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Clinical and histological assessment of efficacy of theracal LC and biodentine as direct pulp capping agents- An in-vivo study

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Abstract--Context: Since there is paucity of clinical studies, concern arises regarding the safety of direct application of resin-containing

material like TheraCal LC on the pulp tissue. Aim: To assess clinically and histologically the efficacy of TheraCal LC and Biodentine as Direct Pulp Capping agents Materials and Method: Sixty caries-free maxillary first premolar teeth which were scheduled for orthodontic extraction were selected for the study which were divided equally into Group 1 (Theracal LC) and Group 2 (Biodentine). Thermal and electric pulp testing was performed on the teeth to assess pulp vitality followed by tooth preparation to expose pulp horns under local anaesthesia. After achieving hemostasis, the direct pulp capping agent was placed and composite restoration was done. All the teeth were evaluated and compared in terms of clinical and histological findings after 6 weeks. Statistical analysis used was Kruskal-Wallis test. Results: Teeth with Theracal LC showed no sensitivity to heat, cold, or percussion, whereas sensitivity to heat, cold, or percussion was noted with Biodentine. Histological evaluation revealed that TheraCal LC has higher efficiency in complete dentin bridge formation, had maximum dentin thickness and showed minimal or no pulpal disorganization and pulpal inflammation as compared to Biodentine. Conclusion: TheraCal LC proves to be a promising future as direct pulp capping agent.

Keywords---Dental pulp capping, Pulp capping, Tricalcium silicate cement.

Introduction

Direct pulp capping (DPC) helps to maintain pulp vitality through healing or repair. The most popularly used direct and indirect pulp capping agents are calcium oxide and calcium hydroxide-based materials. Because of the solubility of these materials, they tend to raise local pH resulting in formation of a necrotic layer at the material-pulp interface.¹ Biodentine (Septodont, Saint Maur des Fosses, France), a calcium-silicate based restorative cement, has dentin-like mechanical properties, which can be used as dentin substitute on crowns and roots. It also promotes formation of tertiary and reparative dentin when placed in direct contact with vital pulp tissue.²

TheraCal LC (Bisco, Schaumburg, IL, USA), a resin modified calcium silicate (RMCS) cement, has been reported to stimulate apatite formation and secondary dentin formation. It also provides the early high alkalinity (pH 10-11), that is helpful for pulp healing, which later goes down to a neutral pH after several weeks.³ Because of self-sealing property, it reduces the chance of being accidentally rinsed off or blown off during air-drying. Being a calcium-silicate based material, TheraCal LC should be a favourable pulp capping agent, however since it is in a resin matrix, the leaching ability of calcium hydroxide to induce pulp capping requires evaluation. Thus, the present study was undertaken to compare, clinically and histologically, the efficacy of TheraCal LC and Biodentine as direct pulp capping agents.

Material and Method

A total of 60 caries-free maxillary first premolar teeth which were scheduled for extraction due to orthodontic reasons were enrolled for the present study. Ethical clearance was obtained from the Institutional Ethical Committee for the study protocol. Inclusion criteria comprised of patients indicated for orthodontic extraction of maxillary first premolar with closed apices, no sensitivity to percussion/palpation and biting, positive pulp response to application of thermal and electric pulp test, and teeth with no periapical changes evident on periapical radiographs. Teeth with open apices, periapical radiograph showing periradicular radiolucency, presence of any signs of swelling, sinus or fistulas and those with mobility or tenderness to percussion were excluded from the study. All the patients who met the inclusion criteria were randomly allocated into following two groups:

Group 1: Teeth capped with Theracal LC

Group 2: Teeth capped with Biodentine

Prior to the treatment, a complete medical history was taken to ensure the absence of any systemic disease and sensitivity to local anesthesia or dental materials. Each patient was explained in detail about the treatment procedure and a written informed consent was taken from each of them. Preoperative clinical photograph and pre-operative radiograph was taken before commencement of clinical study to check for caries or periapical pathology.

