Submitted: 24 August, 2022 Accepted: 03 November, 2022 Published: 03 March, 2023 DOI:10.22514/jocpd.2023.004

ORIGINAL RESEARCH

Journal of Clinical Pediatric Dentistry

Evaluation of four vital pulp therapies for primary molars using a dual-cured tricalcium silicate (TheraCal PT): one-year results of a non-randomized clinical trial

Mariem Wassel[1,*], Dina Hamdy[1], Reham Elghazawy[1]

[1] Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Ain Shams University, 11566 Cairo, Egypt

***Correspondence**
mariem.wassel@dent.asu.edu.eg
(Mariem Wassel)

Abstract

Selecting an appropriate vital pulp therapy (VPT) for primary teeth with reversible pulpitis can sometimes be confusing for clinicians. Encouragingly, continuous developments in capping materials with bioactive properties help the selection of less-invasive treatments. This non-randomized clinical trial aimed to assess the clinical and radiographic success rates of indirect pulp treatment (IPT), direct pulp capping (DPC), partial pulpotomy (PP) and pulpotomy in primary molars utilizing TheraCal PT over a 12-month period. Different inclusion criteria were assigned for each treatment to assess the eligibility of each treatment type for specific clinical scenarios. Additionally, the association of tooth survival with some variables was assessed. The trial was registered at clinicaltrials.gov (NCT04167943) on 19 November 2019. Primary molars (n = 216) with caries extending into the inner dentin third or quarter were included. Selective caries removal was employed in IPT. Non-selective caries removal was employed in other groups, and treatment was decided according to pulp exposure characteristics, whereby the most conservative treatment was selected for the least clinically detectable pulp inflammation. Cox regression was performed to assess the effects of different variables on tooth survival using $p < 0.05$ for detecting statistical significance. The 12-month combined clinical and radiographic success rates for IPT, DPC, PP and pulpotomy were 93.87%, 80.4%, 42.6% and 96.15%, respectively. Proximal surface involvement, provoked pain and first primary molars were associated with increased odds of treatment failure. According to the specified inclusion criteria, IPT, DPC and pulpotomy using TheraCal PT demonstrated acceptable results, while PP was associated with poor treatment outcomes. The odds of failure increased with proximal surface involvement, provoked pain and first primary molars. These results provide insights into different scenarios when managing deep carious lesions in primary teeth. The effects of clinical predictors on treatment outcomes may guide clinicians in case selection.

Keywords

Indirect pulp treatment; Direct pulp capping; Partial pulpotomy; Pulpotomy; Primary teeth; TheraCal PT

1. Background

Pulpotomy remains the most widely accepted treatment for pulpally-exposed primary teeth with reversible pulpitis since its introduction in the 1900s [1]. However, with the availability of new bioactive materials, more conservative pulp therapies, such as indirect pulp treatment (IPT), direct pulp capping (DPC), and partial pulpotomy (PP), are becoming attractive therapeutic options [2, 3].

IPT is a single-step procedure that entails selective caries removal (SCR) of heavily infected superficial necrotic dentin while the affected firm dentin is left over the pulp. Then, the affected dentin is covered by a biocompatible liner and sealed with a hermetic seal for coronal restoration [4, 5]. IPT deprives the remaining bacteria of nutrients, shifting the carious process towards repair and deposition of reparative dentin without needing a re-entry [6, 7]. IPT has the advantage of reducing pulp exposures in primary teeth and decreasing treatment time and the need for local anesthesia [4–6, 8]. Moreover, early exfoliation of pulpotomy treated primary molars compared to primary molars treated with IPT was reported [9].

The use of DPC in primary teeth has been debatable due to the risk of internal resorption associated with calcium hydroxide (CH) [10]. However, the introduction of biocompatible alternatives with better antibacterial, sealing and bioactive abilities has renewed interests in DPC procedures [11–13].

PP is indicated for immature permanent teeth with carious or traumatic pulp exposures in which 1–3 mm of pulp tissue

beneath an exposure is removed until healthy pulp tissue is reached [14]. However, the effectivity of PP has been scarcely evaluated in primary teeth.

Biocompatibility of materials used for VPT and a good coronal seal are two key factors for pulp healing [10, 11]. Materials used for VPT should ideally preserve pulp vitality, promote pulp repair and prevent pulp infection [15]. Currently, tricalcium silicates (TCSs) such as mineral trioxide aggregate (MTA) and Biodentine are the most popular materials for VPT in permanent and primary teeth due to their biocompatibility, bioactivity and excellent sealing ability [15]. Even though CH is the active byproduct responsible for TCSs' bioactivity, its excellent sealing ability and prolonged calcium ion (Ca^{2++}) release provide long-term success [11].

In vitro studies showed that TCSs could form an apatite-like layer that acts as a substrate for cell attachment and their subsequent transformation to odontoblasts. This apatite-like layer also forms tags inside dentinal tubules, enhancing sealing ability and bonding to dentin [12, 13]. Initially, all silicate-based materials release CH during hydration resulting in high alkalinity and cytotoxicity. However, high pH increases the antibacterial effect of the cement. TCSs also act as Ca^{2++} reservoirs ensuring the prolonged release of Ca^{2++}, which in turn stimulates the osteogenic differentiation of mesenchymal stem cells [16].

TheraCal LC (BISCO Dental Products, Schaumburg IL, USA) was introduced in 2011 as a light-cured TCS that can overcome the drawbacks of MTA, namely the long setting time and difficult handling, which are important considerations in pediatric dentistry [17]. Later, in 2019, TheraCal PT, a dual-cured version of its predecessor, was marketed due to its improved chemical properties to overcome the potential adverse effects of residual unpolymerized monomers [18]. *In vitro* stem cell studies have indicated the promising potential of TheraCal PT for clinical use [18, 19]. Its cytocompatibility was comparable to MTA, and both were significantly more biocompatible than TheraCal LC due to higher cell viability, migration rates, cell adhesion and lesser risks of cell necrosis, which are all critical factors influencing healing after pulpal injury. Additionally, bioactivity was also in favor of TheraCal PT, where significantly higher numbers of mineralization nodules were formed by MTA, followed by TheraCal PT, and lastly, TheraCal LC [19]. Another study reported that the levels of cytocompatibility and bioactivity of TheraCal PT were similar to those of Biodentine [18].

A systematic review of VPTs in primary teeth reported that the 24-month success rates of such therapies were 94.4% for IPT, 88.8% for DPC and 82.6% for pulpotomy. Yet, due to the lack of strong evidence, no single VPT was found to be more successful than another [2], suggesting a primary tooth with reversible pulpitis could be successfully treated with any of these techniques, leaving the choice of treatment on the subjective evaluation of clinicians. However, since the management of caries was recommended to be based on a biological approach, this encouraged the choice of more conservative therapies [2].

It is worth mentioning that the dental pulp was found to segmentally react to bacterial irritation, such that the area closest to the insult was more affected by inflammation and areas further away were minimally or not affected [20]. Thus, more conservative pulp treatments rather than complete removal of coronal pulp tissues may be considered if there are remaining healthy pulp tissues as they still maintain a healing potential.

Therefore, the aim of this present non-randomized trial was to investigate the clinical and radiographic success rates of IPT, DPC, PP and pulpotomy in primary molars over the course of a 12-month period. Each type of treatment was performed according to specific inclusion criteria using a dual-cured resin-based calcium-silicate material (TheraCal PT) as a capping agent. Additionally, the effects of some clinical predictors on tooth survival were assessed.

2. Materials and methods

This was a non-randomized clinical trial performed in accordance with the principles of the Declaration of Helsinki and reported following the TREND guidelines. Both participants and outcome assessors were blinded. A power analysis revealed that 160 teeth (40/group) were needed to achieve a power of 99% while adopting an alpha of 0.05, a beta of 0.01, and a hazard ratio of 2.26 [8]. The sample size was increased by 35% to compensate for possible dropouts, *i.e.*, 54/group.

