Clinical and radiographic evaluation of indirect pulp capping with three different materials: a 2-year follow-up study

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Abstract

Aim Indirect pulp capping (IPC) is a treatment that preserves pulp vitality. Several materials have been used for this procedure. The aim of this study is to evaluate the radiographic and clinical outcomes of TheraCal LC (Bisco Inc., Schaumburg, IL, USA) and to compare it with mineral trioxide aggregate (MTA) (Pro Root MTA, Dentsply Tulsa, Johnson City, TN, USA) and calcium hydroxide [$Ca(OH)_2$] (Dycal, Dentsply De Trey Konstanz, Germany) biomaterials in IPC treatment.

Materials and methods A total of 295 teeth, including second primary molars and first permanent molars with IPC indications from healthy and cooperative children aged between 4–15 years, were included in this study. Teeth were divided into three groups according to the materials used for pulp capping. Indirect pulp treatment was applied using Dycal for 91 teeth, ProRoot MTA for 89 teeth and TheraCal LC for 115 teeth. Primary molars were restored with the compomer material, and permanent molars were restored with the resin composite material. Restorations were evaluated with the Modified United States Public Health Service (modified USPHS) criteria. Clinical and radiographic findings were evaluated for 24 months at follow-up. Statistics**:** Statistical analysis was performed using the IBM SPSS Statistics 22 (IBM SPSS, Turkey) program, with descriptive statistical methods (means, standard deviations) and Chi-square, Fisher's exact test, and Yates's continuity correction ($p<0.05$ significance level) to evaluate the data.

Results There were no statistically significant differences between the materials ($p>0.05$). The respective success rates of ProRoot MTA, Theracal LC, and Dycal were 94.4%, 87.8%, and 84.6%. There was no statistically significant difference between primary and permanent teeth according to the modified USPHS criteria ($p>0.05$).

Conclusions These results support the idea that the success of IPC is independent from the capping material. Recently produced calcium-silicate based materials can also be used for IPC. The most important factors are to apply the indirect pulp treatment carefully, avoiding bacterial contamination, and to seal the teeth with hermetic restoration. More clinical studies with longer follow-up periods are required for understanding the clinical efficiency of these materials.

KEYWORD Calcium hydroxide, Indirect pulp treatment, Mineral trioxide aggregate, Pulp capping, Theracal LC.

Introduction

Dental pulp integrity is important, especially for the apexogenesis of young permanent teeth. The longevity of the teeth in the mouth depends on a proper crown/root ratio and sufficient thickness of the dentine walls. For this reason, protecting dental pulp is the first aim for young permanent dentition [AAPD, 2014].

There are some differences between primary and permanent teeth. When the sizes of teeth are compared, the enamel and dentin layers of primary teeth are thinner, the pulp of primary teeth is closer to the enamel layer and the primary teeth pulp is wider. These factors lead to easy pulpal perforation in primary teeth with very deep caries. However, in the primary dentition, it is important to protect teeth until their normal exfoliation time to provide aesthetics, functional health, phonation, and integrity of the dental arch. These factors are also crucial for the health of the new permanent teeth.

Treatments that preserve tooth vitality are identified as vital pulp therapies. The aim of vital pulp therapy is to protect the pulp vitality, the tooth function and its supporting tissues in the case of dental caries, traumatic injuries and other conditions [AAPD, 2014].

Vital pulp therapies can be divided into three treatments: indirect pulp treatment, which can be used in deep caries cavities, and direct pulp capping and pulpotomy, which can be used in pulp perforations [Fuks, 2008].

Many materials have been used and tested in indirect pulp capping (IPC) treatments for primary and permanent teeth [Marchi et al., 2006; Renata et al., 2007; Gruythuysen et al., 2010]. Calcium hydroxide [$Ca(OH)_2$] is the most popular material of vital pulp treatments [Caprioglio et.al., 2014]. However, researchers have tried to find alternative materials because of the occurrence of resorption and other symptoms after long follow-up periods [Gruythuysen et al., 2010]. Mineral trioxide aggregate (MTA) and TheraCal LC are two alternatives that can be used in direct and indirect pulp treatments [Tuna and Ölmez, 2008; Gandolfi et al., 2012].

