CLINICAL AND RADIOGRAPHIC EVALUATION OF INDIRECT PULP TREATMENT USING LIGHT CURED RESIN MODIFIED CALCIUM SILICATE COMPARED TO LIGHT CURED CALCIUM HYDROXIDE IN SECOND PRIMARY MOLARS: RANDOMIZED CLINICAL TRIAL

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Abstract

Aim: The aim of the current study was clinical and radiographic evaluation of indirect pulp treatment using light cured resin modified calcium silicate compared to light cured calcium hydroxide in second primary molars.

Material and methods: This study was conducted on (46) children with deep class I carious lesions in second primary molars, that were randomly allocated to either resin modified calcium silicate (Theracal LC) and light cured calcium hydroxide (Calcimol LC) groups (n=23). After cavity preparation, deep carious lesions were managed using indirect pulp treatment technique followed by placement of bulk fill resin composite as a final restoration. Clinical assessment was conducted after 3, 6, 9 and 12 months, while radiographic assessment was conducted after 6, and 12 months postoperative by two blinded assessors. Statistical analysis was done with statistical significance level set at ($P \leq 0.05$).

Results: There was no statistical or clinical significant difference between either two materials for all assessed clinical and radiographic parameters at all follow-up periods different follow-up periods. The overall success rate of resin modified calcium silicate (Theracal LC) was 100% and the overall success rate of light cured calcium hydroxide (Calcimol LC) was 95.65% after 12 months.

Conclusions: Indirect pulp treatment is a successful technique for treating deep caries in primary teeth with normal or reversibly inflamed pulps. Both light cured calcium hydroxide and light cured calcium silicates can be used successfully as indirect pulp capping agents in primary teeth. Indirect pulp treatment is not a material dependent technique.

Keywords: Calcium silicates; calcium hydroxide; IPT; primary; pulp capping; vital pulp therapy

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1. INTRODUCTION

Dental caries is still one of the most common health issues among children in most nations. It is becoming increasingly clear that the condition and its associated therapy may impose a significant burden on the kid and parents, with a severe impact on overall quality of life. Managing dental decay, particularly in young children, poses unique challenges to clinicians who are responsible for providing effective and evidence-based therapy to their pediatric patients. [1-3]

Historically, dental caries was thought to be an infectious disease, so treatment was based on the principle that all infected carious tooth tissue needed to be removed to stop caries progression. In view of recent improvements in cariology, the therapy of dental caries has shifted from non-selective, complete removal of affected tissue to more minimally invasive methods. Furthermore, there are several limitations to using traditional non-selective methods for carious lesion management. Elimination of demineralized but structurally intact dentine weakens the tooth structure and raises the danger of pulpal exposure. Using traditional procedures is also connected with higher pain and irritation, which may cause dental anxiety and prevent subsequent dental appointments. [4]

The American Academy of Pediatric Dentistry5 recommends pulpotomy and indirect pulp treatment (IPT) for the management of deep carious lesions near the pulp in primary teeth. The indications for IPT and pulpotomy for deep caries in primary teeth are same; either for reversible pulpitis or teeth with a normal pulp based on clinical and radiographic assessment. The key difference arises when the caries removal technique exposes the pulp, necessitating a pulpotomy. IPT avoids exposure by keeping the deepest layer of decay in place. The fundamental goal of both techniques is to keep the pulp viable without clinical or radiological evidence of failure. [6]

In recent years, selective caries removal or indirect pulp treatment (IPT), which is a minimally invasive method to treat deep caries, has become more common in pediatric dentistry. This method of treatment is less invasive than traditional methods, less expensive, and takes less time. It may also be more appealing to children and easier for both cooperative and uncooperative groups of children to accept. It also works better at treating reversible pulpitis than pulpotomy, which is why it has been getting more attention lately. [7]

Although current evidence suggests that less invasive strategies are effective for managing carious lesions, the literature is lacking in identifying the ideal liner material to be used on the remaining dentin in selective caries removal in primary teeth. The goal of utilizing an indirect pulp capping material is to stimulate the creation of a dentine bridge and tertiary dentine in order to protect pulp tissues from thermal and electrical stimuli, as well as the chemical compounds leached out from adhesive systems. Clear clinical recommendations on which liner material should be used following selective caries removal are still required. [8]

