



Original Article

Clinical Comparison of Resin-modified and Conventional Calcium Hydroxide Pulp Capping Agents in Deep Carious Lesions: A Randomized Trial

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Abstract

Introduction: This study was conducted to compare the clinical success and restoration survival of a resin-based pulp capping material (Apacal ART) with a conventional chemical-cure calcium hydroxide liner (Dycal) in deep carious teeth over a 12-month period.

Methods: This randomized clinical trial was conducted on 120 permanent posterior teeth with deep caries requiring direct pulp capping. Teeth with positive cold test responses and controllable pulpal bleeding were randomly assigned to two groups: Group I (Dycal) and Group II (Apacal ART). Following pulp capping, a glass ionomer liner and composite restoration were placed. Postoperative evaluations were performed at 24 hours, 48 hours, and 12 months. Data were analyzed using the Chi-square test and Kaplan-Meier survival analysis.

Results: Post-operative sensitivity at 48 hours was reported by 17 patients in the Dycal group and 9 patients in the Apacal ART group, with no statistically significant difference between the groups ($P=0.06$). After 12 months, 4 teeth in the Apacal ART group and 5 teeth in the Dycal group met the criteria for failure outcomes. The Apacal ART group demonstrated superior restoration survival, with a statistically significant difference between groups ($P=0.009$).

Conclusion: Both Dycal and Apacal ART showed satisfactory clinical performance as direct pulp capping materials. However, Apacal ART exhibited higher restoration survival over 12 months, likely due to its resin-modified composition that enhances bonding, mechanical strength, and marginal adaptation. Resin-based materials such as Apacal ART appear to be promising alternatives for direct pulp capping procedures.

Keywords: Direct pulp capping, Apacal ART, Dycal, Resin-based liner, Vital pulp therapy

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Introduction

One of the main causes of toothache and oral health issues in the world is dental caries (1). Controlling disease activity, protecting the remaining tooth structure, and restoring the tooth to its natural shape and function are the basic objectives of dental caries management (2). Deep caries refers to lesions that radiographically extend into the inner third of the dentin, posing a potential risk of pulp exposure (3). Treating deep carious lesions poses a notable challenge, particularly in cases where the tooth is asymptomatic (4). Epidemiological studies in developing countries report high prevalence of caries. In India, a prevalence rate of 36.7% has been observed among individuals aged 13-19 years, while in Saudi Arabia, the prevalence reaches as high as 83% among individuals aged 6-8 years (5).

Vital pulp therapy (VPT) is defined as a treatment aimed at preserving and maintaining pulp tissue that is compromised but not destroyed by dental caries, trauma, or restorative and iatrogenic procedures (6). The Indian Endodontic Society recognizes the potential of VPT to enhance patient-centric outcomes in modern endodontic practice, making it an ideal treatment option for a country like India with a high oral disease burden (7). When the pulp is exposed by caries, modern management favors conservative approaches over the previously radical methods. Various pulp conserving procedures have been proposed for managing carious exposures, ranging from conservative procedures such as direct pulp capping (DPC), a procedure in which a biocompatible material is placed directly over the exposed coronal pulp (8), and pulpotomy, a procedure in which the coronal portion of



Table 1. Detailed Composition of the Study Materials

Material	Composition	Application strategy
1. Dycal (Dentsply Sirona, USA)	Base: 1,3butyleneglycoldisalicylate, zinc oxide, calcium phosphate, calcium tungstate, iron oxide pigments. Catalyst: Calcium hydroxide, N-ethyl-o/p-toluene sulfonamide, zinc oxide, titanium dioxide, zinc stearate, iron oxide pigments.	● Apply base and catalyst paste on a clean mixing paper in equal volume and mix with the spatula for 10 seconds. ● Place in the cavity with the help of a clean applicator and leave it for setting for 2.5 to 3.5 minutes.
2. ApaCal ART (Prevest DenPro Limited, Industrial Estate, India)	Calcium hydroxide, tricalcium phosphate, hydroxyapatite, urethane. dimethacrylate, TEGDMA, photoinitiators, stabilizers, barium zirconate.	Apply in incremental layers (layer should not exceed 1 mm in depth). Light cure each increment for 40 seconds.

the vital pulp is removed in order to preserve the vitality of the remaining radicular portion, to more interventional treatment methods like pulpectomy and root canal therapy (9).

