ORIGINAL RESEARCH

Clinical Effectiveness of Biomaterials in Indirect Pulp Therapy Treatment of Young Permanent Molars with Deep Carious Lesions: A Case–Control Study

Gazala Altaf[1], Shalini Garg[2], Bhavna G Saraf[3], Neha Sheoran[4], Anil Gupta[5], Vishal Sharma[6]

Abstract

Aim: The present case–control study was planned to assess the comparative efficacy of resin-modified calcium silicate, resin-modified glass ionomer, and Dycal as pulp capping agents in indirect pulp therapy for deeply carious young permanent molars.

Materials and methods: Thirty deeply carious young posterior teeth were treated by indirect pulp therapy. During the treatment, the cavity floor was lined with TheraCal or resin-modified glass ionomer cement (RMGIC) in the study group and with Dycal (control group) followed by GC IX and composite restoration. The teeth were reviewed and evaluated clinically and radiographically after 6 and 12 months.

Results: None of the study subjects experienced pain in any of the three study groups up to 12 months. Maturogenesis was seen in all 30 study teeth. Maximum% gain in dentin formation was seen in group I (TheraCal), that is, 16.100 ± 2.42, followed by group II (RMGIC), that is, 11.6000 ± 1.42, and group III (Dycal), that is, 9.6000 ± 0.96, and the difference between group I and group II and group I and group III was highly significant ($p < 0.0001$). Dentin formation was observed earlier at 6 months in 82.5% of cases with mesio-occlusal (MO) cavities as compared to 62.5% of cases with disto-occlusal (DO) extension.

Conclusion: TheraCal LC may be preferred as a pulp capping agent in the management of deeply carious young permanent molars for better healing in less time.

Keywords: Bioceramic material, Permanent molars, Young permanent molars.

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Introduction

According to the American Association of Pediatric Dentistry (AAPD), in indirect pulp treatment (IPT), the caries nearing the pulp are left in there to prevent pulp exposure. This left behind carious tissue is covered with a biocompatible material to promote healing.[1] It is not necessary to reenter and remove this left carious dentin later. It remains sealed from bacterial toxins insult and heals itself by the formation of reparative dentin which also forms an impervious seal to pulp.[2,3]

Previously indirect pulp capping (IPC) was performed as stepwise excavation, two steps, consisting of removal of carious dentin in permanent teeth involve two steps, in which a layer of soft and humid dentin, close to pulp is left over to prevent pulpal involvement and lesion is temporarily sealed in first visit. In second visit, the tooth is reopened after reparative dentin formation adjacent to the lesion and the remaining tissue is removed safely without pulpal exposure after 2–6 months. The aim of this procedure is to allow phenomenon like tertiary dentin formation and dentin sclerosis ensuring pulp protection on the reentry. The disadvantages related to this procedure were the need to reopen, additional costs, and discomfort to the patient.[4] A recent procedure is being used by many researchers who managed deep caries in permanent teeth by single-step IPC as a definitive procedure while leaving carious dentin in lesion. Biomimetic materials and impervious coronal seal may lead to the healing of left infected soft carious dentin which did not need further intervention. At a microscopic level, it was seen that there is healing of left carious tissue and IPC could be used as single-step definitive treatment of deep caries in young permanent molars.

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Calcium hydroxide (CH) has been a gold standard as a base material for IPC but it does not adhere to dentin and fails to provide required seal.[5] Resin-modified glass ionomer cement (RMGIC) is a newer lining agent, which acts by sealing the tubules from the oral environment leading to arrest of the progressing lesion. Opal et al. had perceived in the study, they conducted that residual lining material over the tubules by RMGIC material was seen in the RMGIC group and prevents microleakage.

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Mineral trioxide aggregate (MTA) has been seen as a successful biologically active substance that initiates the formation of hard tissue while being biocompatible. Literature has shown MTA as pulp capping material with required physiochemical properties, such as ability to seal is superior, radiopacity, and superior adaptability to dentinal walls.[5] Another new light-cured resin-modified calcium silicate is modified MTA TheraCal LC with better handling and it helps in stimulating apatite formation along with dentin formation (secondary) and is permeable to dentinal fluid and resists dissolving. TheraCal LC may also act as a scaffold for the formation of reparative dentin. The dentinal fluids are easily absorbed, leading to the discharge of calcium and hydroxide ions. One of the immediate responses of the tooth is to generate apatite on the underside of TheraCal LC, thereby enhancing the product's natural sealing capability.[6,7] It can act as biocompatible lining material with additional new tooth adhesive restorative materials to provide an impervious coronal seal. This phenomenon provides a suitable ecosystem for the healing of carious dentin and enhances the defensive responses of the pulp-dentin complex by hard tissue formation and achieving arrest of the carious lesion.[7]

The study we conducted was for the assessment of the effectiveness of resin-modified calcium silicate, resin-modified glass ionomer, and Dycal as agents for pulp capping while performing indirect pulp therapy for deeply carious young permanent molars.