One hundred and fifty-six children attending the outpatient clinic of the pediatric dentistry department were screened for eligibility from November 2019 to August 2020. The last assessment was conducted in August 2021. Fig. 1 shows the flow chart of this trial. The inclusion criteria were: (1) healthy patients aged 4–7-year-old, (2) cooperative and had at least one restorable mandibular primary molar with deep active occlusal or occluso-proximal caries, (3) the lesion should radiographically extend to the inner third or quarter of dentin without pulpal encroachment, and teeth should have at least 2/3 of the roots [8, 21], and (4) asymptomatic teeth or displayed provoked pain of short duration. The exclusion criteria were spontaneous or nocturnal pain, pain on pressure, gingival swelling, sinus tract, pathological mobility, furcation radiolucency with or without peri-radicular radiolucency, internal or external pathological root resorption, widening of periodontal membrane space, discontinuity of lamina dura, and/or absence of successor. One experienced operator conducted the caries removal and capping procedures. Two study-independent pediatric dentistry experts previously calibrated for caries assessment [22] examined each tooth visually and tactilely following SCR and non-selective caries removal (NSCR) if a pulp exposure was encountered. To perform a specific intervention, both experts should individually agree on one of the interventions based on the study's inclusion and exclusion criteria. The kappa coefficient for inter-examiner reliability was 0.89, while the intra-examiner reliability was 0.9 for the first expert and 0.93 for the second expert. A maximum of two mandibular molars per patient received the same intervention. Caries removal was performed under local anesthesia and rubber dam isolation which was disinfected together with the included teeth using 0.12% chlorhexidine gluconate [7, 23].

IPT included removing all carious dentin from peripheral walls using a high-speed 330 diamond bur and copious water spray. The soft, wet, mushy, necrotic dentin was hand-excavated on the pulpal walls until a firm and leathery dentin

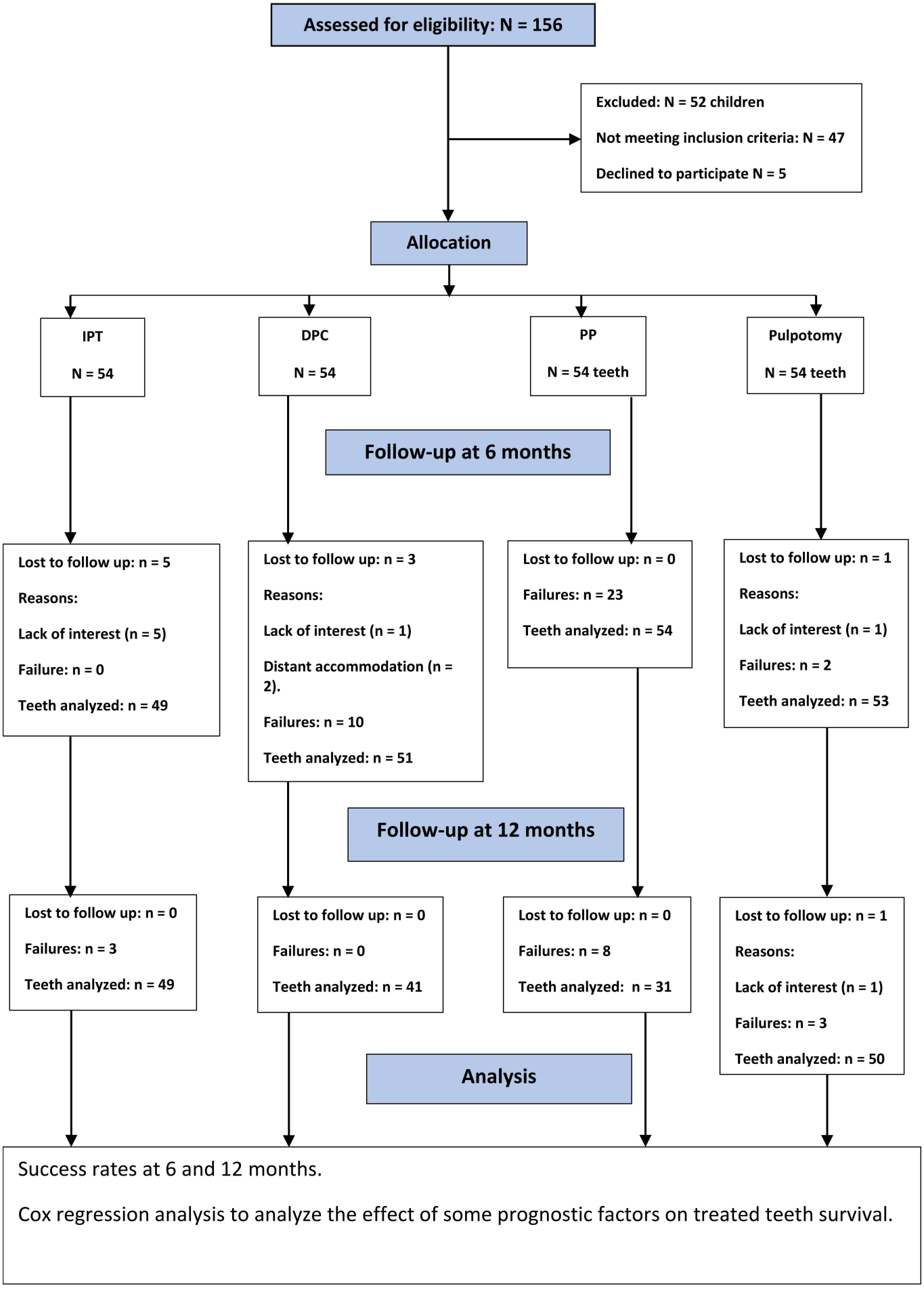

FIGURE 1. Study flow. IPT: indirect pulp treatment; DPC: direct pulp capping; PP: partial pulpotomy.

was reached, which was verified by visual and tactile means [7, 22]. The cavity was flushed with sterile saline and dried with air spray. TheraCal PT was then applied in a 2-mm thickness on the pulpal floor and light-cured for 10 seconds.

For the other 3 groups, NSCR to hard dentin was utilized. All carious dentin was removed using low-speed sterile carbide round bur and water spray [24] until hard dentin was reached. Saline irrigation was used to wash debris every three minutes [25, 26]. The tooth was restored and excluded if no pulp exposure was encountered after NSCR. In case of pulp exposure, the cavity and wound surfaces were rinsed with sterile saline and dried with sterile cotton pellets. An intervention was agreed upon by both experts based on the following exposure characteristics:

—Pinpoint exposures ($\leq$1 mm) that were surrounded by sound dentin and achieved hemostasis after three minutes were considered for DPC [23, 27].

—If a pinpoint exposure displayed hyperemia after attempting hemostasis, the exposure site was enlarged to a depth of 2–3 mm with a sterile high-speed round bur under copious irrigation [28]. The tooth was a candidate for PP if hemostasis was achieved. PP was also the treatment of choice if an initial exposure measured more than 1 mm in diameter, regardless of its bleeding status.

—If hemostasis was not achieved after attempting PP, complete deroofing of the pulp chamber was performed with a sterile high-speed round carbide bur, and complete amputation of coronal pulp tissue was performed with sterile excavators [29]. Pulpotomy was the treatment of choice if hemostasis of root stumps was achieved. If bleeding from root stumps was not controlled after three minutes, the tooth was excluded and treated accordingly.

—On all occasions, hemostasis was attempted by gentle pressure for three minutes with a sterile-saline moistened cotton pellet [23, 29].

The cavities were then dried with sterile cotton pellets, and TheraCal PT was applied in a 2-mm layer over pulp exposures extending 2 mm beyond exposure margins in DPC and PP or the floor of the pulp chamber in pulpotomy. TheraCal PT was then light-cured for 10 seconds. The pulp chamber was filled with reinforced zinc-oxide eugenol (Prevest DenPro, India) in the pulpotomy group. All teeth were then restored with glass ionomer cement (Fuji IX, GC, Tokyo, Japan), followed by stainless-steel crowns (Kids Crown, Navi Mumbai, India) at the same visit and immediate postoperative radiographs were obtained. Parents were asked to report any complaints between follow-ups by phone. To encourage compliance with follow-ups, the participating children and their siblings were offered free biannual check-ups, fluoride varnish application, and free treatment for any other dental needs at the time of their assessment.