The outcome of these procedures is influenced by multiple factors, including the pulp-capping material used, the adequacy of hemostasis, the presence or absence of pulpal infection or inflammation, the size and location of the pulp exposure, and the quality of the final restoration placed on the treated tooth (10). A number of studies have reported success rates ranging between 67% and 100% even in cariously exposed pulps (11), indicating that the pulp possesses inherent healing and regenerative potential. Therapeutic strategies now focus on maintaining pulp vitality (9,12).

Calcium hydroxide remains the “gold standard” among DPC materials (13). It is prepared in several forms, including water-based formulations (Calcicur), base-catalyst type (Dycal), and light-cured (Calcimol LC). Dycal exhibits a pH between 9 and 11, contributing to its bioactivity and antibacterial properties (14). Resin-based pulp capping materials have been introduced to overcome certain limitations associated with calcium hydroxide, such as material dissolution, tunnel defects in dentin bridge formation, and poor adhesion to dentin (15). Apacal ART (Prevest DenPro Limited, Industrial Estate, India) contains tricalcium phosphate and nano-hydroxyapatite, where tricalcium phosphate acts as a phosphate reservoir, enhancing cement reactivity through nucleation of calcium phosphate nanoapatite that can stimulate cells of the pulp and promote formation of dentinal bridge (16). Manufacturers claim that the unique active-release technology of Apacal ART provides benefits for both pulp capping procedures and for use as a protective base or liner (17). These materials can achieve substantial depth of polymerization, which may minimize the risk of premature dissolution and enhance apatite deposition, thereby promoting odontoblastic differentiation (18). When DPC is performed using a resin-based pulp material, preservation of pulp vitality is likely to be achieved. This concept is supported by the findings of several studies demonstrating favourable pulp healing in teeth capped with resin-based materials (19).

Earlier studies have investigated the effectiveness of various pulp capping materials, including resin-based and chemical curing agents. Despite the availability of various pulp capping materials, there is limited research comparing the success rates of resin-based pulp capping

materials with traditional chemical curing agents. This investigation aims to bridge the existing knowledge gap by conducting a randomized clinical trial to evaluate the clinical success of resin-based pulp capping material compared to chemical curing agents. The research was conducted to answer the question “Do resin-based pulp capping materials demonstrate higher clinical success rates compared to conventional chemical-cure pulp capping materials in permanent teeth requiring direct pulp capping?”

The primary outcome of this study was the clinical success of direct pulp capping, defined by preservation of pulp vitality and absence of clinical and radiographic signs of failure during a 12-month follow-up period. The secondary outcomes included restoration survival assessed over the same follow-up period.

Therefore, this randomized clinical trial was conducted to compare the clinical success of a resin-based pulp capping material with that of a conventional chemical-cure calcium hydroxide material in deep carious lesions.

Materials and Methods

This study was approved by the Institutional Ethical Committee (CSICDSR /IEC/O277/2023) and registered in the Clinical Trials Registry of India (ID CTRI/2024/02/062199). The trial was conducted in accordance with CONSORT guidelines (Figure 1). The total sample size was determined to be 120 teeth using G*Power software version 3.1.9.2 (Universität Kiel, Germany), based on an effect size of 0.29 (calculated for the primary outcome variable), an alpha error of 0.05, and a confidence interval of 95%. Participants were recruited between February and May 2024 from individuals visiting the Department of Conservative Dentistry and Endodontics at C.S.I College of Dental Science and Research. The list of patients who met the specified inclusion criteria was subsequently exported to an Excel sheet for random allocation. Written informed consent was obtained from the participants and strict confidentiality of patient information was maintained. An online randomization tool (<http://www.randomizer.org>) was used to generate random numbers, which were exported to an Excel sheet and maintained by a dental nurse who was not involved in patient recruitment or treatment. Randomization was carried out at the patient level, with only one tooth included per patient. Group allocation was concealed from the clinician and communicated by the dental nurse only after patient

enrolment, thereby minimizing selection bias.