Materials and Methods

This study was planned as a prospective, case–control, and double-blind clinical trial approved by the Institutional Ethics Committee. The procedure, possible associated problems, and benefits were explained to the parents and written consent was obtained.

The children between the ages of 6 and 14 years will be screened for young permanent molars with deep caries needing intervention. Deep dentin carious lesions according to clinical [with score of International Caries Detection and Assessment System (ICDAS) 5 or more] and radiographic examinations (with score of 3 or more according to Ekstrand et al.) at risk of exposure of pulpal tissue if excavated completely; with clinical and radiographic features of irreversible pulpitis will be included in study.[8,9] Clinical crown with carious lesions involving >2 surfaces will be excluded from study.

Sample Selection

This is a randomized case control study. Screening was conducted in children who reported in the department of pediatric and preventive dentistry requiring treatment for deeply carious young permanent molar. Thirty young posterior teeth in minimum of 10 patients according to strict inclusion and exclusion criteria were treated. Eligibility criteria included the presence of deep dentinal carious lesions according to clinical (with score of ICDAS 5 or more) and radiographic examinations (with score of 3 or more according to Ekstrand et al.) who were at risk of exposure to pulpal tissue in case the caries was excavated completely and with no clinical and radiographic signs and symptoms of pulpal pathosis.

Teeth were randomly assigned by lottery into three groups, according to the dentin lining materials, TheraCal LC (Bisco Inc, Schamburg, IL, United States), RMGIC (study, GC Fuji II LC®, GC America Inc, Ill., United States), and CH (control, Dycal, DENTSPLY, Milford, Del., United States). Thirty pieces of paper with the names of materials (10 each) were put in a box. Each child was asked to pick a piece of paper before starting with the treatment. Based on the name of the material written on the piece of paper, the child was assigned to that treatment group. The children were blind to their group assignment. The TheraCal LC group consisted of 10 molars, the RMGIC and the control group (Dycal) comprised 10 molars in each groups, respectively, and is illustrated in Figure 1 (flowchart).

Technique

Preoperative Procedure

The tooth was taken as the unit for analysis. Intraoral periapical (IOPA) radiographs were obtained for exclusion and inclusion criteria, selection of the cases, and follow-up visits. Clinical examination of the specific tooth in question was carried out preoperatively by recording the surface involved and signs and symptoms of the reversible pulpitis. After the initial examination and treatment planning, each patient received a complete oral prophylaxis.

Operative Procedure

Patients underwent treatment after the administration of local anesthesia, and isolation was carried out using a rubber dam. Access to the carious tissue was done by using a high-speed bur (no. 245). After necrotic dentin, caries were eliminated from the walls laterally, leaving soft dentin on the floor to avoid pulp exposure. The cavity was cleaned using sterile water and was air-dried with sterilized cotton pellets. The cavity floor then was lined with TheraCal or RMGIC in the study group depending upon the group for which the material is allocated followed by GC IX and composite restoration. The cavity floor in the control group was capped with Dycal (control group) followed by GC IX and composite restoration as depicted in Figures 2A to D. Teeth was reviewed and evaluated clinically after 24 hours, 1 week, and every 3 months up to 12 months and radiographically immediately postoperative after 6 and 12 months.

