Comparative Evaluation of Indirect Pulp Therapy in Young Permanent Teeth using Biodentine and Theracal: A Randomized Clinical Trial

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Objective: *In a tooth with deep dentinal caries; judicious removal of infected dentin and isolating affected dentin from oral fluids with suitable biocompatible material is called indirect pulp therapy (IPT). This randomized clinical trial was done to evaluate and compare the efficacy of Biodentine, Theracal LC and. Dycal as an indirect pulp capping agent in young permanent teeth.* ***Study Design:*** *IPT was performed in 60 young permanent molars with caries approaching pulp in 55 healthy children using Biodentine, Theracal and Dycal. A 2-3mm layer of GIC was placed over the intervening material followed by restoration of cavity with composite. Clinical and radiographic examinations were conducted at 3 weeks, 3 months, 6 months,12 months, 18 months and 24 months. The data was compared using chi-square test at a significance level of 0.05.* ***Results****: By end of 24 months ,54 teeth presented for follow up with overall success rate of 100% in Theracal, 94.44% in Biodentine, and 77.78% in Dycal. Overall success of Theracal was statistically significant in comparison to Biodentine and Dycal at 24 months follow up (p= 0.03)*

Conclusions*: Radiographic and clinical outcomes of Theracal and Biodentine suggest their use as an alternative material for IPT in young permanent molars with higher success.*

Keywords*: Theracal LC, Biodentine, Tricalcium silicate, Indirect pulp therapy,Young permanent teeth*

INTRODUCTION

Dental caries is one of the most frequently occurring diseases affecting human beings that becomes a challenge for dentists as the disease progresses. The ultimate goal of operative and endodontic treatment is to preserve and maintain the vitality of pulp so as to allow continued development of odontogenic apparatus.[1]

The discussion regarding the extent of caries excavation in order to arrest the caries process in a deep carious lesion is not new.[2] John Tomes (1859) wrote "it is better that a layer of discolored dentine be allowed to remain for the protection of the pulp rather than run the risk of sacrificing the tooth".[2]

In a primary / permanent tooth with deep dentinal caries; judiciously removing the infected dentin and isolating the affected dentin from oral fluids with suitable material is referred to as indirect pulp therapy (IPT). IPT has become the front runner in vital pulp therapy in recent years and is a procedure performed in teeth with deep carious lesions approximating the pulp but without any signs or symptoms of irreversible pulpal changes. Peripheral caries along with soft caries on pulpal floor is removed while the caries on cavity floor which is closest to the pulp is not excavated so as to avoid pulp exposure. It is then covered with a suitable biocompatible material.[3]

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In the search for an "ideal" material, a wide range of restorative materials have been introduced over the past years and many have been discontinued. The most popular material is Calcium hydroxide which is also considered as the gold standard for IPT because of its beneficial properties such as high pH, low cytotoxicity and induction of mineralization. However, the poor dentinal bonding, mechanical instability, dissolution over time leading to formation of tunnels in the dentinal barrier are few disadvantages.[4] In this context, an interesting development was the introduction of calcium silicate based cements .[5] Biodentine® also known as "dentin in capsule", is one new formulation which is a biocompatible and bioactive dentin substitute that was developed as a pulp capping agent.[5] It has attracted the attention due to its fast setting time, high compatibility, high compressive strength, high pH (pH=12), excellent setting ability, ease of handling, rich source of calcium ions and remineralizing property as well as its versatile range of clinical applications in restorative dentistry, endodontics and dental trauma etc.[6,7]

One of the recently developed light curable resin –modified calcium silicate material is Theracal®. Its ability to get cured at a depth of 1.7mm decreases the chance of early dissolution with an improved sealing and bonding ability to moist dentin. These properties offer major advantage in pulp capping procedures.[8]

Thus, this study was aimed at evaluation of Biodentine, Theracal and Dycal as indirect pulp therapy agents in young permanent teeth.