MTA is a biocompatible material that has seen increased usage in recent years. Hydroxyapatite crystals are released via the MTA when contact is made with the tissue fluid. MTA has transduction activity at the calcific tissue, which increases the ease of human orofacial mesenchymal stem cell

differentiation and the mineralisation process of human dental pulp cells. MTA can also be used as a pulp capping agent. MTA has been reported to form a thicker dentin bridge when compared to calcium hydroxide and lead to less inflammation, hyperemia and pulp necrosis [Caprioglio et.al.,2014]. However, some drawbacks have been reported, such as its long curing time, high price and potential coloring of the teeth [Qureshi et al., 2014].

TheraCal LC (Bisco Inc., Schaumburg, IL, USA) is a calcium silicate-based resin modifying light-curing material designed for use in indirect and direct capping. It has been reported that it is well tolerated by odontoblasts. Its content is similar to that of MTA [Qureshi et al., 2014; Griffin, 2012].

The aim of this study is to evaluate the clinical and radiographic success rates of these materials in IPC. Additionally, an alternative material, TheraCal LC, was compared with ProRoot MTA and Dycal.

Material and Methods

The ethical approval was obtained within the rules of the Helsinki Declaration of 1975, as revised in 2000. This study was performed in the Istanbul University Faculty of Dentistry, Department of Paediatric Dentistry. Informed consent was obtained from patients' parents.

The G*Power program (version 3.1.9.2 for Windows) was used to determine the success rate of the power analysis: the total number of samples detected was n: 92, for the effect size: 0.293, with a power: 0.80 and α: 0.05.

This study was conducted as a prospective clinical and radiographic evaluation. A total of 295 teeth (second primary and first permanent molars) from 4- to 15-year-old healthy and cooperative children with nonclinical and radiographic evidence of infection symptoms and with indications for indirect pulp treatment were included in this study. The teeth were divided into three groups according to materials and dentition.

Initially, panoramic radiographs were taken for the examination and diagnosis of dental and oral information, and physical examinations and ice-cold tests were performed to assess the vitality of the teeth. Teeth with clinical abscesses, signs of inflammation (abnormal mobility, tenderness to percussion and palpation, spontaneous pain), radiographic lesions in the root apex and furcation and pathological root resorption were excluded from the study. This exclusion criteria are compatible with those for other vital pulp therapies such as direct pulp capping and pulpotomy [Malekafzali et.al.,2011; Ulusoy et.al., 2014; Odabaş et.al., 2012].

A rubber dam kit (Premier Rubber Dams, Glandale, California, USA) was used for isolation.

$Ca(OH)_2$ (Dycal, Dentsply De Trey Konstanz, Germany), MTA (Pro Root MTA, Dentsply Tulsa, Johnson City, TN, USA), and TheraCal LC (Bisco Inc., Schaumburg, IL, USA) were used as capping materials in the study.

Steps of clinical practice

After application of topical and local anaesthesia, deep caries lesions were cleaned according to the revised AAPD guidelines [2014]. Cavities were washed with 2% chlorhexidine gluconate irrigation solution (Klorhex, Drogsan, Turkey) and then were dried with an air-water spray and cotton pellets. Dycal, ProRoot MTA and TheraCal LC materials were applied according to the manufacturer's instructions.

Primary molars were restored incrementally with the compomer material (Dyract XP, Dentsply), and permanent molars were restored with a composite material (Filtek P60, Z350 XT, 3M ESPE).

