Original Article

Direct Pulp Capping – A Controversial Procedure in Primary Teeth with TheraCal LC and Cal LC *In Vivo* Study

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Abstract

Background: Various direct pulp capping (DPC) agents are used to preserve and maintain vitality of carious primary and permanent teeth. However, none of the materials available so far to fulfill all the requirements of an ideal pulp capping agents. Hence, this study was conducted to evaluate clinically and radiographically, dentinal bridge formation using materials: Cal LC and TheraCal LC in DPC treatment in primary teeth for a period of 6 months. **Aim:** the aim of the study was to comparative clinical and radiographic evaluation of dentinal bridge formation using materials: Cal LC and TheraCal LC in DPC treatment in primary teeth. **Materials and Methods:** Following the ethical approval, this randomized control trial was performed among 30 children aged 6–10 years, who presented with bilaterally infected primary molars. They were selected from the outpatient departments of Narsinhbhai Patel Dental College and Hospital, Visnagar. Sixty infected primary molars were divided in two groups and DPC was done with TheraCal LC and Cal LC.All teeth were followed up clinically and radiographically for a period of 6 months postoperatively. **Results:** Statistical analysis of data was performed using paired "*t*" test. Results showed that clinically TheraCal LC has 96.9% success rate as a DPC material in primary molars when compared to Cal LC group clinically 93.8%. Mean dentin thickness formation was higher in TheraCal LC group than Cal LC group which was statistically significant. **Conclusion:** DPC using TheraCal LC in primary teeth has shown good clinical and radiographic success. A study with longer follow-up will highlight the outcome of TheraCal LC in primary teeth as a pulp capping agent.

Keywords: Cal LC, Direct pulp capping, Primary teeth, TheraCal LC.

Introduction

Primary teeth play an integral role in the development of the occlusion. Premature loss of a primary tooth through trauma or infection has the potential to destabilize the developing occlusion with space loss, arch collapse and premature, delayed or ectopic eruption of the permanent successor teeth. Throughout the life of a tooth vital pulp tissue contributes to the production of secondary dentin, peritubular dentin (sclerosis) and reparative dentin in response to biologic and pathologic stimuli.

The ultimate goal of pulp capping or stepwise caries removal is to protect a healthy dental pulp and avoid the need for root canal therapy.[2] Historically, the first pulp capping procedure was performed, by Phillip Pfaff, who packed a small piece of gold over an exposed vital pulp to promote healing in 1756.

To prevent the pulp from deteriorating when a dental restoration approximates the pulp; the clinicians place a small amount of sedative dressing, such as calcium hydroxide (CaH) or mineral trioxide aggregate (MTA). These materials protect the pulp from noxious agents such as heat, cold, and bacteria and also stimulate the cell-rich zone of the pulp to lay down a bridge of reparative dentin. Dentin formation usually begins within 30 days of the pulp capping and is almost completed by 130 days.[2]

The procedure of pulp capping relies primarily on the ability of pulpal tissue to heal. Various factors affect this process including age, periodontal condition, and stage of root formation.[3]

CaH has been expansively used for both indirect (IPC) and direct pulp-capping (DPC). CaH is a benchmark medicament for vital pulp therapy.[3] Both clinically and histologically,

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it has been found to produce satisfactory results in DPC.[2] The presences of tunnels in dentin barrier, extensive dentin formation obliterating the pulp chamber, high solubility in oral fluids, and lack of adhesion and degradation after acid etching are some of the limitations reported with CaH.[3]

To overcome these disadvantages, recently a new calcium-silicate-based restorative material was introduced. TheraCal LC (BiscoInc, Schamburg, IL, USA) is a new light-cured resin-modified calcium silicate-filled base or liner material designed for DPC and IPC which has good sealing capabilities, was well-tolerated, and preserved odontoblast cells.[4] TheraCal LC has the ability to bond to deep moist dentine, unlike Dycal which lacks adhesion,[4] is self-sealing, which aids in antimicrobial activity with initial bonds to dentine to resist accidental air-drying removal.[5]

Recently, TheraCal has been explored as IPC agent among primary and permanent teeth. Although recommended for DPC, there is limited literature establishing its effect as a DPC agent in primary teeth. Hence, the purpose of this clinical study was to evaluate and compare the capabilities of materials: TheraCal LC and Cal LC for secondary dentinal bridge formation in DPC treatment in primary teeth with clinical and radiographic evaluation over a period 6 months.