Two study-blinded expert pediatric dentists independently assessed the teeth for clinical and radiographic outcomes at 6 and 12 months. The Kappa-coefficients for radiographic inter-examiner and intra-examiner agreement were 0.85 and 0.96, respectively. The coronal portions of the teeth were masked to ensure blind radiographic assessments [3]. If both examiners disagreed, an evaluation was reached by consensus, or the worst score was recorded [25]. Criteria for treatment failure included spontaneous pain, swelling, sinus tract, pathological mobility, pain on percussion, furcation radiolucency with or without peri-radicular radiolucency, internal/external pathological root resorption, and/or widening of periodontal membrane space [27]. Failures at six months were also considered as failures at 12 months.

Self-processing x-ray films were used because reusable intra-oral digital receptors were banned during the study period due to the COVID-19 pandemic. These x-ray films were only available as size-2 films, making the paralleling technique very difficult in most cases since the children could not tolerate the intraoral film and holder. Thus, to avoid multiple retakes, the bisecting angle technique was used. Caution was paid to adjust the vertical and horizontal angulations to prevent obscuration of the furcation area with the SSC.

Statistical analysis was performed using the R statistical analysis software version 4.1.2 for Windows (R Core Team (2021), Vienna, Austria).

Numerical data are presented as mean and standard deviation (SD) and categorical data as frequency and percentage. A multivariate Cox regression model was used to assess the effect of some independent prognostic variables on cumulative tooth survival in each group. Survival curves for different treatment groups were generated using the Kaplan-Meier estimator. The significance level was set at $p \leq 0.05$.

3. Results

A total of 216 mandibular primary molars (54/group) in 104 children (55 females, 49 males) were included in this study. The patients' demographics are shown in Table 1, and the characteristics of teeth in each group in Table 2.

Dropouts were <10% in all groups. At six months, seven children (nine teeth) did not return for assessment due to parent-related issues or difficult access to the clinic due to distance and accommodation. No treatment-related complaints were reported by any dropped-out children (Table 3). One molar was not available for evaluation at 6 months in the PP group but was recorded as successfully treated at the 12-month consultation as the tooth displayed no clinical or radiographic failures. At 12 months, the pulpotomy group had another dropout, which was a four-year-old male with a first primary molar.

Table 4 shows the clinical and radiographic failures at the 6- and 12-month follow-ups. All clinical failures were associated with radiographic failure and not vice-versa. Table 5 shows the success rates in the different study groups. Figs. 2–7 show the radiographs of some treated teeth.

Multivariate Cox regression models were built to estimate the effects of different studied variables on the cumulative survival of the treated teeth over the follow-up period (Table 6). For pulpotomy (χ^2 (3) = 2.46, p = 0.483), IPT (χ^2 (3) = 2.56, p = 0.464) and DPC groups (χ^2 (3) = 7.04, p = 0.071) the model was not statistically significant. For PP, the overall model was statistically significant (χ^2 (3) = 37.80, $p < 0.001$), in which proximal decay and history of provoked pain were associated with significantly higher odds of failure ($p < 0.05$). The survival distributions of each group are presented in Fig. 8. The

TABLE 1. Study demographics.

Variables		IPT N = 46	DPC N = 46	PP N = 45	Pulpotomy N = 42
Gender					
	Male N (%)	20 (43.5)	21(45.7)	14 (31.0)	23 (54.8)
	Female N (%)	26 (56.5)	25 (54.3)	31 (69.0)	19 (45.2)
Age (yr)	Mean ± SD	5.28 ± 0.90	5.33 ± 0.85	5.52 ± 0.54	5.48 ± 1.06

SD: standard deviation; N: Number of children/group; IPT: indirect pulp treatment; DPC: direct pulp capping; PP: partial pulpotomy. Note: some children received more than one type of treatment.

TABLE 2. Characteristics of the treated teeth.

Parameter	IPT n (%)	DPC n (%)	PP n (%)	Pulpotomy n (%)
Tooth type				
First primary molar	25 (46.3%)	38 (70.4%)	30 (55.6%)	33 (61.1%)
Second primary molar	29 (53.7%)	16 (29.6%)	24 (44.4%)	21 (38.9%)
Provoked Pain				
No	23 (42.6%)	10 (18.5%)	24 (44.4%)	12 (22.2%)
Yes	31 (57.4%)	44 (81.5%)	30 (55.6%)	42 (77.8%)
Decay				
Occlusal decay	25 (46.3%)	12 (22.2%)	16 (29.6%)	10 (18.5%)
Occluso-proximal decay	29 (53.7%)	42 (77.8%)	38 (70.4%)	44 (81.5%)

IPT: indirect pulp treatment; DPC: direct pulp capping; PP: partial pulpotomy.

mean survival time and 95% confidence intervals were 11.71 (11.44–11.97) months for IPT, 11.18 (10.76–11.59) months for DPC, 10.38 (9.80–10.95) months for PP, and 11.83 (11.61–12.05) months for pulpotomy.

4. Discussion

Despite the advantages of IPT, such as lower exposure rates, shorter operating time, less postoperative pain and reduced frequency of early exfoliation [8–10], some clinicians still prefer NSCR due to: (1) the ability to verify pulpal involvement, (2) objectively assess pulp status, especially in children who cannot adequately report their pain, (3) inability to differentiate between infected and affected dentin, or (4) lack of enough evidence on IPT [30]. Meanwhile, newly introduced TCSs with improved handling properties can ease VPT procedures in children.

This study aimed to assess the different possible clinical scenarios encountered during the management of deep caries in primary molars. Hence, the success rate of SCR was evaluated. Additionally, pulp exposures encountered during NSCR were assigned to DPC, PP or pulpotomy according to the exposure characteristics instead of only assigning exposures of pinpoint size and controlled bleeding to either DPC or pulpotomy, as previously reported [27]. Different inclusion criteria for DPC, PP and pulpotomy were utilized to select the appropriate VPT based on the extent of pulp inflammation displayed by the bleeding status of the remaining pulp tissue. In this context, pinpoint exposures displaying hemostasis were treated with DPC. If a pinpoint exposure displayed hyperemia, the exposure site was enlarged to a depth of 2–3 mm to reach healthy pulp tissues. Hemostasis was then attempted, and if achieved, PP was employed. If hemostasis could not be achieved despite enlarging the exposure site to a depth of 2–3 mm, complete amputation of the coronal pulp and pulpotomy were performed upon achieving hemostasis of the root stumps. In all scenarios, TheraCal PT was used as the capping agent.

In this present clinical trial, IPT achieved 100% and 93.87% clinical and radiographic success rates, respectively, 12 months after treatment, which was in line with previous studies, whereby a success rate of 73–100% in primary teeth was reported regardless of medicament type, technique or follow-up period [4, 17, 31, 34]. TCSs tended to have better success rates than other capping agents [32, 33]. Gurcan *et al.* [35] reported a 24-month success rate of 94.4 % with MTA and 87.8% with TheraCal LC. The 12-month success rates for IPT in asymptomatic primary molars using Biodentine or a light-cured CH were 98.3% and 95%, respectively [7]. In another study, TheraCal LC showed a lower but insignificant success rate (93%) compared to Biodentine (100%) 24 months after treatment [32]. Others demonstrated insignificant differences in the thickness of the tertiary dentin bridge in primary teeth capped with MTA or TheraCal LC 6 months after treatment [17]. Studies comparing IPT to pulpotomy showed significantly higher success rates and normal exfoliation time for IPT [9, 27, 36–38]. These findings

TABLE 3. Dropouts at 6 months.

Gender, age (yr)	IPT 5 teeth (9.2%)	DPC 3 teeth (5.5%)	PP (zero)	Pulpotomy 1 tooth (1.85%)
Female, (5)	Second primary molar	——	——	Second primary molar
Female, (6)	——	First primary molar	——	——
Male, (5)	First primary molar	——	——	——
Male, (4)	First primary molar	First primary molar	——	——
Male, (7)	——	First primary molar	——	——
Male, (5)	Second primary molar	——	——	——
Male, (6)	First primary molar	——	——	——
Teeth evaluated at 6 months	49	51	54	53

IPT: indirect pulp treatment; DPC: direct pulp capping; PP: partial pulpotomy.

TABLE 4. Clinical and radiographic failures at 6 and 12 months.

