"TheraCal Pulpotomy in Primary Molars"

A Randomized Clinical Trial

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Ain Shams University

For

Partial Fulfillment of Requirements of the Doctoral degree in Pedodontics

Title registration: This study will be registered on the Pan African Clinical Trial Registry **.**

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Roles of protocol contributor:

Trial sponsor:

Faculty of Oral and Dental Medicine Ain shams University - Egypt.

Steering committees:

1- Department Board.

2- Research Plan Committee.

3- Ethics Committee, Faculty of Oral and Dental Medicine - Ain shams University

4- Higher Education and Research Committee.

5- Faculty Board.

Trial design:
Randomized Clinical Trial **(RCT),** parallel group with 1:1 allocation ratio.

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Abstract

Background: TheraCal LC® is a light-cured, resin-modified calcium silicate filled liner designed for use in direct and indirect pulp capping, as a protective base/liner under composites, amalgams, cements, and other base materials. It can be used as a replacement for calcium hydroxide, glass ionomer, RMGI, IRM/ZOE and MTA materials. The proprietary formulation of TheraCal LC® consists of tricalcium silicate particles in a hydrophilic monomer that provides significant calcium release making it a uniquely stable and durable material as a liner or base.

Unique Benefits

- ✓ Calcium release which stimulates hydroxyapatite and secondary dentin bridge formation.
- ✓ The alkaline pH promotes healing and apatite formation.
- ✓ Significant calcium release leads to protective seal.
- ✓ Moisture tolerant and radiopaque - can be placed under restorative materials and cements.

Aim of the study: to evaluate the efficacy of **TheraCal LC®** as a pulp medicament in complete pulpotomy in primary teeth.

Methods: The study will be conducted on 60 primary molars with an indication for pulpotomy treatment. Primary teeth were treated with either formocresol (group A) (30 teeth), **TheraCal LC®** (group B) (30 teeth) using standardized criteria for the pulpotomy procedures. Teeth will be clinically and radiographically by digital radiology evaluated during the examination period of **3, 6, 12** months.

1- Introduction

Dental caries is considered the most common chronic childhood disease, **(Dean et al., 2011)** [1]. It has many profound complications from the physiological and social points of view as it reduces food intake, alters sleep habits, and increases the number of missed days in school. Moreover, it can cause parental work loss. It is not recommended to extract the carious molars in young children due to subsequent space loss, blocked out permanent teeth, and difficulty eating. Based on that, pulpotomy seems to be the treatment of choice for such carious molar **(Varags et al., 2006).**[2]

Formocresol has been used for decades as a pulpal medicament. Even though other materials have been introduced for pulpotomy in primary teeth, it proved to be the most efficient, reliable and successful method regardless the debate related to its carcinogenicity and toxicity.[3]

Mineral Trioxide Aggregate (MTA) has been introduced to the field of dentistry in the year 1993 by ***Mahmoud Torabinejad*** [4]. The MTA showed good sealing ability, excellent long term prognosis, good biocompatibility and also favors tissue regeneration.

Recently, **TheraCal LC®** has been introduced as a light-cured, resin-modified calcium silicate material. It can be used as a barrier and protectant to the dental pulpal complex. The formulation of this product consists of tricalcium silicate particles in a hydrophilic monomer. This material can

stimulate hydroxyapatite and secondary dentin bridge formation through calcium release and an alkaline pH. It is indicated for direct and indirect pulp capping and as a protective base/liner under restorative materials including composite, amalgam and cements.

In their review, **Iman Parisay and co-workers** reported that Theracal, as other materials like Bioaggregate and Biodentin, was evaluated for pulp capping but needs further clinical trials to investigate its effect on primary teeth. [5]

The manufacturer of **TheraCal LC®** product (**Bisco dental products company**) claimed that these new bioactive materials have higher physical properties, are easy to handle in clinical practice and are more compatible with classical endodontic procedures as well as with all restorative clinical cases of dentine replacement.[6]

Continues search for dental materials is never ending, especially for the materials needed in pulp treatment procedures.

Impact of this study

In this study, **TheraCal LC®** material will be evaluated as an agent for pulp therapy in primary molars based upon the spectacular success rate achieved by MTA.

