



## Evaluation of Different Indirect Pulp Treatment Materials Used in Deep Carious Primary Molars

Aya S. Ali <sup>1\*</sup>, Samy Y. El-Bioumy<sup>2</sup>, Mohammed H. Mostafa<sup>3</sup>

Codex : 3-01/23.04

azhardentj@azhar.edu.eg

http://adjg.journals.ekb.eg

https://doi.org/10.58675/2974-4164.1488

Pediatric Dentistry & Orthodontics  
( Pediatric Dentistry, Orthodontics )

### ABSTRACT

**Purpose:** To evaluate the clinical and the radiographic outcomes of indirect pulp treatment (IPT) in primary molars using Calcium Hydroxide, Resin Modified Glass Ionomer and TheraCal LC. **Subjects and Methods:** Sample of 45 children aged from 4-8 years with deep carious one or more primary molars allocated randomly into 3 groups according to the capping material. Group I: Calcium Hydroxide (Dycal). Group II: Resin Modified Glass Ionomer (Vitrebond) and Group III: TheraCal LC. Teeth were treated then restored with EQUIA Forte HT in one visit and evaluated clinically and radiographically after three and six months. **Results:** The overall clinical and radiographic success rates were (88.2%) for Dycal group, (94.1%) for Vitrebond group and (100%) for TheraCal LC group. Results showed no statistically significant difference between groups in the overall clinical and radiographic success at 3 and 6 months. **Conclusions:** The indirect pulp treatment may be considered an appropriate procedure when applied on deeply carious primary teeth without irreversible pulpitis to achieve acceptable therapeutic results.

### INTRODUCTION

Dentistry has shifted from the surgical model towards caries elimination, to provide a space for minimal intervention in the control and management of dental caries, abolishing the cariogenic process and alleviating the symptoms <sup>(1)</sup>.

In modern endodontics, tissues preservation is of prime importance, where vital pulp therapy is less technically effortful and more biologically

### KEYWORDS

Indirect pulp treatment,  
primary molars, Dycal,  
Vitrebond, TheraCal LC

1. Assistant Lecturer of Pedodontics and Oral Health, Faculty of Dental Medicine for Girls, Al -Azhar University, Cairo, Egypt
2. Professor of Pedodontics and Oral Health, Faculty of Dental Medicine for Boys, Al-Azhar University, Cairo, Egypt.
3. Assistant Professor of Pedodontics and Oral Health, Head of Pedodontics and Oral Health Department, Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt.

\* Corresponding author email: [ayasalem603@gmail.com](mailto:ayasalem603@gmail.com)  
[ayasalem.26@azhar.edu.eg](mailto:ayasalem.26@azhar.edu.eg)

accepted including indirect pulp treatment (IPT), direct pulp capping, and pulpotomy <sup>(2)</sup>.

Indirect pulp capping has been suggested as a conservative pulp therapy for hundreds of years. Indirect pulp capping (IPC) was alternated by indirect pulp treatment (IPT) and described as "removal of the non-remineralizable caries and a thin layer of caries is left at the deepest parts of the cavity, as complete removal of caries would result in pulp exposure <sup>(3)</sup>.

Many materials have been used and tested in indirect pulp treatment (IPT) for primary and permanent teeth. Calcium hydroxide (CH) has formally been the material of choice for IPT because of its alkaline biocompatible properties and the induction of reparative dentin. However, researchers have tried to find alternative materials because of the occurrence of resorption and other symptoms after long follow-up periods. Resin-modified glass ionomer (RMGI) liners were introduced to overcome the drawbacks of calcium hydroxide <sup>(4)</sup>.

Vitrebond is a light cured resin modified glass ionomer liner/base material. The RMGI liners have high antimicrobial effect against cariogenic bacteria suggesting that when applied on affected dentine, may results in reduction or elimination of residual microbes. RMGI liners have better mechanical and physical properties than those of CH, in addition to the biocompatibility when used in deep cavities <sup>(5)</sup>.

A systematic review was conducted to analyze the effects of CH and RMGI on the clinical and radiographic outcomes. The RMGI cement had the lowest percentage of failures while CH had the highest percentage <sup>(6)</sup>.

