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COMPARATIVE EVALUATION OF A NOVEL CALCIUM SILICATE BASED MATERIAL WITH MTA AND CALCIUM HYDROXIDE AS PULP CAPPING AGENTS IN ADULTS: AN IN VIVO STUDY

Dental Science

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ABSTRACT

Aim: The present study was performed to compare the effectiveness of calcium hydroxide liner (Dycal); mineral trioxide aggregate (MTA) and TheraCal PT as direct/indirect pulp capping agents in adult molars. DESIGN: In-vivo comparative study. **Materials And Methods:** Sixty-nine adult molars, fulfilling the eligibility criteria were randomly divided into three groups: Group I, Group II and Group III. Direct/indirect pulp capping was done using Dycal, MTA and TheraCal PT in Group I, II and III respectively. Clinical and radiographic examination was done at the end of 1 and 3 months. **Statistical Analysis:** The intergroup comparison for the difference of frequencies between two independent groups was done using the Chi Square test. **Results:** Overall success rate was highest with MTA, followed by TheraCal PT and least with Dycal, although statistically significant differences were not seen. MTA showed significantly lesser post-operative pain compared to both the other groups. Thicker dentine bridge formation was shown by MTA and TheraCal PT at the end of three months. **Conclusion:** Within the limitations of this study, it was concluded that no significant difference in overall success rates were observed when performing direct/indirect pulp capping using Dycal, MTA and the recently introduced material, TheraCal PT, within a follow up period of 3 months. All the agents showed significant success rates.

KEYWORDS

Vital pulp therapy, TheraCal PT, MTA, Dycal.

INTRODUCTION:

One of the main goals of operative dentistry is to preserve the health of dental pulp. Pulp can get affected by various irritants including caries, trauma and iatrogenic causes and it possesses an intrinsic capacity for healing through cell reorganization and reparative dentin formation, when a proper biological seal is provided and maintained against microbial leakage. (1)

Vital pulp therapy (VPT) comprises a series of conservative procedures that rely on the intrinsic reparatory mechanisms of the dentin-pulp complex. (2) Calcium hydroxide, mineral trioxide aggregate (MTA), tricalcium phosphate, tetracalcium phosphate, calcitonin, growth factors, resin-modified glass ionomer cement (RMGIC), intermediate restorative material (IRM), and dentin shavings are some materials which stimulate this intrinsic reparative potential of vital pulps, out of which calcium hydroxide, MTA (mineral trioxide aggregate) and other calcium silicate-based cements (CSCs) are the three most common materials that are currently recommended on the basis of in vitro and clinical research. (1)

TheraCal PT is a newer biocompatible, dual-cured, resin-modified calcium silicate material which is indicated for pulp capping, with better handling properties, making placement easier and predictable compared to MTA and calcium hydroxide. Also higher biocompatibility and better tissue response in initial in-vitro studies makes TheraCal PT a better contender against MTA and calcium hydroxide.

This in-vivo study is aimed to evaluate the clinical and radiographic efficacy of a TheraCal PT with MTA and calcium hydroxide as pulp capping agents in adults. However, till date no in-vivo studies have been done comparing its pulp capping ability with other pulp capping agents.

AIM OF THE STUDY:

The aim of this in-vivo study is to compare the effectiveness of conventional calcium hydroxide liner (CH); mineral trioxide aggregate (MTA) and a novel dual cured resin modified calcium silicate cement (TheraCal PT) as direct/indirect pulp capping materials in adult molars.

MATERIALS AND METHODS:

Sixty-nine adults aged 18–40 years, who fulfil the eligibility criteria and following written informed consent, was randomly allocated to three groups:

Group I: Calcium hydroxide (n=23)

Group II: Mineral Trioxide Aggregate (n=23)

Group III: TheraCal PT (n=23)

Inclusion criteria was that patients were aged between 18 – 40 years with 1st or 2nd maxillary or mandibular permanent molar with a proximal carious lesion. No history of pain or the presence of pain indicating, utmost, reversible pulpitis. Positive response to cold test or EPT. Intraoral periapical radiograph showing carious lesion involving 1/3rd of dentin. Periapical radiograph showing closed apex/ normal periapex. No radiolucency or widening of the periodontal ligament space. Attachment loss not exceeding 4mm. Non-contributory medical history (including pregnancy). No use of medication (no antibiotics during previous month).

The exclusion criteria included teeth showing clinical and radiographic evidence of pulp degeneration such as history of spontaneous or nocturnal pain, tenderness to percussion or palpation, necrosis of the pulp (negative to vitality testing). Swelling / fistulous tract. Pathologic mobility due to aggressive periodontitis. Internal/external root resorption. Furcation radiolucency/inter-radicular bone destruction and/or periapical bone destruction. In cases of pulpal exposure, if bleeding was not controlled within 10 minutes using cotton pellets soaked in 3% NaOCl. Teeth with any wasting diseases (attrition, abrasion, erosion, abfraction). Patients with deleterious oral habits and endodontically treated teeth.