Calcium hydroxide was introduced into dentistry about a century ago and has long been regarded as the "gold standard" of pulp-capping materials because to its alkalinity, biocompatibility, and ability to induce pulp-dentine remineralization and prevent bacterial infection. Furthermore, calcium hydroxide has one of the highest clinical success rates and long-term follow-up rates as a pulp capping agent after various periods of up to ten years. Calcium hydroxide, on the other hand, is not conclusive; self-cure formulas are very soluble and can dissolve over time. Furthermore, it has no inherent adhesive qualities and provides a poor seal. Another issue with this material is the formation of "tunnel defects" in reparative dentin produced underneath calcium hydroxide pulp capping. [9]

To mitigate the drawbacks of self-cure formulations, light-curable, resin-modified calcium hydroxide materials were developed. They have the following benefits: command setting, better mechanical characteristics, resistance to acid solubility, limited water solubility, and effective bonding with the subsequent composite restoration. However, many authors have reported that the degree of calcium ion release and antimicrobial properties for light-curable calcium hydroxide is lower than that of self-cure formulations. [10, 11]

As a result, alternative capping materials with a biologic potential to stimulate dentin development were required to be developed. MTA (mineral trioxide aggregate) is a bioactive calcium silicate-based cement that has been shown to be superior to calcium hydroxide for pulp capping of human teeth. However, there are some limitations to using conventional MTA due to poor manipulation, long setting times, high cost, and tooth discoloration. [12]

These disadvantages were overcome by the development of resin modified calcium silicate (Theracal LC), which provides several advantages compared to silicate-based materials such as its easy handling, fast setting time, good antimicrobial activity, acceptable mechanical and physical properties, good bonding ability, lower solubility, improved sealing capability and is well tolerated by odontoblastic cells. Resin modified calcium silicate (Theracal LC) is available commercially as a flowable cement that can be applied with a syringe, making it easy to use. The cement can be applied directly to the operative site and light-cured for 20 seconds. All of these benefits make resin modified calcium silicate (Theracal LC) a good choice for

children who cannot withstand long appointments and may lose their cooperation over time. [13]

To our knowledge, there is limited evidence in the literature evaluating IPT using calcium hydroxide and resin modified calcium silicate in primary molars. Hence, the present study was done for clinical and radiographic evaluation of resin modified calcium silicate compared to light cured calcium hydroxide in IPT in primary molars.

2. MATERIALS AND METHODS

All materials used in the current study are described in **Table (1).**

Trial registration, study design and settings:

All procedures in the current trial were carried out in accordance with the ethical standards of the Research Ethics Committee of the Faculty of Dentistry, Cairo University (Ref. 27/6/19). Verbal consent was obtained orally from the eligible child, and written consent was signed by the child's guardian, agreeing to the clinical procedures. A protocol of the present clinical has been registered on ClinicalTrials.gov (NCT03791255). The current investigation is a randomized clinical trial using a parallel study design, a 1:1 allocation ratio, and a superiority framework. The current study was carried out in the Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry at Cairo University.

Sample size calculation:

According to a previous study 14 in which the probability of no pain for light cured calcium hydroxide (comparator) was (0.76), probability of mild pain was (0.24) with effect size w=0.52 (n=30). If the true probability of resin modified calcium silicate for postoperative pain was (0.96) for no pain, (0.04) for mild pain with effect size w= 0.92 (n=10). By adopting an alpha (α) level of 0.05 (5%), power=80%. The predicted sample size (n) was a total of (40) cases (20 for each group). Sample size was increased by (15%) to account for possible dropouts during follow-up intervals to be total of (46) cases i.e. (23 for each group). Sample size calculation was performed using G*Power 3.1.9.2.

Eligibility criteria:15

Inclusion criteria:

1. Absence of any medical or systemic conditions.
2. Age range from 4-7 years.
3. Deep carious occlusal lesion in lower second primary molars.
4. Teeth with vital normal pulps or reversibly inflamed pulps (no history of spontaneous pain).
5. Clinically: Absence of any signs of loss of vitality (swelling, sinus, fistula, pain on percussion and tooth mobility).
6. Radiographically: Absence of radiolucent lesions at furcation or periapical region and absence of internal or external root resorption, no widening of periodontal membrane space.