Review of literature

Although some researchers and clinicians used different medicaments for many years instead of formocresol for vital pulp therapy in primary teeth and inspite of the hundreds of published articles in the literature that support the genotoxicity and carcinogenicity of this material, others still prefer the use of formocresol.[3]

As an alternative material to formocresol, Glutaraldehyde has been suggested based on its fixative properties, low antigenicity, and low toxicity. Unfortunately, there was a wide range in success rates with this alternative material. This might due to the insufficient depth of antibacterial affect which in turn may result in a deep zone of chronic cell injury. Application of a great amount may result in systemic distribution of this agent.[7] In addition, the internal resorption might occur as a result of inadequate fixation as a deficient barrier is left to sub-base irritation.[8]

In 1988, **Landau and Johnsen** introduced ferric sulphate as a hemostatic agent to be used for pulpotomy in primary teeth. It can agglutinate the blood protein without presence of a blood clot which suggests that it reduces the chance of a blood clot formation.[7,9]

In the last two decades, the electrosurgical and laser pulpotomy have been suggested as nonchemical devitalization forms to replace the use of medicaments.[10]

MTA was found to be the future material for pulp therapy in primary teeth. It proved high success rate in Indirect Pulp Capping (IPC), Direct Pulp Capping (DPC), and Vital Pulpotomy.[11]

Bioactive calcium silicate has shown properties similar to that of the MTA regarding, sealing ability, biocompatibility, cytotoxicity, and even compressive strength.[12]

Apart from the partial pulpotomy technique in primary teeth, **Fuks in 2008** introduced new materials and directions for vital pulp therapy, based on the benefits of the IPC, DPC and Vital pulpotomy. This technique could be a great solution for chronic pulpitis in primary teeth using new materials like MTA and bioactive calcium silicate.[11,13]

In a one-year follow-up study, **Schroder et al.** investigated the differences between partial pulpotomy and calcium hydroxide capping in primary molars. The results of the study revealed a significant difference in favor to partial pulpotomy than the traditional coronal pulpotomy. The authors recommended that partial pulpotomy should be used as the treatment of choice in primary molars with chronic coronal pulpitis. They emphasized that a gentle surgical technique should be used with no blood clot left between the wound and the calcium hydroxide.[13]

It has been shown that **TheraCal LC®** has a chemistry base similar to mineral trioxide aggregate (MTA), which has a favorable regenerative process as it can stimulate apatite formation[14, 15].

TheraCal LC® is considered a light-cured, radiopaque, and regenerative liner which is placed in a thick layer of 1mm (or less) on moist dentin. In general, it can be placed directly or indirectly over the pulp or over the deepest part of the preparation. This material has an early high pH value (10 to 11) which reverting back after several days to reach a neutral pH. It has a stimulating high calcium release and can be considered a self-sealing as well as antimicrobial agent.[16, 17]

In a follow-up study for 10 months, ***Jack D. Griffin*** **(2012)** applied Theracal as a direct liner on a mature central incisor with traumatically pulpal exposure. During this period, no clinical symptoms were reported. ***Griffin*** also stated that Theracal can be used clinically as a general liner under different types of restorations such as: before etching or dentinal bonding, as a protective liner in restorations placed close to the pulp, as a liner over remaining pulp in deciduous pulpotomies or pulpectomies, and as a pulp capping material in permanent or deciduous teeth. [18]

In a comparison between Theracal and Biodentin as indirect pulp capping materials, both materials are very useful in clinical practice but Theracal proved to be the easiest calcium silicate material to use due to its efficient syringe, and, as Biodentin, can regulate the mesenchymal cells to form odontoblasts.[19]

Cannon et al (2014) in their in-vivo study, compared the effectiveness of (TheraCal LC, Bisco), pure Portland cement, resin based calcium hydroxide and glass ionomer in the healing of contaminated primate pulp exposures (exposure of approximately 1 mm). The authors concluded that, both the Portland cement and TheraCal groups had significantly more frequent hard tissue bridge formation. Moreover, in the histologic part of this study, TheraCal LC appeared to have less pulpal effects than others.[20]

Pulpal exposures, either carious, mechanical or those due to trauma, can be treated by placing a thin layer of Theracal directly on the exposure area after obtaining a good hemostasis.[21]