MATERIALS AND METHOD

This randomized clinical trial was conducted in the Department of Pediatric and Preventive Dentistry between December 2016 and May 2019 using a protocol that was reviewed and approved by the Institutional Review Board and Ethical committee letter number (ITSCDSR/L/2018/136) and registered under CTRI (CTRI/2018/02/014782).

Sixty children aged 7-15 years who had at least one deeply carious permanent molar were selected for this study. The lesion was evaluated clinically and radiographically and diagnosed as deep dentinal caries approaching pulp without potential pulp exposure.

The parents / guardians of the patients were explained about the study and an informed consent was obtained.

Inclusion criteria

Permanent posterior teeth with deep dentinal caries (ICDAS 5 & 6) and open apices were included from patients who presented with clinical symptoms of sensitivity to cold and pain on mastication. Radiographically, the caries involvement of >70% or 2/3rd of dentin thickness without any presence of periapical pathology, pathologic external / internal root resorption or pulp calcification were included.

Sample size calculation

Considering type I error to be 5% (α – 0.05) and power equal to 80 % with 10% outcome difference and 10% dropout rate led to the required sample size of 45 which was divided into 3 equal groups of 15 each. The sample was increased to 20 in each group to improve the validity of the study as well as to compensate for possible follow up loss.

Sampling technique and Randomization

The study was carried out with the help of two investigators. The first investigator randomized the subjects in accordance with the CONSORT 2010 guidelines. Three different colored balls were coded for the three different intervening materials. Simple randomization was done by asking the patients to choose one of the three differently colored balls which would determine the intervening material to be placed for IPT. In case the patient had more than one tooth fulfilling the inclusion criteria, randomization was done separately for each tooth. The samples were divided into following three groups:

Group 1: Biodentine (Septodont, France)

Group 2: Theracal (BiscoInc, Schamburg, IL)

Group 3: Dycal (Dentsply Caulk Milford, DE, USA)

Once the sample size of one particular group was achieved, the colored ball representing that group was removed from further randomization process. The present study is a double blinded study. The participant was blinded from the intervening material used, the clinician doing the excavation was not blinded since different materials require different manipulating instructions and the investigator assessing the signs and symptoms was unaware of the intervening material placed.

Clinical procedures

All the procedures were carried out by one investigator who was trained and had conducted pilot study on a sample of 8 similar patients. Cold pulp testing was performed by placing a small cotton pellet sprayed with ENDO FROST (propane-butane mixture, Roeko, Germany) frozen gas (-50°C) on the buccal surface of tooth. The tooth was anesthetized and isolated using rubber dam. Removal of enamel caries was done using diamond fissured bur No. 330 mounted in high speed hand piece with copious water. Based on hardness, tactile sensation and visual criteria, the soft infected dentin layer was carefully removed with a sharp spoon excavator. Excavation was stopped when the dentin showed increased resistance, thus, leaving behind the hard affected dentin over the pulpal floor so that the pulp tissue was not exposed. A solution of 1% NaOCl in a syringe with needle was used to irrigate the cavity every 3 minutes in order to wash away dentinal debris. In case of an accidental pulp exposure, the tooth was excluded from the study.

After excavation, the remaining dentin layer was covered with corresponding randomly assigned intervening liner material manipulated according to manufacturer's instructions. This was followed by restoration with a layer of GIC and bulk restoration with resin composite.

Two investigators performed the clinical and radiographic evaluations at 3weeks, 3months, 6 months, 12 months, 18 months and 24 months.

Result analysis criteria

Result of IPT was analysed as success or failure according to clinical and radiographic criteria.

Clinical/ primary criteria included a record of the presence of postoperative pain, sensitivity to palpation and percussion, mobility and a visual examination of surrounding soft tissues for the presence of any inflammation, sinus tract or fistula.

Radiographic/ secondary criteria included presence of external or internal resorption of tooth, PDL widening, periapical involvement and teeth showing root apex development.

In order to maintain the same contrast and brightness, all radiographs were captured on standard settings and same angulation using paralleling technique and to reduce the bias of methodology.

Statistical analysis

The statistical assessment was done using Chi Square test to compare the qualitative data. Data was analysed using the SPSS 16 software (IBM, Chicago, IL, USA) considering $p< 0.05$ as statistically significant.

