Efficacy of Calcium Hydroxide and Mineral Trioxide Aggregate in the Formation of Dentin Bridge - A Randomized Controlled Trial

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OBJECTIVE: This study is to compare the dentin bridge thickness achieved using calcium hydroxide and MTA using radiographs.

METHODOLOGY: Single blinded randomized controlled trial conducted in the Operative Dentistry department at Fatima Jinnah Dental College and Hospital, Karachi. A total of 100 premolar and molar teeth with class I and II cavities were included in this study. The study participants were assigned into two groups, A and B of 50 participants each. Under local anesthesia, Group A was indirectly pulp capped with Calcium hydroxide (Dycal) and Group B received Mineral Trioxide Aggregate as an indirect pulp capping material. Both groups were then restored with Glass Ionomer Cement. Radiographic follow up was carried out at three and six months to determine mean dentin thickness of reparative dentin bridge.

RESULTS: Statistical analysis was performed using SPSS v 23. Independent Sample t-test was applied to evaluate the formation of dentin bridge formation using Ca(OH)\textsubscript{2} and MTA at 3 months & 6 months, the outcomes were highly significant (p-value<0.001). Paired sample t-test was applied to evaluate the difference in dentin bridge formation at three months and 6 months, the results were highly significant (p-value <0.001).

CONCLUSION: Statistically significant difference was observed in the dentin thickness of reparative dentin bridge amongst the two groups after three months and six months. A greater success rate was noted in the MTA group as compared to the Ca(OH)\textsubscript{2} group after 6 months.

KEYWORDS: Dentin bridge, Endodontic treatment, Indirect pulp capping, Reparative dentin, randomized controlled trial.


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INTRODUCTION

A dentin bridge seals off the dental pulp from bacterial toxins and helps in maintaining pulp vitality.\textsuperscript{1} It is formed when a protective dressing is placed over a thin layer of carious dentin remaining above the dental pulp (indirect pulp cap).\textsuperscript{2}

Pulp capping can be achieved on vital teeth with normal pulp or with reversible pulpitis. Many materials have been used for this purpose such as Calcium Hydroxide (Ca(OH)\textsubscript{2}), Resin Modified Glass Ionomer Cement (RGMIC), Mineral Trioxide Aggregate (MTA) & Biodentin. Ca(OH)\textsubscript{2} is the most used material for pulp capping procedures and has been measured a gold standard.\textsuperscript{3} Studies have revealed that one hour contact with Ca(OH)\textsubscript{2} results in a 100% reduction in infection causing organisms.\textsuperscript{4} It is also known to stimulate a variety of proteins such as Bone Morphogenetic Protein (BMP) and Transforming Growth Factor Beta One (TGF) which induce dentinogenesis.\textsuperscript{5}

Mineral Trioxide Aggregate (MTA) is a hydrophilic & biocompatible cement which stimulates remedial & bone formation in cases of root resorption, apexification, perforation and as a pulp-capping material.\textsuperscript{6} It provides a good seal, an antibacterial pH, and results in rapid
dentin bridge deposition. It has also been reported to be less toxic and the incidence of pulpal inflammation is fewer when matched to Ca(OH)₂. However, it has a longer setting time and higher cost compared to Ca(OH)₂ which is in most cases unacceptable and inconvenient for both patients and dentists.

The antimicrobial activity of MTA is also less strong when compared with that of Ca(OH)₂. Tooth discoloration has also been reported with the use of MTA. Researches have been done to compare the effectiveness of different pulp capping material for dentin formation.²,³ Ca(OH)₂ and MTA both have proven to be clinically effective in root repair and dentin bridge formation.⁴ However, the literature for comparison of the use of these two materials is limited and particularly in Pakistan there is no data available. Additional researches are required to emphasize and compare the capability of these two materials. The rationale of this research is to evaluate the mean thickness of the dentin bridge formation after indirect pulp capping using Calcium hydroxide (Dycal®) and MTA.

One of the major concerns during the endodontic treatment is the maintenance of pulp vitality. The current study will be beneficial for dentists as it will help them decide the best treatment modality using the best material which will restore the tooth’s strength and vitality, be cost-efficient, generate faster outcomes & guard the patient from the hassle of root canal treatment or tooth loss.

The clinical performance of MTA reportedly has been significantly higher when compared to Ca(OH)₂. The goal of this prospective single blinded randomized controlled trial was to compare the mean thickness of dentin bridge formation after indirect pulp capping with calcium hydroxide and mineral trioxide aggregate in human pre-molar and molar teeth after a period of three and six months.

