

Comparative Evaluation of Efficacy of Resin-modified Glass Ionomer Cement and Light-curable Tricalcium Silicate Cement as Indirect Pulp Capping Materials: A Randomized Clinical Trial

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ABSTRACT

Aim: The study aims to assess the long-term clinical outcomes and biocompatibility of resin-modified glass ionomer cement and light-curable tricalcium silicate cement in preserving pulp vitality and preventing further carious progression in deep carious lesions.

Materials and methods: A total of 46 participants with deep carious lesions and reversible pulpitis were selected and divided into two groups ($n = 23$): Group I was treated with resin-modified glass ionomer cement (RMGIC) and group II was treated with TheraCal LC (a light-curable tricalcium silicate cement). Once the indirect pulp capping (IPC) material was placed on the pulpal/axial walls, the cavity was temporized using intermediate restorative material, while the permanent restoration was done at 3rd-week recall period. Clinical and radiographic assessments were evaluated at intervals of 24 hours, 3 weeks, 3 months, and 6 months. Data were recorded and statistically analyzed.

Results: The mean visual analog scale (VAS) scores for the RMGIC group were 20.21, 12.90, 1.33, 0.00, and 0.00 at baseline, 24 hours, 3 weeks, 3 months, and 6 months, respectively, while the TheraCal LC group showed mean scores of 12.60, 5.95, 2.58, 1.50, and 0.00 at the same intervals. The Mann–Whitney U -test revealed no significant difference in VAS scores between the two groups at any time point ($p > 0.05$). Intragroup comparisons using the Friedman test indicated statistically significant reductions in VAS scores over time within both groups ($p < 0.001$). At the 6-month follow-up, there were no significant differences between the groups regarding pain on palpation, swelling, percussion, or mobility ($p > 0.05$ for all comparisons using the Chi-square test). All teeth in the RMGIC group remained vital at the end of the study, while the vitality rate in the TheraCal LC group was 81%.

Conclusion: The study concluded that both RMGIC and TheraCal LC are effective as IPC materials for deep carious lesions with reversible pulpitis, though RMGIC showed a slight advantage in maintaining pulp vitality, reducing symptoms, and minimizing periapical changes over time.

Clinical significance: The clinical significance of this study is to offer evidence-based guidance for dental practitioners in choosing suitable materials for IPC in cases of deep carious lesions with reversible pulpitis. This research aims to support clinicians in making informed decisions that promote optimal patient care and improve the success and longevity of restorative treatments.

Keywords: Indirect pulp capping, Partial caries excavation, Resin-modified glass ionomer cement, Reversible pulpitis, TheraCal LC.

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INTRODUCTION

The pulp is a highly vascular tissue that has the unique distinction of being encased within a rigid chamber composed of dentin, cementum, and enamel.¹ These hard tissues provide mechanical support and protection from the microorganisms associated with the oral cavity.² Bacteria causing caries are responsible for the disease initiation and progression, which results in dissolution of hard tissue enamel and dentine followed by pulpal tissue damage.³ Formation of hard tissue barrier to protect the underlying pulpal tissue is the sole aim of treating decayed tooth. Vital pulp therapy aims at stimulating formation of reparative dentin to retain the tooth as a functional unit.⁴ Indirect pulp capping (IPC) is defined as a procedure in which a material is placed on a thin partition of remaining carious dentin that, if removed, might expose the pulp in immature permanent teeth.⁵

Calcium hydroxide is the gold standard for IPC as it is biocompatible with the pulpal tissues. However, it is associated with certain drawbacks like it does not bond to dentin and dissipates over time, and hard tissue bridges adjacent to the material may

