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CLINICAL AND RADIOGRAPHIC EVALUATION OF INDIRECT AND DIRECT PULP CAPPING IN PRIMARY MOLARS USING THERACAL (LC): A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Aim: To evaluate the clinical and radiographic success rates of indirect and direct pulp capping in primary molars with reversible pulpitis using a light cured tri-calcium silicate-based material.

Methods: A total of 40 primary molars that had deep dentin caries and signs of reversible pulpitis in healthy cooperative children aged between 4-7 years were randomly allocated to two parallel groups. The first group received indirect pulp capping (IPC) using partial caries removal (PCR), while the second group received direct pulp capping (DPC) using complete caries removal (CCR). TheraCal (LC) was the capping material in both groups. Teeth were restored by high-strength glass-ionomer cement or a stainless-steel crown according to the extent of carious involvement. Teeth were assessed clinically and radiographically at 3, 6, 9, and 12 months. The data was statistically analyzed using Fisher's exact test for intergroup comparisons and Cochran's Q test followed by multiple pairwise comparisons utilizing multiple McNemar's tests with Bonferroni correction for intragroup comparisons. Significance level was set at $p \leq 0.05$.

Results: According to intention to treat analysis, the clinical success rates for IPC were 90% and 85% at 3, and 12 months, respectively. DPC showed 90% clinical success rate at 3 months and 70% at 12 months. Whereas the radiographic success rate for IPC was 90% at 3 months and 85% at 12 months. While radiographic success rate for DPC was 95% in the first 3 months and 70% after 12 months. There were no significant differences in clinical and radiographic success rates of IPC and DPC at all follow-up intervals ($p > 0.05$).

Conclusion: Both IPC and DPC can be reliable treatment options in primary molars encouraging the selection of the most conservative treatment option as a biological management approach for deep caries in primary molars with reversible pulpitis.

KEYWORDS: Deep Caries, Indirect Pulp Capping, Direct Pulp Capping, Reversible Pulpitis, Decayed Teeth, Vital Pulp Therapy

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INTRODUCTION

Minimally invasive biological management of dental caries is a modern concept that has sparked a lot of attention especially with the invention of novel bioactive materials.[1, 2] For extensive caries in primary molars with signs and symptoms of reversible pulpitis, three main vital pulp treatments are recommended: indirect pulp capping (IPC), direct pulp capping (DPC), and pulpotomy.[2, 3]

IPC is a procedure which is carried out to preserve the vitality of teeth with deep caries in which complete caries removal can result in pulp exposure.[4] This procedure depends on partial caries removal approach (PCR). Complete caries removal (CCR) is achieved in all peripheral walls, while on the pulpal floor, infected dentin is only removed leaving the deepest layer of carious dentin (affected dentin) above the pulp which is then covered by a biocompatible material to achieve a good seal. Proper coronal seal inactivates bacteria in the remaining deepest dentin layer which contains a few viable microorganisms, promotes pulp healing, dentin remineralization, and tertiary dentin formation.[5,6]

DPC has been questionable for several years due to low success rates reported in early trials using calcium hydroxide $Ca(OH)_2$ which was attributed to the differentiation of undifferentiated mesenchymal cells to odontoclasts causing internal root resorption.[7-10] Other reasons that was hypothesized to be responsible for failure of DPC by $Ca(OH)_2$ include its high solubility, low antimicrobial effect particularly in comparison to other recent capping materials, and presence of tunnel defects in newly formed dentin which impair the seal against microbes.[9-12] Lately, researchers are re-attempting DPC in primary teeth due to the recent availability of more biocompatible capping materials with excellent sealing ability and less cytotoxicity.[8, 13]

Calcium silicate-based materials are biocompatible materials that can generate reparative dentin. Mineral Trioxide Aggregate (MTA), Biodentine, and TheraCal LC are the most commonly utilized calcium silicate based capping materials. TheraCal LC (BISCO Inc., Schamburg, IL, USA) was developed in 2011 to overcome calcium silicate material's poor adhesion to resins in final restorations.[14] TheraCal LC is a hydrophilic monomer that contains tricalcium-silicate particles that stimulate the production of hydroxyapatite and aid in the formation of reparative dentin bridges by calcium release.[14-16]