Inclusion Criteria

- Posterior teeth (molars and premolars) with class I cavities involving deep caries and a positive response to cold testing using Roeko Endo Frost – Cold spray (Coltene, Whaledent Ltd., USA), indicative of normal pulp or reversible pulpitis, were included in the study.
- Male and female patients aged between 15 and 55 years were included in the study.
- Clinically, the teeth had to be free from swelling, purulent discharge, sinus tract formation, and abnormal mobility. Additionally, any pulpal bleeding had to be controllable within 5-6 minutes, and the teeth needed to be suitable for definitive restoration with resin composite.
- The radiographic criteria required that caries extend into the inner third or quarter of dentin with a potential risk of pulp exposure.

Exclusion Criteria

- Patients with a history of spontaneous, radiating, or nocturnal pain suggestive of irreversible pulpitis.
- Teeth exhibiting an exaggerated and prolonged response (>20 seconds) to cold pulp sensibility testing, indicative of irreversible pulpitis.
- Patients with systemic illnesses or psychiatric disorders, as well as those with a history of analgesic use or prior desensitization therapy.
- Teeth exhibiting any significant radiolucency in the

furcation or periapical regions, evidence of internal or pathological external root resorption or signs of calcification and pulp canal obliteration.

Pulp Capping Procedure

Local anesthesia was administered when it was necessary to minimize discomfort and ensure patient comfort. A rubber dam was used for all patients throughout the procedure. Class 1 cavities were prepared using a No: 2 (Mani, Co., Japan) size round bur in an air-rotor hand piece with ample irrigation. All softened dentin was completely removed (non-selectively). Caries was entirely removed from the cavity walls to ensure that the restoration was placed on sound hard dentin surfaces, after which the cavity was checked for any signs of bleeding. If bleeding occurred at the pulp exposure site, it was controlled by placing a cotton pellet moistened with sterile saline over the site for 1 minute. The cavity was gently dried using sterile cotton pellets. The allocation of materials was revealed to the operator at the time of placement; however, the patients remained unaware of the material assignment throughout the procedure. The teeth were randomly divided into 2 groups. Group I: Dycal (Dentsply Caulk, Milford, DE, USA) and Group II: Apacal ART (Prevest DenPro Limited, Industrial Estate, India). In Group I, the base and catalyst of Dycal were mixed on a paper pad using a plastic spatula, following the manufacturer's instructions. In Group II, Apacal ART was applied according to the manufacturer's guidelines. The chemical compositions of the materials used in this