Exclusion criteria:

1. Patients or parents refusing to participate in the study.
2. Any unmet previous criterion.

Recruitment:

Patients were recruited from Outpatient`s Clinic of Pediatric Dentistry and Dental Public Health Department at Faculty of Dentistry, Cairo University, where there was continuous and high patient flow, to screen all children during diagnosis for their chief complain. Children with deep caries in lower second primary molars were enrolled in the current study if they met eligibility criteria and their legal guardian provided informed consent to participate. Screening of the attending children continued till the planned sample size was achieved. Consort flow diagram showing participants' flow through each stage of the current randomized clinical trial. **Figure (1)**

Allocation of participants:

A total of 46 participants were recruited in the current clinical trial using convenience sampling. Simple randomization was done using the Random Sequence Generator, Randomness and Integrity Services Ltd (https://www.random.org/). Integers from 1:46 were generated into two columns for simple randomization. Each generated random number reflected a random assignment of intervention and comparator. The operator selected a number from an opaque sealed envelope arranged by a teaching assistant who was not involved in any of the clinical trial phases. Due to a discrepancy in the application methodology, the operator was not blinded, however the patients, assessors, and statistician were all blinded to the material assignment.

Interventions:

Local anaesthesia administration and rubber dam isolation:

Each tooth was anesthetized using infiltration technique, by applying topical anesthetic gel (I-gel, Dent dental supply, USA) (20% benzocaine) at site of needle insertion for 2-3 minutes, followed by injection of local anesthesia by the use of 4% articaine (Articaine (D.C.I) 40.00mg hydrochloride, Epinephrine (D.C.I) (tartrate) 0.01mg) (Inibsa Dental S.L.U, Spain) using a short disposable needle (C-k dental ind.co., ltd, Korea) and metallic dental syringe (Bibodent, Egypt). 8 Isolation was done using rubber dam after suitable selection of rubber dam clamps (KSK dentech, Tokoyo, Japan), sheets (Sanctuary Dental Dam, Perak, Malaysia) and frame (SedraDent solutions, Cairo, Egypt).

Cavity preparation procedures:

Cavity preparation was performed with a sterile high-speed diamond round bur (Meisinger Dental Burs, GmbH, Germany) and a high-speed hand piece (CX207, COXO Medical, Foshan, China) with ample water spray revolving at 380,000-450,000 rpm. Each bur/diamond point was only utilized for a maximum of four teeth before being discarded. Throughout the procedure, a low-volume suction tip was used beneath the rubber dam, and a high-volume suction tip was used while operating the hand piece. To avoid pulp penetration, infected dentin at the dentino-enamel junction was removed with a spoon excavator (Dentsply® Maillefer, Switzerland) and remaining caries was removed with low-speed round carbide burs (Meisinger Dental Burs, GmbH, Germany) compatible with the size of the cavity. All carious dentin on the peripheral walls and margins over dentino-enamel junction was removed, except for the pulpal floor to avoid exposure. 8, 16. The operator then opened the opaque sealed envelope to identify the assignment of interventions.

Indirect pulp capping:

Resin modified calcium silicate (TheraCal LC) (BISCO Inc., Schamburg, IL, USA)

Resin modified calcium silicate (TheraCal LC) was applied in layers of 1 mm or less on the clean, visibly moist, deep pulpal floor, followed by light curing for 20 seconds using an LED light curing device (LED F, Guilin Woodpecker Instruments Co., Guilin, Guangxi, P.R.China) of an intensity 1600-1800 mW/cm2 according to manufacturer's instructions. 6

Light cured calcium hydroxide (Calcimol LC) (Voco GmbH, Cuxhaven, Germany)

Light cured calcium hydroxide (Calcimol LC) was applied on the clean, dry, deep pulpal floor in layers of 1 mm or less, followed by light curing using LED light curing device (LED F, Guilin Woodpecker Instruments Co., Guilin, Guangxi, P.R.China) of an intensity 1600-1800 mW/cm2 according to manufacturer's instructions for 20 seconds. 16

Final restoration placement:

Selective enamel etching was done using (Select HV Etch, BISCO Inc., Schamburg, IL, USA) for 15 seconds, followed by rinsing for 15 seconds then gentle air dryness according to manufacturer`s instructions. Universal adhesive system (All-Bond Universal, BISCO Inc., Schamburg, IL, USA) was applied to both enamel and dentin using microbrush (TPC, Advance Technology, China) and scrubbed for 10-15 seconds. The excess solvent was evaporated thoroughly by gentle air-drying using air syringe for 10 seconds until no visible movement of the adhesive was observed. The adhesive layer was then light cured for 10 seconds using LED light curing device (LED F, Guilin Woodpecker Instruments Co., Guilin, Guangxi, P.R.China) of an intensity 1600-1800 mW/cm2.