RESULTS

After screening 372 patients, 60 young permanent molars in 55 patients met the inclusion criteria.

Inter examiner agreement

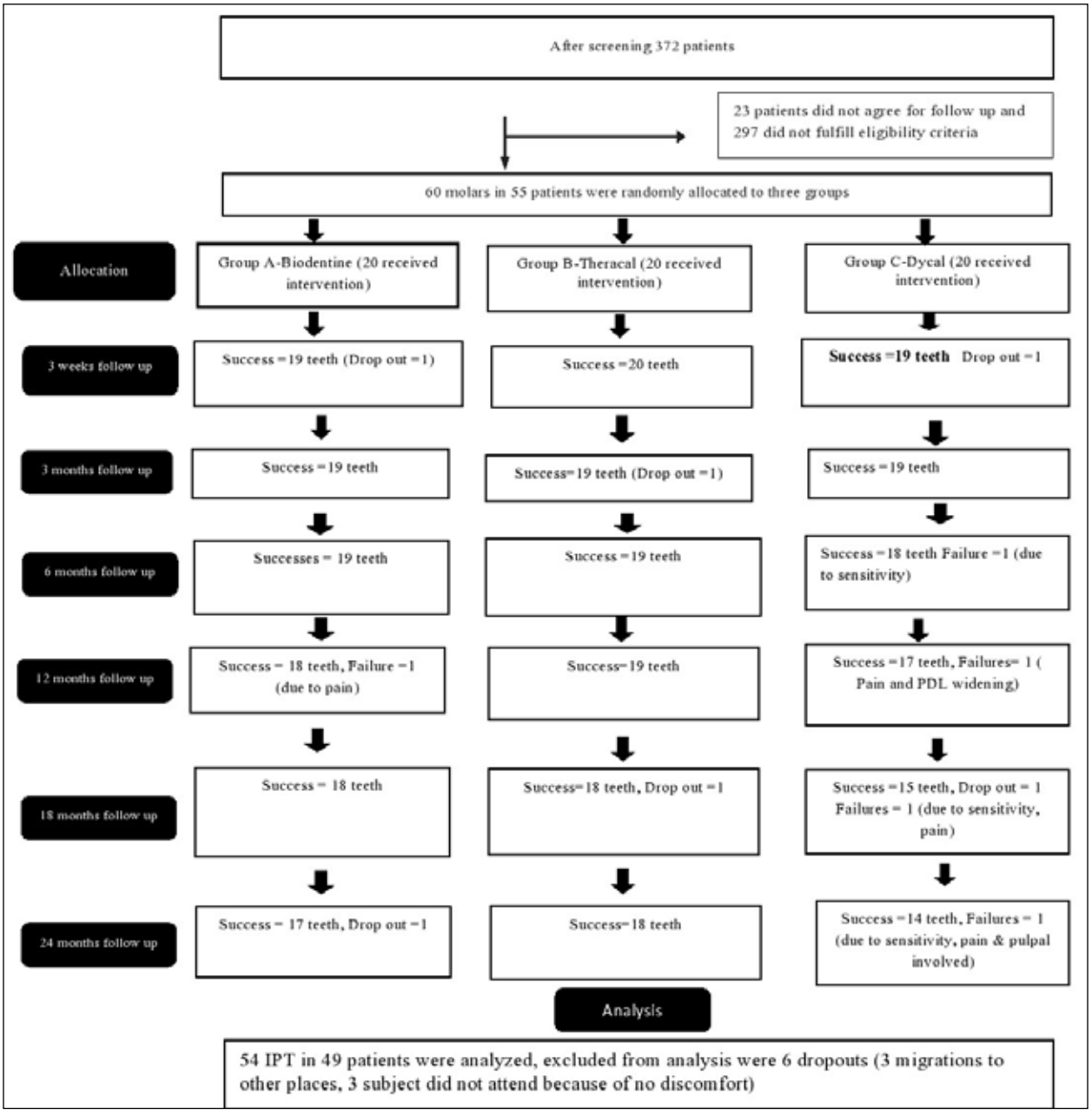
Baseline agreement between the examiners was 0.91 and 0.94 at final follow up which was considered excellent and p value for both baseline and follow up was significant. ($p < 0.05$)

Follow up loss

Two teeth each from Biodentine, Theracal and Dycal groups (10% each) were dropped from the study because the patients failed to report for the follow up (shown in Figure 1).