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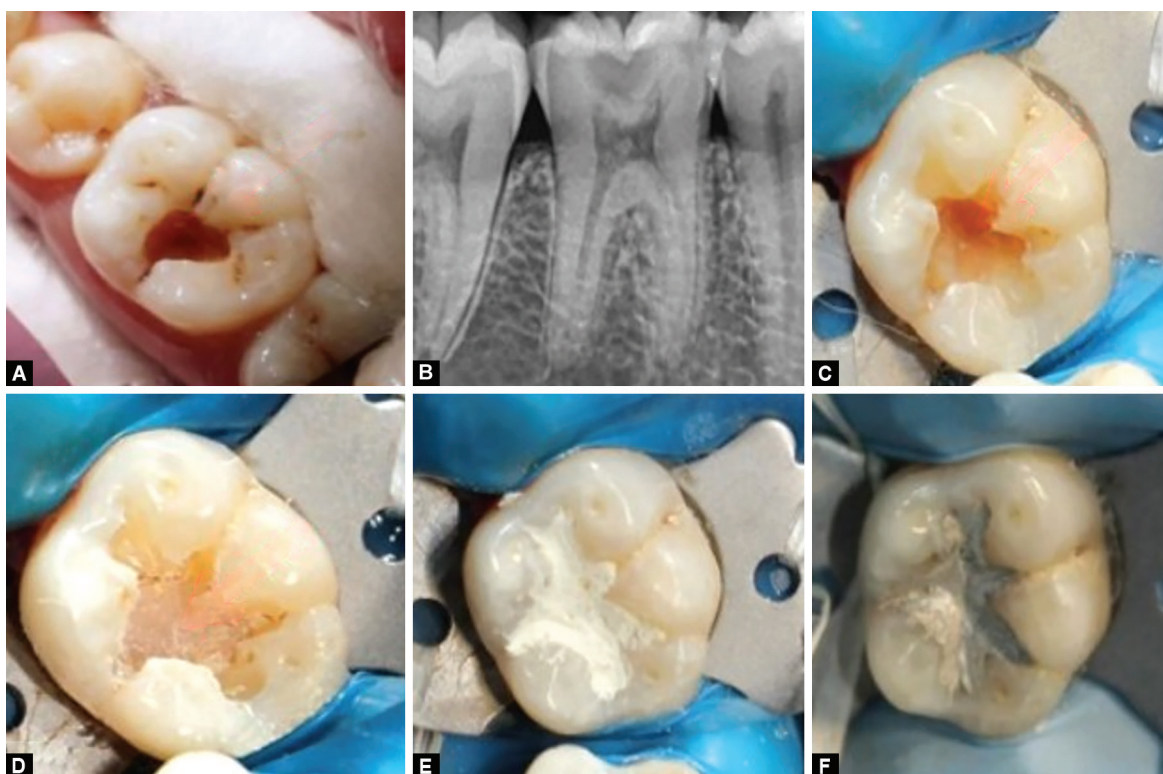
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contain multiple tunnel defects.⁶ To overcome this, newer pulp capping agents were introduced.



Figs 1A to F: Clinical photographs of IPC procedure using RMGIC on tooth no. 36. Preoperative (A) clinical and (B) radiograph photographs showing caries involving inner two-third of dentin; (C) Cavity preparation: the soft carious was excavated with the help of spoon excavator; (D) RMGIC was placed as indirect pulp capping agent; (E) Temporization with IRM; (F) Silver amalgam restoration done at 3 weeks

Recently, resin-based glass ionomer cements (RMGIC) are used as liner in IPC procedures. These materials act as a reservoir of fluoride ions which are taken up by the associated enamel and dentin, rendering those tooth structures less susceptible to acid challenge by a combination of decreased solubility and disruption of the activity of cariogenic bacteria.⁷ Gruythuysen et al. reported a survival rate of 93% after a period of 3 years when teeth were indirectly capped with RMGIC.⁸