Material and Methods

The study was initiated with approval of ethical committee, Narsinhbhai Patel Dental College, Visnagar. Patients were designated based on the inclusion criteria with the written informed consent of the parents/patients. The study protocol considered 30 Children aged 6–10 years, with bilateral carious lesion on maxillary/mandibular primary teeth. Randomization was facilitated by the chit pick method; teeth were assigned to TheraCalLC or Cal LC accordingly. Baseline evaluation was performed clinically and radiographically. Intraoral periapical radiographs were standardized by using the paralleling technique. The vitality of all teeth was assessed.

Inclusion and exclusion criteria

The clinical inclusion criteria were pinpoint inadvertent pulp exposure during caries excavation, bleeding controlled under pressure at exposure site, and vital pulp. Radiographically - radiolucency involving enamel, dentin, and approaching the pulp. The clinical exclusion criteria were unilateral carious primary molars, uncontrollable bleeding, non-vital pulp, large pulp exposure (more than 1 mm), the presence of spontaneous pulpal pain, intraoral or extraoral swelling, sinus tract formation, and carious pulpal exposure. Radiographically, the exclusion criteria were pulp calcification, internal or external root resorption, and periapical radiolucency.

Treatment procedure

Bilateral primary molars with carious involvement were enrolled in the study and were assigned to DPC procedure. A single operator performed all DPC procedures in a single sitting. After local anesthesia administration (Lignox 2% ADR; Warren Pharmaceutical Pvt Ltd, Mumbai, India), rubber dam (Hygienic; Coltene/Whaledent AG, Altst€atten, Switzerland) isolation was done. Carious lesion was removed using spoon excavator and high-speed round diamond bur–BR31 (Mani Inc, Utsunomiya, Japan). On encountered exposure, hemostasis was achieved by application of pressure with a cotton pellet moistened with saline. If bleeding persisted, the tooth was excluded in the study. According to the randomization, TheraCal LC or Cal LC was used for DPC.

TheraCal LC/Cal LC was directly applied to the pulp exposure site and light cured for 20 s in 1 mm increments. A semi-permanent restoration with composite was performed for all teeth. Immediately, a baseline radiograph was made. All radiography was standardized with a project indicator device. Subsequently, at 3rd and 6 months, the teeth were clinically and radiographically evaluated. Clinical success was considered by absence of pain, tenderness to percussion, discoloration of teeth, and sinus tract. Radiographic evaluation for success was absence of root resorption, widening of periodontal ligament (PDL) space, periapical radiolucency, dentin formation, and any intra pulpal calcifications. Appraisal on the digital radiographs was performed at 3rd and 6th months. The increase in dentin thickness was measured using Coral Draw Software (Version 10).

Results

On the basis of clinical and radiographic parameters, the study reported 96.9% success rate with TheraCal LC and 93.8% success rate with Cal LC at the end of 3 months follow-up. There was absence of clinical and radiographic success in 1 tooth in TheraCal LC group and 2 teeth in Cal LC group at the end of 3 months.

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Discussion

The primary objective of pulp therapy is to maintain integrity and health of pulp tissue. It is desirable to maintain pulp vitality whenever possible. The healing process of pulp occurs in the form of tertiary dentinogenesis.[46]

The first documented pulp-capping treatment was conducted in 1756 by Pfaff, using gold foil. Since then, many agents have been recommended for DPC. However, due to incompetency of the sealing ability of previously available materials and improper case selection, DPC procedure in primary teeth was discredited. After evaluation of Calcium Silicate materials this procedure has become a popular practice.

This Randomized Clinical Trial focused on the use of dental materials which preserve the vitality of the dental pulp in primary molars and assessed the clinical and radiographic

effects of TheraCal LC and Cal LC in DPC during 6 month of follow-up.