Operative Procedure

Thermal pulp test (cold test by using Endo-frost and heat test by heated ball-burnisher) and electric pulp test (Digitest pulp vitality tester, Parkell, NewYork, USA) were utilized to assess pulp vitality. Then patient was asked to perform oral rinsing with 0.2% chlorhexidine gluconate. Following infiltration with a local anesthetic agent and placement of rubber dam, a high-speed handpiece with a sterile 1.2 mm diameter round carbide bur was used for tooth preparation under ample water irrigation. All cavities were prepared to a depth similar to the bur length (~3 mm), thus exposing the pulp horn of each tooth through the cavity floor. The exposed area was then washed with sterile saline solution and homeostasis was achieved with cotton pellets saturated with sterile saline that was kept in place for 10-20 sec. After this, direct pulp capping was done with either Theracal LC or Biodentine as per the respective manufacturer's instruction, which was followed by permanent restoration with composite resin. (Figure 1)

Clinical Examination

After 6 weeks, all the patients were recalled and their clinical symptoms were meticulously recorded during the 6-week period. Any spontaneous or prolonged pain were interpreted as failure. In asymptomatic patients, thermal and electric pulp test was performed to evaluate the pulpal status of teeth and any history of postoperative sensitivity or pain throughout the study period was recorded.

Radiograph was taken prior to extraction to observe signs of periapical pathology. (Figure 1) Then the teeth were extracted as atraumatically as possible by the Oral Surgeon, following which it was immediately sent for histological examination.

Histologic Examination

The specimens were fixed in 10% buffered formalin solution for a period of 2 weeks, following which they were demineralized in a decalcifying solution (10% nitric acid) and embedded in paraffin. 3 μ thick serial sections of the paraffin-embedded teeth were obtained in the linguo-buccal plane using microtome which were then stained with hematoxylin-eosin stain. These slides were evaluated by a histopathologist, blinded to the patient group, under the light microscope (BX41; Olympus, Tokyo, Japan) using the modified criteria based on those of Nowicka et al.⁴

Statistical Analysis

Data were analyzed using SPSS version 22 (SPSS Inc, Chicago, IL). Categorical variables are mentioned as frequency and percentage in each study group and descriptive statistics included computation of means and standard deviations. Kruskal-Wallis test was utilized to compare distribution of dependent variables between study groups. P values of <0.05 were considered statistically significant.

Results

Clinical findings

There was no sensitivity to heat, cold, or percussion in TheraCal LC during the 6-week period, whereas in Biodentine group, two patients reported significant pain and discomfort at 1 and 6 weeks respectively. Electric pulp test after 6 weeks suggested normal pulp response without any hypersensitivity in both the groups. None of the teeth showed periapical pathology in preoperative periapical radiographs.

Histologic Findings

There was absence of pulp inflammation in all cases except for two cases of mild chronic inflammation in Biodentine group after 6 weeks of treatment. (Table 1) In TheraCal LC group, 80% of teeth showed normal pulp organization, whereas in Biodentine group, 70% teeth showed normal pulp. This difference was statistically significant ($p=0.016$). 4 cases in TheraCal LC group showed pulp tissue disorganization beneath the cavity wall, while 6 cases in Biodentine group showed similar changes. In TheraCal LC treated teeth, 2 cases showed complete pulp destruction, whereas 3 cases in Biodentine treated group showed complete pulp disorganization. 86.66% cases in TheraCal LC group showed complete dentin bridge formation, whereas Biodentine group showed complete dentin bridge in 80% cases, which was significant ($p=0.001$) (Table 2). However, maximum thickness of dentin bridge was observed with TheraCal LC as compared to Biodentine. (Figure 2)

Discussion

Since critical evaluation of pulp-capping materials can be done only histologically, it becomes inappropriate to consider clinical criterion to determine the long-term prognosis. Assessment of extent of pulp tissue disorganization is of prime importance since it suggests the sequel of initial pulp inflammation. Thus, the present *in-vivo* study compared the efficacy of TheraCal LC and Biodentine as direct pulp capping agents in sound human teeth indicated for orthodontic extraction, both clinically and histologically.

