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Two Calcium Silicate and Two Calcium Hydroxide-Based Materials Used in Indirect Pulp Capping (In-Vivo Study)

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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.*

Patients 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, calcium hydroxide*

I. INTRODUCTION

Dental caries is the most prevalent chronic disease of people worldwide throughout their lifetime. Vital pulp therapy procedures involve removal of local irritants and placement of a protective material directly or indirectly exposed dentin or vital pulp on the floor of deep cavities after removing deep caries or after exposure to trauma. These protective biomaterials should have specific properties such as biocompatibility, bio-interactivity, and bioactivity to activate the pulp cells and the formation of reparative dentin.[1-3]

Calcium hydroxide has traditionally been used as the pulp capping material of choice in permanent teeth. Calcium hydroxide $Ca(OH)_2$ cements have the ability to release hydroxyl (OH) and calcium (Ca) ions upon dissolution. Its alkaline pH stimulates the formation of reparative dentin in direct contact with the pulp. Unfortunately, self-curing $Ca(OH)_2$ cement is soluble, raises alkalinity, and forms a necrotic layer at the material–pulp interface and also it has greater chances of microleakage. [4,5]

Therefore, there is a need for developing other capping materials with a biologic ability to enhance dentin formation. A bioactive calcium silicate-based cement as mineral trioxide aggregate (MTA), was developed which is composed of a mixture of tricalcium silicate, dicalcium silicate, tricalcium aluminate, tetracalciumaluminoferrite, and calcium sulfate dehydrate with an addition of bismuth oxide as a radio-opacifier [6] MTA has been reported superior to calcium hydroxide for pulp capping of human teeth. However, some limitations remain regarding the use of conventional MTA due to poor manipulation and long setting times [7].

TheraCal LC and light cured calcium hydroxide a light-curable hydrophilic resin combined with MTA or calcium hydroxide technology, is indicated for direct and indirect pulp capping. The proprietary resin formula in TheraCal LC is unique, consisting of tricalcium and dicalcium silicate particles in a unique hydrophilic monomer that provides significant calcium and hydroxide ion release which stimulates hydroxyapatite and secondary dentin bridge formation providing good seal [9].

This study was designed to evaluate and compare the short term clinical and radiographical outcomes of IPC using MTA and TheraCal LC in prospective randomized controlled clinical study.

II. SUBJECTS AND METHODS

A. Study Design: A randomized controlled clinical study.

B. Study setting: The study was carried out at the Operative Department, Faculty of Dentistry Al Azhar University, Assuit Branch.

C. 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:

1. Male patients aged (17-35years).
2. The presence of deep class I where carious lesions involving 75% or more of the dentin without pulp exposure.
3. Absence of clinical diagnosis of pulp exposure, fistula, swelling of periodontal tissues, abnormal tooth mobility, and history of spontaneous pain or sensitivity to pressure.
4. Possibility to get proper isolation with rubber dam.

Exclusion criteria:

1. Clinical symptoms of irreversible pulpitis requiring endodontic treatment.
2. Presence of fistulas or swelling.
3. Mobile teeth or tenderness to percussion.
4. Patients unable to give consent.

D. Ethical considerations: Approval for this research was obtained from Research Ethics Committee, Faculty of Dentistry, Al Azhar University. The purpose of the present study was explained to the patients and informed consents were obtained according to the guidelines on human research adopted by the Research Ethics Committee, Faculty of Dentistry, Al Azhar University.

E. Group assignment: Twenty patients were randomly divided into two equal groups (n = 10). Group 1: pulp were capped using MTA (ProRoot MTA, Dentsply, USA). Group 2: pulp were capped using chemical-cured calcium hydroxide (Dycal, Dentsply, USA) Group 3: pulp were capped using TheraCal LC (Bisco, USA). Group 4: pulp were capped using light-cured calcium hydroxide (Urbical, Promedica, Germany).

F. Pulp capping procedure: After local anesthetic injection and rubber dam application, the carious lesions were removed 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. (10) Teeth which developed

pulp exposure were excluded from the study. In **group 1**: ProRoot MTA was mixed according to the manufacturer's instructions, then it was carried with a sterile amalgam carrier and gently condensed with wetted cotton pellet. In **group 2:** Dycal was applied on the cavity dentin with a material thickness of approximately 0.8–1mm using a calcium hydroxide applicator. In **group 3:** TheraCal LC was applied directly to the prepared cavity in 1mm layer and light cured for 20 s. In **group 4:** Urbical was applied directly to the prepared cavity in 1mm layer and light cured for 20 s. Following the application of the pulp-capping materials, Kavitan Lc a light cured resin modified glass ionomer cement base (Spofa dental, Czech Republic) was mixed according to the manufacture instructions then applied and light cured for 20 seconds using a light-emitting diode (LED) device Monitex Industrial Co. Ltd, China; 1000 mW/cm^2). Finally Tetric N-Ceram nano hybrid composite (Ivoclar Vivadent, Switzerland) was applied and then curing was done for 40s after Selective etching bonding protocol.