A total of 54 young permanent molars from 49 patients (23 males and 26 females) with a male to female ratio of 0.88:1.00 were followed up till the end of study. Overall mean age was 12.36 years ±2.29 with a range of 7 to 15 years. Out of 54 teeth, 17(33.33%) teeth were mandibular and 37 (66.66%) were maxillary teeth (Table 1).

Figure 1: CONSORT flow chart



At the end of 24 months, 94.44% teeth in Group A were asymptomatic (shown in Figure 2). while one tooth presented with pain and was tender to percussion. In Group B, none reported with any clinical or radiographic failures, thus with an overall success of 100% (shown in Figure 3). In Group C, 4 teeth failed due to clinical symptoms of sensitivity and pain and radiographic signs of PDL widening culminating in an overall success of 77.77% (shown in Figure 4).

Overall success of group B was statistically more significant in comparison to group A and C at 24 months follow up period with a p value of 0.03 (Table 2). No significant difference was found in success and failure at 3 weeks, 3 months and 6 months,12 months and 18 months in group A, B and C respectively (Table 2).

No significant difference was found at 24 months in terms of sensitivity, pain, PDL widening and pulp involvement between group A, B and C (Table 3).

Table 1: Gender, mean age and site distribution

Gender	Number (percentage)	Mean age(years) ± SD	Mandibular teeth (n)	Maxillary teeth (n)
Male	23 (46.93%)	12.63±2.42	12	16
Female	26 (53.06%)	12.20±2.15	05	21
Total	49	12.36±2.29	17	37

SD-standard deviation, n-number of teeth

Table 2: Overall outcome of different groups at different follow up interval

Time interval	Outcome	Group n=20(z)			p-value
		Group A	Group B	Group C	
3 weeks	Failure	0(0.0%)	0(0.0%)	0(0.0%)	0.104
	Drop out	1 (5.0%)	0(0.0%)	1 (5.0%)	
	Success	19(100.0%)	20(100.0%)	19 (100.0%)	
3 months	Failure	0(0.0%)	0(0.0%)	0(0.0%)	0.081
	Drop out	0 (0.0%)	1 (5.0%)	0 (0.0%)	
	Success	19(100.0%)	19(100.0%)	19(100.0%)	
6 months	Failure	0(0.0%)	0(0.0%)	1(5.2%)	0.073
	Drop out	0 (0.0%)	0 (0.0%)	0 (0.0)	
	Success	19(100.0%)	19(100.0%)	18 (94.7 %)	
12 months	Failure	1(5.2%)	0(0.0%)	1(6.25%)	0.067
	Drop out	0 (0.0%)	0(0.0%)	0(0.0%)	
	Success	18(94.7%)	19(100.0%)	17(89.47%)	
18 months	Failure	0(0.0%)	0(0.0%)	1 (6.25 %)	0.56
	Drop out	0 (0.0%)	1 (5.0%)	1 (5.0%)	
	Success	18(94.7%)	18(100.0%)	15(83.33 %)	
24 months	Failure	0 (0.0%)	0(0.0%)	1(5.56%)	0.03**
	Drop out	1 (5.0%)	0(0.0%)	0 (0.0%)	
	Success	17(94.44%)	17(100.0%)	14(77.77%)	
	Overall success	94.44%	100%	77.78%	

n-number of teeth, z–overall percentage, **statistically significant

Table 3: Clinical and radiographical findings and overall success in study groups at 24 months of follow up period.