The resin composite (Reveal® HD Bulk, BISCO Inc., Schamburg, IL, USA) was used for the final restoration; the material was applied in bulk and light cured for 20 seconds. The restorations were contoured and finished using a high-speed hand piece and water coolant utilizing a yellow-coded finishing flame stone (No.888, ISO 496, SS White, New Jersey, USA). Occlusion was assessed using a 35-micron double-sided articulating paper (Accufilm II, Parkell Inc., New York, USA), and premature contacts were eliminated. Polishing was performed with pre-impregnated rubber cups and intermittent water spray (Shofu Dental Corporation, California, USA).

Immediate post operative radiograph:

Standardized postoperative periapical radiographs were taken using sensor size 1 (KaVo, Tuusula, Finland) and Sordex X-ray machine (Acteon Group, X-mind DC, Rome, Italy) with the following exposure parameters 70 kVp, 7 mA and 0.05 second exposure time and Digora Software for windows through Digora Optime system as a baseline record using acrylic radiographic stent attached to Rinn XCP film holder and held upright for the paralleling technique. 8

Outcome assessment:

Clinical assessment was done at baseline, 3, 6, 9 and 12 months, while radiographic assessment was done at baseline, 6, and 12 months by two blinded assessors, in case both assessors differ in score, they discussed till reaching for a consensus. Outcomes were described in **Table (2).**

STATISTICAL ANALYSIS:

Data was analyzed using Medcalc software, version 19 for windows (MedCalc Software Ltd, Ostend, Belgium). Categorical data was described as frequency and percentage, intergroup comparison between interventions was performed using the Chi-Squared test, while intragroup comparison within each intervention was performed using the Cochran's-Q test followed by multiple pairwise comparisons, with statistical significance level set at ($P \leq 0.05$). Relative risk was used to assess the clinical significance. The confidence limit was set at 95% with 80% power and all tests were two tailed. [17].

3. RESULTS

Demographic data:

The current study was conducted on (46) children with class 1 deep carious lesions that were randomly allocated to the intervention and the comparator arms (n=23). After 12 months 46 participants completed the follow-up with 100 % retention rate. Mean age of the participants in the current trial was 5.4±0.7 years;

mean age within intervention group was 5.5±0.7 years, while within the comparator group mean age was 5.4±0.8 years, there was no statistically significant difference between both groups regarding age (P=0.715). Regarding gender, there were 24 boys and 22 girls in the current study, in the resin modified calcium silicate (Theracal LC) group there was 11 boys and 12 girls, while in the light cured calcium hydroxide (Calcimol LC) group there were 13 boys and 10 girls, there was no statistically significant difference between both groups regarding gender (P=0.5593)

Clinical evaluation:

The clinical success rate of both materials was 100% after 12 months with no clinical failures. There was no risk for clinical failure for resin modified calcium silicate (Theracal LC) when compared to light cured calcium hydroxide (Calcimol LC) after 12 months (RR= 1.0000 (95% 0.02067 to 48.3735; P = 1.0000))

Radiographic evaluation:

The radiographic success rate of resin modified calcium silicate (Theracal LC) was 100% after 12 months, while the success rate for light cured calcium hydroxide (Calcimol LC) was 95.65% with one tooth suffering from radiographic failure due to widening in the periodontal membrane space after 6 and 12 months. There was 66.6% less risk for radiographic failure for resin modified calcium silicate (Theracal LC) when compared to light cured calcium hydroxide (Calcimol LC) after 12 months (RR= 0.3333 (95% 0.01428 to 7.7807; P = 0.4943))

Frequency and percentage for clinical and radiographic evaluation scores for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods is shown in table (3).

Table (1): Materials used in the current study.