6-Months				12-Months			
IPT	DPC	PP	Pulpotomy	IPT	DPC	PP	Pulpotomy
——	—Abscess (n = 1) —ERR (n = 10)	—Abscess (n = 5) —Spontaneous pain (n = 1) —ERR (n = 15) —Furcation involvement (n = 6) —Widened periodontal membrane space (n = 1) —IRR (n = 1)	—IRR (n = 1) —Furcation involvement (n = 1)	—IRR (n = 3)	——	—Pathological mobility (n = 8) —ERR (n = 8)	——

ERR: External root resorption; IRR: Internal root resorption; IPT: indirect pulp treatment; DPC: direct pulp capping; PP: partial pulpotomy.

TABLE 5. All-cause cumulative clinical, radiographic, and combined (clinical and radiographic) success rates.

Parameter	Time (mon)	IPT	DPC	PP	Pulpotomy
Clinical					
	6	49/49 (100%)	50/51 (98.03%)	48/54 (88.9%)	53/53 (100%)
	12	49/49 (100%)	50/51 (98.03%)	40/54 (74.07%)	52/52 (100%)
Radiographic					
	6	49/49 (100%)	41/51 (80.4%)	31/54 (57.4%)	51/53 (96.22%)
	12	46/49 (93.87%)	41/51 (80.4%)	23/54 (42.6%)	50/52 (96.15%)
Combined					
	6	49/49 (100%)	41/51 (80.4%)	31/54 (57.4%)	51/53 (96.22%)
	12	46/49 (93.87%)	41/51 (80.4%)	23/54 (42.6%)	50/52 (96.15%)

IPT: indirect pulp treatment; DPC: direct pulp capping; PP: partial pulpotomy.

TABLE 6. Cox regression model.

Treatment	Variables	Regression coefficient	SE	Hazard ratio	Hazard ratio 95% CI		Wald z-value	*p*-value
					Lower	Upper		
IPT								
	Tooth (Second molar)[1]	−0.83	1.04	2.30	0.30	17.54	0.65	0.422
	Surface (Proximal)[2]	1.33	1.07	3.78	0.47	30.61	1.55	0.213
	Pain (Yes)[3]	1.42	1.02	4.14	0.57	30.36	1.96	0.162
DPC								
	Tooth (Second molar)[1]	−0.40	0.66	0.67	0.18	2.44	0.37	0.545
	Surface (Proximal)[2]	12.64	250.07	308230.19	0.00	2.24×10^{218}	0.00	0.960
	Pain (Yes)[3]	1.36	1.04	3.89	0.50	29.95	1.70	0.192
PP								
	Tooth (Second molar)[1]	−0.01	0.50	0.99	0.37	2.65	0.00	0.991
	Surface (Proximal)[2]	4.79	1.69	119.98	4.39	3280.63	8.04	0.005*
	Pain (Yes)[3]	1.68	0.51	0.19	0.07	0.51	10.70	0.001*
Pulpotomy								
	Tooth (Second molar)[1]	−11.45	292.95	0.00	0.00	2.45×10^{244}	0.00	0.969
	Surface (Proximal)[2]	11.71	292.95	0.00	0.00	1.90×10^{244}	0.00	0.968
	Pain (Yes)[3]	11.55	281.10	104281.02	0.00	1.95×10^{244}	0.00	0.967

*SE: Standard error; CI: confidence interval; *: statistically significant ($p \leq 0.05$); 1: First primary molar is reference category; 2: Occlusal is reference category; 3: Absence of pain is reference category; *significant ($p < 0.05$).*

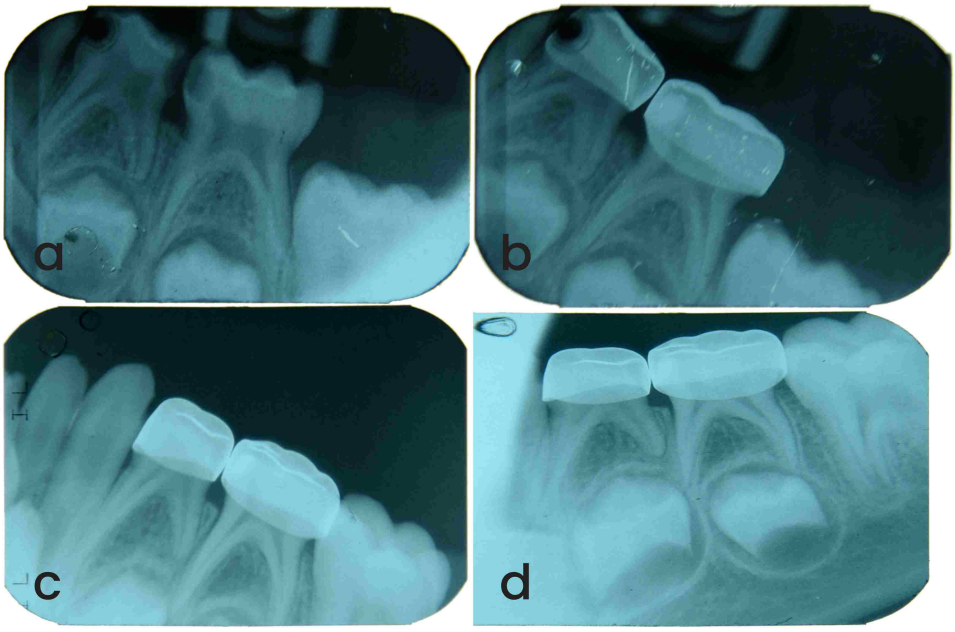

FIGURE 2. IPT in a mandibular second primary molar. (a) Preoperative, (b) postoperative, (c) 6 months, (d) 12 months.

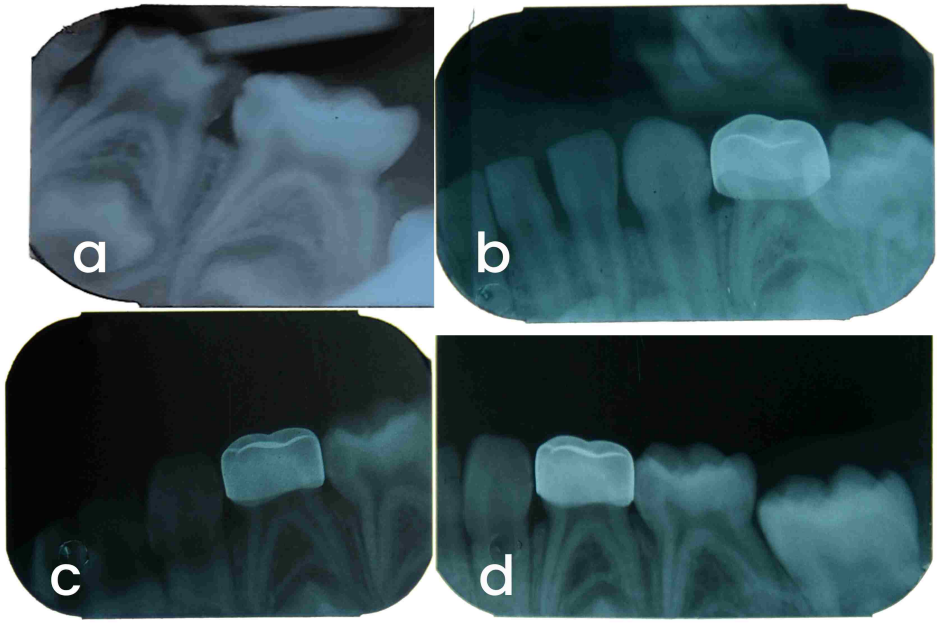

FIGURE 3. DPC in a mandibular first primary molar. (a) Preoperative, (b) postoperative, (c) 6 months, (d) 12 months.

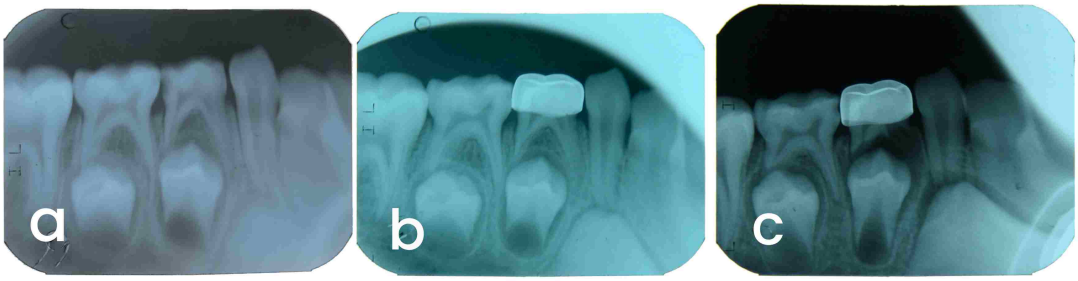

FIGURE 4. DPC in a mandibular first primary molar. (a) preoperative, (b) postoperative, (c) 6 months (ERR).