TheraCal (LC) has several advantages compared to silicate based materials such as its easy handling, fast setting time, acceptable mechanical and physical properties, good bonding ability, lower solubility, and improved sealing capability.[14,17] 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 in 1mm increments and light-cured for 20 seconds as directed by the manufacturer.[15, 16] All of these benefits make TheraCal (LC) a good choice for children who cannot withstand long appointments and may lose their cooperation over time. Although studies reported debatable results regarding the cytotoxicity of TheraCal LC, clinical investigations in primary and permanent teeth reported acceptable success rates.[13, 18, 19]

In 2017, the American Academy of pediatric dentistry reported that, the success rate of IPC, DPC and pulpotomy in primary teeth is good irrespective of the capping materials. However, due to a lack of studies directly comparing different vital pulp therapies, the panel was unable to determine which vital pulp therapy was superior to the other and recommended more research in this area.[1] Therefore, the current study was designed to assess the success rate of indirect and direct pulp capping utilizing a recent resin-based tricalcium silicate capping material.

The research question was: In vital primary molars with deep caries, what is the success rate of partial caries removal and indirect pulp capping versus complete caries removal and direct pulp

capping using a light-cured tri-calcium silicate cement (TheraCal (LC))?

MATERIALS AND METHODS

The study was designed as a block randomized double blinded clinical trial with two parallel arms and a 1:1 allocation ratio. The study was designed and reported according to the CONSORT checklist 2010.[20] On the 17th of April 2019, an institutional ethical approval was received with the approval code (FDASRECIM041919). The study was registered on Clinicaltrials.gov (NCT05167123). Before initiating the treatment procedure, the participating children and their parents/legal guardians were informed of any possible side effects and benefits. Written Consent forms were obtained from one of the Parents / legal guardians, and also the children were given a simplified verbal explanation of the therapy to gain their assent.

Sample size calculation

Considering an effective size of (0.476) [21], α=0.05 and 80% power, the needed sample size was 35 teeth. A total sample size of 40 teeth (20 teeth per group) was used to compensate for possible loss to follow-up during the study period. Sample size was calculated using G*Power version 3.1.9.2.

The eligibility criteria were: [5, 6, 8, 13, 22, 23]

- Healthy cooperative children aged between 4 to 7 years with occlusal or proximal deep caries in any mandibular primary molar that extends beyond half dentin thickness.
- Asymptomatic teeth or teeth with reversible pulpitis.
- Absence of throbbing, spontaneous pain, soft tissue swelling, abscess, fistula, tenderness to percussion, or pathologic tooth mobility.
- No radiographic evidence of periapical or interradicular radiolucency, internal or external pathological root resorption, furcation involvement, or wide periodontal membrane space.

Randomization:

- Block randomization with a block size of four was used.
- The sequence of random numbers was generated online (www.randomizer.org), and kept with a neutral party. Each number was written on a piece of paper that was folded and placed in obscure envelopes, and then an envelope was picked by a neutral party immediately before initiating the clinical procedures. [22, 24]
- In patients who had more than one eligible tooth, teeth were chosen in the following order: lower left second primary molars, lower left first primary molars, lower right first primary molars, lower right second primary molars.[25]

Intervention

Recruitment of children began in September 2019 and stopped in January 2020. The last patient assessment was in December 2021. Ninety children were screened for eligibility in the Pediatric Dentistry Outpatient's Clinic, Faculty of Dentistry, Ain Shams University. Only 40 primary molars in 30 children were eligible for enrollment in the study. Fig (1): represents the flow of participants in the study.

Clinical interventions were carried out by the first author who was not blinded to the type of intervention. Both patients and outcome assessors were blinded. A detailed medical and dental histories were recorded, followed by a thorough clinical examination. Following the clinical evaluation, preoperative radiographs were obtained. Teeth were anesthetized using infiltration anesthesia with 4 % articaine and a 1:100,000 dose of epinephrine (Artinibsa, Inibsa, Barcelona, Spain).[26] For isolation, a rubber dam and low volume suction were used.[27]

In group I: complete caries removal was carried out on axial walls with a high-speed 330 carbide bur under copious water spray. On the pulpal floor the soft infected dentin layer was removed carefully by