Haewon Lee et al (2015), evaluated and compared response of the pulp to ProRoot MTA (Dentsply Tulsa Dental, Tulsa, OK), RetroMTA (Meta Biomed Co, Ltd, Seoul, Korea), and TheraCal (Bisco Inc, Schamburg, IL) in dog partial pulpotomy models in four weeks follow up. It

was concluded that, TheraCal produced lower calcific barrier formation, higher inflammatory reactions, and less favorable odontoblastic layer formation. On the other hand, they reported that a follow up period of four weeks is not enough to accurately assess and evaluate the effects of Pulpotomy agents.[22]

It has been reported that calcium release was higher and solubility was low concerning Theracal when compared with ProRoot MTA and Dycal.[23]

2- *Aim of the study (Objectives)*

- The aim of this study is to evaluate the efficacy of a light-cured resin modified calcium silicate as a pulp medicament in complete pulpotomy in primary teeth.

- Clinical and radiographical follow up will be performed for 12 months to investigate the success rate of a light-cured resin modified calcium silicate in complete pulpotomy procedures.

3- *Study Methodology*

- ***STUDY SETTING***

A randomized clinical trial study is to be conducted from the Outpatient clinic of The Pediatric Dentistry and Dental Public Health department, Faculty of Dentistry, Ain Shams University.

- ***SAMPLE SIZE ESTIMATION***

To evaluate the effect of **TheraCal LC®** as a pulp medicament in complete pulpotomy in primary teeth, based on a previous study (Bharti et al., 2015)[24], A total sample size of 60 (30 for each group) will be sufficient to detect effect size of ***f =0.59*** a power of 95%, and a significant level of 5%. Using the *z* test for testing 2 independent proportions was calculated with an anticipated loss to follow-up of 10% included. Done by Raosoft sample size calculator was used: URL:http://www.raosoft.com/samplesize.html.

4-Study Population

- sixty cases (30 for each group) will be selected from the Outpatient clinic of The Pediatric Dentistry and Dental Public Health Department , Faculty of Dentistry, Ain Shams University.
- Screening of patients will continue until the target population is achieved. Identifying and recruiting potential subjects is achieved through patient database in pediatric dentistry department.
- Patients between ages ***4-7*** years old will be selected. Full detailed treatment plan will be explained to the parents and children.
- Following the Ethical Committee of Faculty of Dentistry approval, written consents for treatment should be obtained from the children's parents prior to the clinical procedures being executed.

- ***RECRUITMENT:***

Children attending outpatient clinic in Pediatric Dentistry Department- Faculty of Dentistry, Ain Shams University- Egypt are screened for diagnosis of their chief complaint .patients with vital pulp therapy needed only will be enrolled for this study if they were compatible with eligibility criteria :-

Children should be exhibiting: [25, 26, 27]

- No History of any chronic systemic Illness or Hospitalization
- Co-operative (Rating 3&4 according to ***Frankle*** classification)

The study purpose, benefits and risks will be clarified to the care giver and a simplified verbal explanation will be explained to the children before participating in the study.

Criteria for teeth selection[25] :

1. Vital deeply carious mandibular second deciduous molars with large carious exposure upon caries removal.

2. No clinical symptoms or evidence of pulp degeneration, such as pain on percussion, history of swelling, or sinus tracts;

3. No radiographic signs of internal or external resorption and no furcation radiolucency or evidence of periapical pathosis

4. Teeth should be restorable with posterior stainless steel crowns or composite restorations.

5. 2/3 of root length remaining.

- ***RANDOMIZATION***

Allocation:

- **Sequence generation**:

Using computer generated randomization (www.randome.org) eligible teeth will be allocated randomly into two groups with1:1 allocation ratio. [28]

- **Allocation concealment mechanism**:

The sequentially generated number will be placed in opaque envelope until intervention.

Blinding:

Participants and assessors will be blinded.

