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**Research Paper**

# A Randomized Trial of Direct Pulp Capping In Primary Molars Using Theracal Compared To 3mixtatin: A Novel Pulp Capping Material

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***ABSTRACT:*** *Direct pulp capping (DPC) has been literally abolished from the repertoire of endodontic procedures for primary teeth. But with the introduction of new biomaterials, there have been numerous reports of improved success rates. Therefore, the aim of the present study was to evaluate the success rate of direct pulp capping in primary molars using Theracal and 3Mixtatin in primary molars. 30 primary molars of aged 5 to 7yrs were included. Pin point exposure of pulp following caries removal were randomly capped with Theracal or 3Mixtatin. All the teeth were restored with glass ionomer cement after pulp capping. Clinical and radiographic evaluations were performed after 3 and 6 months. The results showed that there is no statistical significance difference between Theracal and 3mixtatin. Theracal can be used as appropriate alternative to direct pulp capping of primary molars.*

***KEYWORDS:*** *Direct pulp capping, Theracal, 3Mixtatin*

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## I. Introduction:

In order to maintain good oral health, dental caries must be prevented and treated. Since pulp infection and the early loss of primary teeth may result in malocclusion and the possibility of aesthetic, phonetic, or functional issues, conserving the vitality of primary teeth with conservative or minimally invasive treatment principles, such as interim therapeutic restoration approach, partial carious removal, or atraumatic restorative treatment, is crucial in this situation. Conservative treatments, such as direct pulp capping, may improve the longevity of permanent teeth in the oral cavity[1]. The high risk of internal dentin resorption, which is attributed to the possibility that undifferentiated mesenchymal cells in the primary pulp may become odontoclasts, has led some authors to discourage this treatment for primary teeth, despite some studies showing success rates. There have also been reports of peri-radicular bone loss, pulp inflammation, and calcifications. For that reason, pulpotomy is preferred than direct pulp capping when any kind of pulp exposure occurs e.g., caries, trauma, or cavity processing[2].

The goal of contemporary paediatric dentistry is to encourage the ability of dental tissues to regenerate. Maintaining a primary tooth until normal exfoliation can be aided by an understanding of the mechanisms that

prevent, restrict, and regulate internal resorption. To accomplish this, it is possible to target undifferentiated mesenchymal cells, which will activate and differentiate odontoblasts and regenerate a vital pulp by creating a continuous hard tissue barrier[3]. Simultaneously, bacterial contamination and inflammation, as the main cause of treatment failure in primary teeth, should be reduced or eliminated.

Emerging materials in regenerative dentistry include statin components. The idea of statins having "pleiotropic" effects is supported by evidence from both experimental and clinical studies. Statins enhance osteoblast function and inhibit osteoclast function, resulting in improved bone formation. As a result, they might enhance odontoblastic activity, which would enhance dentin formation. Statins may also stimulate angiogenesis and boost neuronal cell growth. They might therefore play a part in pulp regeneration as well as dentin regeneration. In addition, sufficient evidence exists in support of the potent anti-inflammatory properties of statins. They reduce circulating C-reactive protein (CRP) and pro-inflammatory cytokines levels. Statins are therefore an ideal active component for promoting reparative dentin formation in DPC[3].

TheraCal, a resin-modified Portland cement-based substance, has been introduced for endodontic procedures like DPC, on the other hand. Thercal releases calcium ions after being set by light-curing devices, which causes the environment to become more alkaline and exerts bioactive properties (such as apatite formation followed by the production of new dentine), cell growth, and proliferation) (**Gandolfi et al. 2011**). Greater calcium ion release and less solubility and water absorption have been observed with TheraCal[4].

This current study evaluated the clinical and radiographic success of DPC in primary molars with TheraCal, in comparison to 3Mixtatin with a 3 and 6month follow-up period.

## II. Materials And Methods:

Randomized clinical trial was performed at the Department of Pediatric and Preventive Dentistry, Lenora Institute of Dental Sciences, Rajahmundry. A total of 30 teeth were selected for the study as per the inclusion criteria: Complete physical and mental health, no confounding history of systemic or local disease, no history of allergic reactions, having at least one vital primary molar teeth with deep caries which is capable to restore, with no history of spontaneous pain, pathologic mobility, redness and swelling of vestibule, sinus tracts, as well as no signs of furcal/periapical radiolucencies, pathologic external or internal root resorption, no pathology of succedaneous permanent teeth follicles and parents willing to participate in the study.