Material	Composition	Manufacturer	LOT#
TheraCal (LC)	Portland cement type III (30–50%), polyethelyene glycol dimethacrylate (10–30%), and barium zirconate (1–10%).	BISCO Inc., Schamburg , IL, USA	2100001486
Calcimol LC®	urethane dimethacrylate resin, calcium dihydroxide, dimethylaminoethyl-methacrylate, and triethyleneglycol dimethacrylate (TEGDMA).	(Voco GmbH, Cuxhaven, Germany	2129428
Select HV Etch	35% phosphoric etch available with Benzalkonium Chloride (BAC).	BISCO Inc., Schamburg , IL, USA	2100001026
All-Bond Universal	10-MDP, HEMA, BPDM, Ethanol, Bis-GMA, water, initiators.	BISCO Inc., Schamburg , IL, USA	1700005544
Reveal® HD Bulk	Ytterbium Fluoride, Urethane Dimethacrylate, BisGMA, 3-(Trimethoxysilyl) propyl-2-Methyl-2-Propenoic Acid, Tert-butyl Perbenzoate	BISCO Inc., Schamburg , IL, USA	2000007944

Table (2): Outcomes

Evaluation	Outcome	Tool/device	Unit
Clinical	Postoperative pain	Visual analogue scale [14]	Ordinal • No Pain • Mild • Moderate • Severe
	Swelling	Visual examination by the operator [26]	Binary • Yes • No
	Sinus or fistula		
	Tooth mobility	Mobility and percussion test using back of the mirror [35]	
	Pain on percussion		
Radiographic	Occurrence of radiolucent lesion at furcation or periapical region	Radiographic examination using standardized digital periapical radiograph by parallel technique using bite blocks and film holders [26]	
	Widening in the periodontal membrane space		

	Presence of internal or external root resorption.		

Table (3): Frequency and percentage for clinical and radiographic evaluation scores for the intergroup comparison between materials within each follow-up and intragroup comparison within each material between different follow-up periods

Clinical evaluation									
Postoperative pain									
Follow-up	**Theracal LC**				**Calcimol LC**				**P value**
	No pain	**Mild**	**Moderate**	**Severe**	**No pain**	**Mild**	**Moderate**	**Severe**	
Baseline	23 (100%)	0 (0%)	0 (0%)	0 (0%)	23 (100%)	0 (0%)	0 (0%)	0 (0%)	P = 1.0000
3 months	23 (100%)	0 (0%)	0 (0%)	0 (0%)	23 (100%)	0 (0%)	0 (0%)	0 (0%)	P = 1.0000
6 months	23 (100%)	0 (0%)	0 (0%)	0 (0%)	23 (100%)	0 (0%)	0 (0%)	0 (0%)	P = 1.0000
9 months	23 (100%)	0 (0%)	0 (0%)	0 (0%)	23 (100%)	0 (0%)	0 (0%)	0 (0%)	P = 1.0000
12 months	23 (100%)	0 (0%)	0 (0%)	0 (0%)	23 (100%)	0 (0%)	0 (0%)	0 (0%)	P = 1.0000
P value	P = 1.0000				P = 1.0000				RR= 1.0000
Swelling, Sinus or fistula, Tooth mobility, Pain on percussion									
Follow-up	**Theracal LC**				**Calcimol LC**				**P value**
	No	**Yes**			**No**	**Yes**			
Baseline	23 (100%)	0 (0%)			23 (100%)	0 (0%)			P = 1.0000
3 months	23 (100%)	0 (0%)			23 (100%)	0 (0%)			P = 1.0000
6 months	23 (100%)	0 (0%)			23 (100%)	0 (0%)			P = 1.0000
9 months	23 (100%)	0 (0%)			23 (100%)	0 (0%)			P = 1.0000
12 months	23 (100%)	0 (0%)			23 (100%)	0 (0%)			P = 1.0000
P value	P = 1.0000				P = 1.0000				RR= 1.0000
Radiographic evaluation									
Occurrence of radiolucent lesion at furcation or periapical region and Presence of internal or external root resorption									
Follow-up	**Theracal LC**				**Calcimol LC**				**P value**
	No	**Yes**			**No**	**Yes**			
Baseline	23 (100%)	0 (0%)			23 (100%)	0 (0%)			P = 1.0000
6 months	23 (100%)	0 (0%)			23 (100%)	0 (0%)			P = 1.0000
12 months	23 (100%)	0 (0%)			23 (100%)	0 (0%)			P = 1.0000
P value	P = 1.0000				P = 1.0000				RR= 1.0000
Widening in the periodontal membrane space									
Follow-up	**Theracal LC**				**Calcimol LC**				**P value**
	No	**Yes**			**No**	**Yes**			
Baseline	23 (100%)	0 (0%)			23 (100%)	0 (0%)			P = 1.0000
6 months	23 (100%)	0 (0%)			22 (95.65%)	1 (4.35%)			P = 0.3173
12 months	23 (100%)	0 (0%)			22 (95.65%)	1 (4.35%)			P = 0.3173
P value	P = 1.0000				P = 0.368				RR= 0.3333

