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RANDOMIZED CLINICAL TRIAL TO COMPARE THE EFFICACY OF TWO CALCIUM SILICATE BASED MATERIALS IN TREATMENT OF DEEP CARIOUS LESION

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ABSTRACT

Objective: this study was directed to clinically and radiographically evaluate mineral trioxide aggregate (MTA) and TheraCal LC as indirect pulp capping (IPC) materials. **Subjects and Methods**: Twenty male patients aged 17–35 years with deep caires in class one in lower molars were randomly divided into two equal groups (n = 10). Group 1: pulp were capped using MTA. Group 2: pulp were capped using TheraCal LC. Clinical evaluation was performed at 1 week, 3, and 6 months after IPC for presence/absence of spontaneous pain, tenderness to percussion, draining sinuses and pulp response to thermal pulp vitality test. Digital periapical radiographs were taken at 1 week, 3, and 6 months after IPC to evaluate the changes in the width of periodontal ligament space and presence/absence of periapical lesion. **Results:** Clinically, all cases showed criteria of successful treatment except 1case in each group. Statistical analysis revealed no statistically significant difference between both groups ($P > 0.05$). Radiographically, periapical lesions and the changes in the width of periodontal ligament space were not significantly different between both groups recording ($P > 0.05$). **Conclusion:** Clinically and radiographically, MTA and TheraCal LC are favorable materials for IPC.

KEYWORDS: Indirect pulp capping, mineral trioxide aggregate, TheraCal LC.

INTRODUCTION

Dental caries seems to be the most common chronic disease that affects individuals worldwide throughout the course of their lives. After eliminating deep caries or after exposure to trauma, vital pulp therapy techniques entail the eradication of local irritants and the transplantation of a protective material on the deep cavities' floor that is directly or indirectly accessible vital pulp or dentin. These protective biomaterials should have specific properties such as biocompatibility, bio-interactivity, and bioactivity to trigger the pulp cells and the reparative dentin's formation [1-3].

Historically, calcium hydroxide has been the preferred pulp capping material in permanent dentition. When calcium hydroxide Ca $(OH)_2$ cements are dissolved, they generate hydroxyl (OH) and calcium (Ca) ions. Its alkaline pH stimulates the reparative dentin's formation in direct contact with the pulp. Unfortunately, self-curing Ca $(OH)_2$ cement is soluble, raises alkalinity, and forms a necrotic coating at the material–pulp interface and also it has greater chances of microleakage [4,5].

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Therefore, there is a need for developing other capping materials with a biologic ability to enhance dentin formation. A bioactive calcium silicate-based cement termed as mineral trioxide aggregate (MTA) was established. It is made of a variety of dicalcium silicate, tetracalciumaluminoferrite, tricalcium silicate, tricalcium aluminate, and calcium sulphate dehydrate, with the furthermore of bismuth oxide for radio opacity [6]. MTA has been demonstrated to be better to calcium hydroxide when used to cap the pulp of human teeth. Nevertheless, some limitations remain regarding the use of conventional MTA due to poor manipulation and long setting times [7].

TheraCal LC, a light-curable hydrophilic resin combined with MTA technology, is recommended for directly and indirectly pulp capping, as well as for use as a liner. The proprietary resin formula in TheraCal LC is distinctive in that it contains tricalcium and dicalcium silicate particles suspended in a hydrophilic monomer that releases considerable calcium and hydroxide ions' levels, stimulating the hydroxyapatite production and secondary dentin bridges providing good seal [8,9].

There are little clinical studies evaluating IPC using TheraCal LC and MTA. As such, the objective of this study was to examine and contrast the short-term radiographic and clinical effects of IPC utilizing MTA and TheraCal LC in a prospective randomized controlled clinical study.

SUBJECTS AND METHODS

Study Design: A randomized controlled clinical study.

Study Setting: The study was performed at the Operative Department, Faculty of Dentistry Al Azhar University, Assuit Branch.

Sample Size: Based on previous study [1]. Sample size of 10 restorations in each group has a 80% power to detect an increase of 0.35 with a significance level (alpha) of 0.05 (two-tailed) at 95% confidence intervals. In 80% (the power) of those experiments, the P value will be less than 0.05 (two-tailed) so the results will be deemed "statistically significant". In the remaining 20% of the experiments, the increase will be deemed "not statistically significant". Report created by GraphPad StatMate 2.00.