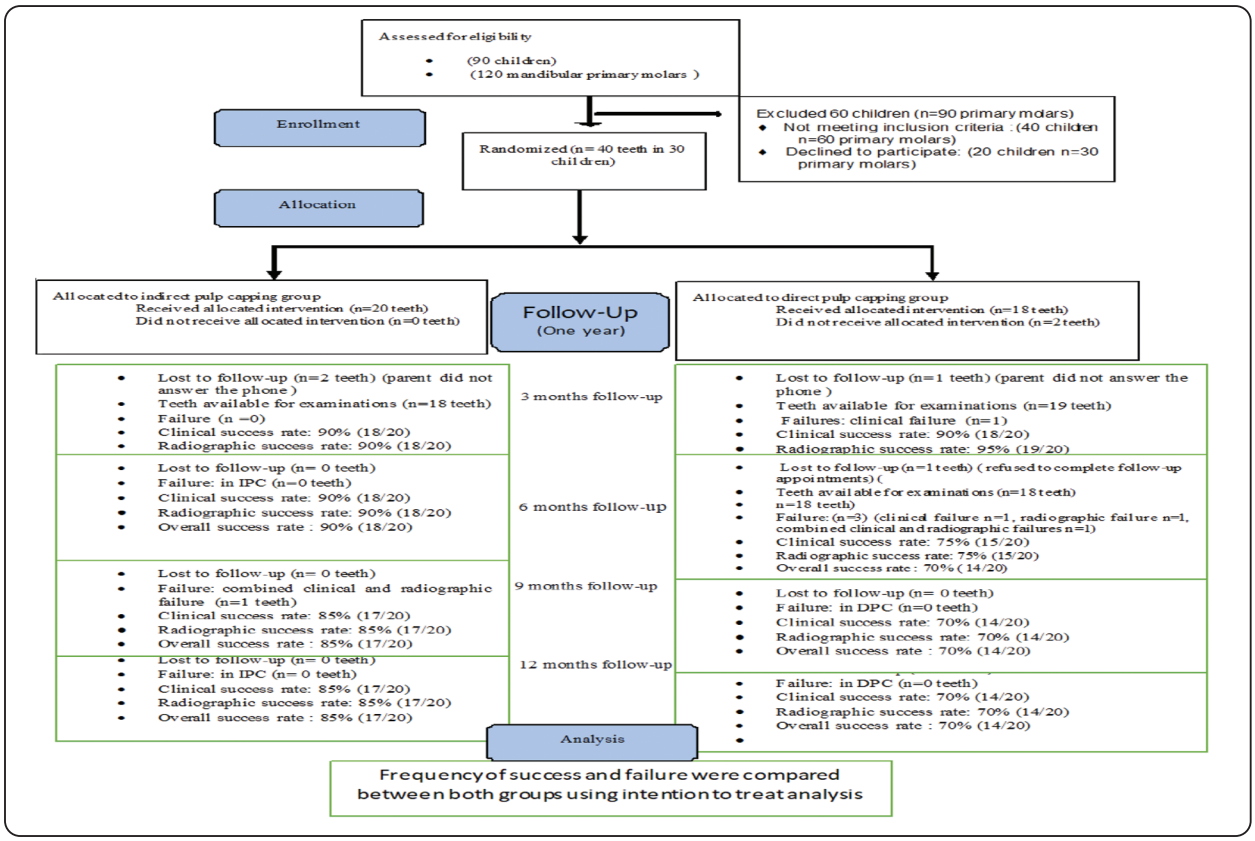

Fig. (1): Consort Flow Chart

a sharp-edged hand excavator till the dried, hardened affected dentin was reached.[23, 28] The cavities were then rinsed with a water spray and dried by cotton pellets after being disinfected with 2% Chlorhexidine Digluconate (Chlor X, PrevestDen-Pro, Digiana, Jammu, India).[6] TheraCal LC (BISCO Inc., Schamburg, IL, USA) was placed in a 1 mm layer on the pulpal floor and light cured for 20 seconds.[6, 15]

In group II: On both the axial walls and the pulpal floor, complete caries removal was carried out. Peripheral caries was removed with a 330 carbide bur set on a high-speed handpiece under profuse water spray, whereas on the pulpal floor, dentin caries was removed with a large round carbide bur (size 3) placed on a low-speed handpiece.[7, 13, 22, 29] Saline irrigation was used every 3 minutes to flush away any debris, then the cavity was dried with cotton pellets.[30, 31] Cavity preparation was continued until all caries was removed, and when a pinpoint pulp exposure surrounded by sound healthy dentin occurred, DPC procedure was undertaken.[13, 22, 29] Two percent chlorhexidine digluconate irrigation (Chlor X, Prevest Den Pro, Digiana, Jammu, India) was used to disinfect the exposure site, followed by drying the cavity with a sterile cotton pellet.[13, 32] Hemostasis was achieved by exerting mild pressure for 2-3 minutes with a sterile cotton pellet moistened with sterile saline.[13, 29, 33] If bleeding did not stop within 2-3 minutes, the tooth was treated with formocresol pulpotomy. TheraCal LC was applied over the exposure site in 1 mm increment and light cured for 20 seconds.[13, 15]

