

Original Article

A comparative evaluation of light cure calcium silicate and resin-modified glass ionomer as indirect pulp capping agent in primary molars: A randomized clinical trial

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ABSTRACT

Background: Minimally invasive techniques should be employed to maintain pulp vitality without affecting physiological tooth resorption for pediatric patients. This study aims to evaluate clinical and radiographic success of light cure calcium silicate and resin-modified glass ionomer (RMGI) as indirect pulp-capping agent in primary molars in children between 5 and 9 years.

Materials and Methods: In this randomized clinical trial study, 40 primary molars with the International Caries Detection and Assessment System criteria 4–6 score were divided randomly into two groups after computerized randomization method. After caries excavation by minimally invasive dentistry principle, affected dentin was lined by either light cure calcium silicate (Group I) or RMGI (Group II) liner followed by composite restoration. Clinical success was determined with the absence of symptoms and bitewing radiographs were taken at baseline, 3, and 6 months' interval to measure increase in dentin increment using ImageJ software. Statistical analysis for intergroup comparison was done using Paired *t*-test, and Independent *t*-test was used for intragroup comparison. The level of statistical significance was set at $P < 0.05$.

Results: Change in dentin increment seen from baseline to 6 months in Group I was 0.19 mm and in Group II was 0.20 mm ($P = 0.924$). Intragroup increment was statistically significant during all follow-up intervals for both the groups (Group I – $P \leq 0.001$, Group II – $P = 0.009$). For baseline remaining dentin thickness > 1.5 mm, statistically significant increase was observed in the dentin increment at 3 months' interval between both the groups.

Conclusion: Both TheraCal LC and Vitrebond show acceptable clinical and radiographic results when used in primary molars as indirect pulp treatment agents. Both the liners are equivalent to each other in terms of feasibility and cost-effectiveness but TheraCal LC can be preferred due to better handling and avoiding the manipulation step thereby reducing treatment time.

Key Words: Deciduous teeth, dental cavity, indirect pulp treatment, pulp capping, reparative dentin, resin-modified glass ionomers, TheraCal LC

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INTRODUCTION

The major dilemma for a pediatric dentist is to decide on the best treatment approach for carious primary

teeth based on clinical and radiographic symptoms as children often present unreliable pain descriptions.

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Preserving deciduous teeth till their exfoliation is crucial for upholding the integrity of the arch, balancing the occlusion, and masticatory function.^[1] The pulp tissue in deciduous and permanent teeth is similar in terms of vulnerability and response to caries attack, restorative procedures, or traumatic injuries. When the harmful stimulus is within the healing capacity of tissues, repair occurs in the pulp-dentin complex after the application of specific agent between the restoration and tooth surface to avoid further challenges to pulp due to possible bacterial penetration and microleakage.^[2]

Vital pulp therapy (VPT) procedures are done to treat deep carious lesions in deciduous teeth thus maintaining its vitality and function. Factors such as adequate vascularity, severity of inflammation, disinfection of exposure site, antibacterial efficacy, biocompatibility of pulp covering agents, and adequate coronal seal may affect the success of VPT.^[2] The procedure is considered successful when the formation of remineralized tissue resembling dentin occurs which is thick enough to provide protection to the pulp.^[3] VPT includes three approaches: indirect pulp capping (IPC), direct pulp capping, and pulpotomy. IPC is recommended for teeth with deep carious lesions approximating the pulp but devoid of any signs/symptoms of pulp degeneration. The deepest layer of carious dentin is covered with biocompatible material with the objective to promote dentin sclerosis and formation of reparative dentin while arresting further demineralization and preserving tooth vitality.^[4]

The first pulp capping was done with a small piece of gold placed over exposed pulp to ensure healing by Phillip Pfaff.^[5] Amidst other materials, calcium hydroxide was popularized for several decades but due to its limitations got replaced by newer agents such as resin-modified glass ionomer (RMGI), Portland cement, mineral trioxide aggregate (MTA), dentin bonding agents, enamel matrix proteins, or bone morphogenetic proteins superfamily members.^[6]

The scientific literature suggests that success rates of indirect pulp treatment (IPT) are high and can be correlated with the increase in remaining dentin thickness (RDT). Numerous studies exist that compare the success rate of IPT with conventional pulp capping agents. However, there is a dearth of literature comparing calcium silicate and RMGIC as IPC agents in primary molars. Furthermore,

very few studies have correlated increase in tertiary dentin based on the depth of RDT at baseline after the application of the aforementioned agents. Thus, this study was undertaken to compare and evaluate clinical and radiographic outcomes and measure the increase in RDT in primary molars treated with light cure calcium silicate and RMGI as IPT agents.