Patient Selection: Twenty patients were recruited from the Conservative Dentistry Department Clinic, Faculty of Dentistry, Al Azhar University, with deep class I cavity in lower molars according to the detailed inclusion and exclusion criteria.

Inclusion Criteria:

Male patients aged (17-35years) with incidence of deep class I carious lesions that include 75% or more of the dentin without exposing the pulp. The lack of a clinical diagnosis of pulp exposure, fistula, periodontal tissue edoema, or aberrant tooth mobility, as well as a record of spontaneous pain or pressure sensitivity. Possibility to get proper isolation with rubber dam.

Exclusion Criteria:

Clinical manifestations of irreversible pulpitis necessitating endodontic therapy. The fistulas or edoema existence. Tenderness to percussion or mobile teeth. Patients unable to give consent.

Ethical Considerations: The Research Ethics Committee of Al Azhar University's Faculty of Dentistry granted approval for this study (EC Ref No. : 105/124). The goal of this study was described to patients, and informed consent was acquired in accordance with the Research Ethics Committee of Al Azhar University's Faculty of Dentistry's rules on human research.

Group assignment: Twenty patients were randomly categorized into two equal groups (n = 10). Group 1: pulp was capped using MTA (ProRoot MTA, Dentsply, USA). Group 2: pulp was capped using TheraCal LC (Bisco, USA).

Pulp Capping Procedure: After injecting a local anaesthetic and applying a rubber dam, the carious lesions were excised following the guidelines published by the International Caries Consensus Collaboration, total caries removal to

hard dentine strategy was used for the peripheral walls of the cavity with the use of a sharp sterile spoon double-ended excavator (No. 51–52, Dentsply® Maillefer, Switzerland). Selective caries removal to Leathery dentine strategy was followed using the hardness criteria (Table: 1) [10]. Teeth exposed to pulp were eliminated from the study. In **group 1**: ProRoot MTA was mixed according to manufacturer recommended ratio (1:1) on a glass slab for 30 seconds with a metal spatula, resulting in a putty-like texture which transported in a sterile amalgam carrier and gradually condensed using a wetted cotton pellet. A cotton pellet soaked in sterile saline was then applied to the surface of the MTA to enable the material to properly set. While in **group 2:** TheraCal LC was applied directly to the prepared cavity in 1mm layer and light cured for 20 s. after the application of pulp-capping materials, Kavitan Lc, a light-cured resin modified glass ionomer cement base (Spofa dental, Czech Republic), was mixed according to the manufacturer's instructions and then was applied and light cured for 20 seconds using a light-emitting diode (LED) device (Monitex Industrial Co. Ltd, China; 1000 mW/cm2). Finally Tetric N-Ceram nano hybrid composite (Ivoclar Vivadent, Switzerland) was applied and then curing was done for 40s after selective etching of enamel only was done using 37% phosphoric acid gel for 30 s. then rinsed using air-water spray for 5 s. A single layer of universal adhesive (All Bond Universal, Bisco, USA) was applied and cured for 20 s.

Base line radiographs: one week after IPC, a base-line periapical radiographs were taken with paralleling technique using a digital radiograph device (New Life Radiology, Italy).

Clinical and radiographic evaluations: Clinical evaluation was performed at 1week, 3, and 6 months after IPC. Thermal pulp vitality test was performed using ice sticks (cold Test). Which applied against the gingival third of buccal surface of the tooth In case where patient did not feel any sensation pellet was removed after 15 seconds. Pain lasting up to 15 to 20 seconds and subsiding spontaneously is classified as light discomfort, whereas pain lasting longer than several minutes and requiring pain medication is classified as severe pain. Radiographic evaluation was performed at 1week, 3, and 6 months after IPC. Periapical radiographs were submitted to evaluate changes in width of PDL space and periapical lesion. Digital periapical radiographs employing phosphor plates were acquired using a dental X-ray unit utilizing a paralleling approach, with TrollByte Plus sensor holder from (TrollDental USA) to achieve standardization. A PA lesion was characterized as radiolucency extending 2 times the breadth of the PDL space from the radiographic apex of the root. The PDL space was defined as being less than twofold the size of the adjacent healthy tooth's equal healthy PDL space [1]. The PA images were viewed as a PowerPoint presentation (Microsoft, USA) on a computer (HP ProBook, USA) with a 15.6-inch backlit LED screen (1920 x 1080 pixel resolution) in a quiet, dimly lit room. The three images of each tooth were seen together by a calibrated examiner who was blindfolded to the image obtained at T1, T2, and T3. Patients were instructed to inform the operator if they developed spontaneous pain that was not relieved by medications. These teeth were deemed to be failures, and patients were encouraged to seek traditional endodontic care.

