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A COMPARATIVE EVALUATION OF LIGHT CURE CALCIUM SILICATE AND RESIN-MODIFIED GLASS IONOMER AS INDIRECT PULP CAPPING AGENT IN PRIMARY MOLARS–RANDOMIZED CONTROLLED TRIAL

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Abstract

OBJECTIVE:
To evaluate the efficacy of light cure calcium silicate and resin-modified glass ionomer (RMGI) as indirect pulp-capping agent in primary molars in children.
To compare the mean remaining dentin thickness in light cure calcium silicate and resin-modified glass ionomer (RMGI) in primary molars in children.
SETTINGS: *Department of Operative Dentistry and endodontics, Nishtar Institute of Dentistry, Multan*
STUDY DESIGN: *Randomized controlled trial.*
DURATION OF STUDY: *Eight months after approval of Synopsis*
Methodology: *A total of 150 children of either gender with primary molars and were divided randomly into two groups using lottery method. Patients in Group-A received light cure calcium silicate and patients in Group-B were receive resin-modified glass ionomer and were were followed up till 6 months to assess the efficacy of the treatment material. Further, the assessment of RDT was done at baseline immediately after restoration, 3 and 6 months. The scale for measurements was determined using the space between two grids which was assigned a value of 1 mm. The RDT was measured in millimeters between the deepest region of the cavity and the dentin pulp border. Two additional measurements were recorded 1 mm mesial and distal to the initial measurement point. Then, the mean value of the three measurements was considered as RDT for that tooth. Statistical Package for the Social Sciences (SPSS-26) version was used to analyze the data. Mean ± Sd was calculated of quantitative data and frequencies and percentages were reported for categorical variables. Chi-square/fisher exact test was applied to compare the efficacy and RDT was compared using independent t-test. P-value ≤ 0.05 was taken as significant.*
Results:
Of the 150 patients, there were 75 (50%) in each of the 2 groups. Overall, there were 68 (45.3%) males and 75(68%) females. The mean age of the sample was

6.25±2.25 years. Both groups were similar in terms of baseline data with no statistically significant difference, as p-value > 0.05. Light cure calcium silicate found effective in 60 (80.3%) of the cases and Resin-modified glass in 59 (78.6%) cases with no statistically significant difference, as p-value > 0.05. Further, mean RDT between two groups was insignificant at baseline and 3 month (p-value > 0.05), however, significant difference was found at 6th month with p-value =0.00. Intragroup comparison showed a significant increase in dentin thickness during all the follow-up evaluations high statistical significance was noted when baseline was compared with 3 and 6 months, respectively

Conclusion: *Both light cure calcium silicate and resin-modified glass ionomer show acceptable clinical and radiographic results as IPT agents in primary molars with deep carious lesion involving dentin and demonstrate similar efficacy in the deposition of tertiary dentin.*

INTRODUCTION:

Dental caries is one of the most common global oral health problems in the world. Untreated caries can progress to involve pulpal tissue and lead to pain, infection and compromise quality of life. Management of deep carious and grossly decayed teeth is often challenging to the pediatric dentist.[1] The principal objective of the management of deep carious lesion is to preserve the vitality of the teeth while causing as little trauma as possible to the pulp. This helps in providing protective resistance to masticatory forces compared with root canal filled teeth.[2] In terms of fragility and responsiveness to caries, restorative operations, or traumatic traumas, the pulp tissue in deciduous and permanent teeth is identical.[3] When the adverse stimulus is within the tissues' healing capacity, repair occurs in the pulp-dentin complex after the application of a particular agent between the restoration and tooth surface to avoid future pulp challenges due to probable bacterial penetration and microleakage.[4] Vital Pulp treatment (VPT) procedures are used to treat deep carious lesions in deciduous teeth, preserving their vitality and function. Affecting the success of VPT may be factors such as appropriate vascularity, intensity of inflammation, cleanliness of the exposed region, antibacterial efficacy, biocompatibility of pulp covering agents, and adequate coronal seal.[5] The surgery is regarded successful when re-mineralized tissue resembling dentin forms and becomes thick enough to protect the pulp. VPT is comprised of three methods: indirect pulp capping (IPC), direct pulp capping, and pulpotomy. IPC is advised for teeth with deep carious lesions close to the pulp but no signs or symptoms of pulp deterioration.[6] The deepest layer of carious dentin is coated with biocompatible material in order to stimulate dentin sclerosis and the production of reparative dentin while preventing further demineralization and maintaining tooth vitality.[7]

Phillip Pfaff performed the first pulp capping with a little piece of gold placed over exposed pulp to ensure healing. Calcium hydroxide, among other materials, was popular for several decades but was eventually replaced by newer agents such as resin-modified glass ionomer (RMGI), Portland cement, mineral trioxide aggregate (MTA), dentin bonding agents, enamel matrix proteins, or bone morphogenetic proteins superfamily members due to limitations.[8,9]