TheraCal LC is a light cured, resin modified calcium silicate filled liner used for use direct and indirect pulp capping, as a protective base/liner under composites, amalgams, cements, and other base materials. TheraCal LC formulation consists of tricalcium silicate particles in a hydrophilic monomer which provides high calcium release

making it a special, reliable and durable liner or base material <sup>(7)</sup>. TheraCal LC has the potential to induce reparative dentin (and dentin bridge formation) when used in the direct and indirect pulp capping procedures <sup>(8)</sup>.

Thus this study was held to compare between calcium hydroxide, Vitrebond and TheraCal LC as an IPT material in primary molars both clinically and radiographically.

## MATERIALS AND METHODS

### Study design

This patient-randomized controlled trial was conducted in the outpatient clinic of Pedodontics Department, Faculty of Dental Medicine for Girls, Al-Azhar University.

Research Ethics Committee approval with code (REC-PE-21-06) was obtained from Faculty of Dental Medicine for Girls, Al-Azhar University.

Full details of procedures, possible discomfort and benefits of this study were explained to the parents and informed written consents were signed prior to children enrollment in the study.

### Sample calculation

Assuming an alpha ( $\alpha$ ) level of (5%) and Beta ( $\beta$ ) level of (20%) i.e. power = 80%; the minimum estimated sample size was 17 subjects per group for a total of 51 samples. To compensate for drop-outs, the sample size was increased by 15%. Then, the minimum estimated sample size will be 20 subjects per group. Sample size calculation was performed using IBM® SPSS® SamplePower® Release 3.0.1

### Subject Selection

A total of 60 healthy children ranging from 4 -8 years old of both sexes and their parents, were asked to join to the present study after fulfillment of the following inclusion criteria: <sup>(9)</sup>

**Clinically:** presence of at least one primary molar with deep carious lesion extending on radiographic examination to more than one half of the dentin with normal appearance of gingiva and normal mobility (vital teeth).

**Radiographically:** absence of radiolucent lesions at furcation or periapical region or external or internal resorption. Root length is not a factor in the selection criteria.

Every patient was not necessarily subjected to the three tested materials.

### Clinical and radiographic examination

Before treatment, detailed medical and dental histories were obtained then clinical and radiographic examinations were done. Patient information was collected and recorded in the patient examination chart. Preoperative radiographic assessment was done by digital periapical radiographs.

### Randomization and Blinding Procedures

Following consent, participants were sequentially randomized, using a computer-generated random number list. The randomly generated sequence was enclosed in sealed envelopes to ensure the allocation concealment. The envelopes were randomly picked up by the children for group allocation. Follow up evaluations were carried out by a calibrated examiner who was not participant in the treatment procedures. There was no blinding.

### Study Groups

The sixty primary molars were randomly and equally divided into three groups as follow:

Group I: Included 20 teeth assigned for Dycal.

Group II: Included 20 teeth assigned for Vitrebond.

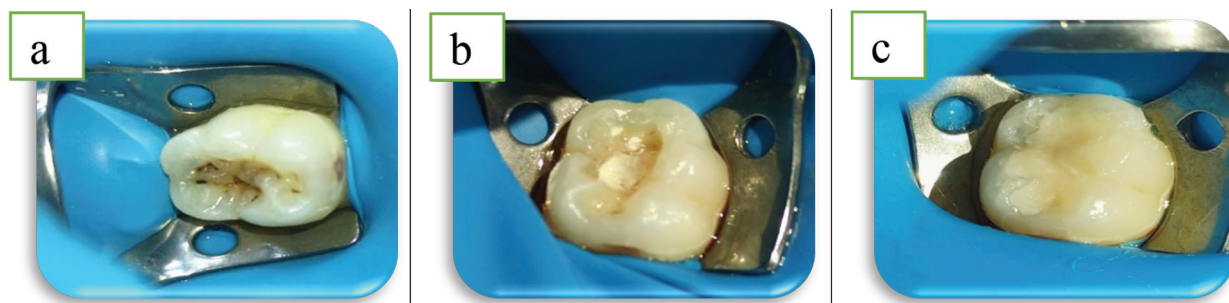
Group III: Included 20 teeth assigned for Theracal LC.