CONSORT 2010 Flow Diagram

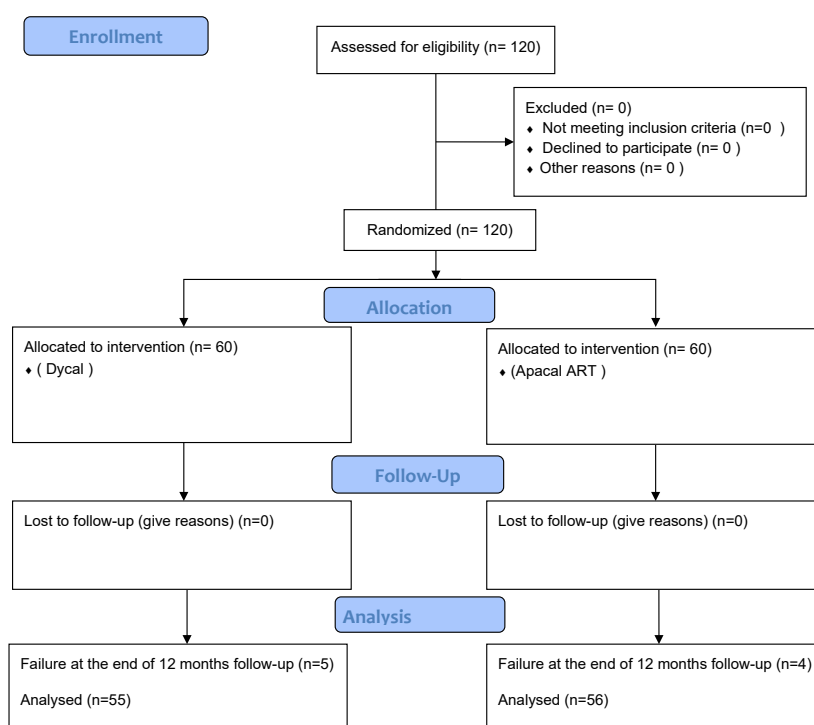


Figure 1. CONSORT Flow Diagram Outlining the Enrolment, Allocation, Follow-up, and Analysis of Participants

study are presented in Table 1.

Following the placement of either pulp-capping material, a liner of glass ionomer cement (GC Fuji II) was used, and the final restoration was completed with composite resin. In both groups, the cavity was etched with a 37% phosphoric acid etchant (EAZ ETCH, Anabond Stedman Pharma, Chennai, India). The etchant gel was placed exclusively on the walls of the cavity, while etching was performed for 30 seconds on enamel and 15 seconds on dentin. After rinsing with water, Prime and Bond NT (Dentsply Sirona, USA) was placed on the etched surfaces and cured for 30 seconds using an LED curing unit (Woodpecker Medical Instrument Co., Ltd., Guilin, China). The resin composite (Tetric N Ceram) was subsequently placed in layers, each layer being cured for 40 seconds, after which the restorations were finished and polished.

Post-treatment Evaluation

Post-treatment evaluation involved assessing treatment success through a normal response to cold testing on the treated tooth, no sensitivity, no tenderness to percussion, absence of spontaneous pain, healthy surrounding soft tissues, and no signs of periapical rarefaction on radiographs (VistaScan; Dürr Dental SE, Bissingen, Germany) during follow-up visits. Any occurrence of symptomatic pulpitis or periapical pathology was considered a treatment failure.

Statistical Analysis

Statistical analysis was carried out using IBM SPSS Statistics version 23 (IBM Corp., Chicago, IL, USA). Descriptive statistics were used to summarize age, gender, and clinical outcomes. The incidence of postoperative sensitivity and the presence of clinical symptoms at the 12-month follow-up were compared between the two groups using the Chi-square test. Restoration survival over the 12-month period was evaluated using Kaplan–Meier survival analysis, and differences in survival distributions between the two groups were assessed using the log-rank test. The level of significance was set at $P < 0.05$.

Results

A total of 120 molar teeth with deep caries were treated using two liners, Dycal and Apacal ART, with mean patient ages of 26 and 28, respectively. In the Dycal group, 17 patients experienced postoperative sensitivity, while in the Apacal ART group, 9 patients reported the same after 48 hours. There was no significant difference between the two groups in terms of postoperative sensitivity after 48 hours ($P = 0.06$). The 12-month follow-up results are presented in Table 2. After 12 months, no statistically significant difference was observed between the two groups in terms of clinical symptoms ($P = 0.36$). In the Dycal group, 22 of the 60 restorations exhibited fractures, whereas in the Apacal ART group, only 9 of the 60 restorations showed fracture. The survival of the restoration in the Apacal ART group was greater compared to the Dycal group. The log-rank test revealed a statistically significant difference in survival distributions between the groups ($P = 0.009$).

Discussion

In this research, the effectiveness of two pulp capping liners was assessed and compared for treating deep carious lesions over a 12-month period. The findings indicated no statistically significant difference in postoperative symptoms between the two materials. The similar postoperative sensitivity observed in both groups after 24 hours suggests that both materials were initially well-tolerated by the pulp tissue, likely due to their biocompatibility and initial sealing capability.