MATERIALS AND METHODS

The study was an *in vivo* clinical study which was undertaken after obtaining ethical clearance (KSDEC/19-20/April/035) from the institution. After screening and eligibility assessment, 32 children were enrolled by a single investigator [Figure 1]. Informed written consent was obtained from the parent/guardian of each child who participated in the study. The final sample size calculated was 40 which was achieved using the following formula:

$$\text{Sample size} = 2 \times (Z_{\alpha/2} + Z_{1-\beta})^2 / (m_1 - m_2 / \sigma)^2$$

Selection criteria

Inclusion criteria

Children between 5 and 9 years with no history of spontaneous pain, International Caries Detection and Assessment System (ICDAS) 4–6 criteria, RDT ≥ 0.25 mm in bitewing radiograph, absence of cavitated lesion on buccal/lingual surface, physiological root resorption not more than apical one-third of root surface of the tooth to be treated.

Exclusion criteria

Exclusion criteria include interradicular/periapical pathology, presence of sinus/fistula, internal resorption, pathologic mobility, and patients without consent.

A preoperative bitewing radiograph was taken with size 0 sensor films (E speed films, Kodak, Eastman) with Intraoral Grid (1 mm \times 1 mm blocks) and Rinn XCP Film holders (Dentsply, XCP film holding system), PSP sensor with same digital imaging system (Port-X II EZX-60) with standardized exposure parameters (60 kV, 2Ma, 0.2s) by single operator. The teeth matching the inclusion criteria were selected and assigned into two groups of 20 each by computerized allocation method. In Group I, Theracal LC (Bisco, Inc., Schaumburg, IL USA) was used as liner, and in Group II, Vitrebond (3M ESPE Dental Products, St. Paul, MN, USA) was used.