G. **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).

H. **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). Ice sticks were 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 s and settling spontaneously consider mild pain, while increased pain for more than several minutes and needing pain killers consider 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 using phosphor plates were acquired using a dental X-ray unit using a paralleling technique, with TrollByte Plus sensor holder from (TrollDental USA) to achieve standardization. A PA lesion was defined as radiolucency associated with the radiographic apex of the root, ≥2 times the width of the PDL space. Widening of the PDL space was defined as less than double that of the equivalent healthy PDL space of the adjacent healthy tooth. [(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 viewed together by a calibrated examiner who blinded as to which image was taken at T1, T2 and T3. Patients were informed to return to contact the operator if they experienced spontaneous pain that was not ameliorated with analgesics. These teeth were considered failures and then patients were advised to undergo conventional endodontic treatment.

Statistical analysis: The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests, qualitative data showed non-parametric (not-normal) distribution, while quantitative data showed parametric (normal) distribution. For qualitative data, Kruskal Wallis test was used to compare between more than two groups in non-related samples. Mann Whitney test was used to compare between two groups in non-related samples. Friedman test was used to compare between more than two groups in related samples. Wilcoxon test was used to compare between two groups in related samples. For quantitative data, One-way ANOVA followed by Tukey posthoc test was used to compare between more than two groups in non-related samples. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

III. RESULTS

A. 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 group1, three cases in group2, one case in group3 and three case in group4 had severe spontaneous pain and during vitality test there was severe pain which was not relieved after removal of cold stimulus which were considered failure cases.

A comparison between the four groups at each follow up period regarding the postoperative pain revealed

Variables		Post-operative pain						
		At 1w		At 3m		At 6m		p-value
		N	%	N	%	n	%	
MTA	No pain	6	60%	7	70%	8	88.9%	0.223ns

no statistical significant difference between both groups as shown in Table [1].

B. Radiographic results:

Periapical lesion and Widening of PDL space: Comparison of periapical lesion between four groups there was no statistically significant difference between both groups as shown in Table [2,3].

Variables		Periapical lesion						
		At 1w		At 3m		At 6m		p-value
		N	%	N	%	n	%	
MTA	No	10	100%	9	90%	9	100%	0.368ns
	Yes	0	0%	1	10%	0	0%	
CH	No	10	100%	7	87.5%	7	100%	0.368ns
	Yes	0	0%	1	12.5%	0	0%	
THC	No	10	100%	9	100%	9	100%	0.305ns
	Yes	0	0%	0	0%	0	0%	
LCCH	No	10	100%	7	77.8%	7	100%	0.154ns
	Yes	0	0%	2	22.2%	0	0%	
p-value		1ns		0.529ns		1ns		

Table (2): The frequencies of different groups for Periapical lesion.

	Mild	4	40%	2	20%	1	11.1%	
	Severe	0	0%	1	10%	0	0%	
CH	No pain	2	20%	3	37.5%	5	71.4%	
	Mild	6	60%	4	50%	2	28.6%	**0.097ns**
	Severe	2	20%	1	12.5%	0	0%	
THC	No pain	5	50%	6	66.7%	6	66.7%	
	Mild	4	40%	3	33.3%	3	33.3%	**0.368ns**
	Severe	1	10%	0	0%	0	0%	
LCCH	No pain	4	40%	2	22.2%	4	57.1%	
	Mild	5	50%	5	55.6%	3	42.9%	**0.135ns**
	Severe	1	10%	2	22.2%	0	0%	
p-value		0.234ns		0.117ns		0.553ns		

Table [1]: The frequencies of different groups for Post-operative pain.

Table [3]: The frequencies of different groups for Widening of PDL.