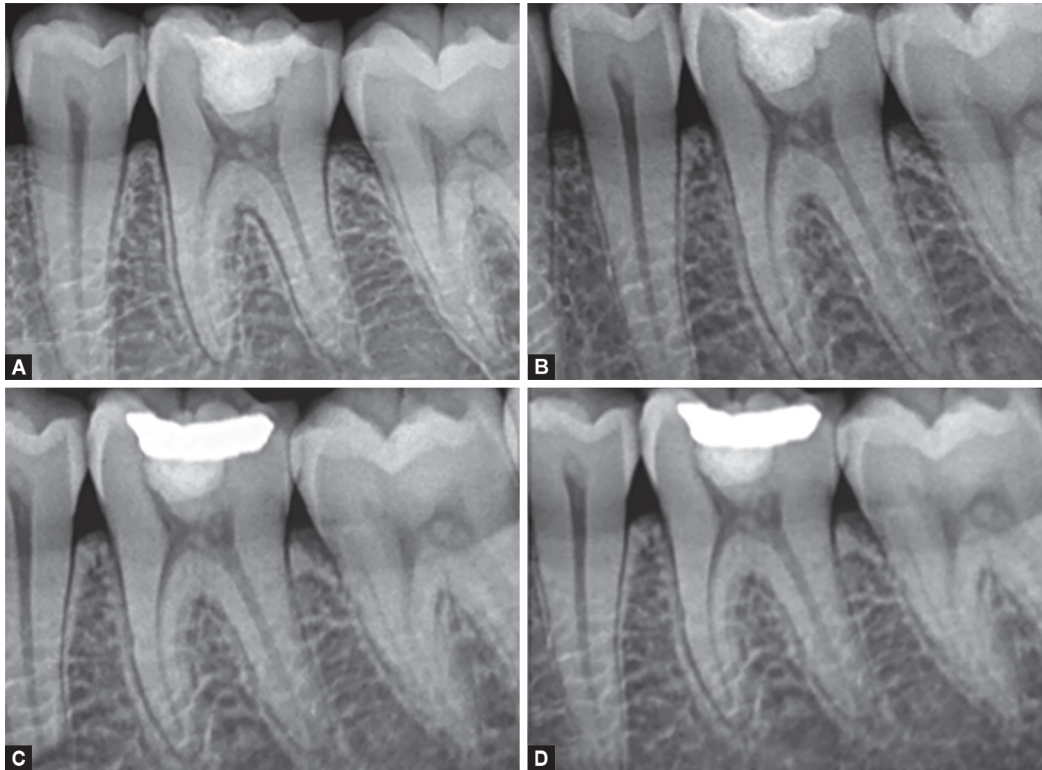
Resin-modified glass ionomer cement has been widely used due to its favorable properties, such as chemical bonding to the tooth structure, fluoride release, and biocompatibility. However, newer materials, such as light-curable tricalcium silicate cement, have emerged, promising superior handling properties, improved sealing ability, and enhanced bioactivity for pulp healing and dentin bridge formation. Light-curable tricalcium silicate cements are a new class of materials, among which TheraCal is a resin-modified calcium silicate cement, that has been reported to stimulate apatite formation and the formation of reparative dentin.⁹ There are few studies in the literature regarding the use of RMGIC and light-curable tricalcium silicate cement as IPC materials.^{8,10} Deep carious lesions pose a significant challenge in restorative dentistry, particularly when the dental pulp is at risk but not yet exposed. Indirect pulp capping is a crucial procedure aimed at preserving pulp vitality by applying a protective barrier over the remaining dentin, allowing the pulp to heal and preventing further bacterial invasion. Despite their potential benefits, limited clinical evidence compares these materials' efficacy in IPC. This study aims to evaluate the clinical outcomes of RMGIC and TheraCal LC in managing deep carious lesions with reversible pulpitis, providing insight into their

effectiveness as pulp capping agents in real-world clinical situations. Thus, the rationale of this study was to evaluate the efficacy of RMGIC and light-curable tricalcium silicate cement (TheraCal LC) in deep carious lesions as IPC materials.

MATERIALS AND METHODS

The study was carried out in the postgraduate clinic of Department of Conservative Dentistry and Endodontics in Mahatma Gandhi Mission Dental college. The design of this study is randomized clinical study from 2019 to 2021. The study was approved by Institutional Ethics Committee and was registered with Clinical Trials Registry India.

Sample size was estimated based on the pulp vitality rates with filling material. The reported pulp vitality is 93% with RMGIC at the end of 6 months.⁹ A sample size of 23 per group and a total sample size of 46 was obtained. Participants were divided into two groups using the table of random numbers by a neutral person. Participants without any systemic illnesses between the age of 18 and 40 years presenting with preoperative pain score of less than 40 mm on visual analog scale (VAS) were selected. Permanent first and second maxillary and mandibular molars with mature apex showing symptoms of reversible pulpitis (pain that lasted only during the application of stimulus and that does not linger) were included in the study. These teeth exhibited a normal response to cold and electric pulp tests, indicating healthy pulp vitality (Fig. 1A), and radiographically the teeth showed carious lesion that involved two-third of dentin with no periapical changes (Fig. 1B). Participants who presented with symptoms of irreversible pulpitis, participants



Figs 2A to D: Follow-up IOPA radiographs of indirect pulp capping procedure using RMGIC on tooth no. 36. Radiograph at (A) 24-hours recall; (B) 3 weeks recall; (C) 3 months recall; and (D) 6 months recall

with VAS score more than 40 mm, delayed or no response to cold test and electric pulp testing, and participants below age of 18 years and above age of 40 years were excluded from the study.