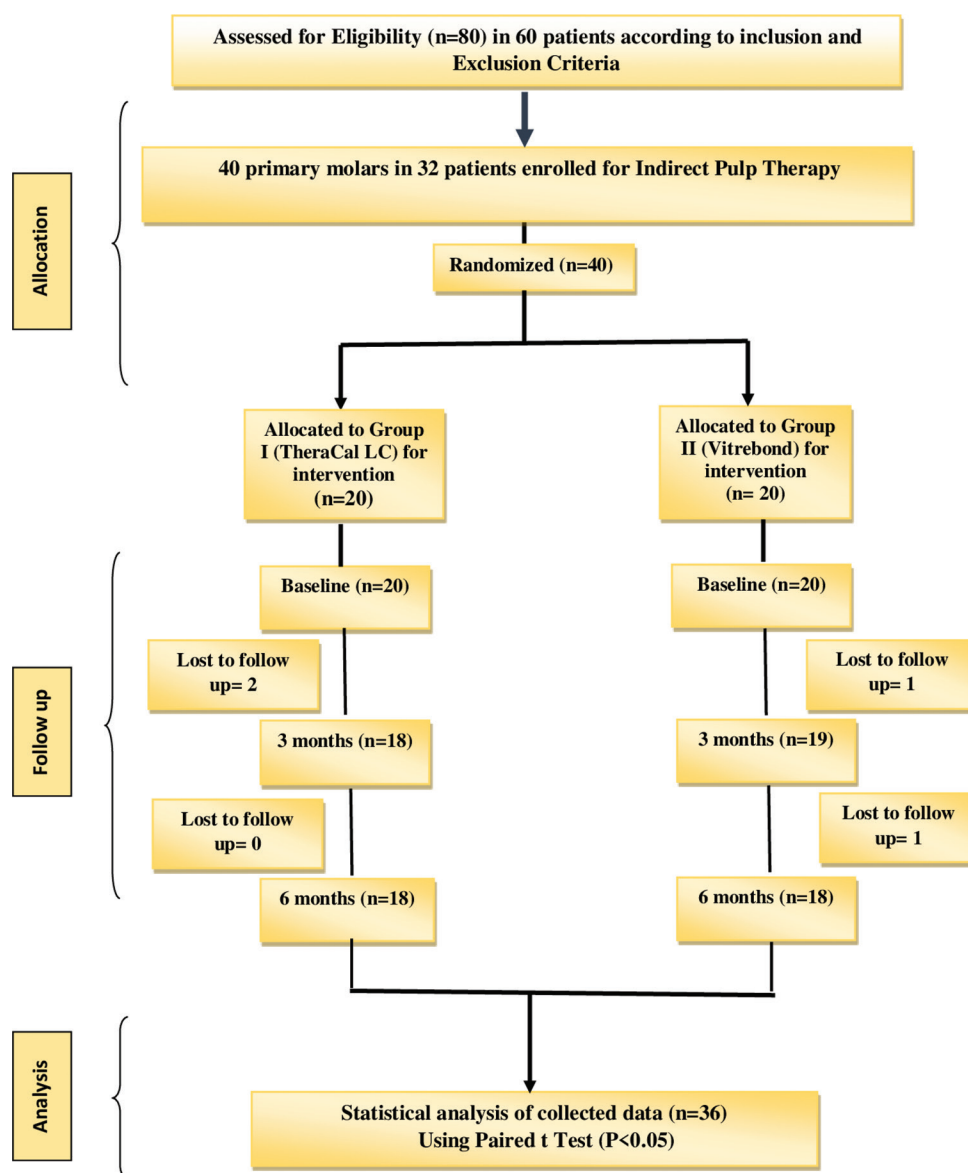


Figure 1: Consort diagram of the study.

Procedure

After the administration of local anesthesia, the teeth to be treated were isolated using rubber dam. Cavity preparation was done using diamond burs (330 SS white) at high speed with water coolant and caries removal was done with a spoon excavator according to principles of minimally invasive dentistry. All of the caries was excavated from cavity walls to ensure adequate bonding. The infected dentin was excavated and a thin layer of affected dentin was left when the pulp was approximated. Ensuring the removal of all infected dentin, the liners were placed in 1 mm increment according to the manufacturers' instruction and light cured [Table 1]. Selective etching was done only for enamel using 37% phosphoric acid (3M

ESPE, St. Paul, MN, USA) for 10 s. The cavity was rinsed off for 10 s to remove any residual particles and air dried for 2 s to leave cavity walls moist avoiding dentin desiccation. Self-etch Adhesive (Scotchbond Universal Adhesive, 3M) was applied with microbrush on both the enamel and dentin and was light cured at intensity of 1200 mw/cm² (Unicorn Dentmart curing light) for 10 s. The cavity was later restored with Filtek Z350 (3M) and light cured for 40 s. The restoration was finished and polished using composite finishing burs and polishing discs (Soflex Discs).

Success criteria

The treated teeth were evaluated at 3 and 6 months' follow-up and were considered success if clinically they did not show any pain symptoms, tenderness to

percussion, sensitivity, swelling, fistula, or mobility and on radiographic evaluation, there was the absence of internal/external resorption, periodontal space widening or periapical/furcal radiolucency.

Radiographic assessment

The assessment of RDT was done at baseline immediately after restoration, 3 and 6 months and all the measurements were recorded with ImageJ Software (Wayne Rasband, National Institutes of Health-NIH, Bethesda, Maryland, USA). The scale for measurements was determined using the space between two grids which were assigned a value of 1 mm. The RDT was measured in millimeters between the deepest region of the cavity and the dentin pulp border. Two additional measurements were recorded 1 mm mesial and distal to the initial measurement point. Then, the mean value of the three measurements was considered as RDT for that tooth [Figures 2 and 3].

Statistical analysis

The data were analyzed with (SPSS version 20, SPSS, Chicago, IL, USA), for windows statistical software. Statistical analysis between the groups was done using paired *t*-test and within group using independent

sample *t*-test. For all statistical analyses, $P < 0.05$ was considered statistically significant.