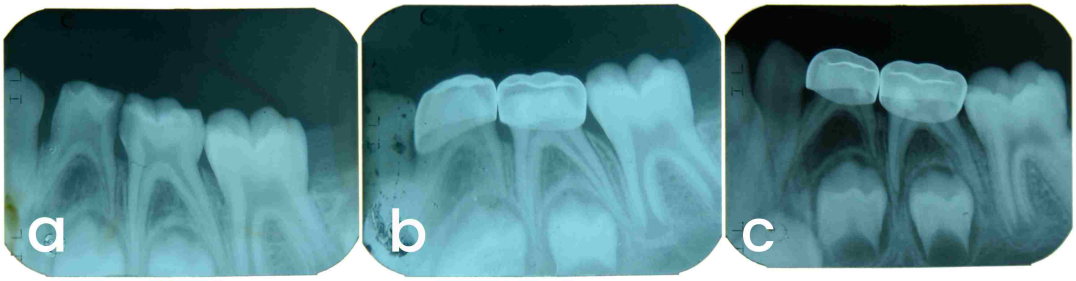

FIGURE 5. PP in mandibular first and second primary molars. (a) Preoperative, (b) postoperative, (c) 6 months (furcation involvement in first primary molar, widening of periodontal membrane space associated with spontaneous pain in second primary molar).

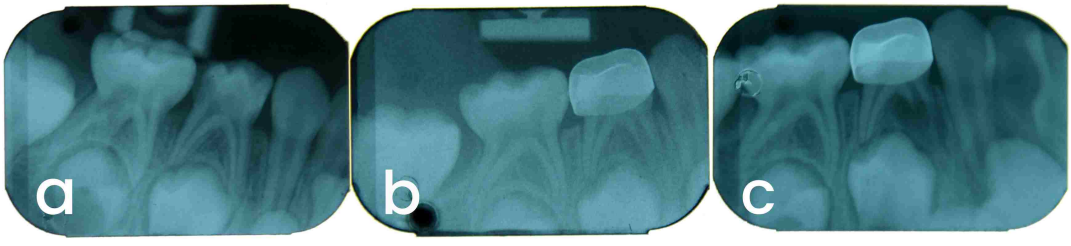

FIGURE 6. PP in a mandibular first primary molar. (a) Preoperative, (b) 6 months (IRR in mesial root), (c) 12 months (progressive IRR in mesial root).

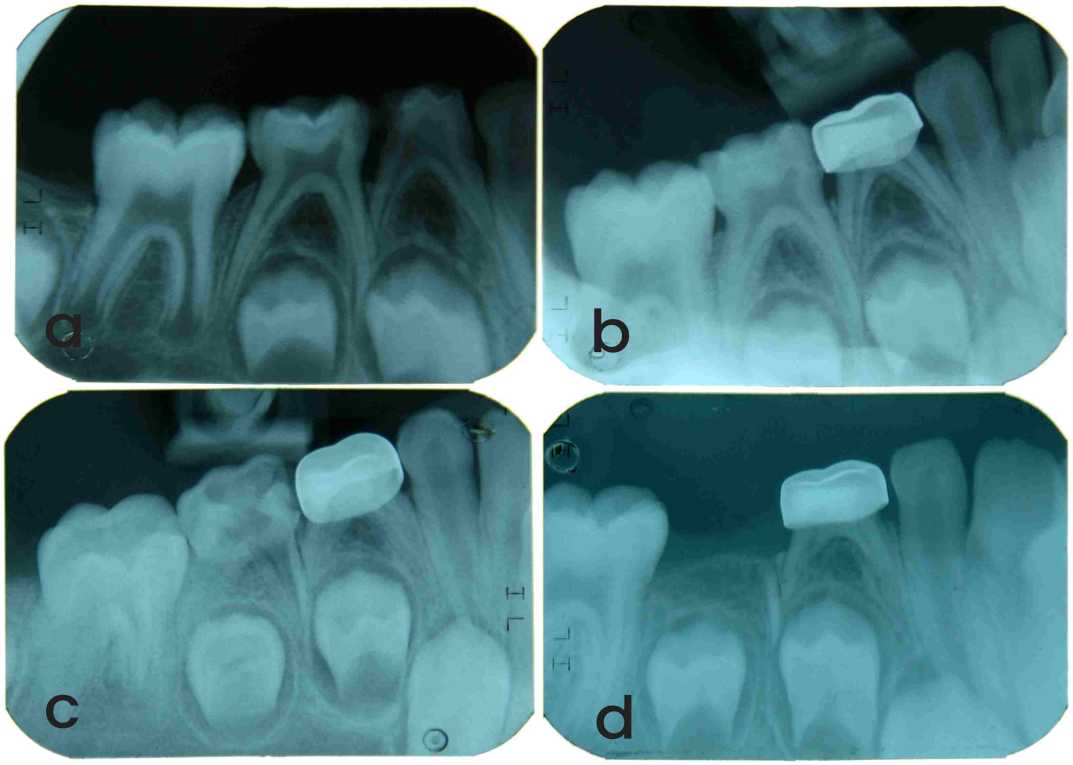

FIGURE 7. Pulpotomy in a mandibular first primary molar. (a) Preoperative, (b) postoperative, (c) 6 months, (d) 12 months.

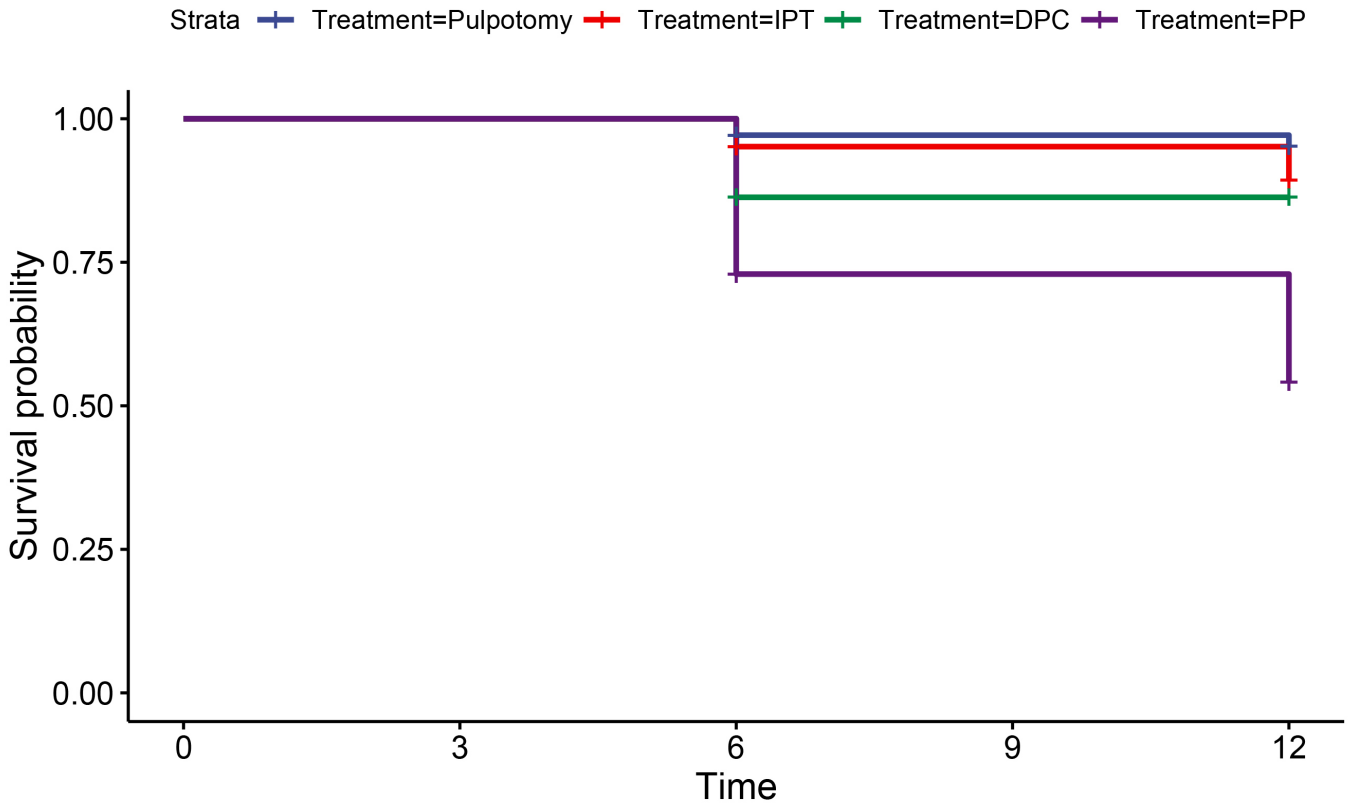

FIGURE 8. Survival distributions of the four VPTs. IPT: indirect pulp treatment; DPC: direct pulp capping; PP: partial pulpotomy.