The curing light LED device (Woodpecker LED. D) that was used in this study had 430- to 480-nanometer wavelength light output for polymerisation. When restoration was completed, the rubber dam was removed, and occlusions were controlled with articulation paper. Finally, polishing was applied with yellow banded burs (Diamant Diamond Dental Burs, Turkey) and varnish discs (Kenda Dental Polishers, Liechtenstein). Dental periapical radiographs were taken at the 1-, 3-, 6-, 12-, 18- and 24-month follow-up.

Evaluation of success criteria used in this study

Clinical exclusion criteria.

- Pain (spontaneous and chronic).
- Fistula.
- Acute pulpal inflammation.
- Pain with percussion.
- Pathologic mobility.
- Abscess.
- Symptoms of absence of vitality (negative response to thermal pulp test).

Radiographic exclusion criteria.

- Progression of caries lesion to pulp.
- Perforation of pulp.
- Intermittent or irregular lamina dura.
- Expanded range of periodontal ligament.
- Periapical radiolucency.
- Internal and external resorption.

In addition to clinical and radiographic criteria, restoration success was evaluated using the modified United States Public Health Service (modified USPHS) criteria. [Katsanos and Arizos, 2011]

Completed treatments were examined clinically and radiographically in the control sessions. If at least one of these criteria existed, treatment was determined to have failed.

Treatments and radiographic and clinical assessments were performed by the same researcher.

Statistical analysis was performed using the IBM SPSS Statistics 22 (IBM SPSS, Turkey) programme, with descriptive statistical methods (means, standard deviations) and Chi-square, Fisher's exact test and Yates's continuity correction ($p<0.05$ significance level) to evaluate the data.

Results

A total of 95 (100%) children, consisting of 52 (54.74%) girls and 43 (45.26%) boys between 4 and 15 years old, were included in this study. The mean age of the patients was 8.55 ± 2.03 years. A total of 295 (100%) teeth were treated, 135 (45.76%) of which were primary teeth, and 160 (54.24%) of which were permanent teeth. Second primary and first permanent molars were treated: 134 of them were in the maxilla, and 161 were in the mandible. A total of 91 teeth were treated with Dycal, 89 teeth were treated with ProRoot MTA and 115 with TheraCal LC.

- There was no statistically significant difference between the distribution of the materials according to primary and permanent teeth (p=0.654) (Table 1).
- A statistically significant difference was not observed in material distributions between male and female groups (p=0.828).
- There was no statistically significant difference between

	Dycal		ProRoot MTA		TheraCal LC		p
	n	%	n	%	n	%	
Primary teeth	45	49.45	38	42.70	52	45.22	0.654
Permanent teeth	46	50.55	51	57.30	63	54.78	
Total	91	100.00	89	100.00	115	100.00	

TABLE 1
Distribution of the materials used in the study.

success rates of the materials (p>0.05). However, the success rate of the ProRoot MTA material was higher than those of TheraCal LC and Dycal (the success rates were 94.4%, 87.8% and 84.6 % respectively).

- No statistically significant differences were observed in the incidence of success in the male and female groups (p>0.05). There was no statistically significant difference between the distribution of success rates of the materials in the group of primary teeth (p>0.05).
- There was no statistically significant difference between the distribution of success rates of the materials in the group of permanent teeth (p>0.05).
- Statistically significant differences were not observed between teeth groups based on their clinical symptoms (pain, fistulas, pain upon percussion, pathological mobility, abscess, vitality symptoms) after treatment (p>0.05) (Table 2).
- Statistically significant differences were not observed between teeth groups based on radiological pathology after the treatment (p>0.05).
- Statistically significant differences were not observed between groups of materials based on their clinical symptoms (pain, fistulas, pain upon percussion, pathological mobility, abscess, vitality symptoms) after treatment (p>0.05).
- Statistically significant differences were not observed between groups of materials based on radiological pathology after treatment (p>0.05).
- Success rates of restorations were evaluated according to the modified USPHS criteria.
- There was no statistically significant difference between primary and permanent teeth according to the modified USPHS criteria (p>0.05).
- There were no statistically significant differences between the distribution of material groups' success according to the modified USPHS criteria at the 6-, 12-, 18- and 24-month follow-up (p>0.05) (Table 3).