RESULTS

Forty primary molars in patients aged 5–9 years treated for indirect pulp therapy were evaluated clinically and radiographically at baseline, 3, and 6 months. Of 40 specimens included, 4 teeth were dropped out due to denial of patients to turn up for follow-up post-COVID-19 Pandemic and were therefore excluded from final analysis and statistics. Hence, the sample size after considering the dropouts was 36 teeth (18 teeth per group) during the final analysis at 6 months. Out of 36 teeth evaluated, none showed any signs of resorption, furcal radiolucency, pain, sensitivity, or mobility, thus were considered to have a clinical and radiographic success rate of 100%.

Intragroup comparison of mean RDT in Group I and Group II done using Independent *t*-test showed a significant RDT increment in both the groups at interval of 3 and 6 months, respectively. In Group I (TheraCal LC), the mean increment at the end of 3 months was 1.13 mm with increase of 0.12 mm. Between 3 and 6 months, the mean

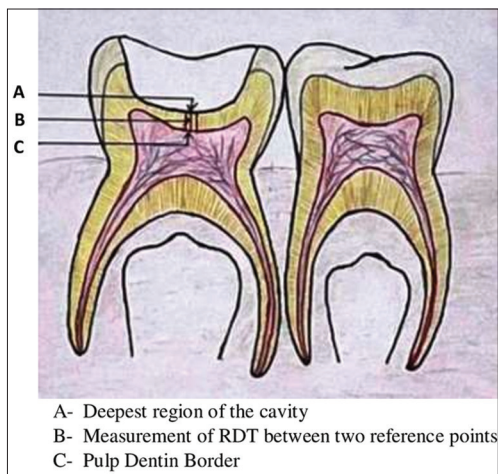


Figure 2: Landmark orientation for measuring RDT. RDT: Remaining dentin thickness.

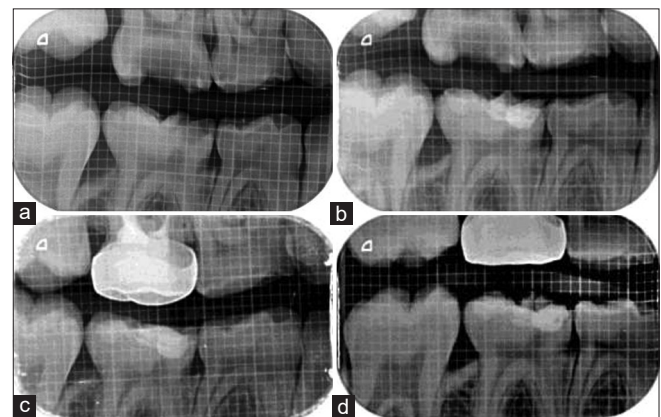


Figure 3: Bitewing radiographs with grid at different intervals: (a) Preoperative bitewing (Upper Left) (b) Baseline bitewing (Upper Right) (c) 3-month follow-up bitewing (Lower Left) (d) 6-month follow-up bitewing (Lower Right)

Table 1: Description of materials used in the study

Product	Manufacturer	Composition	Mode of application
Theracal LC	Bisco, Inc. Schaumburg, IL USA	Portland cement type III HEMA, polyethylene glycol dimethacrylate <50% Barium zirconate <10%	Inject the material into the cavity in 1 mm increments Light cure each increment for 20 s
Vitrebond	3M ESPE Dental Products, St. Paul, MN, USA	Powder: Glass Powder, DPICI Liquid: Copolymer of acrylic and Itaconic Acids, HEMA, water	Weigh powder and liquid of ratio 1.4:1 Mix for 10-15 s Place on dentin and cure for 30 s

HEMA: 2-hydroxyethyl-methylacrylate; DPICI: Diphenyliodonium chloride

increment was 0.07 mm and the total increase was 0.19 mm from baseline till 6 months. Comparison of dentin increment at baseline done with 3 and 6 months, respectively, showed statistically significant ($P < 0.001$) increase and on comparing the increment of 3 months with 6 months, statistically significant increase was seen as well [Table 2]. In Group II (Vitrebond), the mean of tertiary dentin at the end of 3 months was 1.10 mm with mean increase of 0.12 mm. Between 3 and 6 months the mean increment of 0.08 mm was seen and the total increase noted from the baseline to 6 months was 0.20 mm. Significant increase ($P < 0.001$) in thickness was seen at both follow-up evaluations. High statistical significance was found when baseline was compared with 3 and 6 months, respectively ($P < 0.001$). Comparison of the dentin increment between 3 and 6 months was also statistically significant [$P = 0.009$, Table 3].