The selected teeth was anaesthetized and isolated with a rubber dam, following which caries removal was done using a complete excavation strategy (Bjørndal et al. 2010). (3) The cavity outline (Class II) will be prepared using a high-speed sterile carbide bur under water cooling until cavity margins should be on sound tooth structure. Caries free-condition were verified by clinical examination and a caries detector dye (Reveal® caries indicator, Prevest DenPro Ltd). On the pulpal wall, a sharp sterile hand excavator was used to remove the carious dentin until no or little dye staining is seen. The cavity is then carefully cleansed with 3% buffered sodium hypochlorite solution.

In cases of pulpal exposure, the bleeding was controlled using cotton pellets soaked in 3% sodium hypochlorite within 5-10 minutes. Only a single operator performed all the treatments using a dental loupe at every step.

Each patient meeting the inclusion criteria were assigned a number from 1 to 69 (in the order of reporting) and then randomized using

research randomizer software.

GROUP I - A thin layer of Dycal was applied to the pulpal floor or pulpal exposure site and left to set.

GROUP II - White ProRoot MTA powder is mixed according to the manufacturer's instructions and a 2- mm-thick layer was placed directly over the pulpal floor or pulpal exposure site and the surrounding dentine, leaving at least 2 mm of dentine and enamel available circumferentially for the bonded composite restoration.

GROUP III - TheraCal PT was applied directly to the pulpal floor or pulpal exposure site and manipulated into a smooth surface covering all deep dentin areas and then light cured for 10 seconds.

Cavities in all three groups then received a temporary filling (Fuji IX glass–ionomer cement; GC Corp). After 1 week, any postoperative pain was recorded; pulpal status was checked using cold or electric pulp testing, and if there were no symptoms, the temporary filling was reduced to a base and teeth were permanently restored with a nanohybrid composite resin using sandwich technique.

Bitewing and periapical radiographs were taken to evaluate the quality of the restoration. At successive follow ups at 1 and 3 months, radiographic assessment of the periapical status of the tooth and dentine bridge formation were assessed using digital radiography employing a PSP (photo stimulable phosphor) sensor (PSPIX²® Acteon).

Follow-up Examination:
The clinical examination performed consisted of inspection, palpation, percussion, pulp sensibility testing and pocket depth measurement. Intraoral periapical radiographs were taken to evaluate the status of the periapical tissues and the continuity of the periodontal ligament space. The pulpal space was checked for calcific alterations and dentin bridge formation.

All radiographic evaluations were performed by two reviewers who were blinded to the material group assignments by masking the coronal part of the radiographs (while evaluating periapical changes).

Assessment of the pulp capping ability of a particular material was based on 3 different criterias:
a) Clinical scoring criteria – to assess the clinical signs and symptoms after the procedure
b) Radiographic criteria – to assess the periapical changes after pulp capping
c) Dentin bridge formation criteria – to assess the thickness of dentin bridge formed after 3 months of the procedure

CLINICAL SCORING CRITERIA:
(Scores of 1 or 2 suggest success and scores of 3 or 4 suggests failure)

Score 1- Asymptomatic: Pathology: Absent; Functioning: Normal; Percussion and sensitivity: Asymptomatic; Mobility: Nil

Score 2- Slight Discomfort: Pathology: Questionable; Functioning: Chewing sensitivity, short-lasting; Percussion and Sensitivity: TOP -ve and sensitivity only to cold; Mobility: Grade I.

Score 3- Minor Discomfort: Pathology: Initial changes present; Functioning: Chewing sensitivity, long-lasting; Percussion and Sensitivity: TOP +ve and sensitivity only to cold; Mobility: Grade I or II

Score 4- Major Discomfort: Pathology: Late changes present; Functioning: Spontaneous pain; Percussion and Sensitivity: TOP +ve and sensitivity to cold & hot; Mobility: Grade II or III.

RADIOGRAPHIC SCORING CRITERIA:
(Scores of 1 or 2 suggest success and scores of 3 or 4 suggest failure)
Score 1- No changes present: PDL: Normal Width; PAI Index*: 1; Root & Alveolar Bone Status: Normal

Score 2- Questionable pathologic changes: PDL: Widened PDL; PAI Index: 1 or 2; Root & Alveolar Bone Status: Normal

Score 3- Minor pathologic changes: PDL: Widened PDL; PAI Index: 3 or 4; Root & Alveolar Bone Status: Minor external root resorption or bone resorption.