Clinical procedure:

In all the 2 groups, teeth were anesthetized using 2% lidocaine with 1/80000 epinephrine and teeth were isolated using rubber dam. Enamel caries was removed using diamond fissure bur with a high speed rotary handpiece under copious water supply. Dentin caries was removed using carbide bur in a slow handpiece under water coolant. NaOCl was used to constantly for irrigation to wash away the debris. Teeth with pulp exposure of less than 1mm and surrounded by sound dentin and bleeding arrested in two to three minutes were considered for DPC. If the pulp exposure is greater than 1mm in diameter and bleeding did not stopped with a moistened cotton pellet within 1-5min, then the tooth was excluded from the study. In those cases where the pulp was not exposed then restoration was done for those teeth and were excluded from the study.

For the direct pulp capping procedure, first the cavity was thoroughly washed and hemostasis was achieved using a cotton pellet soaked in sterile saline solution. The cavity was then dried using dry cotton pellet and tooth was restored with their respective direct pulp capping materials.

In 3mixtatin group, 3Mix was prepared by mixing three commercially available antibiotics. Drugs were pulverized by porcelain mortars and pestles to a fine powders after removing the coating materials. A total of 100 mg ciprofloxacin, 100 mg metronidazole, and 100 mg cefixime were mixed in a ratio of 1 : 1 : 1. Because of minocycline contraindicated in children, it was replaced by cefixime. Two milligrams of simvastatin were added to this drug mixture. to form 3Mixtatin. 3Mixtatin was stored in a tightly capped porcelain container, adding a small amount of silica gel in a bag inside the container to maintain low humidity. This powder was mixed with normal saline to form a creamy paste of 3Mixtatin at the time of application. In Theracal group, it was applied in a layer with a maximum thickness of 1 mm, with peripheral margins extending approximately 1 mm beyond the exposure site. The cement was then light-cured for 20 s.

Finally, the cavities were filled with Glass Ionomer cement and periapical radiographs were immediately obtained and Patients were followed up periodically after 3 and 6 months. The presence of one of the following signs or symptoms was considered as failure of treatment: pain, swelling, sinus tract, pathologic mobility, tenderness to palpation, sensitivity to percussion; and radiographic sign of internal and/or external root resorption, periodontal space widening, inter-radicular radiolucency, periapical lesions.

## III. Statistical Analysis

Difference in treatment outcomes between the two materials was evaluated using Chi Square test and data statistically analysed using SPSS 23 Software ($\alpha$=0.05).

## IV. Results:

In total, 30 DPC treatments were performed (15 in the Theracal group and 15 in the 3Mixtatin group) and followed for 3 and 6 months. At the end of three months there were no failure cases in Theracal group. But in 3Mixtatin group, out of 15 cases 2cases were failed at the end of three months. Both the failed cases at the end of three months the tooth had shown spontaneous pain, sensitivity to percussion, increased mobility.

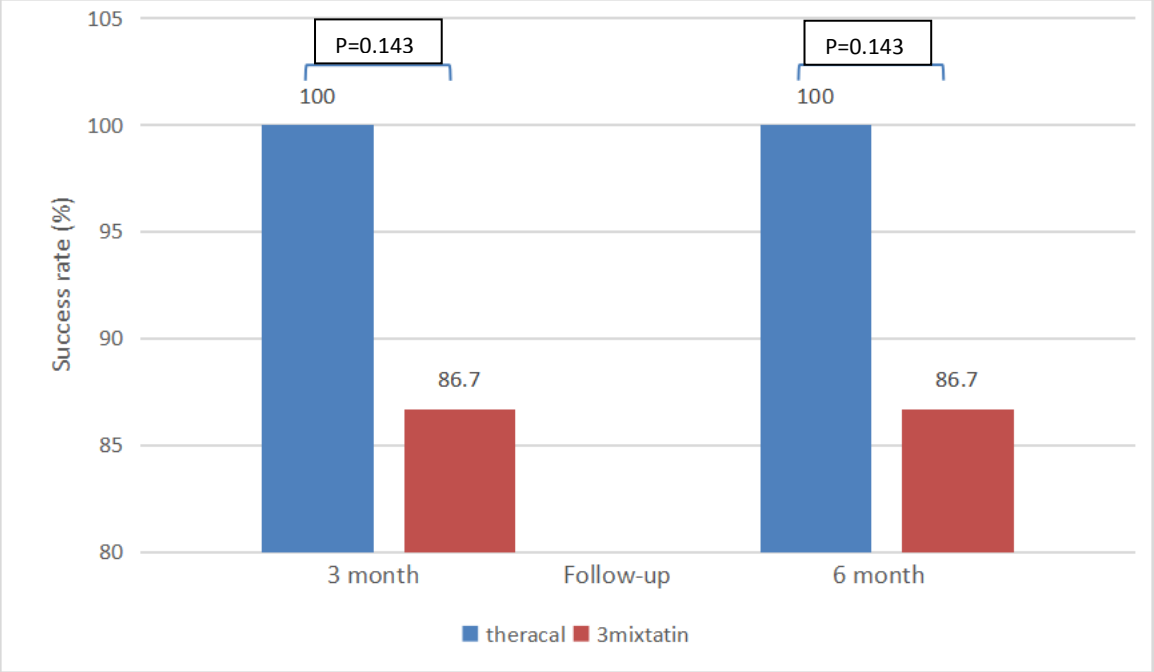
At the end of 6months, Theracal group had showed no failure cases, but in 3mixtatin group there were two failure cases. One tooth had shown spontaneous pain, swelling, sensitivity to percussion, increased mobility and root resorption. One other tooth had shown spontaneous pain and increased mobility. The signs and symptoms at 3 and 6 months in both groups is shown in Table 1.