Parameters	After 24 months follow up			
	Group A (n=20)	Group B (n=20)	Group C (n=20)	p-value
Sensitivity	0	0	3	0.93
Pain	1	0	3	0.88
PDL widening	0	0	1	0.93
Pulp involvement	0	0	1	0.93
Overall success, n (x/y = %)	17(17/18=94.44)	18(18/18=100%)	14(14/18=77.77%)	0.03*
Drop out	2	2	2	

n- Number of teeth, x-total success teeth, y-total teeth followed up for 24 months, *-significant

Figure 2: Group A (Biodentine)Preoperative (A) and postoperative follow up radiographs (B- 3 weeks, C- 3 months, D- 6 months, E- 12months, F- 18 months, G- 24 months)

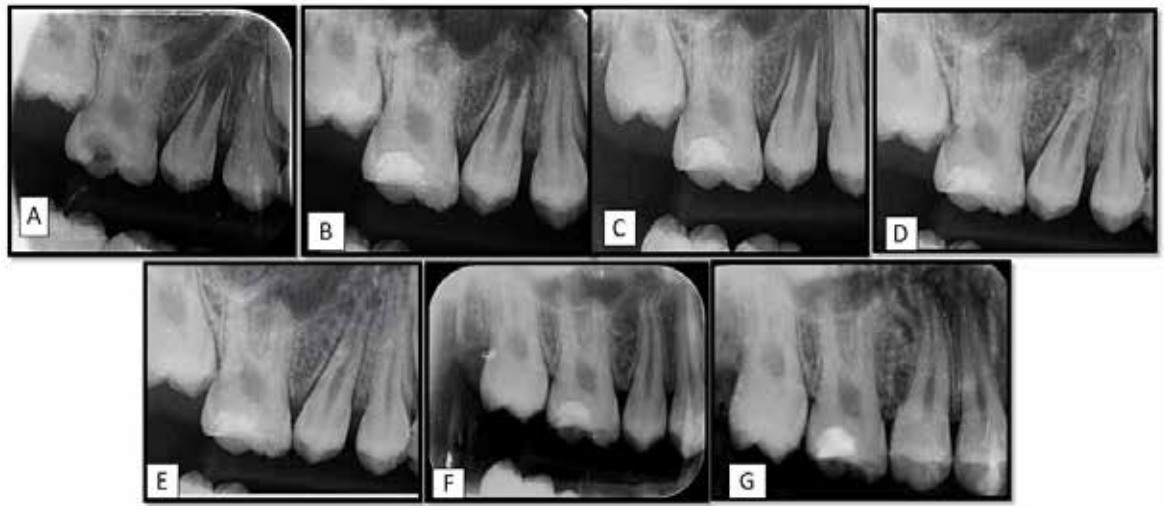


Figure 3: Group B (Theracal LC) Preoperative (A) and postoperative follow up radiographs (B- 3 weeks, C- 3 months, D- 6 months, E- 12months, F- 18 months, G- 24 months)