Record and Data Analysis

The criteria employed to assess the clinical success of the technique encompassed the absence of spontaneous pain and/or sensitivity to pressure, as well as the lack of sinus tract and/or swelling. Any

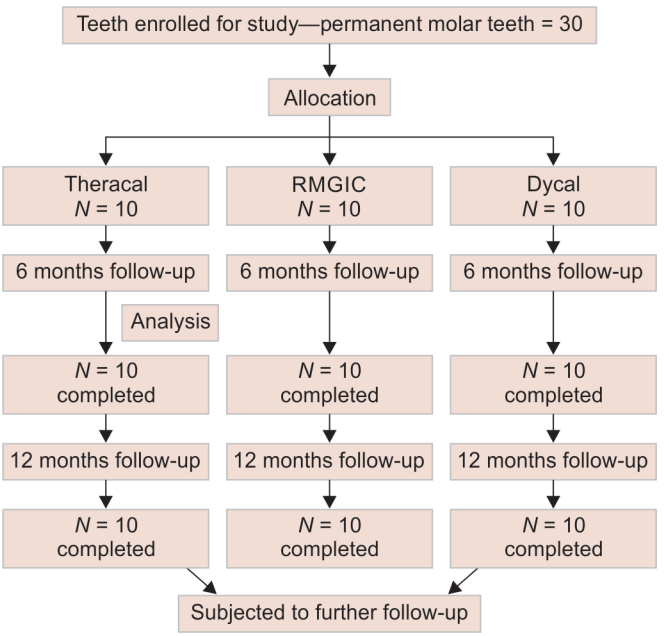
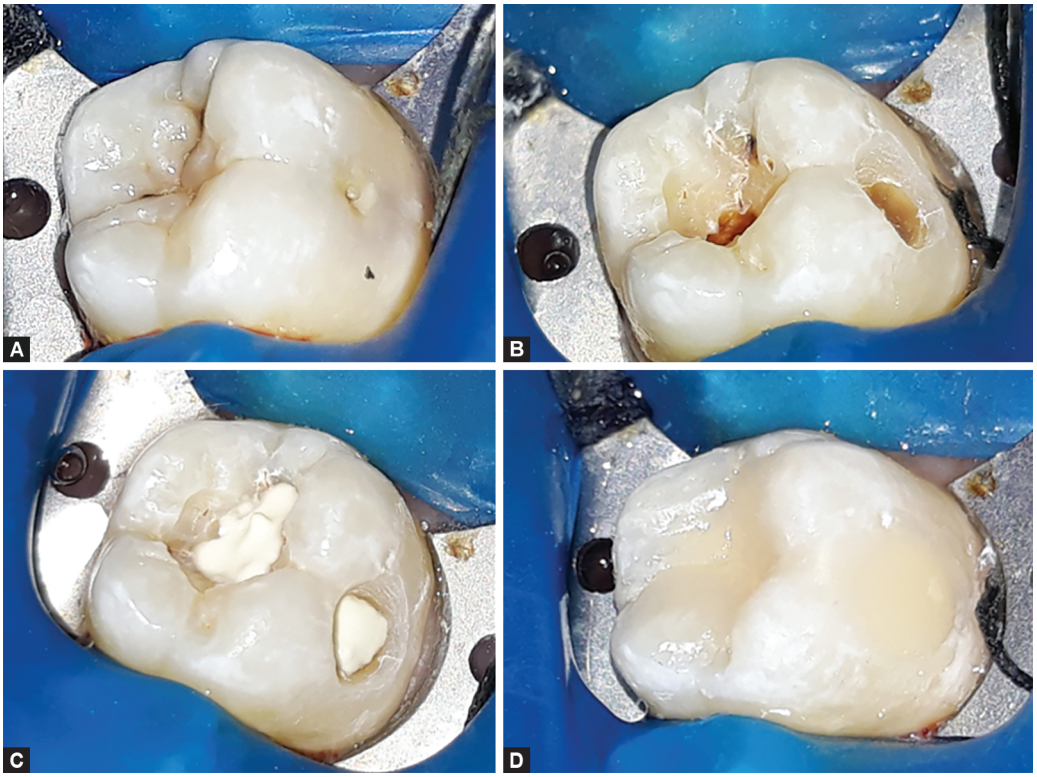


Fig. 1: A flowchart of participants in the study, per consort guidelines



Figs 2A to D: Clinical photographs showing the technique used for IPT and restoration with composite resin. (A) Close-up view of tooth A before excavation (first permanent molar, lower left quadrant); (B) Cavity preparation for final IPT (caries was not completely removed at sites nearest to the pulp); (C) Placement of a layer of the TheraCal LC; (D) Final restoration with the composite resin

tooth that presented with signs and symptoms of irreversible pulpitis and an unfavorable radiographic presentation, such as advancement of the initial carious lesion or periapical changes like radiolucency in the interradicular (furcation) or periapical regions, thickening of the periodontal spaces, pulp abscess or necrosis, and/or internal or external root resorption during or at the follow-up period, were recorded as treatment failures and are depicted in Figures 3A to C preoperative radiographs, Figures 3D to F shows immediate postoperative radiographs, Figures 3G to I shows 6 months follow-up, and Figures 3J to L t depicts 12 months follow-up.