Score 4- Major pathologic changes: PDL: Widened PDL; PAI Index: 4 or 5; Root & Alveolar Bone Status: Definite radiolucency seen w.r.t root/ periapical bone.

*Periapical Index (PAI) by Orstavik et al.(1986)(4)

DENTIN BRIDGE FORMATION SCORING CRITERIA (RADIOGRAPHICALLY):
(Scores of 1 or 2 sugges success and score of 3 suggests failure)
Score 1 - Complete dentin bridge formation: More than 0.25 mm thickness

Score 2 - Partial dentin bridge formation: 0.1mm - 0.25 mm thickness

Score 3 - Initial/ No dentin bridge formation: Less than 0.1 mm thickness or no evidence of dentin bridge formation.

RESULTS:
In this in- vivo study, results showed based on the clinical, radiographic and dentin bridge formation assessment after direct and indirect pulp capping that the overall success rates were highest with MTA (91.3%), followed by TheraCal PT (86.95%) and Calcium hydroxide (78.26%) **(Table 4).**

A) CLINICAL SCORING IN CALCIUM HYDROXIDE, MTA AND THERACAL PT
Table 1: Results Of Clinical Scoring In Calcium Hydroxide, MTA and TheraCal PT

	Score 1	Score 2	Score 3	Score 4
Calcium hydroxide	7	11	3	2
	30.43%	47.82%	13.04%	8.69%
MTA	16	5	1	1
	69.56%	21.73%	4.35%	4.35%
TheraCal PT	8	13	2	0
	34.78%	56.52%	8.69%	0%

Intergroup comparison showed statistically significant differences in clinical success rates between MTA and Dycal group (p= 0.045); & between MTA and TheraCal PT group (p=0.049).

B) RADIOGRAPHIC SCORING IN CALCIUM HYDROXIDE, MTA AND THERACAL PT
Table 2: Results Of Radiographic Scoring In Calcium Hydroxide, MTA And TheraCal PT.

	Score 1	Score 2	Score 3	Score 4
Calcium hydroxide	10	9	4	0
	43.47%	39.13%	17.40%	0%
MTA	15	6	2	0
	65.22%	26.09%	8.69%	0%
TheraCal PT	14	7	2	0
	60.87%	30.43%	8.70%	0%

Intergroup comparison showed no statistically significant differences between groups based on periapical radiographic assessment.

C) SCORING BASED ON DENTIN BRIDGE FORMATION IN CALCIUM HYDROXIDE, MTA AND THERACAL PT
Table 3: Results Of Scoring Based On Dentin Bridge Formation In Calcium Hydroxide, MTA And TheraCal PT.

	Score 1	Score 2	Score 3
Calcium hydroxide	6	10	7
	26.08%	43.48%	30.44%
MTA	15	6	2
	65.22%	26.09%	8.69%
TheraCal PT	14	7	2
	60.87%	30.43%	8.70%

Intergroup comparison showed statistically significant differences in dentin bridge formation when MTA and Dycal groups were compared

(p=0.050). Comparison of other groups showed statistically insignificant differences.

D)OVERALL SUCCESS RATE AMONG THE GROUPS

Table 4: Overall Success Rates In Calcium Hydroxide, MTA and TheraCal PT

	Successful outcome	Non successful outcome
Calcium hydroxide	18	5
	78.26%	21.74%
MTA	21	2
	91.30%	8.69%
TheraCal PT	20	3
	86.95%	13.04%

Intergroup comparison showed no statistically significant differences in the overall success rates between each group.

DISCUSSION:

Pulpal healing can be achieved even after a carious exposure if the inflammation is no more severe than reversible pulpitis. (5) (6) In the present study, asymptomatic teeth or teeth with atmost signs and symptoms of reversible pulpitis were selected for vital pulp therapy.

A wide range of materials have been suggested in the literature to be used as pulp capping protective dressing materials. Since its introduction into literature in 1920 by Hermann, calcium hydroxide was considered as the gold standard material for pulp capping. Schröder explained that the superficial layer of necrosis caused by calcium hydroxide is believed to be responsible for the irritation of the pulp and stimulating its defense mechanism and repair. (7) The repair process begins with vascular and inflammatory cell migration and proliferation, followed by the migration and proliferation of mesenchymal and endothelial pulp cells and the formation of collagen. Subsequently odontoblast differentiation occurs and the formation of tertiary dentine underneath the protective agent takes place. (7) Some drawbacks associated with calcium hydroxide includes pulp surface inflammation and necrosis, the presence of tunnel defects in the newly formed tertiary dentine, which fails to provide an adequate seal against recurrent infections, high solubility in oral fluids, lack of adhesion (8) (9) and inability to kill Enterococcus faecalis in the dentine.(10)