Intergroup comparison of mean RDT was calculated using Paired *t*-test. The comparison was done for three different intervals: baseline to 3 months, baseline to 6 months, and between 3 and 6 months. The intergroup comparison between both the groups during all three-time frames yielded no significant

difference ($P > 0.05$). Thus, the results showed that both the materials were equally effective in inducing the formation of tertiary dentin after IPT [Graph 1].

In our study, RDT thickness at baseline was categorized into four groups: >1.5 mm, 1.5–1 mm, 0.5–0.9, and <0.5 mm to correlate increase in the dentin increment with residual RDT. There was no significant difference ($P > 0.05$) observed in Groups I and II for RDT values between 1.5–1 mm and 0.5–0.9 mm. However, at 3 months' interval between both the groups, for RDT ranging >1.5 mm, statistically significant ($P = 0.019$) increase was observed [Table 4].

DISCUSSION

A paradigm shift is seen in caries excavation techniques from aggressive radical removal to minimal intervention protocols.^[7] A successful vital pulp capping relies on accurate diagnosis and appropriate case selection. Although the indications for IPT and pulpotomy are almost similar, IPT is preferred due to consequences such as internal root resorption, formocresol toxicity, discoloration, and rare dentigerous cysts.^[8-11] The concept of IPT is based on the distinction between affected and infected dentin. The infected layer contains maximum microorganisms thus removing it declines bacteria and toxins decelerating demineralization and allows reparative dentin formation.^[12] The residual caries intentionally left behind contain appreciable number of microorganisms but the evidence suggests that the cavity becomes sterile after restoration. Partial caries excavation is a single-visit procedure which preserves vital pulp portion thus overcomes drawbacks of stepwise excavation like risk of pulp exposure while

Table 2: Intragroup comparison of mean remaining dentin thickness in group I (TheraCal LC) done using Independent *t*-test

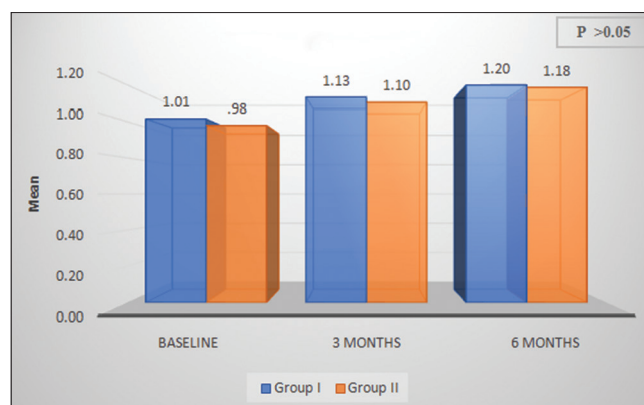
Parameter	Duration	Mean (mm)	n	SD	SEM	Mean difference	P
Remaining dentin	Baseline	1.01	18	0.36	0.08	0.110430	$<0.001^{**}$
	3 months	1.13	18	0.36	0.08		
Remaining dentin	Baseline	1.01	18	0.36	0.08	0.182333	$<0.001^{**}$
	6 months	1.20	18	0.37	0.09		
Remaining dentin	3 months	1.13	18	0.36	0.08	0.065133	$<0.001^{**}$
	6 months	1.20	18	0.37	0.09		

**Highly significant ($P < 0.001$). SD: Standard deviation; SEM: Standard error of mean

Table 3: Intragroup comparison of mean remaining dentin thickness in group II (Vitrebond) done using independent *t*-test

Parameter	Duration	Mean (mm)	n	SD	SEM	Mean difference	P
Remaining dentin	Baseline	0.98	18	0.37	0.09	0.125342	$<0.001^{**}$
	3 months	1.10	18	0.38	0.09		
Remaining dentin	Baseline	0.98	18	0.37	0.09	0.206444	$<0.001^{**}$
	6 months	1.18	18	0.41	0.10		
Remaining dentin	3 months	1.10	18	0.38	0.09	0.081639	0.009*
	6 months	1.18	18	0.41	0.10		

*Significant ($P < 0.05$), **Highly significant ($P < 0.001$). SD: Standard deviation; SEM: Standard error of mean



Graph 1: Graph depicting intergroup comparison for mean RDT at various intervals. RDT: Remaining dentin thickness.