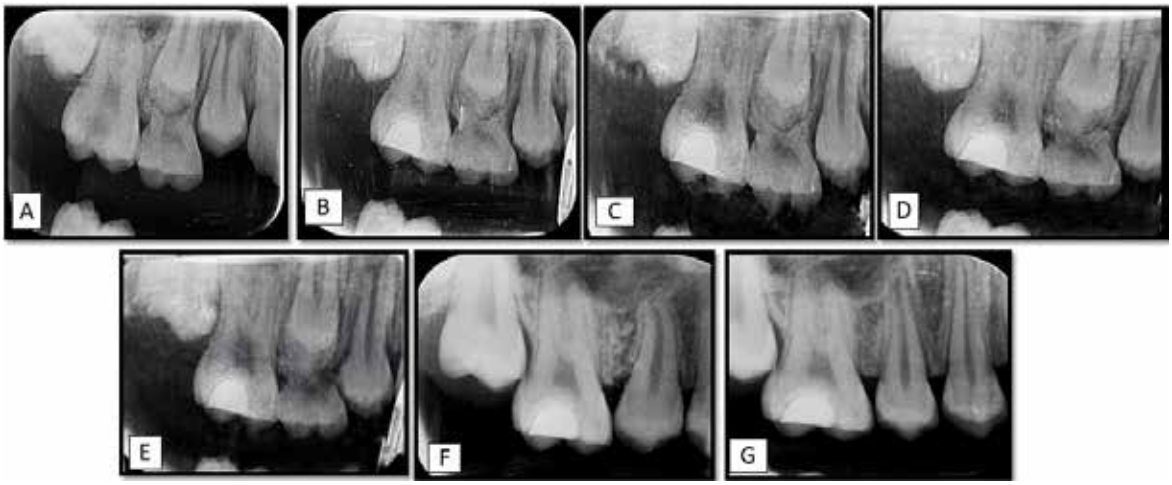
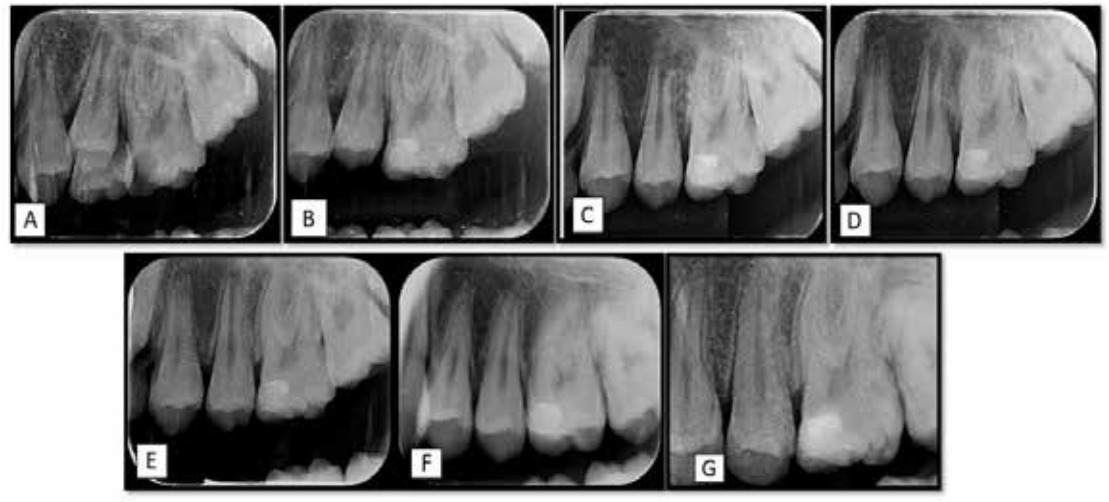


Figure 4: Group C Dycal) Preoperative (A) and postoperative follow up radiographs (B- 3 weeks, C- 3 months, D- 6 months, E- 12months, F- 18 months, G- 24 months)



DISCUSSION

The treatment of deep carious lesions may be challenging due to an increased risk of pulp exposure in such cases which reduces the predictability of the treatment outcome.[9-12] Studies by Banerjee *et al*, Maltz *et al* , Gruythuysen *et al*, Bjorndal *et al* found that the selective removal of the heavily infected dentin biomass while leaving affected dentin has favorable results.[13-16] One method of achieving this is by indirect pulp protection where carious dentine near the pulp is preserved in order to avoid pulp exposure and is covered with a suitable material.[14] Although there is no accurate method to determine the extent of removal of carious dentin, clinically it has been suggested to remove soft, amorphous and necrotic dentin while leaving behind firm and intact dentin. Caries removal should be done until the cavity floor is "moisture free", "firm" and leathery" where its removal may lead to exposure of pulp.[2,17]

The results from the present study suggest that bioactive calcium silicate dentine liners i.e. Biodentine and Theracal have comparable clinical and radiographic success for IPT procedure in young permanent teeth even after 24 months, as compared to calcium hydroxide which has lower success rate.