Variables		Widening of PDL						
		At 1w		At 3m		At 6m		p-value
		N	%	n	%	N	%	
MTA	No	10	100%	7	70%	7	77.8%	**0.135ns**
	Yes	0	0%	3	30%	2	22.2%	
CH	No	10	100%	4	50%	5	62.5%	**0.050ns**
	Yes	0	0%	4	50%	3	37.5%	
THC	No	10	100%	7	77.8%	6	66.7%	**0.097ns**
	Yes	0	0%	2	22.2%	3	33.3%	
LCCH	No	10	100%	5	62.5%	4	57.1%	**0.097ns**
	Yes	0	0%	3	37.5%	3	42.9%	
p-value		1ns		0.675ns		0.844ns		

IV. DISCUSSION

There are many modes to preserve pulpal vitality in teeth with deep caries. Indirect pulp treatment is one such therapeutic modality that attempt to maintain pulp vitality and avoid more extensive treatments.[11]

The materials were selected as they have similar clinical applications in terms of being used as restorative dentine replacements and as provisional bulk restorative materials in deep cavities.[12]

Mandibular molars were the treated teeth in this study as they are the most common teeth requiring vital pulp therapy as the onset of caries takes place soon after the eruption of molars into the oral cavity. [13,14]

Bjørndal, for instance, defined deep caries as one that has penetrated three-quarters of the entire dentin thickness when evaluated on a radiograph. Thus, a combination of a detailed clinical interview, clinical

examination, and radiographic assessment is essential for correct case selection as has been followed in the present study.[15]

Complete caries removal, which involves the removal of all of the decayed and infected dentin in one visit, has been reported to be the preferred method of treatment.[16-18] Browning [19] compared the stepwise and complete caries removal techniques and reported a 90% success rate of treatment as well as no significant differences in the outcomes between the two methods. Franzon and others [20] reported greater treatment success with complete caries removal in comparison to the stepwise approach.

Permanent restorations were used in IPC procedures in this study as the success rate was found more in using permanent restorations than temporary restorations (80.8% versus 47.3%) [21] .RMGI cement was used as a base under final composite restoration in this study as Kasraei et al. [22] proved that RMGI cement showed reduced microleakage compared to composites.

Favorable IPC treatment outcomes, both clinically and radiographically, were found in the four groups. Regarding post-operative pain, there were no statistically significant differences in the four groups at different follow up periods. One case was excluded in MTA group, three cases were excluded in CH group, One case was excluded in THC group and three cases were excluded in LCCH group as they felt pain which may be due to previous inflammation in these cases prior to treatment but without clinical signs of such inflammation. The initial postoperative pain is likely to be a sign of an exacerbation of this inflammation following treatment as explained by Caicedo et al. [23]

Regarding widening of PDL space, there were no statistically significant differences between all groups. This result was in agreement with George et al. [24] who found normal thickness of PDL space in all observed teeth.

Regarding PA radiolucencies, there were no statistically significant differences between all groups. In this study, the majority of teeth with PA lesions seen after three months this association may be explained by the success rates were comparable for the used four materials at 6 months, but they differed at 3 months. Thus, the critical period for the success of the capping procedure seems to be within the first 3 months. When looking at these success rates, and with regard to the potential toxic effects of the capping materials, we considered, as reported by Pashley [21], that there was no difference between direct and indirect pulp capping for the restoration of deep cavities, because of the fast increase in dentine permeability near the pulp. In deep cavities with a residual thickness of dentine of less than 0.5 mm, the number and size of open tubuli are such that communication with the pulp is comparable with that of a true pulp exposure [25].

The favorable response to treatment is possibly due to a combination of factors such as removing all bacteria, the sealing effect and the low toxicity of the used materials [26] . Bortoluzzi et al. [27] showed that all of freshly-set CSCs (resin-modified and resin-free) were initially cytotoxic which could be due to their high alkalinity. However, such an alkaline pH may be in favor of the cement's bacteriostatic properties.

Another study showed that in vitro cytotoxicity of calcium-silicate based products (such as MTA and TheraCal LC) was lower than Ca $(OH)_2$- based materials[28] . Also, Hebling et al. [29] showed that resin-modified calcium silicate (TheraCal LC) was less cytotoxic for cultured immortalized odontoblast cells than resin-modified $Ca(OH)_2$ and RMGI.

This was in disagreement with Lee et al. [30] who found that TheraCal LC showed less favorable results than ProRoot MTA. This might be attributed to the increased cavity depth in pulpotomy treatment and limited access of the curing light. Therefore, a reduced polymerization degree might cause elevated uncured resin monomeric, which eventually might lower the cement's biocompatibility.

The present study suggested that calcium silicates based materials (MTA and TheraCal LC) are effective capping materials both tested materials owing to the fact that both materials release calcium ions in sufficient

quantities to promote reparative dentin formation [28]. In general, $Ca(OH)_2$ is released during the hydration reaction of MTA/calcium silicates and the material slowly sets by gelation. Consequently, the favorable biological mechanism of MTA is attributed to $Ca(OH)_2$ release [31] .

V. CONCLUSION

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

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