The participants were randomly divided into two groups: group I: RMGIC (GC Gold Label light-cured universal restorative) and group II: TheraCal LC (Bisco, USA) using table of random numbers. Following randomization, allocation concealment was done using sealed opaque envelopes. Participants were informed about the procedure, and written informed consent was obtained. Local anesthesia (2% lignocaine with 1:2,00,000 adrenaline) (Lox 2%, Neon, India) was administered in participants who reported of pain. After rubber dam (Hygienic, Coltene/Whaledent Inc., USA) application, caries excavation and cavity form establishing were carried out with sterile tungsten carbide round bur No. 2 and No. 245 (MANI, Prime Dental Products, India), respectively, in an airtor handpiece, using high speed. The soft carious was excavated with help of spoon excavator (Fig. 1C). When all the soft carious dentin had been excavated and the remaining dentin felt hard, yet appeared discolored, the caries excavation was stopped. Residual caries-affected dentine was retained on the pulpal/axial aspect of the cavity, as any additional excavation would have led to pulp exposure. The randomly allocated IPC material was then placed in the cavity (Fig. 1D). Both the materials (RMGIC and TheraCal LC) were manipulated according to manufacturer's instructions. The cavity was temporized with intermediate restorative material (IRM) (Dentsply, USA) (Fig. 1E) and at 3-week recall, if the participant was asymptomatic, IRM was reduced to function as base, and cavity was restored with silver amalgam restoration (DPI alloy, Dental Products of India, India) (Fig. 1F). Participants were recalled at 24 hours, 3 weeks, 3 months, and 6 months for follow-up, with intraoral

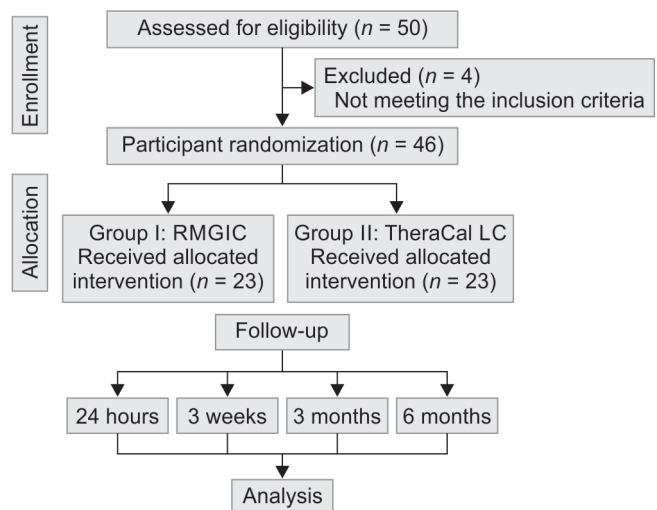


Fig. 3: CONSORT flowchart of the study

periapical (IOPA) radiographs taken of the IPC procedure using RMGIC on tooth no. 36 (Fig. 2). The study was summarized using a Consolidated Standards of Reporting Trials (CONSORT) flowchart, outlining the participant flow and stages of the trial (Fig. 3).

Recall Visit

At every recall visit, VAS score was recorded, and integrity of restoration was checked. The tooth was percussed to evaluate presence/absence of pain. The soft tissue around the tooth was examined and palpated. Pulp vitality was checked by using electric

Table 1: Evaluation of pain parameters using VAS

VAS score	RMGIC			TheraCal LC			Mann–Whitney U-test
	Mean	Median	SD	Mean	Median	SD	p
Baseline	20.21	25.0	13.29	12.60	16.0	13.23	0.246
24 hours	12.90	7.5	14.45	5.95	0.0	9.23	0.278
3 weeks	1.33	0.0	4.22	2.58	0.0	6.56	0.689
3 months	0.00	0	0.00	1.50	0	4.89	0.644
6 months	0.00	0	0.00	0.00	0	0.00	–
Within group (Friedman test)							
p		<0.0001			<0.0001		

pulp tester and cold spray. Intraoral radiographs were taken to evaluate periapical changes.