CaH was used because it has been the bench mark material for vital pulp preservation treatments for several decades. Several reports have indicated that CaH has numerous disadvantages; it sets only in a dry environment, the dentinal bridges produced might have tunnel defects, and it shows dissolution over time. However, since the introduction of MTA, most clinicians have altered their practice in favor of MTA because of its more predictable success. In recent times, diverse Calcium Silicate-based materials have been developed to counter the limitations of MTA. Among them, biodentine stands out for its biocompatibility, rapid setting, mechanical strength, ability to bond to dentin, and easy manipulation. However, the main drawback of biodentine is its water-based chemistry and thus poor bonding, mainly micromechanical to the overlying resin restoration. To overcome these limitations, a light-cure resin-modified Tri Calcium Silicate (TheraCal LC) was introduced as a pulp capping material.

TheraCal LC may act as a scaffold for reparative dentine formation. Dentinal fluids are absorbed within it, resulting in the release of calcium and hydroxide ions, and the tooth responds to form apatite and a bond, supporting the natural sealing ability of the apatite, plays a crucial role in pulpal protection. The release of hydroxyl ions raises the pH of the surrounding environment and causes irritation of the pulp tissue. This develops superficial necrosis on exposed pulp, provoking mineralization directly against the necrotic zone. An alkaline pH also creates a hostile environment for bacterial survival and proliferation. TheraCal LC has provided a very alkaline (10.66) pH after 3 h and displayed a non-significant reduction in pH (9.85) after 24 h. Gandolfi *et al*. reported that TheraCal LC induced lower pH alkalization than the conventional self-setting Dycal. Calcium silicate-based materials have better antibacterial activity than CaH based materials. TheraCal LC showed very low cytocompatibility. TheraCal LC, which is a resin-based material, helps layering with composite resin. It is opaque and "whitish" in color. The polymerization of TheraCal LC is associated with low heat generation, and this could reduce adverse pulpal effects when used in pulp capping procedures. The manufacturer recommends placing it in 1 mm layers and curing it for 20 s.

Gopika *et al*. compared and evaluated the response of the human pulp following DPC with TheraCal LC, SeptoCal LC, and Dycal. Their study found that TheraCal LC and SeptoCal LC (CaH with hydroxyapatite) cements were as effective as Dycal in inducing the formation of reparative dentin and evoking an inflammatory response. There is a scarcity of studies reporting the outcome of using TheraCal LC in pulp capping procedures in primary and permanent teeth.

Clinical pulp conditions related to patient symptoms are to be considered before the DPC material placement. For evaluating clinical pulp conditions, the most important test is pulp vitality. Sign of vital pulp can be divided into three different categories depending on the clinical symptoms: Normal pulp, reversible pulpitis, and irreversible pulpitis. Normal pulp has no clinical symptoms. Reversible pulpitis usually has a short-lived thermal sensitivity, which will disappear immediately once the thermal stimulation is removed. Irreversible pulpitis usually has spontaneous and/or lingering pain and it could also have referred pain. Pulp-capping could be performed on tooth with normal pulp or reversible pulpitis. Percussion, palpation, and periodontal probing test results should be within normal limits.[47]

In current study, thermal and pulp vitality test was done before the procedure, immediate post-operative, after 3 and 6 months intervals. In clinically successful cases the pulp remains vital with a normal response, and there was absence of pain, gingival swelling, sinus tract, mobility. In clinically unsuccessful cases in TheraCal LC group, pulp was not vital. In Cal LC group, pulp was not vital, gingival swelling and sinus tract was present.

In radiographically successful cases, reactionary dentin was present over the lesion, and absence of furcation radiolucency, PDL space widening, and internal and external root resorption. In unsuccessful cases, furcation radiolucency, PDL space widening, and external root resorption were observed.

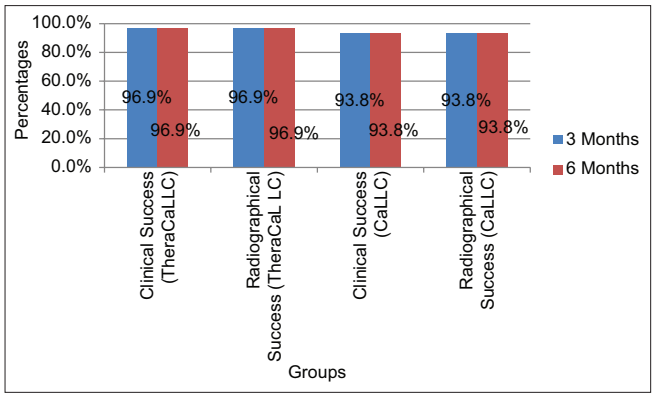
In current study, clinical success was directly related to radiographic success.