Appraisal of Dentin Bridge Formation

We digitalized both preoperative and last postoperative IOPA radiographs of each subject tooth. These images were stored in Joint Photographic Experts Group (JPEG) format and further opened in Adobe Photoshop. Both IOPA radiographic images were opened with a grid option to measure changes in preoperative vs last postoperative radiograph as shown in Figures 4A and B. The change, that is, the dentin bridge was seen as an increased radiopaque area in the postoperative radiograph. Square grid lines of 0.3 mm were superimposed on radiographic images and the pulp chamber was traced. Percentage increase was calculated by subtracting the two measurements of pre- and postoperative images.

Statistical Analysis

Data followed the normal distribution; parametric tests of significance were used. One-way ANOVA test followed by *post hoc* Tukey's test for pairwise comparison was used to compare the means of more than two groups. Chi-squared test was used for categorical variables. A level of significance was set at 0.05.

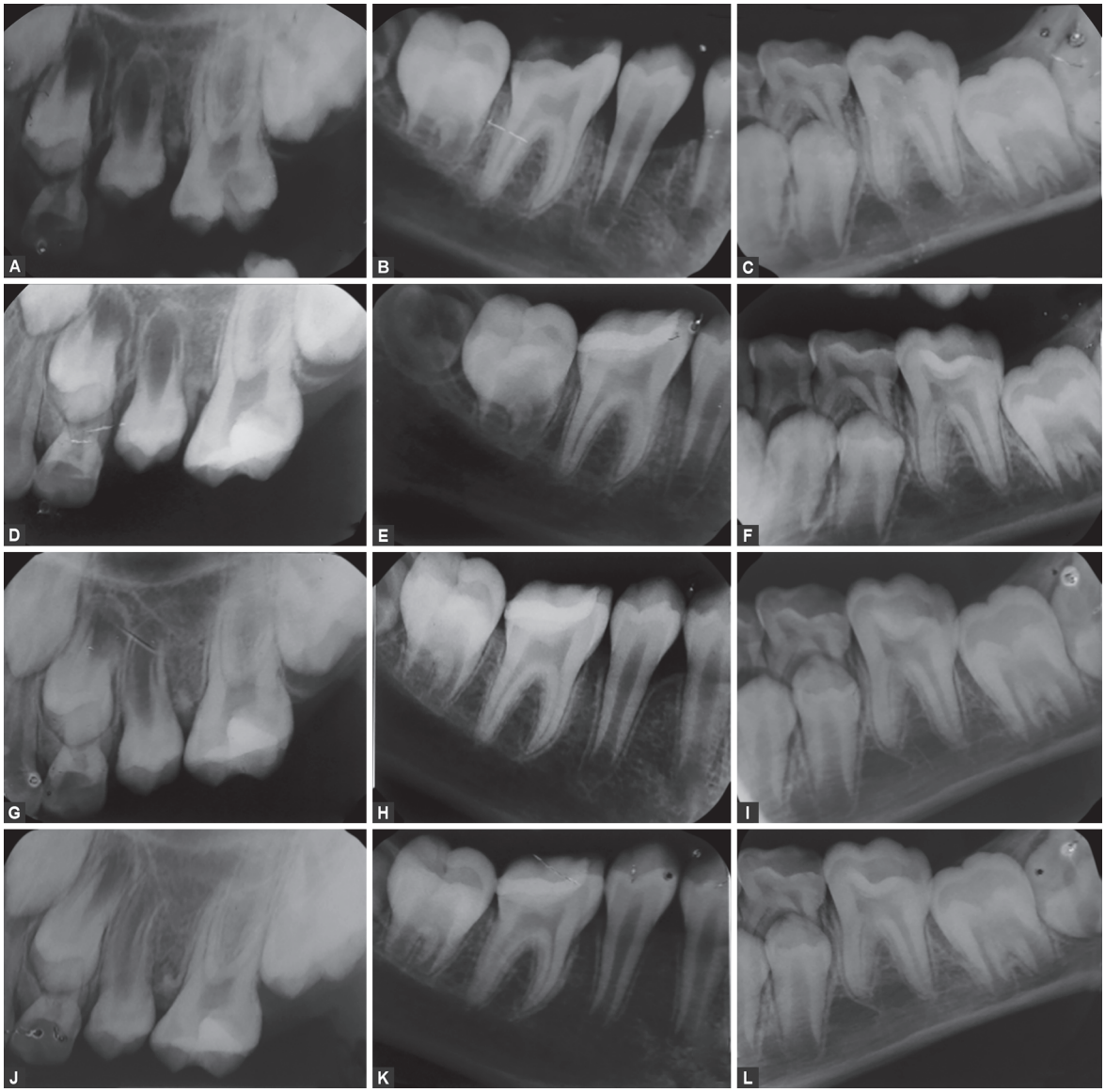
Results

There were a total of 30 teeth, namely 10 in each group I (TheraCal LC), II (RMGIC), and III (Dycal), respectively. The mean age of the study population was found to be 10.28 ± 1.8 years. There were 17 females and 13 males in total and no significant difference were found in the distribution of male and female subjects among three groups when compared using Chi-squared test. There were a total of 30 teeth among three groups. Out of which 16 were maxillary and 14 were mandibular teeth.