Statistical Analysis

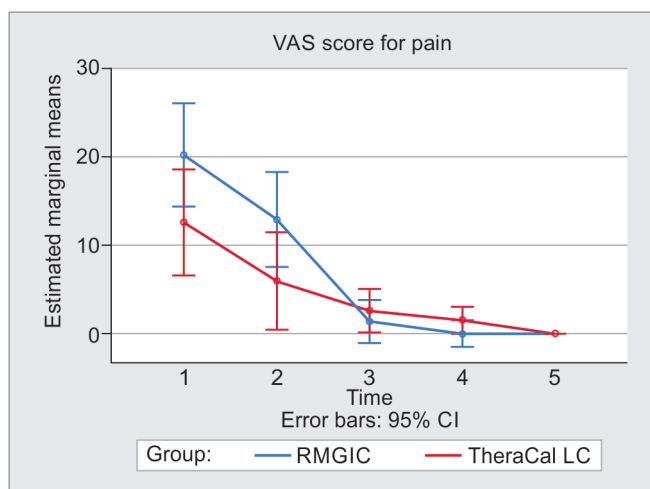
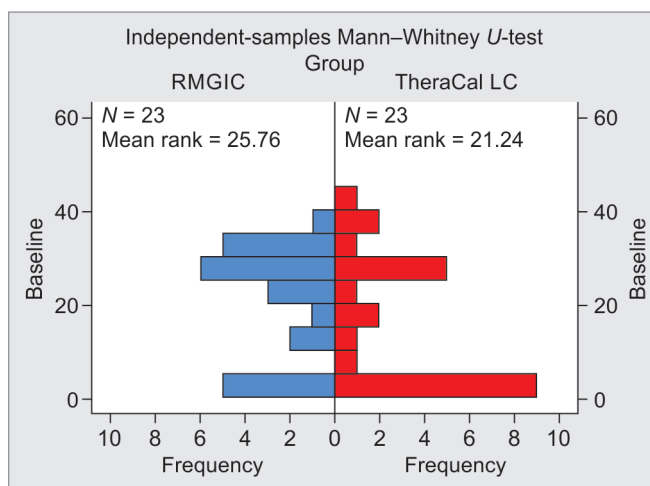
For data analysis, MedCalc Statistical Software version 19.0.6 (MedCalc Software, Ostend, Belgium; <http://www.medcalc.org>; 2020) was used. Data normality testing was done for VAS scores (pain) using Shapiro–Wilk test for normal distribution. Since the data collection was not as per planned schedule due to COVID-19 pandemic, a *post hoc* power analysis was done. The variations in the scores for VAS was compared between the two groups (RMGIC and TheraCal LC) using nonparametric Mann–Whitney U-test, whereas within-group comparisons were done using Friedman test. Categorical data and nominal data will be compared between the groups/subgroups using Chi-square test.

RESULTS

A total of 46 participants, aged between 18 and 40 years, were initially included in the study. The mean age of the participants was 29, with 30 males and 16 females. After accounting for dropouts, 14 participants remained in group I (RMGIC) and 17 in group II (TheraCal LC) at the 6-month follow-up. The mean VAS scores for pain were recorded at baseline, 24 hours, 3 weeks, 3 months, and 6 months. For the RMGIC group, the mean VAS scores were 20.21 at baseline, decreasing to 12.90 at 24 hours, 1.33 at 3 weeks, and 0.00 at both 3 and 6 months. In comparison, the TheraCal LC group exhibited mean VAS scores of 12.60 at baseline, 5.95 at 24 hours, 2.58 at 3 weeks, 1.50 at 3 months, and 0.00 at 6 months (Table 1). This data indicates a reduction in VAS scores over time for both groups, with both groups achieving a score of 0.00 at the 6-month mark. Although the TheraCal LC group started with a lower initial pain score compared with the RMGIC group, the reduction in pain occurred more rapidly in the TheraCal LC group (Fig. 4).

