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Clinical Research

Randomized Clinical Trial to Evaluate MTA Indirect Pulp Capping in Deep Caries Lesions After 24-Months

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Clinical Relevance

The application of MTA and calcium hydroxide showed similar clinical performance over a 24-month period.

SUMMARY

Objective: This clinical study aimed to assess the efficacies of mineral trioxide aggregate (MTA) and calcium hydroxide [$Ca(OH)_2$] in the treatment of deep carious lesions by the direct complete caries removal technique.

Methods and Materials: A total of 100 permanent molar/premolar teeth were capped with either $Ca(OH)_2$ (n=49) or MTA (n=51) and restored with composite resin in 73 patients. Periapical radiographs were acquired prior to the treatment as well as at six, 12, and 24 months posttreatment. Two calibrated examiners performed the clinical and radiographic assessment of the periapical pathology and pulpal symptoms. Intergroup comparisons of the observed values were performed using the Fisher exact test. Significance was predetermined at $\alpha = 0.05$.

Results: The recall rates were 100% at six and 12 months posttreatment and 98.6% at 24 months posttreatment. Four teeth capped with $Ca(OH)_2$ (two each at six and 12 months posttreatment) and two capped with MTA (one each at 12 and 24 months posttreatment) received endodontic emergency treatment because of symptoms of irreversible pulpitis, which were clinically and/or radiographically established. There were no significant differences in pulp vitality between the two pulp-capping agents at six, 12, or 24 months posttreatment ($p=0.238$, $p=0.606$, and $p=0.427$, respectively).

Conclusions: Both pulp-capping materials were found to be clinically acceptable at 24 months posttreatment.

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INTRODUCTION

Infected deep carious lesions can be clinically managed either by preservation of the tooth tissue or by root canal therapy. Preservation of the dental

pulp vitality is important in the treatment of deep carious lesions. The success of the pulp-capping procedure relies primarily on the type of capping material, patient's age, periodontal condition, stage of root formation, size and nature (traumatic/mechanical/carious) of the exposure, and status of microbial contamination of the site.[1]

Conservative approaches for the treatment of deep carious lesions still show favorable prognosis for pulpal healing. Alternative approaches for the vital treatment of deep carious lesions include complete caries removal, stepwise excavation, indirect pulp capping, and partial caries removal. Complete caries removal, which involves the removal of all infected and affected carious dentin, is preferred by a majority of the professionals for the treatment of deep carious lesions.[2,3] In this procedure, the pulp is covered with a protective base at areas where the remaining dentin thickness is $\leq$ 0.5 mm. Although stepwise excavation has gained popularity in recent times, the results of a previous histological study indicate that infected dentin should be completely removed to arrest the carious process.[4]

A wide array of materials have been used in the treatment of deep carious lesions for maintaining pulp vitality, including calcium hydroxide [$Ca(OH)_2$], which is regarded as the gold standard for pulp capping.[1] Following pulp exposure, pulpal tissue is usually in disarray, and subsequent capping with $Ca(OH)_2$ can cause coagulation necrosis, in spite of which stimulation of the vital pulp can still elicit a response.[5] However, several disadvantages of $Ca(OH)_2$ have been reported, including high solubility in oral fluids[6] and the formation of tunnel defects in dentin bridges, leading to the failure of capping over time.[1] New materials, including mineral trioxide aggregate (MTA), have been tested as alternatives to $Ca(OH)_2$. The use of MTA has increased following its approval by the US Food and Drug Administration. Although it was first introduced as a root canal–filling material in 1993, MTA has shown promising results in many areas, particularly in direct pulp capping.[1] This material is essentially composed of Portland cement and bismuth oxide in a 4:1 proportion and is capable of releasing calcium ions into the environment.[7] The application of MTA has been evaluated in several experiments; it has been found to exhibit good sealing ability, biocompatibility, and resistance to bacterial penetration; in addition, it is insoluble, unlike $Ca(OH)_2$, which resorbs over time.[8,9] Witherspoon[10] reported MTA as being an optimum material for application in vital pulp therapy. These advantages have led investigators to evaluate the possibility of its use as an alternative to $Ca(OH)_2$ in pulp capping.

Although comparative studies on the treatment of deep carious lesions have been performed previously, only a few studies have compared the efficacies of MTA and $Ca(OH)_2$ in the treatment of deep carious lesions by the complete caries removal technique. The present clinical study aimed to compare the efficacies of MTA and $Ca(OH)_2$ (control group) as indirect pulp treatment (indirect pulp-capping) materials using the complete caries removal technique in patients with deep carious lesions. The null hypothesis tested was that no significant differences would be observed between the pulps capped with MTA and $Ca(OH)_2$ at six, 12, and 24 months posttreatment.