Afterwards, the cavity was dried with a cotton pellet and conditioned with GC dentin conditioner

(GC Corporation, Tokyo, Japan) for 20 seconds and a high-strength GIC restoration was placed (EQUAI FIL, GC Corporation, Tokyo, Japan).[28, 29, 34] The restoration was covered with a layer of EQUAI Coat LC (GC, Tokyo, Japan) and light cured.[35] In extensive primary molar wall destruction, stainless steel crowns (Kidz, Shinhung, Korea) were used. Restorations were placed at the same appointment to avoid bacterial leakage between visits and to maintain coronal seal.

Outcome assessment

Clinical and radiographic outcome assessments were performed by two calibrated and blinded pediatric dentistry experts. The Kappa coefficients for inter-examiner and intra-examiner reliability were 0.87 and 0.9, respectively. The worst score was recorded in case of disagreements.[36] The coronal portion of the radiographs were concealed to ensure blind radiographic assessment. A missed appointment was scored as its next appointment score whether success or failure.

The following criteria were recognized as clinical failures: spontaneous pain, tenderness to percussion pathological tooth mobility, abscess, erythema, draining fistula tract, or broken restoration. [6, 13, 22, 29]

Radiographic failures were considered if any of the following criteria occurred: periapical radiolucency, inter-radicular radiolucency, internal or external root resorption, or widening of the periodontal ligament space.[6, 13, 22, 29]

Statistical analysis

Age data were presented as mean and standard deviation values and were compared using independent t-test. Categorical data were presented as frequency and percentage values and were analyzed using Fisher's exact test for intergroup comparisons and Cochran's Q test followed by multiple pairwise comparisons utilizing multiple McNemar's tests with Bonferroni correction for intragroup comparisons. The significance level was set at $p \leq 0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.1.2 for Windows.

Success rates were assessed according to intention to treat analysis (ITT), all patients were analyzed in the group to which they were originally assigned because any action that disrupts randomization may bias the outcome.[24, 37]

RESULTS

In the current study, forty teeth were enrolled in 30 patients. Table (1): shows characteristics of included children and teeth. Four children (with 4 primary molars) missed follow-up visits in the, (two in IPC group and two in DPC group), Figure 1.

Glass ionomer restorations were placed in 11 primary molars (55%) with IPC and 8 primary molars (40%) with DPC, while SSCs were placed in 9 primary molars (45%) with IPC and 12 primary molars (60%) with DPC. Only two primary molars with glass ionomer restoration failed (the two failures were in the DPC group), while three primary molars with SSCs failed (one in the IPC group and two in the DPC group).

Clinical success rate in IPC was 90% in the first 6 months, and 85% at 9-12months. While in DPC, success rate was 90% in the first 3 months, 75% at 6 months, and decreased to 70% at 9-12 months. Radiographic success rate in IPC was 90% at 6 months, and 85% at 9-12months. Whereas in DPC, success rate was 95% at 3 months, 75% at 6 months, and 70% at 9-12 months. No statistically significant differences between both groups were evident regarding clinical or radiographic success. Worst case scenario was used assuming the four dropped-out teeth had failed.[36] Tables (2 and3) show success rates at different intervals. Tables (4 and 5) show types and frequencies of clinical and radiographic failures.

TABLE (1): Baseline characteristics of study sample.

Parameter			IPC	DPC	p-value
Sex	Male	N	7	8	1ns
		%	35.0%	40.0%	
	Female	N	13	12	
		%	65.0%	60.0%	
Age (years)		Mean± SD	4.60± 0.82	4.30± 0.72	0.226ns
Tooth	First primary molar	N	7	12	0.205ns
		%	35.0%	60.0%	
	Second primary molar	N	13	8	
		%	65.0%	40.0%	
Type of restoration	Direct restoration	N	11	8	0.527ns
		%	55.0%	40.0%	
	SCC	N	9	12	
		%	45.0%	60.0%	
Type of decay	Class (I)	N	11	1	0.001*
		%	55.0%	5.0%	
	Class (II)	N	9	19	
		%	45.0%	95.0%	

TABLE (2): Clinical success rates (ITT).