**METHODOLOGY**

It was single blinded randomized controlled trial (RCT) which was done in the Operative Dentistry department, Fatima Jinnah Dental College and Hospital, Karachi. The ethical approval for conducting this study was taken from Institutional Ethical Review Committee of Fatima Jinnah Dental College and Hospital (Ref No: FJDC/OPR-01) to conduct the study on human subjects.

The sample size was calculated using OpenEpi-Epidemiologic calculator software. As per the literature search Calcium hydroxide and Mineral Trioxide Aggregate showed mean dentin bridge formation of 0.221±0.05mm and 0.235±0.11mm respectively at six months follow up. Confidence level 95%, and power 80%, the sample size obtained was 58 (29 in each group). To overcome the possibility of dropouts due to reinfection, or patients not turning up, the sample size was doubled to 116.

The patients visiting the Fatima Jinnah Dental OPD for any restorative procedure were evaluated and recruited in the study, after taking informed consent, if they fulfilled the inclusion criteria. The inclusion criteria involved patients aged between 20 to 40 years of age, who were able to maintain good oral hygiene and showed good compliance with the procedure. The teeth that were included involved vital premolars and molars of both arches and having deep occlusal caries (3-4 mm) on the surface of posterior teeth (Class I or Class II).

The posterior teeth which had deep caries but were periodontally compromised or showed root resorption on radiographs were excluded. The patients who had any systemic diseases such as diabetes mellitus, hypertension or any other illness were also omitted from the study.

A written consent was taken from the patients, and they were fully explained about the advantages and disadvantages of the procedure. A sealed envelope enclosing the material to be applied with the label of alphabet A or B was used. Patient was asked to pick one envelope which determined which material they would be treated with. Group A subjects were provided pulp capping using Ca(OH)₂, (Dycal® Ivory, Caulk, Dentsply, L.D. Caulk, Milford, DE, USA) while Group B patients were given MTA (ProRoot; Dentsply/Tulsa Dental, Tulsa, OK, USA) as indirect pulp cap agent.

Periapical radiographs were taken preoperatively and pulp vitality tests were also performed. To test the pulp vitality cold and electric pulp tests were applied. Ethyl Chloride spray was applied to the surface of the tooth to perform cold testing. Electric testing was performed by using an electric pulp tester (Electric Pulp Tester Averon® PT 2-0, VEGA-PRO, Ekaterinburg, Russia). The readings were recorded in the data collection form. The tooth to be treated was anesthesized using lidocaine 2% solution in 1.8 ml unit accessible for dental use. The moisture control of the operational field was maintained by using rubber dam. High-speed handpiece (NSK) with round diamond bur (no 1/6 or ¼) was used to prepare the cavity. The soft carious dentin was removed using a spoon shaped excavator and a round tungsten carbide bur in a slow hand piece. A 2 mm thin layer of carious dentin was left over the pulp. The pulp capping agent was mixed and placed in the cavity. The Glass ionomer cement (Chemfill superior Caulk, Dentsply, L.D. Caulk, Milford, DE, USA) was then positioned as over the pulp capping material as a temporary filling material for the duration of the study.

The patients were recalled at 3 months and 6 months for follow up. The radiographs taken at baseline & follow-up were exposed on a metallic 1-mm Fixott-Everett grid.
(Fixott-Everett X-ray Grid Large Ea, Miltex Instrument Co, Inc., York, PA, USA). The instrument was used to perform the radiologic scaling of the digital images so the measurements could be done later, using the Mesurim Pro® Software (©J-F. Madre, Academy of Amiens, Amiens, France). The thickness of the newly made dentin bridge by both the materials was measured and compared. The radiographic evaluation was performed by two calibrated examiners to rule out discrepancy in measurements.

The statistical analysis of the data was accomplished using the SPSS software version 23 (SPSS Inc., Chicago, IL, USA). Descriptive statistics of age and gender were tabulated. Cohen's Kappa statistic test was applied to calculate the inter-examiner reliability of the radiographic measurements by the examiners (K=0.771, significant agreement in quantities). Student's t-test was applied to compare mean dentin thickness in both groups after three and six months. Paired Sample t-test was applied to compare the outcome of dentin bridge formation at 3 months and 6 months. P-value <0.05 was kept as significant.