4. DISCUSSION

Dental caries in primary teeth is a significant oral health issue that affects a considerable proportion of the world's young population today. The preservation of deciduous teeth until exfoliation is an important objective in pediatric dentistry for preventing cosmetic, phonetic, and functional difficulties, as well as preserving space for the eruption of permanent successors. Primary tooth decay can range from enamel demineralization to partial tooth structural loss to full crown mutilation. Treatment options for deep carious lesions approximating the pulp that do not show symptoms of loss of vitality include indirect pulp capping, direct pulp capping, and pulpotomy. 9, 18

Recent approaches in the treatment of deep carious lesions are aimed at preserving pulp vitality and increasing strength of the tooth. Moreover, the avoidance of pulpal exposure in the treatment of teeth with symptom-free deep carious lesions contributes to long-term maintenance of pulp vitality and restorative success without requiring high cost, painful, and invasive endodontic treatments. Therefore, indirect pulp treatment was the treatment of choice in the current study. 19

Furthermore, IPT has also become popular over the last years in the management of deep carious lesions in addition to conventional approaches that require complete removal of the caries. In particular, IPT has

gained remarkable attention in pediatric dentistry, mainly because children require a fast and accurate treatment and on the other hand, IPT enables the affected primary tooth to be preserved until exfoliation without causing any pain or infection, IPT was also reported to have a higher success rate than pulpotomy and DPC as stated by AAPD latest guidelines. 5, 6

Calcium hydroxide was selected as the pulp capping agent in the control group as it is considered the gold standard for pulp capping. It enables successful maintenance of pulp vitality, allows the formation of reparative dentin through cellular differentiation, extracellular matrix formation, and subsequent mineralization. Furthermore, it protects the pulp against thermoelectrical stimuli as well as antimicrobial action. 14

However, in long term clinical studies the chemically cured calcium hydroxide showed increased failure rates. This was attributed to its high solubility, gradual degradation and tunnel defects in the newly formed dentine bridge that makes it fail to provide a permanent barrier and a long-term biological seal against bacterial infection, therefore light cured calcium hydroxide was selected in the current study as it was introduced In an attempt to control the limitations of the chemically cured one, as it has the following advantages, on command setting, improved mechanical properties, no acid solubility, and minimal solubility in water and successful bonding with the overlaying composites. 20

On the other hand, it was reported that the degree of calcium ion release, combined with definite antimicrobial properties for light-cured calcium hydroxide is lower than that of the chemical cured forms of calcium hydroxide. 16

Resin modified calcium silicate (Theracal LC) which is a new class of materials called light-cured resin-modified calcium silicate was selected as an indirect pulp capping agent in the intervention group because it combines the regenerative and antibacterial properties of calcium silicates beside its attractiveness for clinicians, because of its ease of handling and on demand setting, it requires no conditioning for the dentine surface and it can be bonded with different types of adhesives directly after application. More importantly, literature suggests that mechanical properties of TheraCal were far superior to other pulp capping materials, especially calcium hydroxides. Porosity, water sorption and solubility were least seen with Theracal as compared to other pulp capping materials. 21

In the present study, eligibility criteria were in alignment with the 15 guidelines which recommends performing IPT to molars judged clinically and radiographically to have healthy pulp or pulp with reversible pulpitis and excludes those which are judged clinically or radiographically to have irreversibly damaged pulps. Choosing teeth with healthy or reversibly inflamed pulps is a key element in the success of any IPT as this guarantee having healthy odontoblasts capable of tertiary dentin deposition. 6

Primary lower second molars were chosen for this study in accordance with previous clinical trials, 22-24 they reported that the second primary molar has higher successful treatment outcomes than the first primary molar. They related the higher success rate associated with second primary molar to its larger-sized pulp chamber and potentially more progenitor cells, further possibilities would be that second primary molar erupt later than the first primary molar in a child's life, making the latter more prone to the mastication and chemical insults associated with dietary intake.