In the present study, calcium hydroxide was selected as the control material due to its proven antibacterial effects, biocompatible properties and ability to promote remineralization.[18] However, the dentinal barrier formed by calcium hydroxide is reported to have perforations due to formation of tunnels and cell inclusion and hence, does not provide adequate seal to underlying pulp from infections due to continuous microleakage. Furthermore, it is soluble and has been found to disintegrate within 6 months leaving voids beneath the restoration which act as pathways for bacterial infection and subsequently recurrent pulpal inflammation and necrosis.[19]

Clinical trials with long term follow up have shown that failure rates of calcium hydroxide increases with time as it lacks in providing a close adaptation to dentin, slowly degrades over time, does not aid in consistent differentiation of odontoblasts and is also found to be cytotoxic.[18-20]

In the present study, clinical and radiographic signs and symptoms have been assessed for 24 months in young permanent teeth after performing indirect pulp treatment with calcium hydroxide, that showed success rate of 77.8%. Benoist *et al* and Rafeza *et al* reported almost similar results of 73% and 76% success respectively.[21,22]

A higher success rate of calcium hydroxide i.e.94.1%, 94.6%, 97.8%, 93%, 86.9% and 93.6%, has been reported by Nirschl and Avery *et al* [23], Bjorndal *et al* [11],Gruythuysen *et al* [15], Petrou *et al* [24] and Mathur V P *et al* [25]respectively. Orhan *et al*[26] studied a sample of 52 teeth for 3 months and reported success of 97.8%, however in another sample of 154 teeth followed up for one year they reported 92-94% success.[27]

Martz and Oliveria reported the decrease in success rate over a period of 10 years from 97% at 1.5 years, 90% at 3 years, 82% at 5 years, and as low as 63% at 10 years follow up.[28]

Alternative materials like calcium silicate cements having similar properties of calcium hydroxide have been developed. One such material is Biodentine; which is biocompatible and bioactive dentin substitute that induces mineralization by enhancing the secretion of TGF-61 from pulpal cells following its application. It also acts by increasing odontoblastic stimulation and rapid cell differentiation which leads to reactionary and tertiary dentin formation.[7]

Biodentine can induce immortalized murine pulp cell differentiation into odontoblast like cells which further induces mineralization and can therefore be a suitable material for dentin-pulp complex regeneration.[29] Because of its high alkalinity, Biodentine has inhibitory effects on microorganisms and has shown strongest antibacterial activity against *Streptococcus sanguis*. Other well-known advantages are its easy manipulation, smooth consistency with optimum working and setting time of about 12 minutes, compressive strength of 220 MPa which is nearly close to that of dentin (290 MPa), good marginal integrity and an enhanced sealing ability which makes it superior to previously introduced calcium silicate materials.[7]

Hashem *et al* evaluated the efficacy of Biodentine for IPT in 18-76-year-old adults, and reported a clinical success rate of 83.3% whereas in the present study the success of Biodentine is higher i.e. 94.4%.[30]

Theracal is a hybrid material belonging to calcium silicate group composed of Portland cement (30–50%), polyethelyene glycol dimethacrylate (10–30%), and barium zirconate (1–10%). It has displayed significantly more calcium releasing properties as compared to Dycal.[31,8] However, calcium ion release was found to be lower when compared to Biodentine.[32] The paucity of calcium hydroxide in Theracal after setting suggests that calcium ions released are not in the hydroxide form.[33] Theracal secures a consistent protective physical lining regardless of coming in contact with dentinal or pulpal fluids. Hence, it can be considered as a scaffold for reparative dentine formation. Further, the apatite-forming ability of Theracal plays a crucial role in forming excellent biological seal, dentine repair and mineralization.[34,35] Also, immediate placement of final restoration is possible with Theracal as it sets by light curing and no delay is there for final restoration as shown by other pulp capping materials, so possibility of contamination is nil suggesting it as a favorable IPT material.[8,35]

CONCLUSION

Following conclusions can be drawn from present trial:

- The success rate of Calcium hydroxide for IPT is significantly lower in comparison to Theracal, and Biodentine at 24 months follow-up.
- Calcium silicate based materials are better alternatives for IPT in young permanent teeth.
- With improved physical and chemical qualities, calcium silicate materials such as Biodentine and Theracal are proven to be superior to calcium hydroxide.

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