clinically and radiographically over nine months using MTA and TheraCal LC in primary molars with deep carious lesions. The case selection criteria were stringent, including only asymptomatic teeth with pulp exposure ≤1 mm, following studies by Canoğlu et al. [9] and Kotsanos et al. [4]. Diagnosis of pulp status is pivotal to the success of vital pulp therapy.

Teeth were evaluated at 3, 6, and 9 months post-treatment, with clinical success defined as the absence of pain, swelling, fistula, and pathological mobility, and radiographic success as the absence of resorption, furcation involvement, or periapical pathology [4,9,12,13,14]

In this study, the overall success rate for DPC at 9 months was 84.1%, supporting DPC as a viable conservative treatment option in primary molars, in agreement with previous studies [8][14][16]. Perez et al. [10], Chatzidimitriou et al. [15], and Dimitraki et al. [16] reported encouraging outcomes with bioactive materials in primary molars. Success rates in other studies have ranged from 90% to 95%, highlighting DPC's potential [14,17,18,19].

Several materials have been used for DPC, including calcium hydroxide, MTA, and calcium silicate-based cements [2][3]. MTA and TheraCal LC were chosen for this study due to their proven bioactivity and clinical performance.

At 9 months, TheraCal LC showed a higher success rate (95.4%) compared to MTA (72.7%), which was statistically significant. TheraCal LC's superior performance may be attributed to its better handling properties, immediate setting, and controlled calcium ion release [20,21]. Its ability to maintain moisture stability, create an alkaline antibacterial environment, and promote hydroxyapatite formation supports reparative dentinogenesis [2,20,21].

Although MTA is considered a gold standard due to its biocompatibility, sealing ability, and ability to induce dentin bridge formation [8], certain drawbacks such as difficult handling, long setting time, potential washout, and susceptibility to microleakage can impact clinical outcomes [22,23,24]. In this study, MTA exhibited a steady decline in success over time, consistent with findings from El Saied et al. [12] and Erfanparast et al. [17].

TheraCal LC's resin-modified formulation offers practical advantages, particularly in pediatric patients where faster treatment times are desirable. Studies by Gandolfi et al. [20] and Zeater et al. [21] also support TheraCal LC's favorable calcium ion release and moisture tolerance, critical factors for successful pulp healing.

Although MTA continues to be a preferred material in many cases [25,26], resin-modified materials like TheraCal LC present a promising alternative, particularly when managing young patients requiring rapid, predictable outcomes [13,20,21]. The minor difference in dentin bridge thickness and tubule formation between MTA and TheraCal LC was not statistically significant, as demonstrated by Zeater et al. [21].

Despite the positive outcomes, this study had limitations. The small sample size and relatively short 9-month follow-up period limited generalizability. Additionally, reliance on two-dimensional radiography for pulp status assessment could introduce selection bias. Variability in patient compliance, diet, and oral hygiene, which were not controlled, may also affect healing outcomes.

Further longitudinal studies with larger sample sizes and extended follow-up periods are recommended to validate these findings and establish direct pulp capping as a routine clinical procedure in primary teeth. Advanced imaging modalities and histological evaluations could provide deeper insights into the true biological success of DPC.

Based on the current findings, DPC using TheraCal LC or MTA can be considered a successful and conservative approach for the management of deep carious primary molars. Close attention to operative protocols and material properties remains essential for favourable outcomes.

CONCLUSION

The direct pulp capping procedure in carious primary molars demonstrated clinical and radiographic success at the 9 month follow up.

Both MTA and TheraCal LC have demonstrated favorable outcomes as direct pulp capping medicaments, making them effective and viable options for clinical use in carious primary molar pulp exposure. TheraCal LC demonstrated a higher clinical and radiographic success rate compared to MTA up to the 9-month follow-up.