Discussion

IPC is a conservative treatment of the dentin-pulp complex. Due to the biological cycle of primary teeth in the oral cavity, IPC has been defined as a limited treatment in primary dentition [Marchi et al., 2008].

Duque et al. [2009] stated that the indirect pulp treatments applied to primary teeth supported successful results when they were administered with detailed dental history and controllable caries activity and when they were applied with appropriate capping materials, such as $Ca(OH)_2$. It has been suggested that the success of IPC increases with the usage of $Ca(OH)_2$ and that this material is a good alternative for the control of the decay of the primary teeth. However, usage of $Ca(OH)_2$ should not be perceived as a decisive factor, as the applied technique was independent of the material in the

		Primary teeth	Permanent teeth	p
		n (%)	n (%)	
Pain	+	7 (5.2%)	10 (6.3%)	[1]0.888
	-	128 (94.8%)	150 (93.8%)	
Fistula	+	3 (2.2%)	0 (0%)	[2]0.095
	-	132 (97.8%)	160 (100%)	
Pain upon percussion	+	7 (5.2%)	9 (5.6%)	[1]1.000
	-	128 (94.8%)	151 (94.4%)	
Radiological pathology	+	12 (8.9%)	11 (6.9%)	[1]0.671
	-	123 (91.1%)	149 (93.1%)	
Mobility	Normal	129 (95.6%)	153 (95.6%)	[1]1.000
	Abnormal	6 (4.4%)	7 (4.4%)	
Abscess	+	6 (4.4%)	9 (5.6%)	[1]0.846
	-	129 (95.6%)	151 (94.4%)	
Vitality	Vital	128 (94.8%)	151 (94.4%)	[1]1.000
	Non-vital	7 (5.2%)	9 (5.6%)	

[1]*Continuity (Yates) correction* [2]*Fisher's exact test*

TABLE 2 Distribution of clinical post-treatment symptoms according to tooth groups.