METHODS AND MATERIALS

In this single-blinded, randomized, controlled clinical trial, MTA was evaluated as the test pulp-capping material and $Ca(OH)_2$ as the control. This study was not operator blinded because of the different application procedures of the two materials.

This clinical study was approved by the local ethics committee with the reference number HEK 11/106. Informed written consent was obtained from all participants after they were clearly instructed regarding the reporting of their pain history and the influence of this report on the treatment they would receive. This study was conducted in full accordance with the World Medical Association Declaration of Helsinki.

The study population was comprised of patients with deep carious lesions who were admitted to the outpatient clinic at our department. A single operator, trained in the standardization of the procedures, performed all of the restorative treatments. Clinical assessment was performed by electric pulp testing (Parkell, Farmingdale, NY, USA), thermal testing using an air-water syringe, palpation, and percussion as well as the evaluation of the presence of signs of inflammation. Periapical radiographs were acquired prior to the treatment as well as at baseline (one week) and six, 12, and 24 months posttreatment; they were assessed to exclude any signs of irreversible pulpitis. All the teeth were clinically and radiographically examined to ensure the absence of widening of the periodontal ligament or periapical lesions.

The inclusion criteria were the presence of deep carious lesions involving 75% or more of the dentin

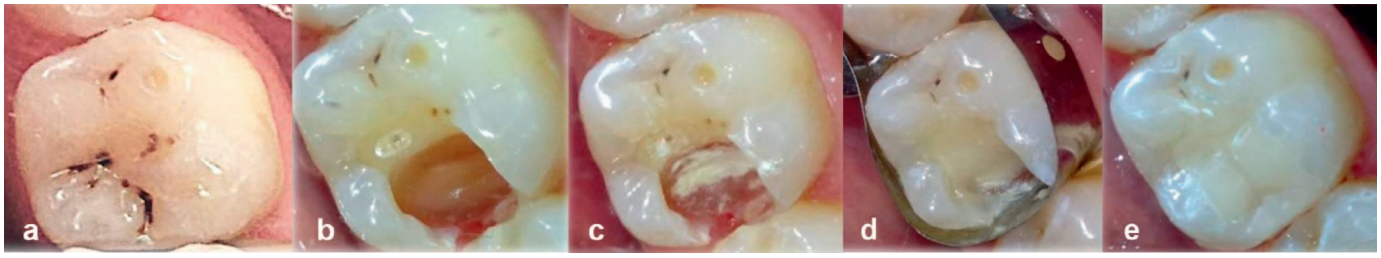

Figure 1. *Restoration procedure of an indirect pulp capping. (a): Preoperative stage. (b): Cavity preparation. (c): mineral trioxide aggregate application. (d): Glass ionomer cement (GIC) base. (e): Final restoration.*

without pulp exposure, restorable permanent posterior teeth without a history of spontaneous and severe pain, abscesses, and a sinus tract or other clinical signs of irreversible pulpitis. A maximum of two teeth per patient were included in this study. A simple randomization method was used for selection—the first tooth selected was assigned to be treated with MTA and the second with $Ca(OH)_2$.

Isolation was performed using a saliva ejector and cotton rolls. Cavities were prepared using sterile diamond burs at high speed under water cooling. After gaining suitable access through the cavitated enamel, superficial, soft, and infected dentin was excavated using sharp hand instruments, particularly wide spoon excavators. The remaining caries were removed using a single-use steel bur, applied at a low speed to avoid pulp exposure (Figure 1a,b). Patients were asked whether they experienced severe sensitivity or pain during the preparation, and, if required, a local anesthetic was administered. Teeth that developed pulp exposure were excluded from the study.

The teeth were then divided into two experimental groups. Indirect pulp capping was performed using $Ca(OH)_2$ (Dycal, Dentsply/Caulk, Dentsply International Inc, Milford, DE, USA) in group I and MTA (Dentsply Tulsa Dental, Johnson City, TN, USA) in group II. In cases where two teeth were restored in the same patient, one of the teeth was capped with MTA, while the other was capped with $Ca(OH)_2$.

All of the materials (Table 1) were applied according to the manufacturers' instructions.