Statistical analysis

Each group's mean and standard deviation were computed for each test. The Shapiro-Wilk and Kolmogorov-Smirnov experiments were utilized to recognize the normality of the data; qualitative data revealed a non-parametric (abnormal) distribution, whilst quantitative data revealed a parametric (normal) distribution. When comparing more than two groups in unrelated samples using qualitative data, the Kruskal Wallis test was applied. The Mann Whitney test was employed to determine the difference in mean between two groups in unrelated samples. The Friedman test was used to contrast samples that contained more than two groups. The Wilcoxon test was used to determine the difference in mean between two groups in related samples. To contrast more than two groups

in unrelated samples using quantitative data, a one-way ANOVA accompanied by a Tukey posthoc test was utilized. P less than 0.05 was chosen as the criterion of significance. IBM® SPSS® Statistics Version 20 for Windows was used for statistical analysis.

RESULTS

Clinical results

Clinical evaluation was performed at 1 week, 3 and 6 months after IPC procedures. All cases had no tenderness to percussion, no draining sinuses, no swelling and they respond to thermal pulp vitality test at all-time intervals. However, one case in each group had severe spontaneous pain which were considered failure cases which had severe pain and consider failure cases.

A comparison between MTA and TheraCal LC groups at each follow up period regarding the postoperative pain revealed no statistical significant difference between both groups as shown in Table 2.

Radiographic results

Periapical lesion and Widening of PDL space: Comparison of periapical lesion between two groups revealed that there was no statistically significant difference between both groups as shown in Table 3,4.

TABLE (1) Hardness criteria used for excavation of carious tissue.

Hardness criteria	Description
Soft dentine	Deformation occurs when a hand instrument is pressed onto it and could be easily scooped up (e.g., using a sharp hand excavator) without much force.
Leathery dentine	Although the dentine does not deform when an instrument is pressed onto it, leathery dentine can still be easily lifted without much force being required. The hardness of leathery dentine is between that of soft and firm dentine.
Firm dentine	Physically resistant to hand excavation and some pressure needs to be exerted through an instrument to lift it.
Hard dentine	A pushing force needs to be used with a hand instrument to engage the dentine and only a sharp cutting edge or a bur will lift it. A scratchy sound or "cri dentinaire" can be heard when a straight probe is taken across the dentine.

TABLE (2) The frequencies of different groups for Post-operative pain

Variables		Post-operative pain						p-value
		At 1w		At 3m		At 6m		
		N	%	N	%	n	%	
MTA	No pain	6	60%	7	70%	8	88.9%	0.223ns
	Mild	4	40%	2	20%	1	11.1%	
	Severe	0	0%	1	10%	0	0%	
THC	No pain	5	50%	6	66.7%	6	66.7%	0.368ns
	Mild	4	40%	3	33.3%	3	33.3%	
	Severe	1	10%	0	0%	0	0%	
p-value		0.234ns		0.117ns		0.553ns		

TABLE (3) The frequencies of different groups for Periapical lesion.

Variables		Periapical lesion						p-value
		At 1w		At 3m		At 6m		
		N	%	N	%	N	%	
MTA	No	10	100%	9	90%	9	100%	0.368ns
	Yes	0	0%	1	10%	0	0%	
THC	No	10	100%	9	100%	9	100%	0.305ns
	Yes	0	0%	0	0%	0	0%	
p-value		1ns		0.529ns		1ns		

TABLE (4) The frequencies of different groups for Widening of PDL.