The comparison of VAS scores using nonparametric Mann–Whitney U-test indicated no statistically significant difference in VAS scores between the two groups at any time point ($p > 0.05$) (Figs 5 and 6). However, intragroup comparison using the Friedman test showed that the changes in VAS scores over time within each group were statistically significant ($p < 0.001$). Additionally, a *post hoc* power analysis yielded a power of 44.8% for between-group comparisons of pain scores using a repeated-measures analysis of variance (general linear model) procedure.

The presence or absence of swelling was assessed at baseline, 24 hours, 3 weeks, 3 months, and 6 months. No participants in either group reported swelling at any of these time points. A comparison between the two groups at each time interval, using the Chi-square test, revealed no statistically significant difference between them ($p > 0.05$) (Table 2).

**Fig. 4:** Estimated marginal means for pain scores (VAS)**Fig. 5:** Mann–Whitney U-test for VAS scores at baseline

At the respective follow-up, on evaluation, the integrity of the permanent restorations in both groups revealed that none of the participants experienced dislodgement of either temporary or permanent restorations at any recall visit (Table 3). Additionally, no participants in either group reported tenderness on palpation or percussion at any of the recall visits. A Chi-square test comparing both groups at each time interval showed no statistically significant difference in tenderness on palpation or percussion between the groups ($p > 0.05$) (Table 4).

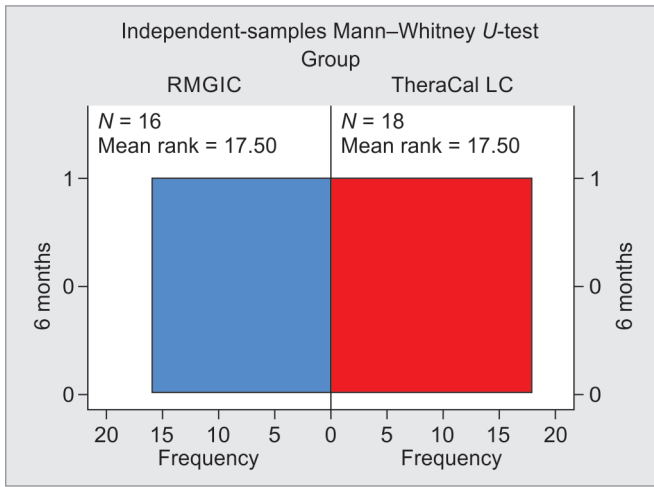


Fig. 6: Mann–Whitney U-test for VAS scores at 6 months

Table 2: The measurements of swelling at intervals for RMGIC and TheraCal LC

Swelling	RMGIC			TheraCal LC			χ^2 test
	N	No.	%	N	No.	%	p
Baseline							
No swelling	23	23	100.0	23	23	100.0	1.000
24 hours							
No swelling	16	16	100.0	19	19	100.0	1.000
3 weeks							
No swelling	19	19	100.0	21	21	100.0	1.000
3 months							
No swelling	10	10	100.0	15	15	100.0	1.000
6 months							
No swelling	14	14	100.0	17	17	100.0	1.000

Table 3: Inspection findings for RMGIC and TheraCal LC

Inspection	RMGIC			TheraCal LC			χ^2 test
	N	No.	%	N	No.	%	p
Baseline							
Disto-occlusal caries	23	3	13.0	23	4	17.4	0.432
Fractured amalgam restoration		2	8.7		0	0.0	
Fractured restoration		1	4.3		0	0.0	
Mesio-occlusal caries		9	39.1		5	21.7	
Occlusal caries		8	34.8		11	47.8	
Old composite restoration		0	0.0		1	4.3	
Temporary restoration		0	0.0		1	4.3	
White restorative material		0	0.0		1	4.3	
24 hours							
No dislodgement of restoration	16	16	100.0	19	19	100.0	1.000
3 weeks							
No dislodgement of restoration	19	19	100.0	21	21	100.0	1.000
3 months							
No dislodgement of restoration	10	10	100.0	15	15	100.0	1.000
6 months							
No dislodgement of restoration	14	14	100.0	17	17	100.0	0.296

Vitality tests conducted at 24 hours, 3 weeks, 3 months, and 6 months also showed no significant differences between the groups, as determined by the Chi-square test. At the 3-week mark, 19 participants in the RMGIC group showed a normal response, whereas in the TheraCal LC group, out of 21 participants, one exhibited a delayed response to the cold test and electric pulp testing and was advised to undergo root canal treatment (Fig. 7). No mobility was detected in any participant at any recall visit. Similarly, no changes in the periapical region were observed in either group at any time point. Comparisons between the two groups at each interval using the Chi-square test revealed no statistically significant differences ($p > 0.05$).