### Operative procedure: <sup>(10)</sup>

1. Application of topical anaesthesia then injection of local anaesthesia whether infiltration or inferior alveolar nerve block.
2. Rubber dam isolation.
3. Caries removal you starting with sterile high-speed bur with copious water coolant followed by low-speed bur then sharp excavator gently.
4. Removal of all carious dentin on the peripheral walls and over dentino-enamel junction except that over pulp to avoid exposure.
5. If the shadow of the pulp appeared, profuse bleeding or exposure occurred, the tooth was excluded and pulpotomy was done.
6. Application of tested capping material.

### Group I, Figure 1:

Application of Dycal, after mixing equal quantities of both base and catalyst paste to a homogeneous mix. Then this mix was applied to the deep sites using small ball burnisher, leaving it to dry before applying the final restoration.



Figure(1) a) Preoperative photo; b) After caries removal and application of Dycal; c) postoperative photo.

**Group II, Figure 2:**

Application of Vitrebond after mixing the powder and liquid to a homogeneous mix, this mix was applied to the deep site using small ball burnisher, then polymerized using light cure for 30 seconds according to manufacturer's instructions.

**Group III, Figure 3:**

Application of TheraCal LC directly from the syringe to the deep site of the cavity at a maximum thickness of 1 mm and was light cured for 20 seconds according to manufacturer's instructions.

1. Final restoration was done in the same visit with high viscous glass ionomer (Equia Forte HT).
2. Removing of rubber dam and removing of high spots using articulating paper. Finishing and polishing of the restoration with finishing stones was done after 24 hours.
3. Post-operative intraoral photograph and a baseline radiograph were taken.

**Follow Up**

Recalling of children for clinical and radiographic evaluation was after 3 and 6 months. The data was recorded in an evaluation chart. The outcomes were determined by the following criteria <sup>(11)</sup>:

**Clinical evaluation criteria**

Teeth showing the following criteria were considered as successful: absence of spontaneous pain, absence of swelling of pulpal origin, no fistula formation, and absence of abnormal tooth mobility.

**Radiographic evaluation criteria**

Teeth showing the following criteria were considered as successful: absence of pathological internal or external root resorption, no furcation involvement, no widening of periodontal membrane space and absence of periapical radiolucency.

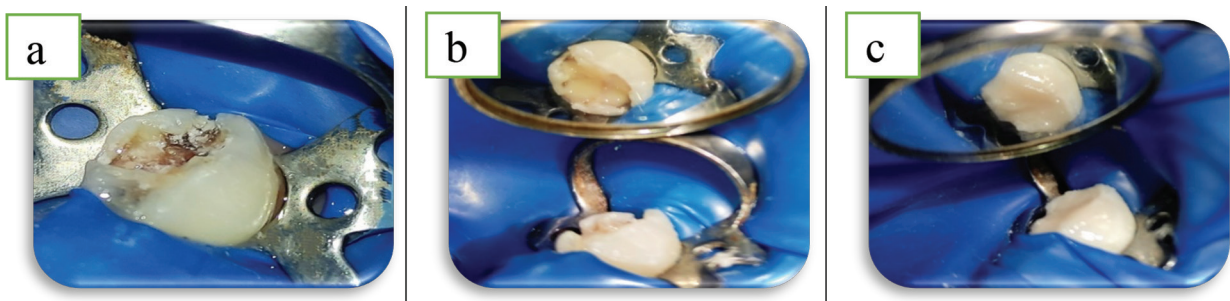


Figure (2) a) Preoperative photo; b) After caries removal and application of Vitrebond; c) postoperative photo.



Figure (3) a) Preoperative photo; b) After caries removal and application of TheraCal LC; c) postoperative photo.

## RESULTS

### Statistical analysis

Statistical analysis was performed using SPSS program. Values were presented as number and percentage. Chi square test was used for comparisons. The level of significance was set at  $P \leq 0.05$ .