**RESULTS**

The figure 1 shows the allocation of the participants in the group and loss of participants due to loss of follow-up and failure of the restoration. The failure of the restoration was judged as negative pulp test on the follow-up visit. At 3 months the failure rate of MTA was more than the failure rate of Ca(OH)\(_2\), and a total of 7 participants did not appear for follow up visit at 3 months. At 6 months, there was no loss of the participants due to negative pulp testing, however, one was excluded in Ca(OH)\(_2\) group due to loss of restoration. A total of 4 participants did not appear for their 6 months follow-up visit. Therefore 100 patients were analyzed in the final analysis.

**Table 1:** Distribution of the teeth according to gender and age of the subjects and the type of capping material

<table>
<thead>
<tr>
<th>Capping Material</th>
<th>Gender</th>
<th>N</th>
<th>Age (Mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ca(OH)(_2)</td>
<td>Male</td>
<td>23</td>
<td>29.8 ±7.65</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>27</td>
<td>29.5 ±7.24</td>
</tr>
<tr>
<td>MTA</td>
<td>Male</td>
<td>26</td>
<td>31.30 ±6.96</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>24</td>
<td>28.41 ±6.40</td>
</tr>
</tbody>
</table>

**Table 2:** Distribution of teeth according to types of caries treated

<table>
<thead>
<tr>
<th>Tooth Type</th>
<th>Type of Caries</th>
<th>Class I (%)</th>
<th>Class II (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary 1st Premolar</td>
<td>N (%)</td>
<td>7 (14.3)</td>
<td>6 (11.8)</td>
</tr>
<tr>
<td>Maxillary 2nd Premolar</td>
<td></td>
<td>11 (22.4)</td>
<td>6 (11.8)</td>
</tr>
<tr>
<td>Maxillary 1st Molar</td>
<td></td>
<td>9 (18.4)</td>
<td>7 (13.7)</td>
</tr>
<tr>
<td>Maxillary 2nd Molar</td>
<td></td>
<td>3 (6.1)</td>
<td>12 (23.5)</td>
</tr>
<tr>
<td>Mandibular 1st Premolar</td>
<td></td>
<td>7 (14.3)</td>
<td>9 (17.6)</td>
</tr>
<tr>
<td>Mandibular 2nd Premolar</td>
<td></td>
<td>4 (8.2)</td>
<td>4 (7.8)</td>
</tr>
<tr>
<td>Mandibular 1st Molar</td>
<td></td>
<td>7 (14.3)</td>
<td>5 (9.8)</td>
</tr>
<tr>
<td>Mandibular 2nd Molar</td>
<td></td>
<td>1 (2.0)</td>
<td>2 (3.9)</td>
</tr>
</tbody>
</table>

Table 2 shows the number of teeth that were treated for either class I or class II cavity type. The maximum number of class I caries were treated in maxillary 2nd premolar (22.4%) and class I caries in maxillary 2nd molar (23.5%).
Table 3: Average thickness of dentin bridge at 3 months

<table>
<thead>
<tr>
<th>Pulp-capping Material</th>
<th>Follow-up duration</th>
<th>t-test&lt;sup&gt;a&lt;/sup&gt;</th>
<th>t-test&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 months</td>
<td>6 months</td>
<td>p-value</td>
</tr>
<tr>
<td>Ca(OH)₂</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>50</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Mean (mm)</td>
<td>0.13</td>
<td>0.21</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>SD</td>
<td>0.01</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>MTA</td>
<td></td>
<td></td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>N</td>
<td>50</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Mean (mm)</td>
<td>0.11</td>
<td>0.23</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>SD</td>
<td>0.01</td>
<td>0.02</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> p-value computed using paired sample t-test for 3 and 6 months follow up
<sup>b</sup> p-value computed using independent sample t-test for evaluating the two groups.