Time	Parameter		Groups		p-value
			IPC	DPC	
3 months	Success	N	18	18	1ns
		%	90.0%	90.0%	
6 months	Success	N	18	15	0.407ns
		%	90.0%	75.0%	
9 months	Success	N	17	14	0.451ns
		%	85.0%	70.0%	
12 months	Success	N	17	14	0.451ns
		%	85.0%	70.0%	

TABLE (3): Radiographic success rates (ITT).

Time	Parameter		Groups		p-value
			IPC	DPC	
3 months	Success	N	18	19	1ns
		%	90.0%	95.0%	
6 months	Success	N	18	15	0.407ns
		%	90.0%	75.0%	
9 months	Success	N	17	14	0.451ns
		%	85.0%	70.0%	
12 months	Success	N	17	14	0.451ns
		%	85.0%	70.0%	

TABLE (4): Frequency and percentage values for clinical failures.

Radiographic failure		Groups		p-value
		IPC	DPC	
External root resorption	n	1	2	1ns
	%	25.0%	28.6%	
Widening in periodontal ligament space	n	1	1	
	%	25.0%	28.6%	
Inter-radicular bone resorption	n	1	2	
	%	25.0%	14.2%	
Periapical radiolucency	n	1	2	
	%	25.0%	28.6%	
Internal resorption	n	0	0	
	%	0%	0%	

TABLE (5): Frequency and percentage values for radiographic failures

Clinical failure		Groups		p-value
		IPC	DPC	
Spontaneous pain	N	0	3	
	%	0.0%	37.5%	
Tenderness to percussion	n	0	3	
	%	0.0%	37.5%	
Abscess or fistula	n	1	0	
	%	100.0%	0.0%	
Broken restoration	n	0	2	
	%	0.0%	25.0%	
Tooth mobility	n	0	0	0.111ns
	%	0.0%	0.0%	

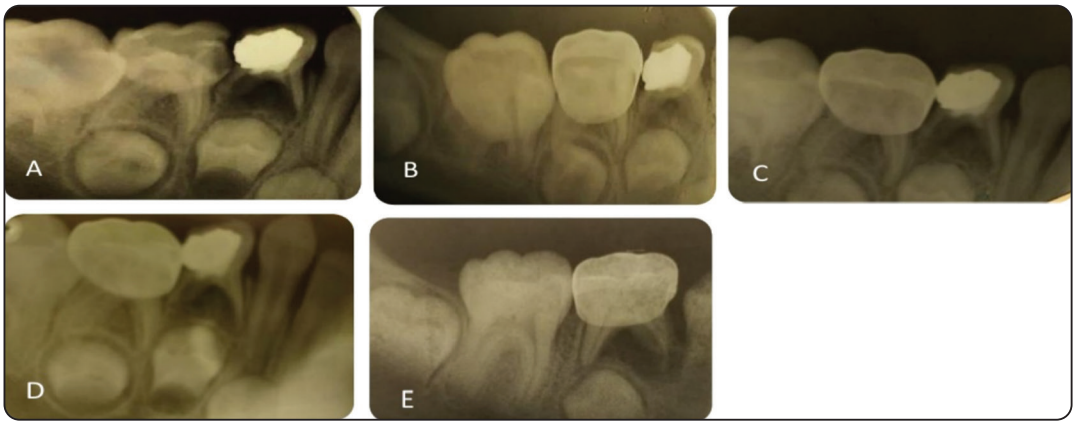

Fig. (2) : Radiographs showing faliure in IPC, performed in the lower second primary molar, (A) Pre-operative radiograph, (B) Post-operative radiograph, (C) 3 months radiograph, (D) 6 months radiograph, (E)12 months radiograph (external root resorption, inter-radicular and periapical bone resorption, widening in peridontal ligment space) **Note :** Patient missed 9 months follow –up appointment. lower D was clinically asymptomatic and mother refused extraction and space maintenance.