support IPT as a simple, biological and patient-friendly approach that should be first attempted when treating deep caries in teeth with reversible pulpitis. An important factor to consider is the remaining dentin thickness (RDT) because the pulp has an excellent repair capacity with an RDT of 1 mm or more, while an RDT thickness below 0.5 mm could indicate irreversible pulp damage [10].

The combined success rate of DPC in this present study was 80.4% at 12 months, which lies within the success rates of DPC of pulp exposures encountered during NSCR [12, 13, 21, 23, 24, 27, 39]. Yet, the success rate of DPC in our study was lower than those reported using other bioactive agents [21, 26, 27, 39], including TheraCal LC, which showed comparable success to MTA [23]. But, in the latter study, only asymptomatic teeth were included, and disinfection with 0.12% chlorhexidine was employed before capping. Additionally, the authors did not report the caries lesion depth or involved tooth surfaces. However, Dimitraki *et al.* [27] reported a 79.7% success rate in primary molars treated with DPC using MTA at 12 months which was close to our results. Similar to our study, teeth with provoked pain were included, and most teeth had proximal decay. In a previous study [27], pulpotomy-treated teeth with the same inclusion criteria as those for DPC demonstrated similar survival over 12 months, supporting the use of DPC in a clinical situation of carious pulp exposures with controlled bleeding.

It has been argued that DPC is not indicated for carious exposures in primary teeth as the thin hard tissue and faster caries rate cause early pulp infection compared to permanent teeth [11]. However, teeth with carious exposures can suffer partial or total chronic pulpitis [11]. Thus, factors such as caries' rapidity, size and site of exposure, as well as the duration of exposure to the carious process before treatment, play a key role in determining the degree and extent of the inflammation and hence the healing process and prognosis [11, 24]. Accordingly, not all carious exposures have a poor prognosis. IL8, a strong indicator of late-phase inflammation, was barely found in the pulps of primary teeth with reversible pulpitis and carious exposures, indicating the possibility of repair in such teeth [40]. A systematic review on DPC for carious and non-carious exposures in primary molars concluded that there was no evidence to rationalize the disregard of DPC, especially for bioactive capping materials with low toxicity and systemic side effects. The authors reported a 24-month overall success rate for both exposure types ranging from 70% to 100% [41].

Guidelines recommend PP for carious exposures in young permanent teeth but not in primary teeth, possibly due to the limited evidence and better blood supply of young permanent teeth [14]. Interestingly, PP was mainly investigated in primary teeth with carious exposures and demonstrated success rates ranging from 82% to 95% [3, 42]. However, neither the diameter, the bleeding status of the carious exposure nor the cavity characteristics were reported in these previous studies. In another study, PP using MTA was assessed for carious exposures of 1–2 mm that achieved hemostasis in one minute and reported a success rate of 91.3% 12 months after treatment [43].

In our study, we tested different clinical scenarios; hence, different inclusion criteria for PP were employed. We hypothesized that for exposures with uncontrolled bleeding, resection of the inflamed tissues could be judged as complete based on the hemostasis of the remaining pulp tissue, thus, avoiding complete amputation of the coronal pulp. However, despite that all treated teeth in our study displayed hemostasis after 3 minutes, 57.4% of PP cases failed after 12 months. The high failure rate might be partly related to the inclusion criteria of this group, where it was observed that uncontrolled bleeding at the carious exposure site could be associated with generalized inflammation of the pulp [25]. Thus, failure might have resulted due to the wrong diagnosis, given the frequent lack of correlation between clinical findings and histological evaluation of the pulp [44, 45]. However, if these were the main reasons behind failure, pulpotomy in the current study would have also demonstrated high failure rates.

Another plausible explanation might be the lower adaptation of TheraCal PT to dentin, impairing its sealing ability, especially with wider exposures in PP. One study revealed that the gap between TheraCal LC and dentin in primary teeth was significantly higher than that with MTA and Biodentine [46]. Thus, although this could be true for TheraCal PT, no studies have evaluated this parameter. Moreover, enlarging exposure size can increase the risk of contamination with dentin chips and bacteria [11], indicating that the treatment might have benefited from a disinfection procedure prior to capping. Altogether, these could be considered important points requiring further clarification in future studies.

Pulpotomy in our study displayed a high success rate (96% at 12 months) close to those cited in the literature for other TCSs [29, 47, 48]. The inclusion criteria for pulpotomy in this present study may have caused the inclusion of teeth with a wider spread of inflammation in the coronal pulp, which differed from previous investigations, suggesting that pulpotomy could be successfully attempted as a last treatment option when more conservative VPTs are not feasible based on the size of exposure and/or extent of pulp inflammation. The high success rate of pulpotomy in this present study might be related to the complete removal of the coronal pulp tissues, thus decreasing the chances of incorrect diagnosis of pulp status [20].

Our study's most frequent radiographic failure was ERR, especially in DPC and PP followed by furcation radiolucency. The type of radiographic failures reported in different VPT studies was not consistent for a single type of treatment. However, an inflamed pulp resulting from infection is a common cause for ERR [49]. Furcation radiolucency is also a common finding in primary teeth with infected and inflamed pulp due to the high prevalence of accessory canals in the floor of pulp chambers [3, 34, 48, 50]. Thus, the high frequency of ERR followed by furcation radiolucency in this present study might be related to the misdiagnosis of the pulp status, or as stated earlier, due to possible gap formation between TheraCal PT and exposure site leading to microbial leakage and pulp inflammation. On the other hand, it was generally reported that IRR is a reaction of an inflamed vital pulp in response to irritation [50]. Since IRR frequency was low in all groups, it can be hypothesized that TheraCal PT may not stimulate a severe inflammatory response, which could in turn stimulate

the differentiation of odontoclasts.

Cox regression models revealed that proximal surface involvement and the presence of pain tended to increase the odds of failure. However, this was only significant in PP. On the other hand, second deciduous molars (SDMs) showed a non-significant tendency to decrease the odds of failure in all groups. Evidence indicated that proximal carious lesions were associated with a wider spread of inflammatory changes [20, 51]. Furthermore, it has been claimed that capping proximal pulp exposures might deprive the occlusal pulp tissues of the biological properties of the agent [11, 24]. It might also be that the coronal pulp tissue is deprived of its blood supply and undergoes necrosis [41].

Similarly, Franzon *et al.* [8] found an insignificantly lower success rate of IPT when proximal surfaces were involved compared to occlusal cavities. Others demonstrated no association between caries location and the success of IPT [36, 52, 53]. Disagreements with our results could be related to variations in the study design in terms of caries depth and methods of assessment. For instance, Maqbool *et al.* [36] included teeth with caries extending to the inner half of dentin and only conducted clinical evaluations.

Our results also showed that the absence of provoked pain and SDMs were associated with lower odds of failure, which were consistent with other studies assessing IPT and pulpotomy in primary teeth [36, 37, 54, 55]. SDMs have a larger pulp chamber compared to first deciduous molars (FDMs); thus, more progenitor cells would be available. The earlier eruption of FDMs makes them more liable to decay, and their thinner enamel and dentin allow for faster progression of dental caries. As for pain history, Farooq *et al.* [9] conducted a retrospective study in which they reported that IPT and pulpotomy-treated teeth with provoked pain had a lower success rate than asymptomatic teeth. The authors also speculated that teeth with pain compatible with reversible pulpitis could be successfully treated with either modality since the difference between successful and failed treatment in both groups was not significantly related to provoked pain.