Only mandibular molars are included in the present study. Exclusion of maxillary molars comes in accordance with 25 who stated that anatomical barriers like hard palate prevent the proper use of parallel radiographic imaging in addition to the overlapping anatomy and overlapping permanent tooth buds in the maxilla which could complicate radiographic diagnosis and evaluation of abnormalities.

Indirect Pulp Treatment in primary molars could be followed up until one year, as most of failures were observed during the first year of clinical and radiographic follow-up. Moreover, IPT in primary teeth exhibited favorable characteristics of color, consistency, and reduced bacterial contamination of the remaining dentin three to six months after the procedure. 16, 26, 27 Therefore, in the present study, one year was a suitable follow up period for such a treatment modality. 6, 8, 16, 28, 29

Radiographic examination was conducted using intraoral periapical radiograph as it is considered as the most reliable method for detection and long term assessment of periapical and furcation pathologies in preoperative, postoperative and follow up appointments as denoted by 30, immediate postoperative radiograph was taken as a baseline record that was used for comparison in the subsequent follow up visits, postoperative radiographs were taken at 6 months and 12 months follow up periods to check and inspect any changes at periapical and furcal area, clinical assessment was done at 3,6,9,12 follow up periods while radiographic assessment was done at 6 and 12 months follow up period to avoid exposure of the children to excess unnecessary doses of x-rays. 6

Regarding the demographic data of the present study there was no statistically significant difference between both groups regarding gender (P=0.5593) and age (P=0.715) this was in alignment with 6, 10. Matching of potential confounders between the two groups enhanced causality in current trial this means

that there is cause to effect relationship between interventions and outcomes. 31

Regarding the clinical outcomes of this study the overall clinical success rate for both groups was 100%, Intergroup comparison between both materials in postoperative pain, swelling, development of sinus or fistula, pain on percussion and mobility have shown no statistically significant difference within different follow up periods (P = 1.0000), this was in accordance with previous results 6, 10 who found no statistically significant difference between resin modified calcium silicate (Theracal LC) group and calcium hydroxide group regarding the clinical outcomes.

Intragroup comparison within intervention group have shown no statistically significant difference between different follow-up periods (P = 1.0000) this was in accordance with previous results 6, 10, similarly intragroup comparison within control group have shown no statistically significant difference between different follow-up periods (P = 1.0000) these results were in alignment with previous trials. 6, 8, 10, 16, 28, 29, 32-34

Regarding the radiographic outcomes of this study the overall radiographic success rate for the intervention group was 100% while for the control group the radiographic success rate was 95.65. Intergroup comparison between both materials regarding occurrence of radiolucent lesion at furcation or periapical region and presence of internal or external root resorption have shown no statistically significant difference within different follow up periods; baseline, 6 and 12 months with (P = 1.0000), intergroup comparison between both materials regarding widening of the periodontal membrane space have shown no statistically significant difference within different follow up periods; baseline, 6 and 12 months but with (P = 1.0000, P = 0.3173 and P = 0.3173) respectively, these results are consistent with previous results, who found no statistically significant difference between resin modified calcium silicate (Theracal LC) group and calcium hydroxide group regarding the radiographic outcomes. 6, 10

Intragroup comparison within resin modified calcium silicate (Theracal LC) have shown no statistically significant difference between different follow-up periods (P = 1.0000), this was in accordance with previous trials 6, 10. Intragroup comparison within light cured calcium hydroxide (Calcimol LC) have shown no statistically significant difference between different follow-up periods (P = 1.0000) for occurrence of radiolucent lesion at furcation or periapical region and presence of internal or external root resorption and (P = 0.368) for widening of periodontal membrane space, these results were in alignment with previous studies. 6, 8, 10, 16, 28, 29, 32-34