DPC promotes the healing of reversibly injured pulp by inducing dentin bridge formation and re-establishing the structural and functional integrity of the pulp-dentin complex (20). Accordingly, this procedure was selected based on its proven ability to preserve pulp vitality and maintain pulpal health (21). Although various pulp capping materials are available, Dycal remains the most commonly used material among clinicians. Dycal is a calcium hydroxide-based material composed of a base paste and a catalyst paste and its clinical performance has been assessed in numerous studies. It encourages

Table 2. Frequency Distribution Table

Demographics		Frequency distribution, (n%)		P-value
		Apacal ART	Dycal	
Gender	Female	34 (56.66)	38 (63.33)	0.288
	Male	26 (43.34)	22 (36.67)	
Age (mean)		27	27	
Post-operative sensitivity	Present	9 (15)	17 (28.33)	0.060
	Absent	51 (85)	43 (71.66)	
Fate of teeth after 12 months	No change	56 (93.33)	55 (91.66)	0.500
	Failure	4 (6.67)	5 (8.34)	
Restoration	Fractured	9 (15)	22 (36.67)	0.009*
	Intact	51 (85)	38 (63.33)	
Tooth survival	Success	51 (85)	38 (63.33)	0.006*
	Failure	9 (15)	22 (36.67)	

Chi square test was used in this study, where $P < 0.05$ was considered a significant difference which is indicated with a *

the formation of reparative dentin bridge by inducing cellular differentiation, stimulating extracellular matrix secretion, and facilitating subsequent mineralization (22). In a study conducted by Tronstad, the typical response of exposed healthy pulp to calcium hydroxide was described as necrosis of a well-defined area of the pulp, accompanied by mild inflammation in the adjacent vital tissue, dentin bridge formation at the interface between necrotic and vital zones, and subsequent resolution of the inflammatory process (23).

In recent years, resin-based pulp capping materials have emerged, with manufacturers claiming enhanced physicochemical properties and improved clinical performance in VPT. One of these materials is Apacal ART, a resin-based tricalcium phosphate with added hydroxyapatite. Apacal ART is reported to offer advantages such as rapid calcium ion release and enhanced dentin bridge formation, and it is recommended for use as a pulp-protective liner after achieving hemostasis in both direct and indirect pulp capping of deep cavities (24). Although several *in vitro* studies have been conducted, there is limited clinical evidence regarding the performance of recently introduced resin-based pulp capping materials. Therefore, the present study aimed to clinically evaluate the effectiveness of a resin-based pulp capping agent.

In a study conducted by Shalini et al on resin-based pulp capping agents, TheraCal LC demonstrated superior clinical and histological outcomes compared to Biodentine, showing better dentin bridge formation and minimal pulpal inflammation. It appears to be a promising material for direct pulp capping (25). In an animal study conducted by Costa et al, the biocompatibility of resin-based materials used as pulp-capping agents was evaluated in a rat model using resin-modified glass ionomer cement (RMGIC) and a self-etch adhesive system. The results indicated that both materials supported pulpal healing, evidenced by the formation of cell-rich fibrodentine, tertiary dentine, and a calcific barrier (26).

Jha indicated that using calcium hydroxide for direct pulp capping tends to have lower success rates over long-term follow-ups (27). This may be due to the weak adhesion of calcium hydroxide to tooth structures, as well as its limited mechanical strength, high solubility in acidic conditions, and inadequate sealing capability, which can undermine the effectiveness of DPC (28). Conversely, a retrospective study by Ricucci et al (2023) assessing the long-term results of direct pulp capping in mature teeth found that calcium hydroxide had a very high success rate, especially within the first decade after treatment. The quality of the coronal restoration was the main factor affecting the outcome (29).

The American Association of Endodontists, in its 2021 Position Statement, supported VPT as a suitable treatment for mature permanent teeth showing signs of irreversible pulpitis (30). Several randomized controlled trials and systematic reviews have shown clinical and radiographic success rates for VPT ranging from 81% to 96% when using various techniques and materials (30). At

the 12-month follow-up, treatment failure was observed in 4 cases in the Apacal ART group and in 5 cases in the Dycal group. However, over a 12-month period, Apacal ART showed better restoration survival than Dycal, with a statistically significant difference in survival distributions ($P=0.009$).