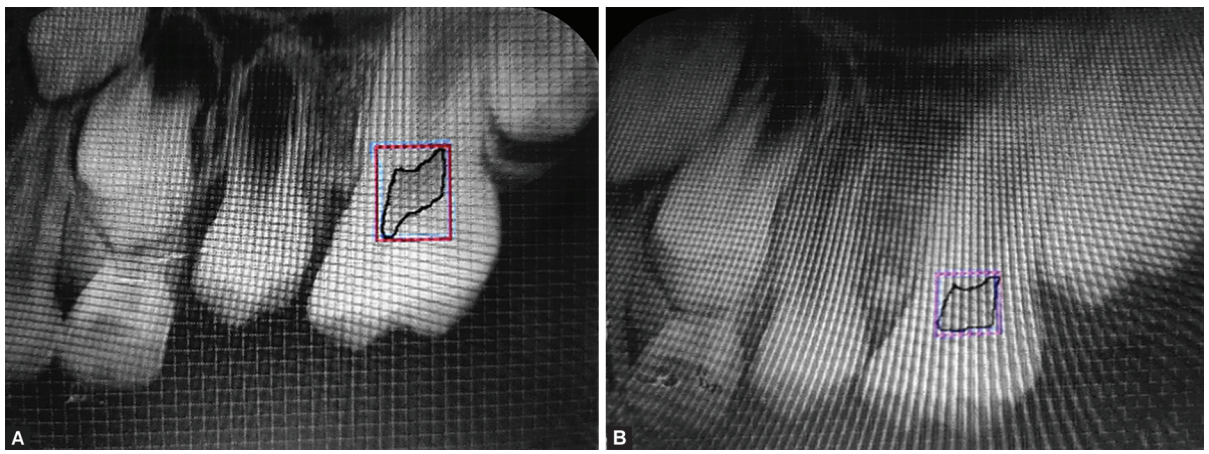
Dentin bridge formation was visually examined and compared by two independent examiners at 6 and 12 months as per site mesio-occlusal (MO) and disto-occlusal (DO) of all the samples independent of pulp capping material used. The dentin bridge thickness was more when the site of carious lesion was mesial as compared to the distal site of carious lesion, but the difference was not statistically significant. Also, dentin bridge formation was observed earlier at 6 months in 82.5% of cases in MO as compared to 62.5% of cases in DO.

None of the study subjects experienced pain in any of the three-study groups during the time interval of 24 hours, 1 week, 1 month, 3, 6, 9, and 12 months.

At 6 months, the difference in the stage of root formation when compared groupwise using the Chi-squared test came out to be insignificant. At 12 months, maturogenesis was seen by all 30 study teeth.



Figs 3A to L: Radiographic evaluation of teeth that received IPT and were considered as successful outcomes after 12 months; (A to C) Preoperative IOPA radiograph for case selection; (D to F) Immediate postoperative radiograph after stepwise excavation; (G to I) 6 months follow-up, and (J to L) 12 months follow-up after IPT



Figs 4A to B: (A) Immediate postoperative; (B) 12 months postoperative

Speed of dentin formation did not vary significantly among three groups at 6 and 12 months when compared using Chi-squared test (Table 1).