### Clinical and radiographic results within the same group

Group I (Dycal) regarding the clinical evaluation, immediately after treatment all clinical signs of failure were absent (100%). At 3 months, one case (5.3%) revealed pain and swelling. At 6 months, 2 cases (11.8%) revealed pain, swelling, sinus tract and abnormal tooth mobility. Regarding the radiographic evaluation, all signs of failure were absent immediately after treatment (100%). At 3 months one case (5.3%) revealed widening in periodontal membrane space and furcation radiolucency. At 6 months 2 cases (11.8%) revealed widening in periodontal membrane space and furcation radiolucency.

Group II (Vitrebond) regarding the clinical evaluation, all clinical signs of failure were absent (100%) immediately after treatment and at 3 and 6 months. Regarding the radiographic evaluation, all signs of failure were absent immediately after treatment and at 3 months (100%). At 6 months, 1

case (5.9%) had revealed widening of periodontal membrane space. The difference by time was not statistically significant.

Group III Theracal LC regarding the clinical evaluation, all clinical signs of failure were absent (100%) immediately after treatment and at 3 and 6 months. Regarding the radiographic evaluation, all signs of failure were absent immediately after treatment and at 3 months and 6 months (100%).

### Overall clinical and radiographic results

Overall clinical and radiographic results are summarized in (Table 1) and (Figure 4).

Immediately after treatment, clinical and radiographic failure were absent in all groups.

After 3 months, one case (5.3%) in Group I (Dycal) had clinical and radiographic failure, in comparison to 100% success in group II (Vitrebond) and group III (TheraCal LC). This difference was not statistically significant ( $p=0.612$ )

After 6 months, 2 cases (11.8%) of Group I (Dycal) had clinical and/or radiographic failure, in comparison to one case (5.9%) in group II, while all cases (100%) of group III (TheraCal) showed clinical and radiographic success. This difference didn't reach the level of statistical significance ( $p=0.329$ ).

**Table (1)** Descriptive statistics and comparison of frequency of overall clinical and radiographic failure between groups at each observation time and within the same group by time (Chi square test)

|                            | Group I             |                | Group II        |                | Group III       |                | X <sup>2</sup> | P (between groups) |
|----------------------------|---------------------|----------------|-----------------|----------------|-----------------|----------------|----------------|--------------------|
|                            | Present<br>n(%)     | Absent<br>n(%) | Present<br>n(%) | Absent<br>n(%) | Present<br>n(%) | Absent<br>n(%) |                |                    |
| <b>Immediate after ttt</b> | 0 (0)               | 20 (100)       | 0 (0)           | 20 (100)       | 0 (0)           | 20 (100)       | 0              | 1 <sup>ns</sup>    |
| <b>3 months</b>            | 1 (5.3%)            | 18 (94.7%)     | 0 (0)           | 18 (100%)      | 0 (0%)          | 19 (100%)      | 0.98           | 0.612 ns           |
| <b>6 months</b>            | 2 (11.8%)           | 15 (88.2%)     | 1 (5.9%)        | 16 (94.1%)     | 0 (0)           | 18(100)        | 2.23           | 0.329ns            |
| <b>X<sup>2</sup></b>       | 2.51                |                | 2.28            |                | 0               |                |                |                    |
| <b>P (within groups)</b>   | 0.285 <sup>ns</sup> |                | 0.32 ns         |                | 1 ns            |                |                |                    |

Significance level  $p \leq 0.05$ , \*significant, ns=non-significant.

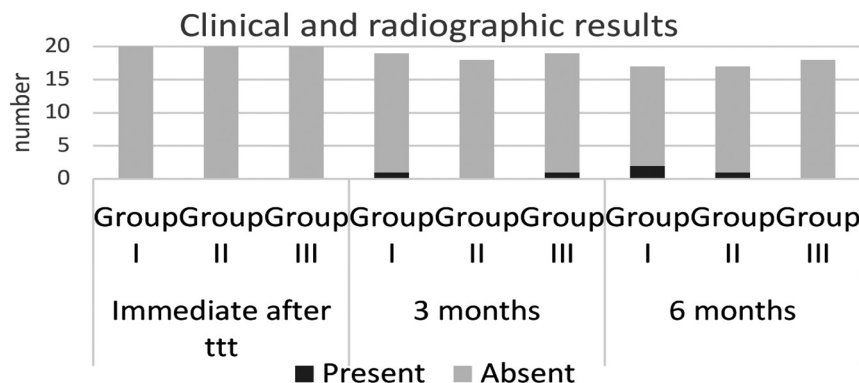


Figure (4) Bar chart illustrating frequency of overall clinical and radiographic failure in different groups at different observation times