Introduction of Mineral trioxide aggregate (MTA) in the 1990s by Torabinejad has broadly led to the use of the material to seal pulpal cavities and external root surface communications. In a meta-analysis, investigators reviewed researches done since 2003 wherein, MTA specimens showed less pulpal inflammation in comparison to the calcium hydroxide specimens and histologically a better calcified dentine bridge formation with higher success rates. (8) (11) (12) The pulp survival rate was 95% for a group that was followed for at least 5 years. (13) Drawbacks of MTA include difficulty in handling, long setting time, high cost and potential discolouration to the tooth. (14)

TheraCal PT is a newer biocompatible, dual-cured, resin-modified calcium silicate material introduced by Bisco, which is indicated primarily for pulpotomy treatments but also as a direct/indirect pulp capping agent. Its predecessor, Theracal LC was associated with some degree of cytotoxicity(15), whereas the initial in-vitro studies with the newer TheraCal PT reveals improved in vitro cytocompatibility and mineralization potential compared to the latter. (16) Initial in-vitro investigations have also shown similar cytocompatibilty and bioactivity of Theracal PT and MTA. This novel calcium silicate-based material combines all the advantages of bioceramic cement ie: alkaline pH, biocompatibility and calcium release (due to hydrophilic matrix which allows for ion exchange).

MTA showed the highest overall success rate (91.30%), followed by Theracal PT (86.95%) and calcium hydroxide (78.26%) after a follow up period of 3 months.

However, statistically significant differences were not observed. The higher success rates associated with MTA can be due to its better biocompatibility and superior dentin bridge formation ability compared to the other groups used.

Comparison between Group I (Calcium hydroxide) and Group II (MTA):

MTA group had lesser incidence of postoperative discomfort in terms of pain and tender on percussion, relatively during first 2 weeks (**Table 1**). Similarly, radiographic analysis of dentin bridge thickness also showed more complete and thicker bridge formed at the end of 3 months in the MTA group (**Table 3**). In the calcium hydroxide group, only 70% of the teeth showed partial or complete dentin bridge formation compared to 91% in the MTA group. This shows the higher reparative dentin formation potential of the calcium silicate based MTA.

Comparison between Group II (MTA) and Group III (TheraCal PT):

TheraCal PT showed clinical signs of mild pain and tender on percussion statistically more compared with MTA (**Table 1**). It could be due to resin components incorporated in Theracal PT, especially in case of direct pulp capping. MTA and TheraCal PT group showed better dentine bridge thickness radiographically **(Table 3)** and also better periapical index (PAI) scoring with lesser incidence of pdl widening**(Table 2)**. More than 90% of the teeth receiving either MTA or TheraCal PT showed complete or partial dentin bridge formation.

Comparison between Group I (Calcium hydroxide) and Group III (TheraCal PT):

Clinical, radiographic, dentin bridge formation and overall success rates were better with TheraCal PT, but no statistically significant differences were seen.

Higher incidence of post-operative pain was associated with calcium hydroxide and Theracal PT**(Table 1)**. Even though Theracal PT shows better in-vitro cytocompatibility than Theracal LC (16), some other studies have shown cytotoxicity and residual monomer release associated with Theracal PT and Thearacal LC. (17) More in-vitro and in-vivo studies need to be done to establish the cytotoxic potential and effects on cell viability associated with Theracal PT.

In the present study, all pulp capping agents showed significant success rates when used as direct/indirect pulp capping material in adult molars. A large number of pulp capping agents are available in the market today. More in-vivo and in-vitro studies comparing them are still required to evaluate and to relate the findings of the present in-vivo study, especially assessing long term clinical and radiographic outcomes.

CONCLUSION:

The present in-vivo study compared the direct/indirect pulp capping pulp capping potential of calcium hydroxide, MTA and TheraCal PT when used in adult molars with deep carious lesions.

Within the limitations of the study, the following conclusions were drawn:

1. All the pulp capping agents showed significant success rates when used as a direct/indirect pulp capping material in adult molars.
2. MTA showed the highest overall success rate with least incidence of post-operative pain, lesser periodontal ligament space widening and thicker dentine bridge formation when observed radiographically.
3. TheraCal PT showed statistically similar results in terms of overall success rate, periapical radiographic assessment and thickness of dentin bridge formed when compared to MTA.
4. Calcium hydroxide showed the least overall success rate. Dentin bridge formation and clinical scoring assessment were inferior to that of MTA and was statistically significant.

Although there were no significant differences seen in clinical or radiographic outcome compared to TheraCal PT. However, further in-vivo and in-vitro studies are required to compare and establish the pulp capping potential of different newer agents.

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