		Material			p
		Dycal	ProRoot MTA	TheraCal LC	
		n (%)	n (%)	n (%)	
Anatomical form 6 month	Successful	90 (98.9%)	89 (100%)	114 (99.1%)	0.635
	Unsuccessful	1 (1.1%)	0 (0%)	1 (0.9%)	
Anatomical form 12 month	Successful	85 (100%)	88 (100%)	108 (99.1%)	0.451
	Unsuccessful	0 (0%)	0 (0%)	1 (0.9%)	
Anatomical form 18 month	Successful	85 (100%)	88 (100%)	107 (100%)	-
	Unsuccessful	0 (0%)	0 (0%)	0 (0%)	
Anatomical form 24 month	Successful	83 (97.6%)	87 (98.9%)	107 (100%)	0.289
	Unsuccessful	2 (2.4%)	1 (1,1%)	0 (0%)	
Marginal integrity 6 month	Successful	90 (98.9%)	89 (100%)	114(99.1%)	0.635
	Unsuccessful	1 (1.1%)	0 (0%)	1 (0.9%)	
Marginal integrity 12 month	Successful	85 (100%)	88 (100%)	107 (98.2%)	0.202
	Unsuccessful	0 (0%)	0 (0%)	2 (1.8%)	
Marginal integrity 18 month	Successful	85 (100%)	88 (100%)	107 (100%)	-
	Unsuccessful	0 (0%)	0 (0%)	0 (0%)	
Marginal integrity 24 month	Successful	84 (98.8%)	88 (100%)	106 (99.1%)	0.618
	Unsuccessful	1 (1.2%)	0 (0%)	1 (0.9%)	
Interproximal contact 6 month	Successful	90 (98.9%)	89 (100%)	114 (99.1%)	0.635
	Unsuccessful	1 (1.1%)	0 (0%)	1 (0,9%)	
Interproximal contact 12 month	Successful	85 (100%)	88 (100%)	107 (98.2%)	0.202
	Unsuccessful	0 (0%)	0 (0%)	2 (1.8%)	
Interproximal contact 18 month	Successful	85 (100%)	88 (100%)	107 (100%)	-
	Unsuccessful	0	0 (0%)	0	
Interproximal contact 24 month	Successful	85 (100%)	88 (100%)	107 (100%)	-
	Unsuccessful	0 (0%)	0 (0%)	0 (0%)	
Recurrent caries 6 month	Successful	90 (98.9%)	89 (100%)	115 (100%)	0.325
	Unsuccessful	1 (1.1%)	0 (0%)	0 (0%)	
Recurrent caries 12 month	Successful	85 (100%)	88 (100%)	107 (98.2%)	0.202
	Unsuccessful	0 (0%)	0 (0%)	2 (1.8%)	
Recurrent caries 18 month	Successful	85 (100%)	88 (100%)	107 (100%)	-
	Unsuccessful	0 (0%)	0 (0%)	0 (0%)	
Recurrent caries 24 month	Successful	85 (100%)	87 (98.9%)	106 (99.1%)	0.636
	Unsuccessful	0 (0%)	1 (1.1%)	1 (0.9%)	
Surface texture 6 month	Successful	90 (98.9%)	89 (100%)	115 (100%)	0.325
	Unsuccessful	1 (1.1%)	0 (0%)	0 (0%)	
Surface texture 12 month	Successful	85 (100%)	88 (100%)	109 (100%)	-
	Unsuccessful	0 (0%)	0 (%0)	0 (0%)	
Surface texture 18 month	Successful	85 (100%)	88 (100%)	107 (100%)	-
	Unsuccessful	0 (0%)	0 (0%)	0 (0%)	
Surface texture 24month	Successful	84 (98.8%)	86 (98.9%)	106 (100%)	0.537
	Unsuccessful	1 (1.2%)	1 (1.1%)	0 (0%)	

TABLE 3 Success rates of restorations according to materials and modified USPHS criteria.

success of the restoration [Duque et al., 2009]. In accordance with Duque's study, IPC in primary teeth was found to be successful in this study. In addition to Dycal, Theracal LC and ProRoot MTA were also found to be successful.

Falster et al. [2002] applied indirect pulp treatment to primary teeth with an adhesive resin system (Scotchbond MultiPurpose) and $Ca(OH)_2$ (Dycal); the teeth were then followed clinically and radiographically for 2 years. This study had similar clinical and radiographic success rates as the Falster's study [Falster et al., 2002].

Rosenberg et al. [2013] stated that proper case selection and an adequate marginal seal were required for successful results and that IPC is an effective treatment for primary molars. Al-Zayer et al. treated patients with IPC, who were then followed clinically and radiographically for 73 months. It was reported that indirect pulp treatment was a successful alternative technique for primary molar teeth with deep caries and that the use of $Ca(OH)_2$ (Dycal) as a pulp capping material significantly enhanced the success rate. The results of this study are consistent with Al-Zayer's study.

Marchi et al. [2006] evaluated primary teeth treated with IPC using $Ca(OH)_2$ (Dycal) and glass ionomer (Vitremer 3M Espe) clinically and radiographically. After 48 months, they found no statistically significant differences between the two groups. These results demonstrate that IPC prevents the development of dental decay in primary teeth. That study's results were consistent with this study.

Gruythuysen et al. [2010] treated primary and permanent teeth with IPC and reported a 3-year survival rate. The teeth were evaluated clinically and radiographically and were cleaned with a partial excavation technique that left the center of the infected part of decay. Although the patient selection criteria (age, status of cooperation), the number of treated teeth, the capping material used and the follow up time were different, the results of Gruythuysen's study are compatible with those of the present one. It is conceivable that the success of the treatment was due to the hermetic restoration rather than the capping material.