According to the scientific literature, indirect pulp treatment (IPT) success rates are high and can be connected with an increase in remaining dentin thickness (RDT). There have been numerous studies that compare the success rate of IPT with standard pulp capping agents.[10] There is, however, a paucity of research comparing calcium silicate and RMGIC as IPC agents in primary molars. Furthermore, very few studies have linked an increase in tertiary dentin based on RDT depth at baseline to the use of the aforementioned drugs. Thus, this study was designed to compare and evaluate efficacy and to measure the increase in RDT in primary molars treated with light cure

calcium silicate and RMGI as IPT agents in our population, which has various demographics, as there is no local study of the subject. Our region of the world (Eastern and southern Asia), which has a diverse geographical configuration, climate, dietary habit, and lifestyle, lacks information in this regard. Our study's findings could differ from previous ones and contribute significantly to the body of existing information.

Methodology:

This study was carried out in the department of Operative Dentistry and endodontics, Nishtar Institute of Dentistry, Multan over a period of eight months. After taking the written informed consent, a total of 150 children of either gender with primary molars had age between 5-9 years, with no history of spontaneous pain, International Caries Detection and Assessment System (ICDAS) 4–6 criteria, RDT ≥0.25 mm on bitewing radiograph, absence of cavitated lesion on buccal/lingual surface, physiological root resorption not more than apical one-third of root surface of the tooth which was treated were included via non-probability sampling technique. Patients with history of allergic reactions or with interradicular/periapical pathology, presence of sinus/fistula, internal resorption, pathologic mobility was excluded from history. OPENEPI calculator was used to calculate the sample size by taking mean RDT in calcium silicate group i.e. 0.112 ± 0.05 and RMGI group 0.08 ± 0.085, level of significance = 5%, power of study = 80%, then estimated sample size was 150 patients i.e. 75 in each group. The patients were divided randomly into two groups using lottery method. Baseline data like age, and gender was be noted, then, patients in Group-A received light cure calcium silicate and patients in Group-B were receive resin-modified glass ionomer after the administration of local anesthesia. Patients were followed up till 6 months to assess the efficacy of the treatment material. The treatment was considered as effective if clinically there was no pain (VAS < 3), no tenderness to percussion, no sensitivity, no swelling, no fistula, or no mobility and on radiographic evaluation, there was absence of internal/external resorption, periodontal space widening or periapical/furcal radiolucency. Further, the assessment of RDT was done at baseline immediately after restoration, 3 and 6 months. The scale for measurements was determined using the space between two grids which was assigned a value of 1 mm. The RDT was measured in millimeters between the deepest region of the cavity and the dentin pulp border. Two additional measurements were recorded 1 mm mesial and distal to the initial measurement point. Then, the mean value of the three measurements was considered as RDT for that tooth. Statistical Package for the Social Sciences (SPSS-26) version was used to analyze the data. Mean ± Sd was calculated of quantitative data like age, VAS score and remaining dental thickness baseline, 3 month and at 6 months. Frequencies and percentages were reported for categorical variables like gender, and outcome (efficacy). Chi-square/fisher exact test was applied to compare the efficacy between the two groups. To compare the RDT between two groups at 6-month, independent t-test was applied. P-value ≤ 0.05 was taken as significant.

Table#1 Description of the material used in the study

Product	Manufacturer	Composition	Mode of the Action
Light Cure Calcium Silicate	Bisco Inc, USA	Calcium silicate particles in hydrophilic monomers (HEMA, BiS, GMA)	**Applied in 1 mm.** Increment over deepest dentin, light cure for 20 seconds
Resin-Modified Glass	Havard Dental International GmbH, Germany	Fluoroaluminosilicate Glass, Poly acrylic Acid, HRMA Resin	Mixed according to the manufacturer instructions.

			Applied in a thin layer on Dentin, light cured for 20 seconds

Results:

Of the 150 patients, there were 75 (50%) in each of the 2 groups. Overall, there were 68 (45.3%) males and 75(68%) females. The mean age of the sample was 6.25±2.25 years. Both groups were similar in terms of baseline data with no statistically significant difference, as p-value > 0.05 **(Table#1)**. Light cure calcium silicate found effective in 60 (80.3%) of the cases and Resin-modified glass in 59 (78.6%) cases with no statistically significant difference, as p-value > 0.05 **(Table#2)**. Further, mean RDT between two groups was insignificant at baseline and 3 month (p-value > 0.05), however, significant difference was found at 6th month with p-value =0.00. Intragroup comparison showed a significant increase in dentin thickness during all the follow-up evaluations high statistical significance was noted when baseline was compared with 3 and 6 months, respectively **(Table#3)**.