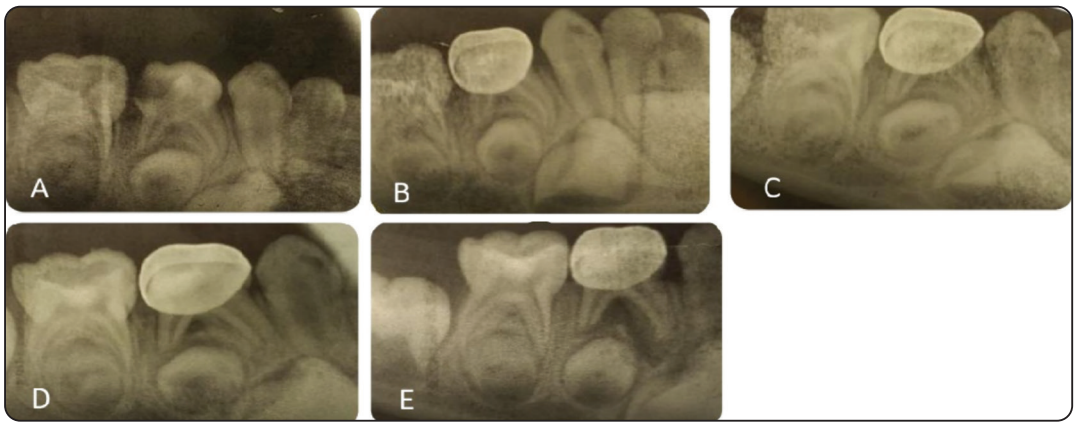

Fig . (3) : Radiographs showing faliure in DPC , performed in the lower first primary molar ; (A) Pre-operative radiograph, (B) Post-operative radiograph, (C) 3 months radiograph, (D) 6 months radiograph, (E) 9 months radiograph (external root resorption, inter-radicular and periapical bone resorption) **Note :** tooth was extracted at 9 months

DISCUSSION

The current study used intention to treat analysis (ITT) to assess the success rates of the two techniques performed.[37] There were no pulp exposures in any of the teeth treated with PCR. On the other hand, all teeth treated with CCR had pulp exposures. Two teeth were not suitable for DPC due to inability to achieve hemostasis at the exposure site, thus they were treated with formocresol pulpotomy and included in the final analysis based on the ITT. Throughout the trial, pulpotomized teeth showed no signs of failure.

In IPC, a sharp excavator was used to remove carious dentin from the pulpal floor as tactile sensation is considered an important factor in PCR, to distinguish between infected and affected dentin.[38] **Celiberti et al. (2006)**[39] compared four caries excavation methods, which were hand excavator, round low speed bur, YAG laser, and polymer bur. The authors stated that using an excavator seemed to be the most acceptable method for carious dentin removal in primary dentition as it combines good excavation time with efficacious caries removal. While in DPC, a low speed round bur was used to remove caries on pulpal floor similar to other studies. **Dogan et al.(2013)**[40] stated that incidents of pulpal exposure caused by an excavator and a bur during caries removal was insignificant , but exposures caused by bur during vital pulp treatment showed a higher success rate when compared to exposure caused by an excavator. Peripheral caries was removed before pulpal floor caries to avoid dentin chips and debris from accessing pulp during the DPC procedure through the exposure site.[9, 13, 41] The success rates of IPC and DPC in the present study are in line with previous studies.[5,6,7, 8,13,22,24,28,33]

IPC studies reported a success rate of 78% to 100% regardless of the technique, follow-up period, or materials used.[4,5,6,25,28,38, 42-45] Moreover, compared to pulpotomy, **Farooq et al. (2000)[43], Vij et al. (2004)**[44]**, and Fang et al. (2019)**[45] reported that IPC had a higher success rate than that of pulpotomy however not statistically significant. Thus, IPC was regarded as a less invasive, and a more successful option than pulpotomy.

In IPC, statistical analysis revealed that clinical and radiographic success rates were 90% in the first three months and 85% at 12-months. This finding is comparable to previous findings. **Gurcan and Seymen (2019)**[6] assessed IPC in 295 primary molars using MTA, TheraCal LC, and $Ca(OH)_2$. The overall success rates after two years were 94.4 %, 87.8%, and 84.6%, respectively. Also, **Shain et al (2021)**[42] evaluated clinically, radiographically, and histologically primary molars treated with IPC using TheraCal LC, Biodentine, and MTA for a 24-months period. The authors reported that IPC showed high success rates; TheraCal LC (93%), Biodentine (100%), and MTA (100%), with no significant differences among the three groups. Furthermore, **Menon et al (2016)**[5] assessed reparative dentin deposition in 43 primary molars treated with IPC utilizing MTA and TheraCal LC as capping agents over a six-month follow-up period. The authors stated that TheraCal LC is a better alternative to MTA in pediatric restorative procedures due to its better handling properties and comparable reparative dentin-forming capabilities.