The other factors that play a critical role in the success of direct capping are adequate blood supply, the severity of inflammation, obtaining hemostasis, microbial contamination of the pulp tissue, disinfection of the exposure site, biocompatibility properties of pulp-covering agents, and provision of an adequate seal.

In our study, we found that in TheraCal LC group, clinical and radiographic success rate was 96.9% at the end of 3 and 6 months. In Cal LC group, clinical and radiographic success rate was 93.8% at the end of 3 and 6 months. Absence of clinical and radiographic success rate was in 1 tooth in TheraCal LC group and in 2 teeth in Cal LC group at the end of 3 months and 6 months. An extensive literature survey did not bring to light any comparative trials with TheraCal LC and Cal LC as DPC agents. Others such as Katge and Patil compared biodentine and MTA as DPC agents, in young permanent molars by clinical and radiographic evaluation among 7–9-year-old children with a reported 91% success rate in both materials.

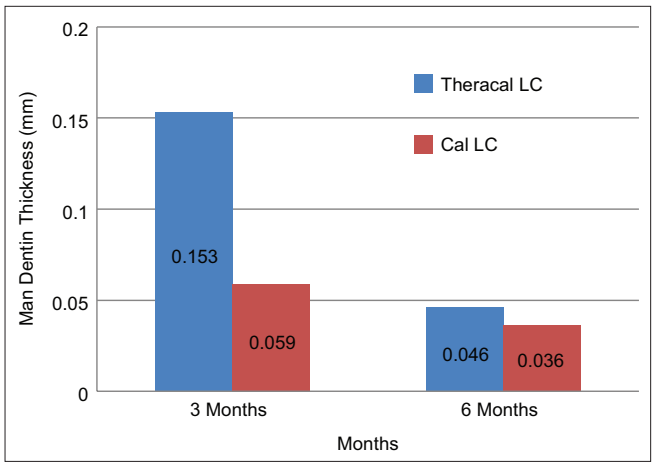
The dentin thickness was measured using Coral Draw Software (version 10).ref. The thickness of dentine formed was higher in the TheraCal LC (≤0.05 S) group at the end of 3 months and almost same in both groups at the end of 6 months. Statistically, significant difference was present in dentin thickness between TheraCal LC (≤0.05 S) and Cal LC (≤0.05 S) at the end of 3 and 6 months.

In our study, TheraCal LC shows higher dentin bridge formation which may be due to its greater calcium releasing



Graph 1: Clinical and radiographic success group wise distribution in TheraCal LC and CaL LC Group at 3 months and 6 months

Time	Dentin thickness (mm)			*t* value
	Mean	SD	Difference	*P* value
3 Months				
Theracal LC	0.153	0.241	0.094	2.220
Cal LC	0.059	0.004		≤ 0.05 S
6 Months				
Theracal LC	0.046	0.009	0.009	11.172
Cal LC	0.036	0.008		≤ 0.05 S



Graph 2: Dentin thickness wise distribution between TheraCal LC and Cal LC Group at 3 months and 6 months (Paired *t* test)

ability. In a study by Gandolfi *et al*., TheraCal LC was found to release significantly more calcium than Dycal throughout the tested period (28 days). However, the amount of leached calcium decreased with the advancing time for all the materials (28 days). Gandolfi *et al*. stated that the calcium release of ProRoot MTA and TheraCal LC was not marked but constant (no statistically 2 International Journal of Dentistry significant changes over time). This is in contrast to a study by Camilleri *et al*. which investigated the hydration of TheraCal LC and compared it with biodentine. The study reported that both materials leached Calcium ions in solution; however, TheraCal LC displayed lower calcium ion release and a slower reaction rate than biodentine. This difference was attributed to the different methodologies used in each study. Moreover, Yamamoto *et al*. reported that ProRoot MTA released significantly greater amounts of calcium ions than the TheraCal LC. The study also showed that TheraCal LC does not form CaH after setting, although it releases calcium ions and produces calcium apatite on its surface. The absence of CaH in set TheraCal LC suggests that calcium ions leached from this material are not in the hydroxide form.