While MTA powder was mixed with its respective solution for application, $Ca(OH)_2$ paste was mixed in a 1:1 ratio. The capping materials were placed with the passive application on the deepest part of the cavity (Figure 1c). Only light pressure was applied

Table 1: *Description of the Materials*

Material	Composition	Manufacturer
Dycal	Base paste:	Dentsply/Caulk, Dentsply International Inc (Milford, DE, USA)
	1,3-Butylene glycol disalicylate, zinc oxide, calcium phosphate, calcium tungstate, iron oxide pigments	
	Catalyst paste: Calcium hydroxide, N-ethyl-o/p-toluene sulfonamide, zinc oxide, titanium dioxide, zinc stearate, iron oxide pigments (dentin shade only)	
ProRoot MTA	Oxides: lime(CaO), silica (SiO_2), aluminum oxide (Al_2O_3), ferric oxide (Fe_2O_3), bismuth trioxide	Dentsply Tulsa Dental (Johnson City, TN, USA)
	Tricalcium aluminate, tetracalcium aluminoferrite, tricalcium aluminate	
Riva Light Cure	Compartment 1: polyacrylic acid, tartaric acid, 2-hydroxyethyl methacrylate, dimethacrylate cross-linker, acidic monomer	Southern Dental Industries (Bayswater, Australia)
	Compartment 2: fluoroaluminosilicate glass powder	
Prime and Bond NT	Di- and trimethacrylate resins, PENTA (dipentaerythritol penta acrylate monophosphate), nanofillers—amorphous silicon dioxide, photoinitiators, stabilizers, cetylamine hydrofluoride, acetone	Dentsply DeTrey (Konstanz, Germany)
Gradia Direct Posterior	Methacrylate monomers, silica, fluoro-alumino-silicate glass, prepolymerized filler, pigments, catalysts	GC (Tokyo, Japan)

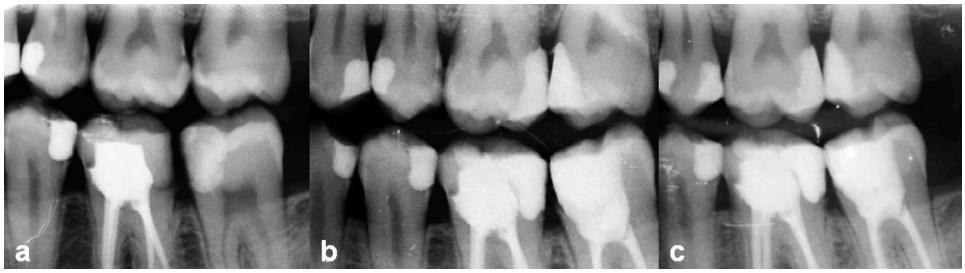

Figure 2. *X-rays of maxillary left first and second molar; #14 indirectly capped with mineral trioxide aggregate, #15 indirectly capped with $Ca(OH)_2$. (a): Preoperative stage. (b): 12 months. (c): 24 months.*

on the MTA mixture using a wet cotton pellet to ensure adaptation of the material onto the dentin. When necessary, excess material was carefully removed using hand instruments.

Following the application of the pulp-capping materials, a light-cured glass ionomer cement base (Riva Light Cure LC, Southern Dental Industries, Bayswater, Australia) was applied and light cured for 20 seconds using a light-emitting diode (LED) device (Radii Plus, Southern Dental Industries; 1500 mW/cm^2) (Figure 1d). The teeth were than etched using 37% phosphoric acid (Condac 37, FGM, Setubal, Portugal) for 30 seconds, and the one-bottle adhesive system Prime and Bond NT (Dentsply DeTrey, Konstanz, Germany) was used. A microfilled hybrid composite resin material (Gradia Direct Posterior, GC, Tokyo, Japan) was then incrementally inserted into the cavities and light cured for 20 seconds using the same LED device, thus completing the restoration process (Figure 1e). The teeth were then polished using diamond-composite finishing burs, discs, and rubber cones. Phosphor plate images were acquired using a dental X-ray unit (Soredex, Tuusula, Finland; 70 kVp, 7 mA) using a paralleling technique, with Rinn film holders to achieve standardization.

The patients were informed of the recall appointments at baseline (one week) and six, 12, and 24 months posttreatment (Figure 2). During the observation periods, two calibrated and experienced dentists assessed all subjective symptoms, including pain or tooth sensitivity to various stimuli. The treatment was recorded as being clinically successful when pulp vitality was observed along with a normal response to thermal, electrical, and tactile tests without signs of spontaneous pain, and it was considered to be radiographically successful in the absence of radiolucency and periodontal ligament space widening.

The data were statistically analyzed using the chi-square, frequency, and Fisher exact tests. Significance was predetermined at $\alpha = 0.05$. Power analysis of noninferiority tests of two independent proportions was performed by using NCSS 2007/PASS program. The margin (Δ), the maximum acceptable extent of clinical noninferiority, was defined as 6%. Power of this study was calculated as 82%.