George et al. [2015] investigated the clinical and radiographic effects of IPC with white MTA and $Ca(OH)_2$ (Dycal) over 6 months in primary molars. Permanent restorations were then applied in the second session. In contrast to George's study, restorations were applied at the single stage in this study. The inclusion criteria and the evaluation of the clinical and radiographic success criteria of George et al.'s study were compatible with this study. In the study conducted, it was stated that MTA was superior to Dycal both clinically and radiographically in indirect pulp treatment for primary molar teeth. In this study, there were no statistically significant differences between success rates of the Dycal, ProRoot MTA and TheraCal LC materials. However, the success rate of the MTA material (MTA=94.4%, Theracal LC=87.8%) Dycal=84.6%) was found to be higher than those of other materials. It was thought that the different results were obtained because of the number of patients and teeth, the age range, the restoration method, the follow-up period and the methods used for radiographic evaluation. Longer follow-up work including more teeth is needed [George et al., 2015].

Büyükgüral and Çehreli [2008] compared three adhesive systems with $Ca(OH)_2$ as protective materials of the dentin-pulp complex and evaluated their success rates. Teeth were evaluated clinically and radiographically for 24 months. Although there was no pulp protection with adhesive systems, no teeth showed clinical and radiographic symptoms during the study. At the end of two years, the success rate was 100%. Similar results were observed in all groups, and it was concluded that $Ca(OH)_2$ was not a determining factor for the success of the treatment. The success rates of Büyükgüral's study are compatible with those of this study, which are also compatible with studies that reported pulp capping treatments with high success rates.

Renata et al. [2207] applied indirect pulp treatment to primary teeth and evaluated clinical and radiographic changes for 36 months. Hydro-C (a lining material containing $Ca(OH)_2$) and gutta-percha sheets were used in the second group. At the end of 36 months, the success rate of the first group was 73.3%, and the success rate of the second group was 85.7%, with a general total success rate of 79.3%; there were no significant differences between the two groups (p=0.36). The stated results are compatible with this study. In addition to these results, it was noted that composite resin-based material could stop the progression of decay at the bottom of the cavity regardless of the capping material used, as it is thought that a sealed continuous restoration determines the success in IPC treatment.

Casagrande et al. [2010] followed 40 primary teeth clinically and radiographically after indirect pulp treatment with a self-etching adhesive system and $Ca(OH)_2$ material for a long time (up to 60 months). At the end of the follow-up, there was no statistically significant difference between the two groups, and the general success rate was 78%. As a result of the study, it has been stated that indirect pulp treatment is a simple and effective alternative treatment to protect pulp vitality in primary teeth with deep caries. The results of this study are compatible with Casagrande's study. However, it was thought that longer follow-up times were necessary for failures to be observed.

Conclusions

IPC is important for the longevity of primary teeth's vitality and young permanent teeth's apexogenesis.

In this study, IPC could be successfully applied in a single session in primary and permanent molar teeth. Treatment success was independent of capping material and was also compatible with other study results that indicate the importance of the hermetic seal of the restoration. No statistically significant differences were found between the results comparing the materials according to the modified USPHS criteria (p>0.05). As there are many other dental and patient status factors (such as remaining dentin thickness, proximity to the pulp, and the patient's dietary and brushing habits) that can affect the restoration success, it is thought that the capping materials do not have a direct effect on the treatment success.

These results are consistent with previous reports; there were no statistically significant differences between the materials, likely due to the similarities of standards and follow-up periods. These results support the idea that the success of IPC is independent from the capping material.

Recently produced calcium silicate-based materials can also be used for IPC. The most important factors are to apply the indirect pulp treatment carefully, avoiding bacterial contamination, and to seal the teeth with hermetic restoration.

More clinical studies, including a larger sample and longer follow-up times, are necessary for achieving a better

understanding of the clinical efficiency of the materials.

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