The speed of dentin bridge formation was faster and more when observed at 6 months in group I and group II (80% cases) than group III (60% cases), though the difference came out to be insignificant statistically. The difference was not seen in the speed of dentin bridge formation among all the groups at 12 months during radiographic and visual examination by two independent examiners.

A Chi-squared test revealed no notable difference in the rate of dentin formation between the DO and MO sides at both the 6 and 12 months. Dentin bridge formation was visually examined and compared by two independent examiners at 6 and 12 months as per site MO and DO of all the samples independent of pulp capping material used. The dentin bridge thickness was more when the site of carious lesion was mesial as compared to distal site of carious lesion, but the difference was not statistically significant. Also, dentin bridge formation was observed earlier at 6 months in 82.5% of cases in MO as compared to 62.5% cases in DO. Significant differences were observed in mean% gain when compared groupwise using ANOVA, that is, maximum% gain in dentin formation was seen in group I, that is, 16.100 ± 2.42 followed by group II, that is, 11.6000 ± 1.42, and group III, that is, 9.6000 ± 0.96 and the difference between group I vs II and I vs III was highly significant (<0.0001) as shown in Figure 5.

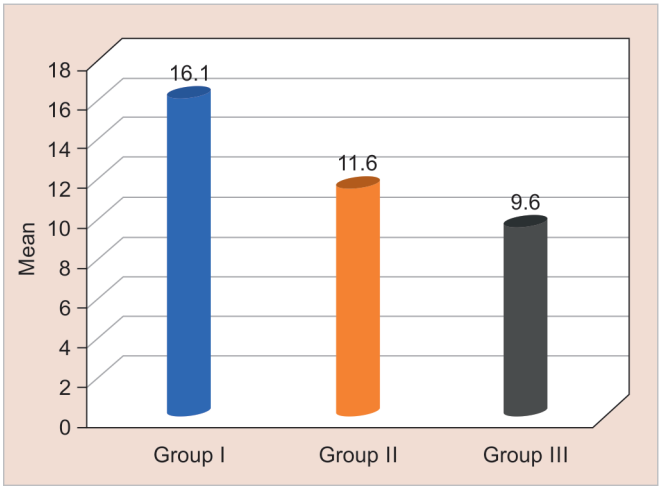


Fig. 5: Groupwise comparison of mean% gain in dentin formation

Discussion

Minimal intervention and partial caries removal followed by pulp capping prevents pulp exposure and promotes the remineralization of adequately sealed deep carious lesions. The emphasis on minimal invasion and maximum preservation pertains to the techniques utilized in indirect pulp therapy.[3]

The terminology of IPC has been updated to the IPT (American Academy of Pediatric Dentistry Reference Manual).

The complete removal of carious tissue from cavo surface margins and lateral walls is necessary to prevent the progress of caries and to achieve adequate coronal seals. The carious tissue required to avoid pulpal exposure should be left at floor. Falster et al. recommended IPT and the definitive tooth restoration in a single appointment.[5] Bjørndal et al. demonstrated remineralization and hardening, and no signs of caries progression on reopening.[10]

Kuzmanovic Radman et al. assessed the effect of IPT based on bacteria population and reported significant microbial reduction in cases with intact coronal seals.[11]

This study was conducted to evaluate the clinical efficacy of various lining materials in deep carious dentin in young permanent molars, which were treated using a single-step IPT method. The materials assessed included TheraCal LC, RMGIC, and Dycal, the latter serving as the control. The current study selected young permanent molars due to the pulp's ability to heal in these teeth, even after experiencing various forms of damage, including bacterial toxins and trauma. Recent research on pulp therapy techniques indicates that young patients tend to exhibit a greater prevalence of vital pulps without apical radiolucency in comparison to older patients after undergoing vital pulp therapy procedures.[11] In the present study, 6–14-year-olds were selected for the single-step IPT technique, as the ages correspond to the eruption of first as well as second permanent molars, which are known to be most prone to develop fast and aggressive dental carious lesions.[12]

None of the teeth examined in this study were classified as failures according to the clinical assessment. There were no instances of postoperative pain suggestive of irreversible pulp pathology, and none of the patients exhibited signs of a fistula, swelling in the periodontal tissues, or increased tooth mobility.