5. Limitations

This trial was not randomized as the different inclusion criteria for each treatment group would require screening of a large population if randomization was employed, which was not convenient, especially during the COVID-19 pandemic, whereby few parents were willing to come for multiple visits. Statistical comparison between groups was not feasible due to the different inclusion criteria. Future RCT can be designed to assess each treatment modality (with its specific inclusion criteria) in relation to different clinical variables (*i.e.*, occlusal versus proximal cavities, absence versus presence of provoked pain, different capping agents, disinfection protocols, *etc.*). In addition, each treatment type can be assessed in relation to different inclusion criteria. No differentiation was made between wide exposures and pinpoint exposures in PP due to the low percentage of wide exposures in this group. Considering that TheraCal PT was only recently introduced, it might be difficult to determine whether the current findings are related to the provided treatment or capping material, indicating the need for assessing other capping agents. Other limitations included the short follow-up period, lack of preoperative RDT measurement and small sample size for detecting significant associations between some studied predictors and treatment outcomes.

6. Conclusions

Upon using TheraCal PT as a capping agent, and assigning teeth to IPT, DPC, PP, or pulpotomy according to the method of caries removal and exposure characteristics, the following can be concluded:

- The 12-month combined success rates of IPT (93.87%), DPC (80.4%) and pulpotomy (96.15%) were acceptable and were within the reported success rates of previous studies.
- PP was not successful in the clinical event of initial pinpoint exposures with uncontrolled bleeding, which might be related to the misdiagnosis of pulp status, gaps between TheraCal PT and the amputation site, or lack of disinfection prior to capping. Thus, clinical studies investigating different capping agents and disinfection protocols are needed.
- Proximal decay, provoked pain, and first primary molars were associated with higher odds of failure in all groups, which might be important in the treatment planning process.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

MW—Conducted clinical procedures, wrote the first draft of the manuscript; RE assisted in the clinical steps; RE and DH—Performed data collection and analysis; RE and DH—revised and edited the manuscript. All authors participated in the study conception and design. All authors have read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the Research Ethics Committee of the Faculty of Dentistry, Ain Shams University (FDASU-REC IR 091902) and complied with the principles of the Declaration of Helsinki. Parents of all participating children provided written informed consent before the clinical procedures.

ACKNOWLEDGMENT

Not applicable.

FUNDING

This research received no external funding.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

REFERENCES

[1] Monteiro J, Ní Chaollaí A, Duggal M. The teaching of management of the pulp in primary molars across Europe. European Archives of Paediatric Dentistry. 2017; 18: 203–208.

[2] Dhar V, Marghalani AA, Crystal YO, Kumar A, Ritwik P, Tulunoglu O, *et al*. Use of vital pulp therapies in primary teeth with deep caries lesions. Pediatric Dentistry. 2017; 39: E146–E159.

[3] Nematollahi H, Noorollahian H, Bagherian A, Yarbakht M, Nematollahi S. Mineral trioxide aggregate partial pulpotomy versus formocresol pulpotomy: a randomized, split-mouth, controlled clinical trial with 24 months follow-up. Pediatric Dentistry. 2018; 40: 184–189.

[4] Dos Santos NM, Leal SC, Gouvea DB, Sarti CS, Toniolo J, Neves M, *et al*. Sealing of cavitated occlusal carious lesions in the dentine of deciduous molars: a two-year randomized controlled clinical trial. Clinical Oral Investigations. 2022; 26: 1017–1024.

[5] BaniHani A, Santamaría RM, Hu S, Maden M, Albadri S. Minimal intervention dentistry for managing carious lesions into dentine in primary teeth: an umbrella review. European Archives of Paediatric Dentistry. 2022; 23: 667–693.

[6] Schwendicke F, Frencken JE, Bjørndal L, Maltz M, Manton DJ, Ricketts D, *et al*. Managing carious lesions: consensus recommendations on carious tissue removal. Advances in Dental Research. 2016; 28: 58–67.

[7] Garrocho-Rangel A, Quintana-Guevara K, Vázquez-Viera R, Arvizu-Rivera JM, Flores-Reyes H, Escobar-García DM, *et al*. Bioactive tricalcium silicate-based dentin substitute as an indirect pulp capping material for primary teeth: a 12-month follow-up. Pediatric Dentistry. 2017; 39: 377–382.

[8] Franzon R, Guimarães LF, Magalhães CE, Haas AN, Araujo FB. Outcomes of one-step incomplete and complete excavation in primary teeth: a 24-month randomized controlled trial. Caries Research. 2014; 48: 376–383.

[9] Farooq NS, Coll JA, Kuwabara A, Shelton P. Success rates of formocresol pulpotomy and indirect pulp therapy in the treatment of deep dentinal caries in primary teeth. Pediatric Dentistry. 2000; 22: 278–286.

[10] Boutsiouki C, Frankenberger R, Krämer N. Relative effectiveness of direct and indirect pulp capping in the primary dentition. European Archives of Paediatric Dentistry. 2018; 19: 297–309.

[11] Sujlana A, Pannu PK. Direct pulp capping: a treatment option in primary teeth? Pediatric Dental Journal. 2017; 27: 1–7.

[12] Chatzidimitriou K, Vadiakas G, Koletsi D. Direct pulp capping in asymptomatic carious primary molars using three different pulp capping materials: a prospective clinical trial. European Archives of Paediatric Dentistry. 2022; 23: 803–811.

[13] Canoğlu E, Güngör CH, Uysal S. Direct pulp capping of primary molars with calcium hydroxide or MTA following hemorrhage control with different medicaments: randomized clinical trial. Pediatric Dentistry. 2022; 44: 167–173.

[14] Winters J, Cameron AC, Widmer RP. Pulp therapy for primary and immature permanent teeth. Handbook of Pediatric Dentistry. 2013; 30: 103–122.

[15] Ibrahim S. Vital pulp therapy an insight over the available literature and future expectations. European Endodontic Journal. 2020; 5: 46–53.

[16] Koutroulis A, Kuehne SA, Cooper PR, Camilleri J. The role of calcium ion release on biocompatibility and antimicrobial properties of hydraulic cements. Scientific Reports. 2019; 9: 1–10.

[17] Varma B, Menon N, Janardhanan S, Kumaran P, Xavier A, Govinda B. Clinical and radiographic comparison of indirect pulp treatment using light-cured calcium silicate and mineral trioxide aggregate in primary molars: a randomized clinical trial. Contemporary Clinical Dentistry. 2016; 7: 475.

[18] Sanz JL, Soler-Doria A, López-García S, García-Bernal D, Rodríguez-Lozano FJ, Lozano A, *et al*. Comparative biological properties and mineralization potential of 3 endodontic materials for vital pulp therapy: Theracal PT, Theracal LC, and Biodentine on human dental pulp stem cells. Journal of Endodontics. 2021; 47: 1896–1906.

[19] Rodríguez-Lozano FJ, López-García S, García-Bernal D, Sanz JL, Lozano A, Pecci-Lloret MP, *et al*. Cytocompatibility and bioactive properties of the new dual-curing resin-modified calcium silicate-based material for vital pulp therapy. Clinical Oral Investigations. 2021; 25: 5009–5024.

[20] Duggal MS, Nooh A, High A. Response of the primary pulp to inflammation: a review of the Leeds studies and challenges for the future. European Journal of Paediatric Dentistry. 2002; 3: 111–114.

[21] Vafaei A, Azima N, Erfanparast L, Løvschall H, Ranjkesh B. Direct pulp capping of primary molars using a novel fast-setting calcium silicate cement: a randomized clinical trial with 12-month follow-up. Biomaterial Investigations in Dentistry. 2019; 6: 73–80.

[22] Nyvad B, Baelum V. Nyvad criteria for caries lesion activity and severity assessment: a validated approach for clinical management and research. Caries Research. 2018; 52: 397–405.

[23] Erfanparast L, Iranparvar P, Vafaei A. Direct pulp capping in primary molars using a resin-modified Portland cement-based material (TheraCal) compared to MTA with 12-month follow-up: a randomised clinical trial. European Archives of Paediatric Dentistry. 2018; 19: 197–203.