Table 4: Intergroup comparison of mean remaining dentin thickness increment at 3 month and 6 month follow up based on remaining dentin thickness at the baseline

RDT	Group	Baseline		3 months increment		6 months increment	
		Mean (mm)	SD	Mean (mm)	SD	Mean (mm)	SD
>1.5	Group I	1.55	0.01	0.11	0.00	0.13	0.11
	Group II	1.78	-	0.14	-	0.14	-
	<i>P</i>	0.043*		0.019*		0.628 (NS)	
1.5-1	Group I	1.23	0.15	0.12	0.03	0.05	0.02
	Group II	1.16	0.13	0.14	0.12	0.10	0.16
	<i>P</i>	0.280 (NS)		0.704 (NS)		0.408 (NS)	
0.5-0.9	Group I	0.75	0.19	0.13	0.04	0.06	0.02
	Group II	0.63	0.17	0.11	0.01	0.05	0.01
	<i>P</i>	0.235 (NS)		0.380 (NS)		0.576 (NS)	
<0.5	Group I	0.45	-	0.12	-	0.04	-
	Group II	0.45	-	0.09	-	0.05	-

*Significance= $P < 0.05$, NS= $P > 0.05$. RDT: Remaining dentin thickness; SD: Standard deviation; NS: Not significant

re-entering the cavity, caries recurrence due to failure of temporary restoration, and discomfort to patients.^[13-15] Carious lesions extending towards the pulp without involving pulp are ideally indicated for IPT and this clinical/radiographic scenario correlates with ICDAS score 4–6 therefore the teeth with those scores were included in the study. ICDAS criteria rely on surface changes and potential depth of caries which correlates strongly with the real depth of the lesion.^[16,17] Bitewing radiographic technique was preferred in our study due to its simplicity and reliability. Apart from this it has an added advantage of eliminating the need of predetermining and positioning the child's head therefore the same angle can be duplicated at subsequent visits as well.

The materials preferred for IPT initially were calcium hydroxide, glass ionomer cement, and MTA. However, calcium hydroxide demonstrated drawbacks such as high solubility, poor dentin bonding, disintegration, tunnel defects, necrosis in superficial region, and fiber-rich scar tissue formation due to alkaline pH. Despite of several advantages of MTA, there are still some shortcomings with its usage such as longer setting time, difficulty in handling, tooth discoloration, and incompatibility with other materials. Hence, newer agents are being introduced and tested to overcome all such limitations. TheraCal LC AWWis fourth-generation light-cure calcium silicate material. It releases calcium ions which act as stimulation for fibroblasts and odontoblasts forming mineralized hard tissues. It forms a scaffold on affected dentin, triggers reparative dentin formation, and provides a biologic seal by bonding chemically with dentin thus provides pulp protection. TheraCal LC demonstrates

greater bond strength than biodentine when followed by GIC or composite restoration.^[18,19] Vitrebond is an RMGIC liner which demonstrates inhibitory action against cariogenic bacteria. This antibacterial efficacy is due to its low initial pH which is 4.0 but increases up to 5.5 in the first 24 h.^[20] The success of RMGI liners attributes to its good adhesion through micromechanical and chemical adhesion with dentin, release of sustained levels of fluoride inducing remineralization, low solubility, favorable modulus of elasticity, and coefficient of thermal expansion similar to that of dentin.

According to Bjørndal and Mjör IA a carious lesion is considered deep when it involves three-fourth or more of total dentin thickness on radiograph.^[21] According to Fuks *et al.*, when RDT is >1.1 mm the inflammation is negligible, for RDT <0.5 mm, there is severe inflammation, and RDT <0.25 mm stimulates pulpal inflammation significantly decreasing tertiary dentin formation.^[22] In this study, a significant RDT increment is noted in both the groups at interval of 3 and 6 months. In Group I, statistically significant increase is noted from baseline to 3 months. This initial burst might be due to a spike in calcium release during the initial period of 28 days which later declined. In Group II, intragroup comparison showed a significant increase in dentin thickness during all the follow-up evaluations high statistical significance was noted when baseline was compared with 3 and 6 months, respectively. The amount of tertiary dentine formed is affected by the degree of operative trauma and the time elapsed after the treatment. The formation is rapid initially till 30–48 days but later declines