Table 1 : Overall Clinical and Radiographic Success of MTA and TheraCal at Different Time Intervals

TIME	SUCCESS	MTA N = 22		THERACAL N = 22		TOTAL		P-VALUE
		n	%	n	%	n	%	
3 MONTHS	CLINICAL	22	100	22	100	44	100	-
	RADIOLOGICAL	22	100	22	100	44	100	-
6 MONTHS	CLINICAL	19	86.3	21	95.4	39	88.6	0.294
	RADIOLOGICAL	21	95.4	22	100	43	97.7	-
9 MONTHS	CLINICAL	16	72.7	21	95.4	37	84.1	**0.039**
	RADIOLOGICAL	16	72.7	21	95.4	37	84.1	**0.039**

Table 2 : Comparative Evaluation of Clinical Success of MTA and TheraCal LC as Pulp Capping Agents at Different Time Intervals

Absence of Symptom	Group	3 Months		6 Months		9 Months		P-Value
		n	%	n	%	n	%	
Pain	MTA	22	100	22	100	19	86.4	0.123
	TheraCal	22	100	22	100	21	95.4	
Tenderness on Percussion	MTA	22	100	22	100	19	86.4	0.123
	TheraCal	22	100	22	100	21	95.4	
Oedema/ Fistula	MTA	22	100	20	90.9	19	86.4	0.123
	TheraCal	22	100	20	90.9	21	95.4	
Pathological Mobility	MTA	22	100	22	100	21	95.4	0.365
	TheraCal	22	100	22	100	22	100	

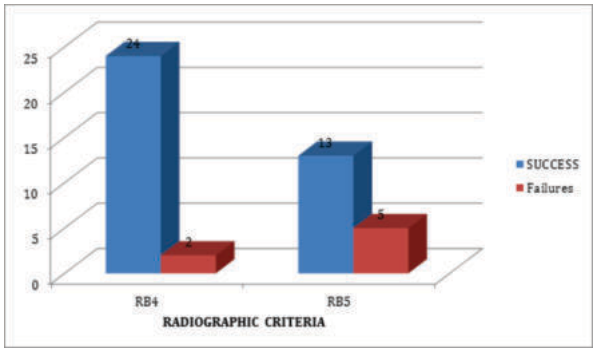
Table 3 : Comparative Evaluation of Radiographic Success of MTA and TheraCal LC as Pulp Capping Agents at Different Time Intervals

Absence of Symptom	Group	3 Months		6 Months		9 Months		P-Value
		n	%	n	%	n	%	
Pathological Resorption	MTA	22	100	21	95.4	18	81.8	0.026
	TheraCal	22	100	22	100	21	95.4	
Internal Root Resorption	MTA	22	100	22	100	21	95.4	0.131
	TheraCal	22	100	22	100	21	95.4	
Pdl Space Widening	MTA	22	100	21	95.4	18	81.8	0.039
	TheraCal	22	100	22	100	21	95.4	
Calcification Of Pulp Canal	MTA	22	100	22	100	22	100	-
	TheraCal	22	100	22	100	22	100	

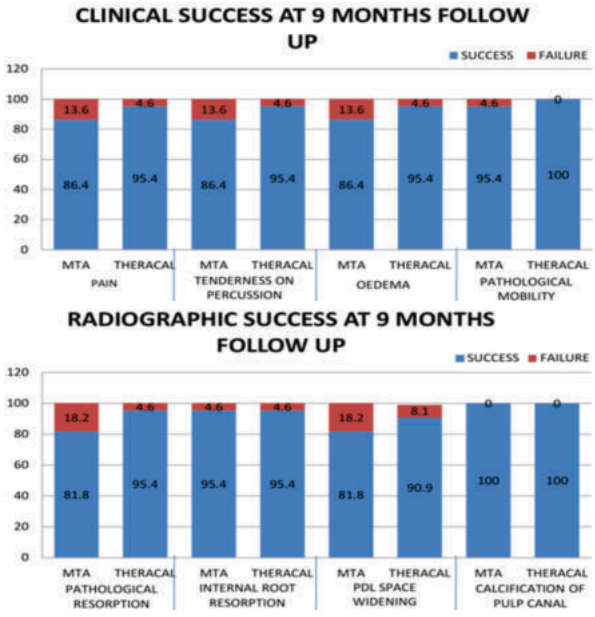
Table 4 : Distribution of Success in Case Selection According to ICDAS Radiographic Criteria

ICDAS	Radiographic Criteria	N=44	Success	Failures	P-Value
	RB4	26	24	2	0.111
	RB5	18	13	5	

Figure a-d : Clinical and Radiographic pictures of Direct pulp capping : a. Pre-operative radiograph; b. Post-operative radiograph at 9-month follow up; c. Pre-operative clinical photograph; d. Post-operative clinical photograph.