In the present study, none of the patients experienced sensitivity to heat, cold, or percussion in the TheraCal LC group during the 6 week follow up period whereas in Biodentine group 20% of patients reported sensitivity to heat, cold, or percussion. However, the results of electric pulp test yielded normal pulp response and no periapical pathology on radiographic examination after 6 weeks.

In TheraCal LC group pulp disorganization beneath the cavity was observed in 13.3% of the cases, while in Biodentine group, it was seen in 20% cases. Similarly, entire pulp tissue disorganization was seen in 6.66% cases of TheraCal LC group and in 10% cases of Biodentine group. Dentinal bridge formation at the junction of pulp and pulp-capping material is a debatable subject since it can either represent as a sign of healing or may be a reaction to irritation.⁵⁻⁷ In the present study, dentinal bridge formation was considered as a positive response suggestive of healing. Dispersed mineralization in the form of a discontinuous dentinal bridge was noted in least cases treated with TheraCal LC than Biodentine. The setting reaction of tricalcium silicate represents a hydration reaction, which produces calcium hydroxide as a hydration by-product, and releases calcium ions responsible for dentinal bridge formation.⁸⁻⁹ Formation of an organized dentinal bridge was observed histologically in both TheraCal LC and Biodentine groups.

The handling features of any material plays a vital role when considered for clinical use.^{3,10} TheraCal LC can be cured to a depth of 1.7 mm, thus avoiding the risk of untimely dissolution.³ Because of the chemical properties of TheraCal LC, it received competent results for material handling and performance after restoration placement in the present study. On the other hand, Biodentine placement required the use of a dental triturator for preparation which made it more time consuming and difficult. Application of TheraCal LC is simple since it is available in the form of a syringe with a small tip and an immediate setting after curing, whereas Biodentine has a setting time of 9 to 12 min. Hence TheraCal LC can be a suitable alternative as direct pulp capping agent to Biodentine.¹¹

The formulation of TheraCal LC incorporates tricalcium silicate particles in a hydrophilic monomer that results in remarkable calcium release rendering it a stable & durable liner or base material.¹² Calcium release stimulates hydroxyapatite crystal formation and secondary dentinal bridge formation.¹³ Calcium ions are required for differentiation and proliferation to odontoblast-like cells. The rapid release of calcium makes it an excellent material which helps in repairing and healing of dentine. Studies reported in literature have shown it to

be more effective in stimulating pulpal healing than other traditional liners with the advantage of less pulpal necrosis.³ The significant calcium release supplies reparative ions and creates a sustaining alkaline environment essential to promote wound healing, provides immediate bond and sealing properties, and also stimulates hydroxyl-apatite crystals, secondary dentine formation and re-apatite potential of affected dentine.^{10,14,15}

Hydrophilic resin formula of TheraCal LC is unique since it is permeable to the dentinal fluid but is relatively tough to resist dissolution.¹⁶ It absorbs dentinal fluids easily resulting in release of calcium and hydroxide ions. One of the tooth's immediate responses is to form hydroxyapatite crystals underneath the TheraCal LC, which assist in the formation of apatite, thus playing an important role in pulpal protection by potentiating the natural sealing ability.¹⁷ Prevention from microleakage is a determinant factor responsible for the success of direct pulp capping materials which is adequately seen with TheraCal LC.