It can be inferred that both RMGIC and TheraCal LC are effective as IPC materials for deep carious lesions with reversible pulpitis, though RMGIC showed a slight advantage in maintaining pulp vitality, reducing symptoms, and minimizing periapical changes over time.

DISCUSSION

The discussion of how much carious dentin must be removed in order to arrest the carious process exists already more than

Table 4: Percussion findings for RMGIC and TheraCal LC

Percussion	RMGIC			TheraCal LC			χ^2 test
	N	No.	%	N	No.	%	p
Baseline							
Negative	23	23	100.0	23	23	100.0	1.000
24 hours							
Negative	16	16	100.0	19	19	100.0	1.000
3 weeks							
Negative	19	19	100.0	21	21	100.0	1.000
3 months							
Negative	10	10	100.0	15	15	100.0	1.000
6 months							
Negative	14	14	100.0	17	17	100.0	1.000

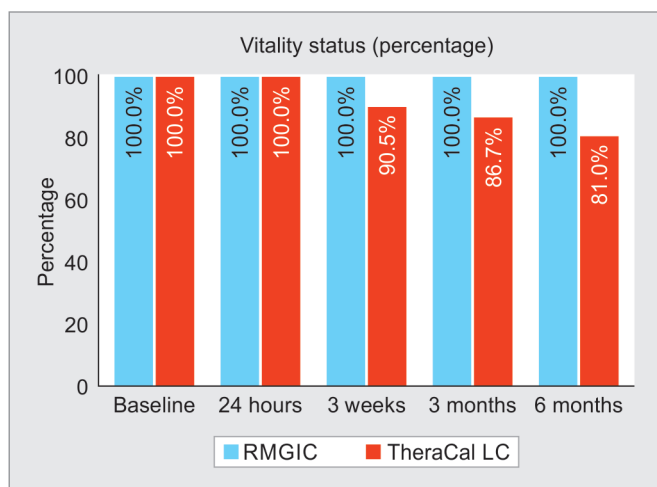


Fig. 7: Vitality status at each follow-up (%)

150 years.¹¹ Sato and Fusayama identified two distinct zones of carious dentine which could be differentiated with the use of dyes: The inner demineralized (formerly known as “affected”) zone and the outer bacterially contaminated (formerly known as “infected”) zone.¹² Infected dentin appears dry and leathery, has bacteria present, and the collagen is irreversibly denatured, whereas affected dentin has no bacteria, is reversibly denatured, is remineralizable, and should be preserved.¹³ It was recognized that only the outer zone needed to be removed during cavity preparation and that the inner zone, which was often stained but minimally contaminated, resisted excavation (it was firm) and had the potential to remineralize, could be left.¹⁴ Thus, in the present study, affected dentin was left and covered with IPC material.

The pulp capping materials used in the study are RMGIC and TheraCal LC. The RMGICs exhibit effective antimicrobial activity against cariogenic bacteria suggesting that their application on affected dentine could contribute to decrease or to eliminate residual microbiota.¹⁵ Release of chemical components such as fluoride and other metallic ions and low initial pH attributed to the inhibitory activity.¹⁵ The RMGICs have an initial pH of about 4.0, which increases to approximately 5.5 in the first 24 hours.^{15,16} The entry of high levels of H⁺ protons in the cell cytoplasm results in loss of activity of the relatively acid-sensitive glycolytic enzymes (which severely affects the ability to produce adenosine triphosphate) and structural damage to the cell membrane and macromolecules such as DNA and proteins culminating with cell death.¹⁷

The TheraCal LC may act as a scaffold for reactionary dentine formation. Dentinal fluids are absorbed within it, resulting in the release of calcium and hydroxide ions, and the tooth responds to form apatite and a bond, supporting the natural sealing ability of the apatite, playing a crucial role in pulpal protection.¹⁸ The alkaline pH of TheraCal LC decreases from 10–11 to 8–8.5 in 7–14 days, creating a favorable environment for pulp cell viability and metabolic activity with the formation of reparative tertiary dentin.¹⁹