* p-value significant at 1%

**DISCUSSION**

The current study is a single blinded randomized controlled trial which was conducted to assess the efficacy of MTA and calcium hydroxide during indirect pulp capping procedures. The procedure involves using a pulp capping material over a thin layer of carious dentin. The procedure is done to retain the vitality of the pulp rather than risking its exposure. The tooth is kept on follow up for 3-6 months and then it is re-assessed. The time of 3-6 months is important for the proliferation, migration & differentiation of secondary odontoblasts before they begin forming reparative dentin. Studies have reported that there is little evidence of formation of reparative dentin before 30 days of application of pulp capping agents. Initially the rate of formation is highest during the 27 to 48 days interval (3.5 u/ day), 49-71 days interval (0.74 u/ day) & 72-132 days interval (0.23 u/day).<sup>12</sup>

Ca(OH)₂ possesses an alkaline pH which does low grade pulpal irritation and results in forming a zone of obliteration in the tissue adjacent to the pulp capped dentin.<sup>13</sup> The subjacent area results in a zone of coagulative necrosis which reorganizes and resumes normal architecture within thirty days.<sup>14</sup> It is also reported that it solubilizes certain bioactive molecules like BMP and TGF which are released from dentin and plays significant role in restoration of the pulp.<sup>15,16</sup>

In this study MTA, was compared with the existing conventional Ca(OH)₂. MTA permits the formation of the dentin bridge while maintaining the pulp vitality. It is a biocompatible material and induces matrix formation and mineralization by odontoblasts and other hard tissue forming cells.<sup>17</sup> It also interacts with phosphate containing fluids to create apatite crystals which trigger the dentinogenic activity of MTA. In addition its physical properties are also superior to Ca(OH)₂ in terms of lower degree of dissolution, thus providing a better seal and structural integrity.<sup>18</sup>

The findings of Group A in this study demonstrated mean values of 0.13±0.01 mm dentin bridge thickness at the end of three-month period. Similar results were seen in studies by Aeinehchi et al.<sup>19</sup> where a thickness of 0.02 mm and Benoist et al.<sup>8</sup> where a 0.13 mm thickness was recorded. The MTA group B showed results of 0.11±0.01 mm thickness at three months which was lesser than the dentin thickness of Group A. The findings are like the findings of Benoist et al.<sup>8</sup> but differ from the study of Aeinehchi et al.<sup>19</sup> The difference in the findings could be due to a difference in the methodology and a different radiographic software being used without a radiographic grid.

Six-month results of Group A 0.21±0.02 mm was again comparable with the findings of Aeinehchi et al.<sup>19</sup> results of 0.15mm and Benoist et al. 0.221mm. George et al.<sup>20</sup> saw a difference from the results of study with 0.097mm dentin thickness at three months in the MTA group. This can be explained by difference in permeability in dentinal tubules of primary and permanent teeth. The density & the diameter of the dentinal tubules in deciduous molars are found to be less than the permanent teeth. Six-month results of MTA group B showed a thickness of 0.23±0.02 mm. This was confirmed by findings from Benoist et al.<sup>8</sup> while Aeinehchi et al.<sup>19</sup> showed differing values of 0.43mm in their studies, which could be because of reasons stated above. Difference in dentin bridge deposition can be explained by differences in release concentration of growth factors by MTA and Ca(OH)₂. Histological studies show more inflammatory cells and greater zones of necrosis formed when Ca(OH)₂ was used when compared with MTA.<sup>21,22</sup>

In this study, it was perceived that the formation of the dentin bridge at six months was greater in Group B when compared to Group A. The findings support the fact that MTA can store Calcium Hydroxide ions over a longer period and releases them slowly over time.<sup>23</sup>

Studies have been done which evaluated outcomes with percentages with success of 97.96% in favor of MTA<sup>24</sup> but the results of this study have been provided in quantitative data which is more accurate and gave exact values of mean dentin thickness. MTA has produced greater thickness of dentin bridge at both 3 months and 6 months, despite its disadvantages it has proven to be a superior material over Ca(OH)₂. The findings are in accordance with long term clinical trials that have been conducted over a period of 9-10 years and provided 92-97 % success rate of MTA.<sup>25</sup>

The current study was single centered study and lacked controls which if included could have given even more
reliable data and result evaluation. The current study was based on radiographic evaluation using conventional 3D periapical radiographs, better results could have been observed using 3D radiographic methods. Furthermore, the evaluation should be extended over a longer period to further confirm the results. The histological observations can give further evidence of outcome which should be conducted to accurately observe the thickness and quality of dentin bridge formed. Further studies and clinical trials are required to find a better cost effective material to promote dentin formation and improve clinical outcome while preserving the tooth.

CONCLUSION

Greater thickness of the dentin was noted in the MTA group as compared to the Ca(OH)$_2$ group. MTA exhibited a superior performance as indirect pulp capping material when compared to Ca(OH)$_2$.

CONFLICT OF INTEREST

None declared

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