[24] Ali H, Raslan N. Direct pulp capping (DPC) in primary molars using (3Mix-MP) and the characteristics of the carious lesion as predictor factors for its success: a randomized controlled trial. European Archives of Paediatric Dentistry. 2021; 22: 633–642.

[25] Doğan S, Durutürk L, Orhan AI, Batmaz I. Determining treatability of primary teeth with pulpal exposure. Journal of Clinical Pediatric Dentistry. 2013; 37: 345–350.

[26] Asl Aminabadi N, Satrab S, Najafpour E, Samiei M, Jamali Z, Shirazi S. A randomized trial of direct pulp capping in primary molars using MTA compared to 3Mixtatin: a novel pulp capping biomaterial. International Journal of Paediatric Dentistry. 2016; 26: 281–290.

[27] Dimitraki D, Papageorgiou SN, Kotsanos N. Direct pulp capping versus pulpotomy with MTA for carious primary molars: a randomized clinical trial. European Archives of Paediatric Dentistry. 2019; 20: 431–440.

[28] Trairatvorakul C, Koothiratrakarn A. Calcium hydroxide partial pulpotomy is an alternative to formocresol pulpotomy based on a 3-year randomized trial. International Journal of Paediatric Dentistry. 2012; 22: 382–389.

[29] Guven Y, Aksakal SD, Avcu N, Unsal G, Tuna EB, Aktoren O. Success rates of pulpotomies in primary molars using calcium silicate-based materials: a randomized control trial. BioMed Research International. 2017; 2017: 4059703.

[30] Smaïl-Faugeron V, Porot A, Muller-Bolla M, Courson F. Indirect pulp capping versus pulpotomy for treating deep carious lesions approaching the pulp in primary teeth: a systematic review. European Journal of Paediatric Dentistry. 2016; 17: 107–112.

[31] Smaïl-Faugeron V, Glenny AM, Courson F, Durieux P, Muller-Bolla M, Fron Chabouis H. Pulp treatment for extensive decay in primary teeth. Cochrane Database of Systematic Reviews. 2018; 5: CD003220.

[32] Sahin N, Saygili S, Akcay M. Clinical, radiographic, and histological evaluation of three different pulp-capping materials in indirect pulp treatment of primary teeth: a randomized clinical trial. Clinical Oral Investigations. 2021; 25: 3945–3955.

[33] Mathur V, Dhillon J, Logani A, Kalra G. Evaluation of indirect pulp capping using three different materials: a randomized control trial using cone-beam computed tomography. Indian Journal of Dental Research. 2016; 27: 623.

[34] Boddeda K, Rani CR, V Vanga N, Chandrabhatla S. Comparative evaluation of biodentine, 2% chlorhexidine with RMGIC and calcium hydroxide as indirect pulp capping materials in primary molars: an *in vivo* study. Journal of Indian Society of Pedodontics and Preventive Dentistry. 2019; 37: 60.

[35] Gurcan AT, Seymen F. Clinical and radiographic evaluation of indirect pulp capping with three different materials: a 2-year follow-up study. European Journal of Paediatric Dentistry. 2019; 20: 105–110.

[36] Maqbool M, Noorani TY, Samsudin NA, Awang Nawi MA, Rossi-Fedele G, Karobari MI, *et al*. Association of vital pulp therapy outcomes with tooth type, arch location, treatment type, and number of surfaces destroyed in deciduous teeth: a retrospective study. International Journal of Environmental Research and Public Health. 2021; 18: 7970.

[37] Vij R, Coll JA, Shelton P, Farooq NS. Caries control and other variables associated with success of primary molar vital pulp therapy. Pediatric Dentistry. 2004; 26: 214–221.

[38] Fang RR, Chang KY, Lin YT, Lin YTJ. Comparison of long-term outcomes between ferric sulfate pulpotomy and indirect pulp therapy in

primary molars. Journal of Dental Sciences. 2019; 14: 134–137.
[39] Fallahinejad Ghajari M, Asgharian Jeddi T, Iri S, Asgary S. Treatment outcomes of primary molars direct pulp capping after 20 months: a randomized controlled trial. Iranian Endodontic Journal. 2013; 8: 149–152.
[40] Waterhouse PJ, Nunn JH, Whitworth JM. Prostaglandin E2 and treatment outcome in pulp therapy of primary molars with carious exposures. International Journal of Paediatric Dentistry. 2002; 12: 116–123.
[41] Garrocho-Rangel A, Esparza-Villalpando V, Pozos-Guillen A. Outcomes of direct pulp capping in vital primary teeth with cariously and non-cariously exposed pulp: a systematic review. International Journal of Paediatric Dentistry. 2020; 30: 536–546.
[42] Schröder U, Szpringer-Nodzak M, Janicha J, Wacińska M, Budny J, Mlosek K. A one-year follow-up of partial pulpotomy and calcium hydroxide capping in primary molars. Dental Traumatology. 1987; 3: 304–306.
[43] Gateva RKN. Success of direct pulp capping and partial pulpotomy of primary teeth using MTA. International Journal of Science and Research. 2015; 4: 287–291.
[44] Mutluay M, Arikan V, Sari S, Kisa Ü. Does achievement of hemostasis after pulp exposure provide an accurate assessment of pulp inflammation? Pediatric Dentistry. 2018; 40: 37–42.
[45] SCHRÖDER U. Agreement between clinical and histologic findings in chronic coronal pulpitis in primary teeth. European Journal of Oral Sciences. 1977; 85: 583–587.
[46] Al Tuwirqi AA, El Ashiry EA, Alzahrani AY, Bamashmous N, Bakhsh TA. Tomographic evaluation of the internal adaptation for recent calcium silicate-based pulp capping materials in primary teeth. BioMed Research International. 2021; 2021: 1–10.
[47] Çelik BN, Mutluay MS, Arıkan V, Sarı Ş. The evaluation of MTA and Biodentine as a pulpotomy materials for carious exposures in primary teeth. Clinical Oral Investigations. 2019; 23: 661–666.
[48] El Meligy OAES, Alamoudi NM, Allazzam SM, El-Housseiny AAM. BiodentineTM versus formocresol pulpotomy technique in primary molars: a 12–month randomized controlled clinical trial. BMC Oral Health. 2019; 19: 3.
[49] Vieira-Andrade RG, Drumond CL, Alves LPA, Marques LS, Ramos-Jorge ML. Inflammatory root resorption in primary molars: prevalence and associated factors. Brazilian Oral Research. 2012; 26: 335–340.
[50] Ahuja S, Surabhi K, Gandhi K, Kapoor R, Malhotra R, Kumar D. Comparative evaluation of success of Biodentine and mineral trioxide aggregate with formocresol as pulpotomy medicaments in primary molars: an *in vivo* study. International Journal of Paediatric Dentistry. 2020; 13: 167–173.
[51] Kassa D, Day P, High A, Duggal M. Histological comparison of pulpal inflammation in primary teeth with occlusal or proximal caries. International Journal of Paediatric Dentistry. 2009; 19: 26–33.
[52] Dalpian DM, Ardenghi TM, Demarco FF, Garcia-Godoy F, De Araujo FB, Casagrande L. Clinical and radiographic outcomes of partial caries removal restorations performed in primary teeth. American Journal of Dentistry. 2014; 27: 68–72.
[53] Casagrande L, Bento LW, Dalpian DM, García-Godoy F, De Araujo FB. Indirect pulp treatment in primary teeth: 4-year results. American Journal of Dentistry. 2010; 23: 34–38.
[54] Al-Zayer MA, Straffon LH, Feigal RJ, Welch KB. Indirect pulp treatment of primary posterior teeth: a retrospective study. Pediatric Dentistry. 2003; 25: 29–36.
[55] Subramaniam P, Konde S, Mathew S, Sugnani S. Mineral trioxide aggregate as pulp capping agent for primary teeth pulpotomy: 2 year follow up study. Journal of Clinical Pediatric Dentistry. 2009; 33: 311–314.

How to cite this article: Mariem Wassel, Dina Hamdy, Reham Elghazawy. Evaluation of four vital pulp therapies for primary molars using a dual-cured tricalcium silicate (TheraCal PT): one-year results of a non-randomized clinical trial. Journal of Clinical Pediatric Dentistry. 2023; 47(2): 10-22. doi: 10.22514/jocpd.2023.004.