Bjorndal and Thylstrup stated that it seems important that the temporary filling used between treatments in a two-stage procedure of carious removal provides a good cavity seal.²⁰ Thus, in the present study, IRM was used for temporary sealing of the cavities. It has been shown that carious dentin beneath a restoration contains a decreasing number of viable bacteria over time and “dries out,” which is a parameter for lesion arrest.¹¹ Loss of the

coronal seal leads to high cariogenic activity and clinical failure, as the dentinal tubules, which offer a pathway from the salivary ions or compounds to the pulp, must be sealed to protect the pulp and promote pulpal healing.

In the current study, the success rate for RMGIC at the 6-month follow-up was 100%. In contrast, the success rate for TheraCal LC was 81%, with three failures attributed to loss of vitality and one failure due to endodontic treatment undertaken at a private clinic. Despite these differences in success rates, no statistically significant difference was observed between the two groups overall. However, based on the VAS scores, there was a significant difference in the reduction of pain at subsequent recall visits, indicating that RMGIC was associated with greater pain relief compared with TheraCal LC over time.

Our findings align with several previous studies, reflecting the varying success rates of different materials used in pulp capping and restorative procedures. Bjorndal et al. emphasized that the effectiveness of the liner is secondary to achieving a well-sealed restoration.²¹ Gruythuisen et al. reported a 93% survival rate for teeth capped with RMGIC.⁸

A study by Gurcan and Seymen observed success rates of 94.4% for mineral trioxide aggregate (MTA), 87.8% for TheraCal LC, and 84.6% for calcium hydroxide.²² Hashem et al. found success rates of 77.8% for biodentine and 66.7% for Fuji IX at a 2-year follow-up.²³ Opal et al. found clinical success rates of 100% for calcium hydroxide, 88.8% for RMGIC, and 77.7% for gutta-percha when assessing carious dentin in young permanent teeth.²⁴

Contrasting results were reported by Mente et al., who found lower postoperative sensitivity when restorations were lined with a resin-modified GIC (Vitrebond, 3M ESPE) and a two-step, total-etch adhesive.²⁵ Hilton et al. highlighted that while calcium hydroxide remains a common pulp capping material, newer materials like MTA and TheraCal LC offer comparable or slightly better outcomes in terms of pulp healing and restoration longevity.²⁶

Nowicka et al. demonstrated that MTA generally provides superior dentin bridge formation compared with calcium hydroxide, suggesting better long-term outcomes.²⁷ Schwendicke et al. found that biodentine and MTA showed similar clinical performance, with biodentine offering advantages such as easier handling and quicker setting times.²⁸

Torabinejad et al. have also indicated that MTA exhibits favorable properties for pulp capping, including biocompatibility and effective sealing.²⁹ Moreover, a review by Gandolfi MG et al. highlighted that while various materials including RMGIC and TheraCal LC are effective, MTA remains a gold standard due to its superior clinical and biological performance.³⁰ Our study contributes to the ongoing evaluation of these materials, reflecting both the strengths and limitations observed in current clinical practice.

The limitations of this study include the relatively small sample size of 46 participants, which may affect the generalizability of the results to a broader population. Additionally, the study’s follow-up period, although including multiple intervals up to 6 months, may not be sufficient to assess long-term outcomes such as pulp vitality and restoration success over several years. Another limitation is the potential for variations in operator technique and patient compliance, which could influence the results. Furthermore, the study only considered two materials, RMGIC and TheraCal LC, without comparing them with other widely used IPC materials. Finally, the assessment of clinical parameters relied partly on subjective measures such as patient-reported symptoms, which may introduce bias or variability in the findings.

Further research with larger sample sizes and extended follow-up periods is necessary to confirm their long-term effectiveness and establish definitive clinical guidelines for their use.

CONCLUSION

The study concluded that both RMGIC and TheraCal LC are effective as IPC materials in the treatment of deep carious lesions with reversible pulpitis. However, RMGIC demonstrated a slight advantage in terms of maintaining pulp vitality, reducing symptoms, and minimizing periapical changes over the follow-up period.

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