Variables		Widening of PDL						p-value
		At 1w		At 3m		At 6m		
		N	%	N	%	n	%	
MTA	No	10	100%	7	70%	7	77.8%	0.135ns
	Yes	0	0%	3	30%	2	22.2%	
THC	No	10	100%	7	77.8%	6	66.7%	0.097ns
	Yes	0	0%	2	22.2%	3	33.3%	
p-value		1ns		0.675ns		0.844ns		

DISCUSSION

There are numerous techniques for preserving pulpal vitality in teeth with extensive caries. Indirect pulp therapy is one such therapeutic approach that aims to preserve the vitality of the pulp while avoiding more invasive therapies [11].

Numerous materials have been employed in the therapy of essential teeth with deep carious lesions as indirect pulp capping agents. Since Zander's 1939 description of its application, calcium hydroxide has remained the gold standard for pulp capping [12].

In comparison to Dycal, MTA is termed to offer superior sealing properties and a lack of water solubility. Because the principal product of MTA's interaction with water is calcium hydroxide, several of the benefits and possible action mechanisms of MTA are similar to those of Dycal [13].

Despite the fact that MTA has an adequate clinical effectiveness, it does have several drawbacks, including a lengthy setting time and poor handling qualities. To solve these issues, TheraCal LC was developed with quick polymerization due to its light curable composition, which results in a shorter treatment period. So, TheraCal LC was compared to MTA in this study as little clinical studies evaluated both materials in IPC [14].

Mandibular molars were managed in this study because they are the most often involved teeth in need of critical pulp therapy, as caries typically begins shortly after molars emerge into the oral cavity [15]. Complete caries clearance, which entails removing all decaying and infected dentin in a single visit, has been considered to be the optimum medication strategy [16,17]. Franzon and others made a comparison to the sequential strategy, observed better treatment success with full caries eradication[18].

Regarding post-operative pain, there were no statistically significant differences in the two groups at different follow up periods. One case was excluded in MTA group and one case was excluded in THC group as they felt pain which may be due to previous inflammation in these cases preceding to therapy but without demonstrating clinical symptoms of such inflammation. As Caicedo et al. describe, the early postoperative discomfort is likely a symptom of an increase of this inflammation preceding treatment [19].

Regarding widening of PDL space, there were no statistically significant differences between all groups. This result was in agreement with George et al. who found normal thickness of PDL space in all observed teeth [20].

There were no statistically significant variations in PA radiolucencies across the groups. The majority of teeth with PA lesions were observed after three months in this study. This result may be attributed

to the fact that success rates for the four materials employed were comparable at six months but varied after three months. Thus, it appears as though the critical period for the capping procedure's effectiveness is the first three months. We evaluated what Pashley discovered while assessing these achievement and the hazardous nature of the capping components [21], which discovered no difference in outcome when pulp capping was performed directly or indirectly for deep cavity restoration, attributable to the quick increase in dentine permeability towards the pulp. The size and number of open tubuli are adequate to approximate genuine pulp exposure in deep cavities with a residual dentine thickness of less than 0.5 mm. [22].

The excellent reaction to treatment could be a result of a number of variables, including the removal of all germs, the sealing impact, and the low toxicity of the materials utilized [23]. Bortoluzzi et al. shown that all freshly established CSCs (both resin-modified and resin-free) were firstly cytotoxic, possibly owing to their great alkalinity. Nevertheless, such an alkaline pH may be advantageous for the cement's antimicrobial qualities [24].

This was in disagreement with Lee et al. who found that TheraCal LC showed less favorable results than ProRoot MTA. This could be explained by the enhanced cavity depth after pulpotomy medication and the curing light's restricted access. As a result, a lesser degree of polymerization may result in an increased amount of uncured resin monomeric, which may eventually diminish the cement's biocompatibility [25].

This was in agreement with Erfanparast et al. who shown that after 12 months, TheraCal LC had comparable radiological and clinical results to Discussion 135 MTA in primary dentition DPC. TheraCal LC and MTA groups achieved a success rate of 91.9 and 94.6 percent, respectively [26].

Controversy, Gandolfi et al. who indicated that the composition of TheraCal LC provides a significant calcium release that is more than that of ProRoot MTA or self-setting Ca(OH)2 and may be beneficial for odontoblasts [27].

CONCLUSIONS

Based on the research findings of this investigation, it can be stated that MTA and TheraCal are both clinically and radiographically favorable materials for IPC.

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