Table#2: Baseline Data of the Patients

Baseline Data	Light Cure Calcium Silicate	Resin-Modified Glass	P-value
Age (years)	6.5 ± 2.5	6 ± 2	0.58
Gender			
• Male	35 (46.6%)	33 (44%)	0.742
• Female	40 (53.3%)	42 (56%)	

Table#2: Comparison of the efficacy of light cure calcium silicate and resin-modified glass ionomer (RMGI) as indirect pulp-capping agent in primary molars in children

Efficacy	Light Cure Calcium Silicate (n=75)	Resin-Modified Glass (n=75)	P-value
Yes	60 (80.3%)	59 (78.6%)	0.84
No	15 (19.7%)	16 (21.4%)	

Table#3: Comparison of the mean Remaining Dentin Thickness in Light Cure Calcium Silicate and Resin-Modified Glass Ionomer (RMGI) in Primary Molars in Children

Remaining Dentin Thickness	Light Cure Calcium Silicate (n=75)	Resin-Modified Glass (n=75)	P-value
Baseline	0.75 ± 0.18 mm	0.70 ± 0.17 mm	**0.08**
At 3 months	0.8 ± 0.2 mm	0.75 ± 0.17 mm	**0.10**
At 6 months	1.00 ± 0.25 mm	0.85 ± 0.2 mm	**0.00**
P-value	**0.00**	**0.00**	

Discussions:

A paradigm shift is seen in caries excavation techniques from aggressive radical removal to minimal intervention protocols.[7] The materials preferred for IPT initially were calcium hydroxide, glass ionomer cement, and MTA. However, calcium hydroxide demonstrated drawbacks such as high solubility, poor dentin bonding, disintegration, tunnel defects, necrosis in superficial region, and fiber-rich scar tissue formation due to alkaline pH. Despite of several advantages of MTA, there are still some shortcomings with its usage such as longer setting time, difficulty in handling, tooth discoloration, and incompatibility with other materials. Hence, newer agents are being introduced and tested to overcome all such limitations. TheraCal LC AWW is fourth-generation light-cure calcium

silicate material. It releases calcium ions which act as stimulation for fibroblasts and odontoblasts forming mineralized hard tissues. It forms a scaffold on affected dentin, triggers reparative dentin formation, and provides a biologic seal by bonding chemically with dentin thus provides pulp protection. TheraCal LC demonstrates greater bond strength than bio-dentine when followed by GIC or composite restoration.[11,12] Vitrebond is an RMGIC liner which demonstrates inhibitory action against cariogenic bacteria. This antibacterial efficacy is due to its low initial pH which is 4.0 but increases up to 5.5 in the first 24 h.[13] The success of RMGI liners attributes to its good adhesion through micromechanical and chemical adhesion with dentin, release of sustained levels of fluoride inducing remineralization, low solubility, favorable modulus of elasticity, and coefficient of thermal expansion similar to that of dentin.

According to Bjørndal and Mjör IA a carious lesion is considered deep when it involves three-fourth or more of total dentin thickness on radiograph.[14] According to Fuks *et al.*, when RDT is >1.1 mm the inflammation is negligible, for RDT <0.5 mm, there is severe inflammation, and RDT <0.25 mm stimulates pulpal inflammation significantly decreasing tertiary dentin formation.[15] In this study, a significant RDT increment is noted in both the groups at interval of 6 months. In Group I, significant increase is noted from baseline to 3 months. This initial burst might be due to a spike in calcium release during the initial period of 28 days which later declined. In Group II, intragroup comparison showed a significant increase in dentin thickness during all the follow-up evaluations high statistical significance was noted when baseline was compared with 3 and 6 months, respectively. The amount of tertiary dentine formed is affected by the degree of operative trauma and the time elapsed after the treatment. The formation is rapid initially till 30–48 days but later declines gradually from 58 to 106 days. The maximum deposition is seen with RDT between 0.25 and 0.5 mm with bacterial presence intensifying the process.[16] Intragroup comparison done for baseline to 3 months, baseline to 6 months, and between 3 and 6 months showed a significant increase in dentin increment but intergroup comparison yielded no significant difference ($P > 0.05$). Thus, both the materials seem equally effective in inducing the formation of tertiary dentin after IPT. Our results contradict the results by de Assunção Pinheiro IV *et al.* wherein no change in RDT was observed even after 12 months which could be due to the inability to precisely measure the lesion depth.[17] The dentin-pulp border was selected as orientation landmark as it eliminates the need to involve additional external landmarks for referencing and has less element of human error in recognizing the identical site in subsequent follow-up images.[18]

The clinical and radiographic success for both groups in this study was almost same with no statistically significant difference which could be credited to the accurate diagnosis, complete excavation of infected dentin followed by tight sealed coronal restoration. These results are in agreement with Elchaghaby *et al.* who reported that teeth without any clinical/radiographic signs and symptoms were considered as success and IPT showed high survival rates in primary and permanent teeth.[19]

The above-mentioned results are based on a short-term clinical trial and further long-term investigations with a larger sample size and histologic evaluation are required to confirm these results.

Conclusion:

Considering the limitations of the study, it can be said that both light cure calcium silicate and resin-modified glass ionomer show acceptable clinical and radiographic results as IPT agents in primary molars with deep carious lesion involving dentin and demonstrate similar efficacy in the deposition of tertiary dentin.

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