Clinical and Radiographic Success at 9 Month Follow up Graph 1



Graph 2 and 3

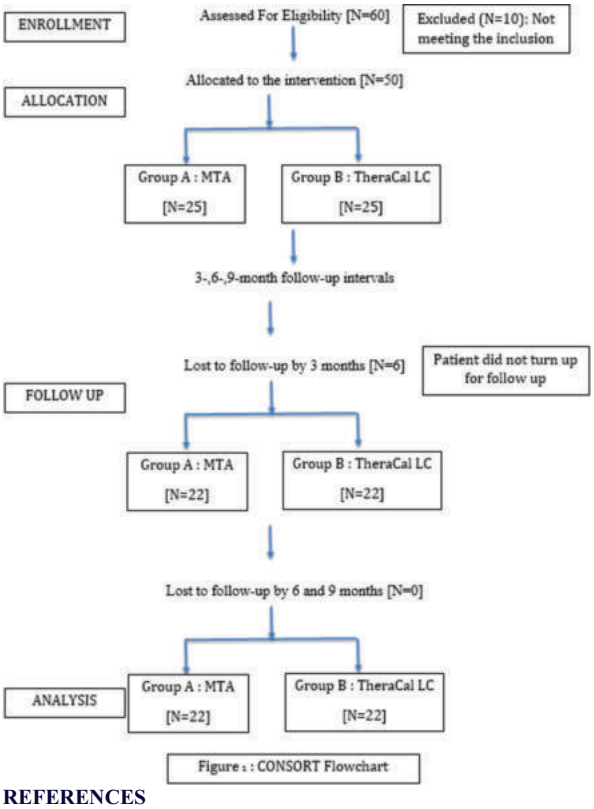


Figure 1 : CONSORT Flowchart

REFERENCES

1. American Academy of Pediatric Dentistry. Pulp therapy for primary and immature permanent teeth. In: The Reference Manual of Pediatric Dentistry. Chicago (IL): American Academy of Pediatric Dentistry 2022; p. 415-23.
2. Qureshi A, Eswaran S, Nandakumar, Pratapkumar, Sambashivarao. Recent advances in pulp capping materials: an overview. J Clin Diagn Res 2014;8(1):316-21.
3. Sujlana A, Pannu PK. Direct pulp capping: A treatment option in primary teeth?? Pediatr Dent J 2017;27(1):1-7.
4. Kotsanos N, Arapostathis KN, Arhakis A, Menexes G. Direct pulp capping of carious primary molars. A specialty practice based study. J Clin Pediatr Dent 2014;38(4):307-12.
5. Kulkarni P, Tiwari S, Agrawal N, Kumar A, Umarekar P, Bhargava S. Clinical outcome of direct pulp therapy in primary teeth: A systematic review and meta-analysis. J Indian Soc Pedod Prev Dent 2022;40(2):105-11.
6. Yu C, Abbott PV. An overview of the dental pulp: its functions and responses to injury. Aust Dent J 2007;52(1 Suppl):S4-S16.
7. Boutsiouki C, Frankenberger R, Krämer N. Relative effectiveness of direct and indirect pulp capping in the primary dentition. Eur Arch Paediatr Dent 2018;19(5):297-309.
8. Gopikrishna V. Vital pulp therapy and apexification. In: Grossman's Endodontic Practice. 14th ed. New Delhi: Wolters Kluwer (India) Pvt. Ltd.; 2021.
9. Canoğlu E, Güngör HC, Uysal S. Direct pulp capping of primary molars with calcium hydroxide or MTA following hemorrhage control with different medicaments: Randomized clinical trial. Pediatr Dent 2022;44(3):167-73.
10. Perez E, Behar-Horenstein LS, Guelmann M. Direct pulp capping in primary molars: Report of two cases. J Pediatr Dent 2015;3:101-3.
11. Milcheva N, Kabaktchieva R, Gateva N. Direct pulp capping in treatment of reversible pulpitis in primary teeth - clinical protocol. J IMAB 2016;22(4):1348-51.
12. El Saied N, Awad S, Alhosainy A. Evaluation of direct pulp capping in carious primary molars: a 12-month randomized controlled clinical trial. J Stomatol 2024;77(4):253-63.
13. Jha S, Namdev R, Singhal R, Goel N, Singhal P, Rani R. Comparative evaluation of effectiveness of TheraCal LC, MTA, and calcium hydroxide in direct pulp capping in primary molars: Randomized clinical study. Int J Clin Pediatr Dent 2023;16(Suppl 2):213-9.
14. Vafaei A, Abed N, Esmaeilzadeh L, Louca H, Ranjbar B. Direct pulp capping of primary molars using a novel fast-setting calcium silicate cement: a randomized clinical trial with 12-month follow-up. Biomater Investig Dent 2019;6:73-80.