Table (1): Materials will be used in the study and their composition

Materials	Manufacturer	Composition
Formocresol	PrevesTDenPRO,Digiana, Jammu ,India	Formo-Cresol (48.5% formaldehyde, 48.5% cresol, 3% glycerine).
TheraCal LC	Bisco, Inc. Schaumburg IL, USA	**Light-curing, resin-modified calcium silicate filled liner single paste** calcium oxide, calcium silicate particles (type III Portland cement), strontium glass, fumed silica, barium sulphate, barium zirconate and resin consisting of Bis-GMA and polyethylene glycol dimethacrylate
Zinc Oxide	PrevesTDenPRO,Digiana, Jammu ,India	Pure zinc oxide (dental grade)
Eugenol	PrevesTDenPRO,Digiana, Jammu ,India	Pure Eugenol Oil (dental grade)
Highly Viscous Packable Glass Ionomer	Fuji IX, GC Europe	(% chemical components by WT) Alumino silicate glass (95%) Polyacrylic acid powder (5%)
Stainless Steel Crowns	3M ESPE St Paul, USA	100% by Wt stainless steel
Ketacfil Plus Aplicap	3M ESPE, St Paul, USA	Conventional Glass Ionomer

5- STUDY PROCEDURE

1. Complete Pulpotomy Group (A) [29]: *(30 cases)*

Procedure:

1. Administration of local anaesthetic
2. Isolation with rubber dam
3. Removal of caries
4. Complete removal of roof of pulp chamber preferably with a non-end cutting bur.
5. Removal of coronal pulpal tissue with sharp sterile excavator
6. Attain initial radicular pulpal haemostasis by gentle application of sterile cotton pledget moistened with saline (haemostasis should be achieved within five minutes)

20% (1:5 dilution) Buckley's formocresol solution will be applied to radicular pulp on a cotton pledget for five minutes to achieve superficial tissue fixation followed by the application of a lining like zinc oxide eugenol cement or reinforced zinc oxide eugenol cement.The primary molar is prepared to receive stainless steel crown as a permanent restoration.

2. Complete Pulpotomy using TheraCal LC® (group B) [6] : *(30 cases)*

Procedure:

Steps 1-6 will be done as mentioned above.

Then **TheraCal LC®**will be applied directly to the radicular pulp by disposal syring tip and light curing will be done for 20 second. Then the tooth is prepared to receive stainless steel crown as a permanent restoration.

- Standardized pre-operative, immediate post-operative radiographs and follow up radiographs at ***3, 6, and 12 months*** after treatment using Periapical radiographic examination.Preoperative periapical

radiographs of the teeth considered for treatment in the study will be obtained by a standardized paralleling technique and an exposure time of 0.25 seconds.

To achieve such technique, the following equipment will be used:

- 1. An XCP film holder *: An anterior film holder was used and trimmed to fit the pedo-sized imaging plate.[1]
- 2. Size 0 reusable imaging plate (Photostimulable phosphor plate(PSP) receptor) **
- 3. X-ray machine ***70Kvp,8mA

- **Clinical success at follow-up visits should meet the following criteria[27] :-**

1. Restoration intact;
2. No spontaneous pain;
3. No mobility;
4. No swelling;
5. No fistula;
6. No gingival inflammation—represented by pain, redness, or bleeding—around the tooth/crown.

Radiographic success at follow-up visits should meet the following criteria[30]:

1. No external root resorption;
2. No internal root resorption;
3. No inter-radicular bone resorption.
4. No Widening of the periodontal ligament space.
5. No periapical bone resorption.

- **Strategies to improve adherence to intervention protocol**

Intense instructions will be given to parents about the importance of follow up visits for the success of intervention treatment.

- **Data collection**

- The data will be collected where each patient has a separate file containing all the details of the treatment with the written consent of the patients. All patients will be recall for follow up periods **3, 6 and 12 months** to evaluate them clinically and radiographically.
- Intense patient motivation for coming back during follow up periods for assessment outcomes with keeping continuous contact with them via telephone and visits for oral hygiene measures.

6- Data management

- All data will be entered electronically and double stored for safety purpose. Each patient will be given a number for easy coding and data management.

- **Confidentiality:**

All study data will be stored securely in a locked file cabinet. All recorded data and photos will be stored in safety position with password to ensure impossible access by any other person.

- **Access to data:**

The investigator have full access to the data related to this study.

7- Adverse event reporting

Any adverse events and other unintended effects of trial intervention or trial conduct will be recorded, documented and treated.

Statistical plan:

All Data will be collected, checked, revised, tabulated and entered into the computer. Data will be presented as frequency and percentage values. Fisher's Exact test will be used at $p \leq 0.05$. Statistical analysis will be performed with IBM® SPSS® Statistics for Windows (SPSS Inc., IBM Corporation, NY, USA).

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