**Table 1**. Number of successful and failed treatments per study group at the 3 evaluation times

| Evaluation criteria | Theracal 3 months (n=15) | 3Mixtatin 3 months (n=15) | Theracal 6 months (n=15) | 3Mixtatin 6 months (n=15) |
|---|---|---|---|---|
| Spontaneous pain | 0 | 2 | 0 | 2 |
| Swelling | 0 | 0 | 0 | 1 |
| Sensitivity to percussion | 0 | 2 | 0 | 1 |
| Sinus tract | 0 | 0 | 0 | 0 |
| Increased mobility | 0 | 2 | 0 | 2 |
| Root resorption | 0 | 0 | 0 | 1 |
| Radiolucency in furcation area | 0 | 0 | 0 | 0 |
| PDL widening | 0 | 0 | 0 | 0 |
| Overall failures (p value at 12 month=0.66) | 0 | 2 | 0 | 2 |

The success rate for group I at the end of three and six months was 100% and for group II the success rate for three and six months was 86.7% (Figure 1).

**Figure: 1 Success and failure percentage at end of 3 and 6 months follow up**




## V. Discussion:

Dental pulp capping has almost disappeared from the wide repertory of pulp treatments in primary teeth, because it is considered to be a compromising and risky procedure owing to its likelihood of producing internal dentin resorption and, with less frequency, pulp calcification, necrosis, and damage to the surrounding alveolar bone[2].

Bacteria play a critical role in the healing of the exposed dental pulp. In the current study, peripheral infected dentin was removed thoroughly and the case selection was strictly limited to exposure site less than one mm with controllable hemostasis. In an attempt to reduce the bacterial load, we constantly irrigated the cavity with sodium hypochlorite before the pulpal exposure and chlorhexidine after the pulpal exposure.

In the present study, we attempted to assess the efficacy of 3Mixtatin, a novel pulp capping paste containing statin and Theracal, in DPC of primary teeth.

The results in the present study showed that there is no significant difference between Theracal and 3Mixtatin. But, in theracal group none of the sample had shown failure cases due to the formulation of TheraCal enables significant higher calcium release and can potentially be stimulating for odontoblasts **(Gandolfi et al. 2012)[5].**

In the present study, Pulp inflammation and necrosis was seen in 3Mixtatin groups due to significant increase in the percentage of apoptotic cells due to cytotoxic effect of statins. The reason may be due to the increased concentration of simvastatin. These results may be mediated through this fact that statin in high concentration inhibits actin fiber formation and cell cycle progression, resulting in suppression of proliferation in DPSCs which is further supported by **Okamoto Y (2009)**[6].

Despite a high risk of resorption in primary molars after pulp therapy, our findings suggested that direct pulp capping might be regarded as a successful conservative treatment in case of proper case selection, application of a biocompatible capping biomaterial, and an appropriate procedure. Further clinical studies with larger sample size and longer follow-ups supplemented with histological evaluations to derive a more definitive conclusion in the success of the 3Mixtatin and Theracal in direct pulp capping of primary molars seem relevant. The clinical and radiographic findings of the current study showed a comparable successful outcome in direct pulp capping of primary molars using Theracal compared to 3Mixtatin after 6 months.

## VI. Conclusion:

Based on the findings from the present study, it can be concluded that Theracal can be used successfully as an appropriate alternative material in DPC of primary teeth. The promising clinical properties of Theracal may lead to a paradigm shift in the vital pulp therapy of primary teeth in future.

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