Failures in IPC may be related to the remaining dentin thickness (RDT) overlying the pulp where studies reported that dentin- pulp complex response is affected by two factors, the RDT and the depth of bacterial penetration, where the thicker the remaining dentin, the lower the pulpal reaction. If RDT is 500 um, this will postpone the spread of toxic and noxious materials to the pulp, which will permit the secretion of tertiary dentin by odontoblasts, leading to an increase in the distance between the pulp and toxic materials. However, in the case of a RDT of less than 500 um, the number of odontoblasts will significantly decrease, which will be compensated for by the differentiation of odontoblast-like cells that migrate to the injury site, leading to tertiary dentin secretion. [46, 47] In the current study, RDT was not measured which might

be acknowledged in future investigations. Fig (2): show radiographic failure in mandibular primary second molar treated by IPC.

On the other hand, DPC had high clinical success rate in the first three months (90%) that declined to 70% at 12 months. Likewise, radiographic success rate in the first three months was 95% and dropped to 70% at 12 months. Clinical and radiographic success rates were significantly different after 6, 9, and 12 months compared to 3 months.

Success of DPC in previous studies has ranged from 53.5% to 95.5%.[7, 13, 22, 23, 24, 29, 33, 34, 36, 47] **Erfanparast et al. (2018)[13]**, conducted a study that compared TheraCal LC to MTA in DPC of primary molars in 5-7 years old children for 12 months. TheraCal LC had a 91.8% combined clinical and radiographic success rates, which was equivalent to MTA's 94.5%, with no significant difference between the two materials. The success rate of TheraCal LC in the latter study was higher than that of the present study. However, this may be related to the differences in study design such as type of restoration, and caries location.

Internal root resorption was not seen in any of the treated molars in our study. This was consistent with the findings of some earlier studies on the use of DPC in primary teeth.[13, 22, 24, 29, 33, 34, 36, 48]

Regarding DPC, failures may be related to the inability to adequately assess the actual state of pulp. Till now, the main clinical criterion that determines if the pulp is inflamed or not is the time it takes to control pulpal bleeding. However **Mutluay et al. (2017) [49]** reported that the histological inflammatory status of the pulp did not always correlate to the amount of bleeding at the exposure site. Furthermore, the chemical composition of TheraCal (LC) could have played a role, therefore more histological clinical trials comparing TheraCal (LC) to other bioactive agents in capping vital pulp exposures are needed to validate this assumption. Fig (3): show radiographic failure in mandibular primary first molar treated by DPC.

Comparing both interventions, IPC in the present study had higher success rates compared to DPC, although the difference was statistically insignificant. Up to our knowledge, this is the first study that directly compares both interventions. Previous studies mainly focused in comparing different capping materials for the same intervention or compared one intervention to pulpotomy for it is the most widely performed intervention for primary molars with deep caries and reversible pulpitis.

When compared to pulpotomy, IPC and DPC provide a more conservative cavity preparation.[50, 51] As a result, a permanent restoration can be used instead of an SSC when the tooth is not significantly decayed. Previous studies revealed that a wide variety of materials were used to restore primary teeth following vital pulp therapies. Despite the fact that SSC has been the recommended treatment for many years, some researchers have stated that there is no strong evidence that SSC is preferable to alternative restorations and that the type of restoration has no impact on the success of vital pulp therapy.[52-54]

Dimitraki et al (2019)[22], and **Choe et al (2017)**[55] reported that class I cavities had showed greater success rates than class II cavities in primary teeth treated by DPC. Also, **Franzon et al (2014)**[28] stated that teeth with occlusal cavities treated by IPC showed higher success rate than teeth with proximal cavities treated by IPC**.** In the present study teeth with proximal decay were more prevalent in DPC which could be a reason for increased failure compared to IPC. **Kassa et al (2009)[56]** demonstrated that primary teeth with proximal caries that extend beyond the outer half of dentin had more prevalent inflammatory changes in their pulp than teeth with occlusal caries of the same depth. As a result, future randomized clinical trials of pulp therapies should consider the location of the decay, whether proximal or occlusal.

CONCLUSIONS

1. Partial caries removal and IPC showed better success rates over 12 months compared to complete caries removal and DPC.
2. TheraCal (LC) showed acceptable outcomes as a capping agent in conservative vital pulp therapies of primary molars.

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