The longer-lasting restorations in the Apacal ART group may be due to its resin-modified composition, which offers enhanced mechanical strength, better marginal adaptation, and lower solubility compared to traditional calcium hydroxide liners like Dycal. Another reason for the higher survival rate of restorations in the Apacal ART group was the superior bonding between the pulp-capping material and the overlying restorative materials. In this study, a layer of GIC was applied over the pulp-capping material, followed by a composite restoration. Both compomers and resin-modified glass ionomer cements are compatible with adhesive composite systems. However, when calcium hydroxide is used beneath these materials, the restoration involves three different components, increasing procedural complexity (31). This may explain the higher survival rate seen in the Apacal group, as its resin-based composition likely facilitated better bonding among the 3 restorative components compared to the Dycal group.

In the randomized controlled trial by Peskersoy et al, the clinical performance of various calcium silicate-based materials was compared with calcium hydroxide for direct pulp capping. Consistent with the findings of the present study, TheraCal LC showed slightly higher success rates (72.1% clinical and 73.6% radiographic) than Dycal (69.4% and 70.2%), though the difference was not statistically significant ($P>0.05$). After a 36-month follow-up, MTA+ and Biodentine demonstrated superior long-term outcomes, confirming their effectiveness as reliable materials for direct pulp capping in permanent teeth. Despite improved handling properties due to resin modification, TheraCal LC showed comparatively lower success rates than MTA+ and Biodentine, likely due to its reduced bioactivity (32).

In an *in vitro* study conducted by Akbiyik, the shear bond strength of different pulp capping materials, including Dycal, ProRoot MTA, Biodentine, TheraCal LC, Calcimol LC, and Apacal ART, was assessed. Dycal exhibited the weakest bond strength, measuring 1.68 MPa, which was significantly lower than the other materials tested. Most fractures observed were cohesive and occurred within the Dycal material. Conversely, Apacal ART, which incorporates nanohydroxyapatite, showed the highest bond strength, especially when paired with two-step etch-and-rinse and universal adhesive systems (24).

The preservation and regeneration of dental pulp have emerged as key goals in modern restorative and regenerative dentistry (33). A significant challenge in pulp-preserving procedures is the inability to accurately evaluate the true status of the pulp tissue after DPC, as we rely primarily on clinical symptoms and radiographic evaluation. Histological examination remains the

definitive method for evaluating pulpal health. Therefore, the evaluation of the depth of the carious lesion should always be correlated with pulpal and clinical findings before finalizing the treatment plan. Extended follow-up of teeth following DPC is advised to reliably evaluate the long-term effectiveness and success of the treatment (34). However, the present study was limited to a 12-month follow-up period, which may not fully evaluate late failures, long-term pulp vitality changes, or material degradation occurring beyond this timeframe. Nevertheless, Jang et al reported that the majority of failures occur within the initial 3 months after treatment (35). Similarly, Ayzin et al emphasized that assessment of postoperative pain during the first 3 months aids in the early identification of treatment failures, with pain being most intense within the first 24 hours and resolving completely within one week in the majority of patients (36). Therefore, while early outcomes can be reliably assessed within 12 months, longer follow-up periods are necessary to confirm sustained pulp vitality and long-term material performance. Furthermore, since the study only compared two pulp capping materials, the materials cannot be generalized to all currently available resin-based or calcium hydroxide-based liners. Future randomized controlled trials with larger sample sizes, extended follow-up periods, and histological validation are recommended to support and expand these findings.

Conclusion

Within the constraints of this study, both Dycal and Apacal ART showed satisfactory clinical performance as direct pulp capping materials for managing deep carious lesions in permanent posterior teeth. However, Apacal ART demonstrated a significantly higher restoration survival rate over the 12-month follow-up period compared to Dycal. Resin-based materials like Apacal ART showed improved handling properties, making them promising candidates for use in direct pulp capping procedures.

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Competing Interests

There is no conflict of interests.

Ethical Approval

This study was approved by the Institutional Ethical Committee

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