RESULTS

A total of 100 permanent molar/premolar teeth of 73 patients were capped randomly with either $Ca(OH)_2$ (n=49) or MTA (n=51) and restored using composite resin. The patients included 47 women (64.4%) and 26 men (35.6%), with a mean age of 21 years (20.93±3.48). The recall rates were 100% at six and 12 months posttreatment and 98.6% at 24 months posttreatment. Molars accounted for 62% of the total number of treated teeth. The distribution of teeth evaluated in the present study is shown in Table 2.

At 24 months posttreatment, one of the patients who was treated with $Ca(OH)_2$ failed to attend the recall; this patient, however, confirmed the absence of discomfort in the treated tooth via telephone. Four teeth indirectly capped with $Ca(OH)_2$ (two each at six and 12 months posttreatment) and two indirectly capped with MTA (one each at 12 and 24 months posttreatment) received endodontic emergency treatment because of symptoms of irreversible pulpitis, which were clinically and/or radiographically established (Table 3). The success rates of pulp vitality were 91.7% for the $Ca(OH)_2$-treated teeth and

Table 2: *Distribution of Tooth Type by Location*

Dental Arch	Tooth Type	n	%
Calcium hydroxide (n=49)			
Upper (n=29)	Premolar	16	16.0
	Molar	13	13.0
Lower (n=20)	Premolar	7	7.0
	Molar	13	13.0
Mineral trioxide aggregate (n=51)			
Upper (n=23)	Premolar	10	10.0
	Molar	13	13.0
Lower (n=28)	Premolar	5	5.0
	Molar	23	23.0
Total		100	100

Table 3: *Clinical Assessment of Tooth Vitality Distribution*

Material	Condition of Pulp Tissue			
	Normal (Vital)		Irreversible Pulpitis	
	n	%	n	%
Calcium hydroxide (n=49)				
Baseline	49	100.0	—	—
Six months	47	95.9	2	4.15
12 months	45	91.8	2	4.15
24 months	44	91.7	—	—
Total			4	8.3
Mineral trioxide aggregate (n=51)				
Baseline	51	100.0	—	—
Six months	51	100.0	—	—
12 months	50	98.0	1	1.95
24 months	49	96.01	1	1.95
Total			2	3.9

96.01% for the MTA-treated teeth; the results of the Fisher exact test revealed no statistically significant differences in pulp vitality between the two capping materials at 24 months posttreatment (p=0.427; Table 3).

At 24 months posttreatment, the frequency of observed symptoms was found to have reduced in both groups. Correlations between the type of pulp-capping material and the frequency of symptoms observed at six, 12, and 24 months posttreatment (p=0.588, p=0.087, and p=0.202, respectively) were found to be insignificant. The symptoms most frequently observed were sensitivity to cold/heat; the distribution of the symptoms according to the type of pulp-capping material is summarized in Table 4.

At 24 months posttreatment, four of the six teeth that were subsequently subjected to root canal treatment were found to be symptomatic at the preoperative time; however, this relationship was not found to be significant (p=0.690).

In the present study, restoration failure due to the loss of materials was not observed in either of the groups at six, 12, and 24 months posttreatment.

DISCUSSION

In this clinical study, we compared the efficacies of MTA and $Ca(OH)_2$ as pulp-capping materials in the treatment of teeth with deep dentin carious lesions using the complete caries removal technique. The results of the present study revealed the high efficacy of complete caries removal using a one-visit approach, along with the high success rate of indirect pulp capping, which was found to be as high as 94% regardless of the material used. This high success rate may be attributed to accurate diagnosis, complete removal of the carious tissue (thus halting the progression of the carious process), and well-sealed restoration preventing microleakage. The remnant cariogenic bacteria in the cavities would have died on the elimination of their source of nutrition because of the tight restoration, resulting in the arrest of the carious lesions.

In most countries, caries in permanent/deciduous teeth make up the most prevalent chronic disease among both children and adults,[11,12] and, therefore, caries removal is a frequently performed operation in dental clinics. However, there are no standard guidelines describing the criteria for the excavation technique, depth, or instruments to be used for caries removal. Different treatment options for deep carious lesions have been reported in the literature. Stepwise caries excavation with a one- or two-visit approach, which is the most discussed technique in the literature, is gaining popularity of late. In the one-visit approach, the caries are partially removed, and permanent restoration is performed with tight sealing of the cavity. In the two-visit approach, an intermediate restoration is initially performed, and the cavity is reopened in the second visit,[13] making the restoration process more complicated, time consuming, and costly. Complete caries removal, which involves the removal of all of the decayed and