## DISCUSSION

The main purpose of indirect pulp treatment is to preserve teeth vitality with reversible pulp injury. The conventional technique for this procedure utilizes two steps for the elimination of bacteria from carious dentin left after partial caries removal, application of antibacterial agent such as CH, and good marginal seal of the cavity by the restoration <sup>(12)</sup>.

IPT has many merits than pulpotomy when treating teeth with reversible pulpitis, as avoidance of pulp exposure by leaving the most deep carious layer in place, lower cost, higher success rate and normal exfoliation pattern <sup>(13)</sup>.

Patients were selected with an age range of 5 to 8 years old irrespective of their sex to obtain good patient cooperation which may be absent in younger age group. This age range also gives more accurate results due to the relative stability and maturation which extends from complete root formation to clinically detectable resorption, and where the maturing pulp has a strong dentinogenetic and repair potential <sup>(9)</sup>.

The primary tooth has a defined biological cycle in the oral cavity; hence the technique suggests that it is not necessary to reopen the tooth after indirect pulp capping. The success of the present study suggest that indirect pulp capping performed in one appointment, is viable in the primary dentition <sup>(3)</sup>.

Following any vital pulp treatment, the objective is that the restorative material should completely seal the involved dentine from the oral environment <sup>(11)</sup>. EQUIA Forte HT is a long-term bulk fill restorative system with enhanced mechanical properties, superior fluoride release, sound marginal seal and excellent handling <sup>(1)</sup>. This makes EQUIA Forte HT an ideal final restoration.

*The results of the present study showed that:*

Group I (Dycal), the overall clinical and radiographic success was 88.2% at 6 months. This is in agreement with previous studies <sup>(14, 15)</sup> that reported 84.6% and 82% success rate at 6 months respectively.

Higher calcium hydroxide success rate reported <sup>(16)</sup> and recorded 100% success rate at 6 months which may be resulted from the use of light-activated calcium hydroxide, while in contrast lower rate was recorded <sup>(17)</sup> and showed 73.3% which may be due to the lengthy four years follow up.

Group II (Vitrebond), the overall clinical and radiographic success was 94.2% at 6 months. This is in agreement with recent studies <sup>(18, 19)</sup> that reported 93% and 96.5% success rate respectively. But disagree with a previous study <sup>(20)</sup>, that recorded 88.8% success rate only, which may be due to the longer 48 months follow up.

Group III Theracal LC, the overall clinical and radiographic success was 100% at 6 months. This is in disagreement with a previous study<sup>(14)</sup> that showed 87.8% success rate, which may be due to larger sample size.

In this study, there were no statistically significant differences between success rates of the Dycal, Vitrebond and TheraCal LC materials. However, the success rate of the TheraCal LC (TheraCal LC=100%, Vitrebond =94.1 % and Dycal =88.2%) was found to be higher than those of other materials. This was in accordance with study<sup>(21)</sup> that compared between RMGI and Dycal, and with the study<sup>(14)</sup> which compared Theracal and Dycal without statistical significant differences between them.

## CONCLUSIONS

Taking in consideration the limitations of the present study, it was concluded that: The indirect pulp treatment may be considered an appropriate procedure when applied on deeply carious primary teeth without irreversible pulpitis to achieve acceptable therapeutic results. IPT with partial caries removal didn't result in caries progression either clinically or radiographically. Theracal LC showed higher success rate in IPT followed by Vitrebond and Dycal that was not statistically significant different.

## RECOMMENDATIONS

Further clinical, radiographic and histological in vivo studies with larger sample size and longer follow up periods are required to evaluate the role of these materials in primary teeth IPT.

## CONFLICT OF INTEREST

No conflict of interest.

## FUNDING

No funding was received for this study.

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