In our study dentin bridge formation was observed in all the three groups, that is, TheraCal LC, RMGIC, and Dycal group (control). Speed of dentin formation did not vary significantly among the three groups when compared at 6 and 12 months. Ten Cate and van Duinen noted the occurrence of hypermineralization in dentinal lesions located near glass ionomer cement restorations after a 12-week period of intraoral placement.[12] A similar zone of

Table 1: Groupwise comparison of speed of dentin formation at different interval

		At 6 months			*At 12 months*		
		+	++	+++	+	++	+++
Group I	*N*	10	8	3	10	10	10
	%	100.0	80.0	30.0	100.0	100.0	100.0
Group II	*N*	10	8	3	10	10	10
	%	100.0	80.0	30.0	100.0	100.0	100.0
Group III	*N*	10	6	0	10	10	10
	%	100.0	60.0	0.0	100.0	100.0	100.0
Total	*N*	30	22	6	30	30	30
	%	100.0	73.3	20.0	100.0	100.0	100.0
p-value		–	0.506 NS	0.153 NS	–	–	–

hypermineralization has also been observed in tissue in contact with glass ionomer restoration by others. Opal et al. observed mineralization of/around tubules in all three groups (RMGIC, CH, and gutta-percha group) and the difference was not significantly different in the three groups.[3,13,14] Remineralization of carious dentin even without fluoride/calcium, strongly suggests that the most important quality of a material is its ability to hermetically seal the cavity thereby reducing or eliminating the supply of the substrate for the remaining organisms and creating a microenvironment, hence, modifying pH and acid profile of the lesions. The dental pulp's capacity to generate a dentin-like matrix plays a crucial role in the development of tertiary dentin and the sclerosis of dentinal tubules. This process is facilitated by the establishment of an effective coronal seal, which aids in the repair mechanisms within the dentin pulp.[13]

Further significant differences were observed in the mean% gain of dentin bridge thickness when compared groupwise. Group I demonstrated a statistically significant increase in the mean percentage gain from baseline to the 12 months mark, indicating a greater deposition of tertiary dentin in comparison to both groups II and III. Specifically, the highest percentage gain in dentin formation was observed in group I, followed by groups II and III. These findings align with those reported in a similar study conducted by Grewal et al.[13] They compared tricalcium silicate with CH and mean percentage gain was seen maximum in tricalcium silicate group than CH group at 12 months and the difference was statistically significant but the difference in mean dentin thickness at 6 and 12 months was insignificant in groups as mentioned.[13]

Cannon et al. reported similar results where they found that TheraCal LC group forms a more consistent and thicker hard tissue bridge than glass ionomer and Dycal groups.[15]

Furthermore, calcium ions play a role in regulating the levels of osteopontin and bone morphogenetic protein-2. The release of calcium increases the activity of pyrophosphatase, which promotes mineralization and the development of a dentin bridge. All the pulp lining materials utilized in our study are capable of releasing calcium.

The bond strength between the coronal restoration and pulp lining material is important for the success of IPT or any other restoration.[16,17] TheraCal LC being a resin-based material, does not need conditioning of the dentin and bonds with various adhesives directly.[18] Meraji and Camilleri studied layering of TheraCal LC with resin composite and found that their in-between bond strength values than self-etch primer bond strength.[19] Similar findings were reported by Deepa et al., who investigated the bonding capacity of resin composite to three distinct liners, namely TheraCal LC, Biodentin, and Fuji II LC. Their results indicated that the bond strength of TheraCal LC was significantly superior to that of Biodentin. Furthermore, light-cured calcium silicate-based cement demonstrated enhanced clinical efficacy as an IPC agent over an extended period, particularly when compared to a direct pulp capping agent for the restoration of teeth affected by deep caries. This evidence-based research advocates for the utilization of TheraCal LC as an effective IPC agent.[20] The results a comparative study of Dycal, Glass ionomer, TheraCal LC and bioactive glass ionomer showed that the success of IPC treatments was independent of the lining material used.[21] In a separate investigation, TheraCal LC demonstrated notably effective clinical and radiographic outcomes when utilized as an IPT for primary molars. Its favorable handling properties and the elimination of the manipulation step make it an advantageous choice for pulp capping in pediatric patients, thereby decreasing the overall treatment duration. TheraCal LC may be particularly beneficial as a pulp capping agent in the treatment of deeply carious young permanent molars, promoting improved healing in a shorter timeframe. Additional research with a larger sample size is recommended to enhance the validity of these findings.

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