Table 4: *Clinical Assessment of the Distribution of Symptoms with Calcium Hydroxide and Mineral Trioxide Aggregate (MTA) at the Pretreatment, Baseline, and Six-, 12-, and 24-Month Posttreatment Examinations*

	MTA				Calcium Hydroxide			
	Cold	Heat	Bite	Percussion	Cold	Heat	Bite	Percussion
Pretreatment	24	16	7	16	17	6	4	10
Baseline	7	1	—	1	6	2	2	2
Six months	5	—	—	2	2	—	1	2
12 months	3	—	—	1	7	1	1	1
24 months	2	—	—	—	3	1	—	—

infected dentin in one visit, has been reported to be the preferred method of treatment.[2,13-16] This method offers the advantage of completing permanent restoration in one visit because of the lack of need for reopening the cavity for caries removal in a subsequent step in addition to there being no doubts regarding the progression of the remaining carious lesion into the pulp. Browning[17] 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. Rohan and others [13] and Franzon and others[18] reported greater treatment success with complete caries removal in comparison to the stepwise approach.

Calcium hydroxide plays an important role in the treatment of deep carious lesions by controlling the growth of microflora and stimulating the pulp.[17] Although MTA exhibits an antibacterial effect on some of the facultative bacteria and no effect on the strictly anaerobic bacteria,[19] it continuously exhibits high pH levels (12.5) for eight weeks. Although this limited antibacterial effect of MTA is less than that demonstrated by $Ca(OH)_2$ paste, the ability of the former to resist the potential penetration of microorganisms appears to be high.[10]

In the present study, the number of observed symptoms was higher in the $Ca(OH)_2$ group than in the MTA group at 12 months posttreatment. Browning and Swift[17] reported that, at one year posttreatment, preoperative pain was significantly less likely to be classified as indicating success. However, in the present study, the frequency of the symptoms reported was reduced in both groups at 24 months posttreatment, and there was no significant correlation between the intensity of the symptoms and treatment outcome; four of the six teeth that were subsequently subjected to root canal treatment were symptomatic at the preoperative time. This result is concurrent with that reported in the literature.[17]

In clinical studies involving pulp therapy, histopathological guides have been used as the gold standard.[1] However, the application of a standard histological reference for the comparison of the two materials evaluated in the present study was not possible because of its design.[20] In the present study, the lesions exhibited a decrease in symptoms such as sensitivity to cold/heat or percussion at the 24-month follow-up. These clinical symptoms are typically observed over time following the removal of caries lesions with sclerotic or reparative dentin formation.[9,13,21,22]

In the present study, no differences were observed in the outcomes between the two indirect pulp-capping materials, and both materials exhibited very similar success rates. Therefore, the null hypothesis was accepted. However, the potential clinical relevance of the difference of 4.32% in the success rates of MTA and $Ca(OH)_2$ can be discussed. Results of clinical and histological studies conducted by exposing the pulp tissue have highlighted the better performance of MTA in comparison with that of $Ca(OH)_2$ in both animal and human teeth, with the former exhibiting faster pulpal healing, early formation of hard and tight tissue barriers within three weeks, and less inflammation, hyperemia, and necrosis as well as thicker dentinal bridges and more frequent odontoblastic layer formation.[1,9,23-25] Additionally, MTA has been reported to demonstrate an improved ability to maintain pulp tissue integrity and produce negligible pulpal necrosis[1,26,27] in the treatment of deep dentin caries.

Since bacteria and/or their toxic products are capable of passing through tubules to induce inflammatory responses in the dental pulp,[28,29] remaining dentin thickness and tubular permeability are crucial factors in the induction of pulpal inflammatory response.[30] To the best of our knowledge, there is no device for the measurement of the remaining dentin thickness in clinical conditions.

Calcium hydroxide, which is the gold standard among indirect pulp-capping materials, is still popular because of its easy handling, paste form, and lower cost compared to MTA. However, Chisini and others[31] reported that, because of their updated knowledge of contemporary literature, MTA was mostly used by professionals working in the university environment, which indicates that MTA might gain more popularity in the future.

CONCLUSIONS

Indirect pulp capping accompanying complete caries removal exhibited a satisfactory success rate in the treatment of deep carious lesions. Both $Ca(OH)_2$ and MTA were found to be clinically effective at 24 months posttreatment. Further clinical research is required to confirm the long-term results of the current study.

Acknowledgment

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee

guidelines and policies of Hacettepe University. The approval code for this study is HEK 11/106.

Conflict of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company presented in this article.

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