Cannon M et al¹⁸ in their study on direct pulp capping with TheraCal LC, suggested that TheraCal shows a complete hard tissue formation, adhesiveness to moist substrate as well as more positive response to the pulp exposure and bacterial contamination. Similar findings were observed in the present study. Makkar S et al¹⁹ compared the sealing ability of TheraCal, biodentine and MTA using confocal laser scanning microscopy and concluded that TheraCal has better sealing ability and less interfacial microleakage as compared to MTA and biodentine. Similarly, in the present study, dentinal bridge formation was more homogenous and uniform with TheraCal LC than Biodentine, which is in accordance with the results of studies by Asgary S et al⁵, Iwamoto CE et al²⁰ and Aeinehchi M et al²¹. In contrast to this, the study by Camilleri J et al have concluded that Biodentine demonstrated the highest calcium ion release in solution whereas TheraCal LC demonstrated the lowest.²²⁻²³

Previous studies have proved the efficacy of TheraCal LC as an indirect pulp capping agent.²⁴ TheraCal contains calcium silicate which has a low specific heat capacity; which signifies that it has high thermal insulation properties. Hence it can be stated that TheraCal LC can be used as a safe and sound direct pulp capping agent and the temperature due to light curing unit will not cause any damage to the underlying pulp.²⁵

The present study was carried out on healthy human teeth without any signs of inflammation which results in reliability of the protocol. However, it does not provide information regarding the effects of these pulp-capping materials on carious teeth having different levels of inflammation. Hence, we recommend that a well-designed long-term study should be undertaken in future on inflamed teeth with pulpitis to establish the use of TheraCal LC as direct pulp capping agent more firmly.

Conclusion

TheraCal LC has high calcium releasing ability, low solubility, and good shear bond strength when compared with Biodentine. Thus, the present study

concludes that TheraCal LC has better performance than Biodentine when used as a direct pulp capping agent which presents with best clinical outcomes.

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Tables:

Table 1: Comparison of inflammation of pulp after Direct pulp capping in Theracal LC and Biodentine group

Materials	Index	TheraCal LC N (%) (N=30)	Biodentine N (%) (N=30)

Intensity of pulp inflammation	Absent	29 (96.66%)	26 (86.66%)
	Mild	1 (3.33%)	3 (10%)
	Moderate	0	1 (3.3%)
	Severe	0	0
Type of pulp inflammation	No inflammation	30 (100%)	28 (93.33%)
	Chronic	0	1 (3.3%)
	Chronic and acute	0	1 (3.3%)
	Acute	0	0
Extension of pulp inflammation	Absent	29 (96.66%)	28 (93.33%)
	Mild	1 (3.33%)	2 (6.66%)
	Moderate	0	0
	Severe	0	0

Table 2: Comparison of Hard and Soft Tissue Formation after Direct pulp capping Based on Histologic Analysis.

Materials	TheraCal LC (N=30) N (%)	Biodentine (N=30) N (%)
<u>Soft tissue formation</u>		
<u>Pulp tissue organization and morphology</u>		
1) Normal or almost normal pulp tissue morphology	24 (80%)	21 (70%)
2) Disorganization of pulp tissue beneath the cavity	4 (13.33%)	6 (20%)
3) Disorganization of entire pulp tissue	2 (6.66%)	3 (10%)
<u>Hard tissue formation</u>		
<u>Dentinal bridge morphology and continuity</u>		
1) Formation of hard tissue beneath cavity in the form of complete dentinal bridge	26 (86.66%)	24 (80%)
2) Formation of discontinuous bridge beneath the cavity (incomplete dentinal bridge)	4 (13.3%)	4 (13.3%)
3) No signs of dentin formation	0	2 (6.66%)
<u>Dentinal bridge thickness</u>		
1) More than 0.25 mm	23 (76.66%)	19 (63.33%)
2) Between 0.1 and 0.25 mm	5 (16.66%)	7 (23.33%)
3) Less than 0.1 mm	2 (6.66%)	4 (13.33%)

Figure Legends:

Figure 1: (a) Preoperative clinical picture of teeth b) Preoperative intra oral periapical radiograph (c) pulp exposure (d) placement of Direct pulp capping agent (e) Composite resin restoration (f) 6 week follow up radiograph

Figure 2: Histological picture showing formation of continuous dentinal bridge after Direct pulp capping done using (a) TheraCal LC (40X) (b) Biodentine (40X) (c) TheraCal LC (100X) (d) Biodentine (100X)