15. Chatzidimitriou K, Vadiakas G, Koletsi D. Direct pulp capping in asymptomatic carious primary molars using three different pulp capping materials: a prospective clinical trial. Eur Arch Paediatr Dent 2022;23(5):803-11.
16. Dimitraki D, Papageorgiou SN, Kotsanos N. Direct pulp capping versus pulpotomy with MTA for carious primary molars: a randomized clinical trial. Eur Arch Paediatr Dent 2019;20(5):431-40.
17. Erfanparast L, Iranparvar P, Vafaei A. Direct pulp capping in primary molars using a resin-modified Portland cement-based material (TheraCal) compared to MTA with 12-month follow-up: a randomized clinical trial. Eur Arch Paediatr Dent 2018;19(3):197-203.
18. Asl Aminabadi N, Satrab S, Najafpour E, Samiei M, Jamali Z, Shirazi S. A randomized trial of direct pulp capping in primary molars using MTA compared to 3Mixtatin: a novel pulp capping biomaterial. Int J Paediatr Dent 2016;26(4):281-90.
19. Fallahinejad-Ghajari M, Asgharian Jeddi T, Iri S, Asgary S. Direct pulp capping with calcium enriched mixture in primary molar teeth: a randomized clinical trial. Iran Endod J 2010;5:27-30.
20. Gandolfi MG, Siboni F, Prati C. Chemical–physical properties of TheraCal, a novel light-curable MTA-like material for pulp capping. Int Endod J 2012;45:571-9.
21. Zeater B, Abboud S, Hanafi L. Comparison of the effects of TheraCal LC and mineral trioxide aggregate on direct pulp capping (DPC) based on histological findings. Cureus 2022;14(5):e25326.
22. Chen L, Suh BI. Cytotoxicity and biocompatibility of resin-free and resin-modified direct pulp capping materials: a state-of-the-art review. Dent Mater J 2017;36(1):1-7.
23. Tez BÇ, Eliaçık BBK, Taşlı PN, Yılmaz H, Şahin F. Biocompatibility and cytotoxicity of pulp-capping materials on DPSCs, with marker mRNA expressions. Int Dent J 2024;74(5):1064-77.
24. Nazemi Salman B, Saburi E, Gheidari MM, Farsadeghi M, Basir Shabestari S. Cytotoxic effects of pulp capping agents on mesenchymal stem cells isolated from human exfoliated deciduous teeth. J Dent (Shiraz) 2024;25(4):342-8.
25. ElSebaai A, Wahba AH, Grawish ME, Elkalla IH. Calcium hydroxide paste, mineral trioxide aggregate, and formocresol as direct pulp capping agents in primary molars: A randomized controlled clinical trial. Pediatr Dent 2022;44(6):411-5.E14-E15.
26. Parirokh M, Torabinejad M, Dummer PMH. Mineral trioxide aggregate and other bioactive endodontic cements: an updated overview - part I: vital pulp therapy. Int Endod J 2018;51(2):177-205.