gradually from 58 to 106 days. The maximum deposition is seen with RDT between 0.25 and 0.5 mm with bacterial presence intensifying the process.^[23] Intragroup comparison done for baseline to 3 months, baseline to 6 months, and between 3 and 6 months showed a significant increase in dentin increment but intergroup comparison yielded no significant difference ($P > 0.05$). Thus, both the materials seem equally effective in inducing the formation of tertiary dentin after IPT. Our results corroborate with a study by Menon *et al.*^[1] wherein IPT done with MTA and TheraCal was compared. TheraCal showed similar results compared to MTA with increments of 0.112 mm after 3 months and 0.057 mm after 6 months. Gandolfi *et al.* compared TheraCal and MTA as pulp capping agents and reported that average dentin increment in first 3 months was significantly higher than average deposition after 6 months due to decreased calcium release by both the materials.^[18]

The clinical and radiographic success for both groups in this study was 100% at all follow-up periods which could be credited to the accurate diagnosis, complete excavation of infected dentin followed by tight sealed coronal restoration. These results are in agreement with Elchaghaby *et al.* who reported that teeth without any clinical/radiographic signs and symptoms were considered as success and IPT showed high survival rates in primary and permanent teeth.^[24] Our results contradict the results by de Assunção Pinheiro IV *et al.* wherein no change in RDT was observed even after 12 months which could be due to the inability to precisely measure the lesion depth.^[25] The dentin-pulp border was selected as orientation landmark as it eliminates the need to involve additional external landmarks for referencing and has less element of human error in recognizing the identical site in subsequent follow-up images.

For a successful IPT procedure, it is detrimental to secure a good marginal seal to minimize microleakage and avoid caries recurrence. Composites have gained immense popularity as restorative material due to their physicochemical properties, adhesion, and esthetics and they exhibit better performance with high success when placed on RMGIC or any calcium silicate liners.^[26,27] Filtek Z 350 was used as restorative material after the IPT procedure under rubber-dam application ensuring optimal isolation and longevity. The ongoing controversy concerning the mode of adhesion state that total-etch adhesives completely eliminate smear

layer demineralizing subsurface intact dentin whereas in self-etch mode the underlying dentin is intact with partially demineralized smear layer acting as bonding substrate. Scotchbond Universal is a multimode adhesive containing methacryloyloxydecyl dihydrogen phosphate (MDP) with silanes. This 10-MDP-based agent chemically adheres to calcium, aluminum ions, and zirconium oxides and also has Vitrebond copolymer which enhances its affinity for Vitrebond liner. The copolymerization of unreacted methacrylates present in oxygen inhibited layer of TC and RMGIC enhances the chemical union between liner and composite. The advantages include decreased clinical steps and working time with less technique sensitivity without compromising the bond efficiency. Studies by Thanaratikul B *et al.*, Marchesi *et al.*, and Wagner *et al.* state that the mode of adhesive application did not affect the bond strength of the universal adhesive to primary dentin and there was no difference in bond strength between either application modes to primary and permanent dentin.^[28-30] Selfetch adhesives have improved bonding ability to dentin but show unsatisfactory enamel adhesion compared to previous generations. Hence, selectively acid etch on enamel is recommended before adhesive application. This pretreatment facilitates deeper infiltration of adhesives, thereby enhancing bonding efficacy and wettability of the substrate by creating longer tags (50 μ), thicker hybrid layer (2–3 μ), and better resin infiltration.^[31]

Limitation

The above-mentioned results are based on a shortterm clinical trial and further longterm investigations with a larger sample size and histologic evaluation are required to confirm these results.

CONCLUSION

Considering the limitations of the study, it can be said that both TheraCal LC and Vitrebond show acceptable clinical and radiographic results as IPT agents in primary molars with deep carious lesion involving dentin and demonstrate similar efficacy in the deposition of tertiary dentin; however, during the first 3 months greater dentin increment was seen in Vitrebond group.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or non-financial in this article.

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