High success rate for resin modified calcium silicate (Theracal LC) in this study could be attributed to its ability to provide a strong mechanical barrier, to act as an insulator to protect the dental pulp complex against microbial damage and to induce formation of a dentine like bridge between restorative material and pulp. This calcium silicate based material when placed over moist dentine results in release of high amounts of calcium (Ca) and hydroxyl ions (OH), The bioavailability of calcium (Ca) ions of resin modified calcium silicate (Theracal LC) is more than that of Calcimol, which in turn plays a key role in the formation of mineralized hard tissues as the Ca ions stimulate the expression of dentin-forming proteins which plays a significant role in the mineralization process leading to the production of calcium apatite on the surface and differentiation of odontoblasts to form reparative dentine. Moreover, hydroxyl ions provide an alkaline pH that creates a hostile environment for the survival of bacteria and its proliferation. In addition, alkaline pH is known to cause an inflammatory reaction with the formation of reparative dentine and also favors the formation of hydroxyapatite. 13, 21, 35

Additionally, resin modified calcium silicate (Theracal LC) contains high molecular weight compounds with higher amounts of additives, these small sized pores increase the sealing ability and decrease the internal and external surface of material, leading to reduced elution and solubility rates. Moreover, Thercal LC has high adhesiveness to moist substrate and overlying resin composite restoration, all of these factors make resin modified calcium silicate (Theracal LC) a promising indirect pulp capping material in pediatric dentistry. 11

Calcimol showed a very good performance in the current study, reasons behind that might be its alkalinity, Calcimol`s high pH irritates pulpal tissues stimulating repair, which is explained by the release of bioactive molecules. Several proteins are known to be incorporated into the dentin matrix during dentinogenesis. (TGF-1) and (BMP) have both been shown to stimulate pulp repair. Because Calcimol is known to solubilize these proteins from dentin, the release of these bioactive molecules acts as a significant mediator in pulp repair following pulp capping treatment. 36

Calcimol is a light cured calcium hydroxide compound which possesses lower solubility and enhanced sealing ability. Calcimol shows strong antibacterial properties which arises from its ability to dissociate into calcium and hydroxyl ions. The hydroxyl ions produce a very alkaline pH, which is extremely toxic to cariogenic bacteria. The impact of hydroxyl ions on growth, structure, metabolism, and bacterial cell division can explain their antibacterial activity on microbes. This indicates that calcium

hydroxide efficiently suppresses bacterial counts rather than only sealing the cavity. 37, 38

In addition to previously mentioned mechanism of action of resin modified calcium silicate (Theracal LC) and Calcimol, high success rate of IPT in both study groups in the present study can be attributed to proper evaluation of pulpal condition and proper selection of subjects who participated in the study, appropriate removal of contaminated dentin and the use of a proper sealing coronal restoration that prevents microleakage, which in turn restricts nutrition to the residual cariogenic bacteria. 6, 10, 37

Limitations of the current study included that IPT was only performed in teeth with deep occlusal caries while teeth with deep proximal caries were excluded from the trial. Only mandibular second primary molars were included in this trial while mandibular first primary molars and maxillary primary molars were excluded. Routinely taking aligned intraoral periapical radiograph in a growing dentition was challenging. In the present study, due to the precise criteria of selection, it was better to do split mouth randomized clinical trial, but it was unfeasible.

5. CONCLUSION

Under the conditions and the limitations of this study, the following conclusions were evident:

1- Indirect pulp treatment is a successful technique for treating deep caries in primary teeth with normal or reversibly inflamed pulps.
2- Both light cured calcium hydroxide and light cured calcium silicates can be used successfully as indirect pulp capping agents in primary teeth.
3- Indirect pulp treatment is not a material dependent technique.
4- Proper case selection with careful diagnosis of pulpal condition, proper removal of contaminated dentin and appropriate placement of a permanent restoration that guarantee a well-sealed margins are the most important factors leading to a successful indirect pulp treatment.

CLINICAL RECOMMENDATIONS:

1- Indirect pulp treatment can be recommended as the first choice for treatment of deep caries in primary teeth.
2- More well conducted RCTs with longer follow up periods are recommended to study the success rate of both light cured calcium silicates and light cured calcium hydroxide as indirect pulp capping agents.
3- Further RCTs are needed to evaluate light cured calcium silicates and light cured calcium hydroxide as a pulp capping agent in indirect pulp treatment of permanent teeth.
4- Indirect pulp treatment modalities for special health care need children and children in rural areas need to be investigated.

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Patient declaration of consent statement:

We have obtained all appropriate patient consent forms. The legal guardians understand that their children names and initials will not be published, and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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