In all investigations, failure with the CaH was encountered as presence of tunnels in dentin barrier, extensive dentin formation obliterating the pulp chamber, high solubility in oral fluids, and lack of adhesion and degradation after acid etching are some of the limitations reported with CaH. High alkaline pH of CaH could cause differentiation of cells into osteoclasts within pulp tissue, leading to the resorption of the primary tooth. In addition, undetected microleakage could allow large numbers of bacteria to overwhelm the pulp and nullify the beneficial effect of CaH.[2]

Literature supports that the TheraCal LC has displayed Calcium release properties and the bioavailability of calcium ions plays a key role in the material-induced proliferation and differentiation of human dental pulp cells that leads to formation of new mineralized hard tissues.

Limitation in a study is inevitable. To mention briefly:

1. The study population examined was 6–10 years, at this age physiological resorption of the primary teeth is just initiated. Hence, comparative assessment of this factor in further studies with long-term follow-up is advocated
2. The present study does not assess the calcium releasing ability of the tested materials.

Conclusion

A better understanding of the reaction of an inflamed pulp toward pulp capping agents and the availability of newer materials like calcium silicate has overcome the earlier controversies which were associated with DPC in primary teeth. In the present study, TheraCal LC has exhibited good clinical and radiographic success at 6 months follow-up visit. This could be attributed to its inherent excellent sealing ability and less interfacial microleakage than the other tested materials. Although Cal LC has shown reasonable clinical success at 6 months interval, its radiographic success was less convincing. This finding suggests that TheraCal LC could prove to be a superior agent for DPC in primary teeth.

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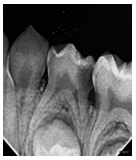
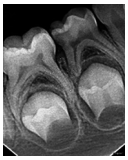
Pre- and post-operative radiograph

TheraCal LC (Study group)	Cal LC (Control group)
	
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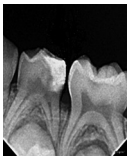	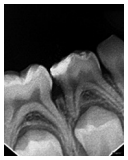
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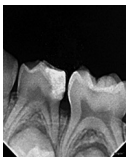
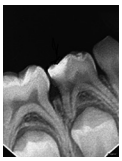
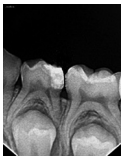
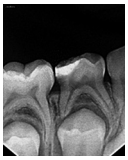
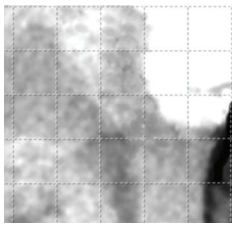
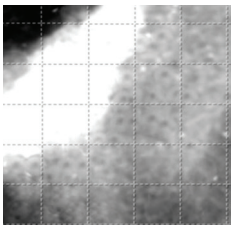
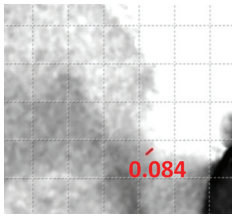
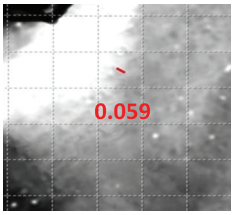
	
3 Month post-operative radiograph	
	
6 Month post-operative radiograph	

Post-operative enlarged images under coral draw software

TheraCal LC (Study group)	Cal LC (Control group)
	
Immediate post-operative coral draw software image	
	
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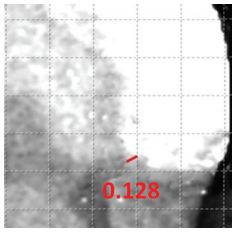	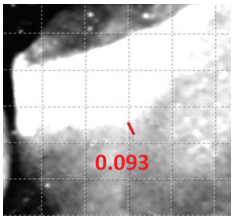
6 month post-operative coral draw software image	