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EVALUATION OF CONSERVATIVE MANAGEMENT OF TEETH WITH DEEP CAVITATED CARIOUS LESIONS USING THREE DIFFERENT LINING MATERIALS – RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Aim: The aim of this study is to compare postoperative pain of RetroMTA and resin-based tricalcium silicate (TheraCal LC) versus chemically Cured Glass Ionomer base material (FujiXI) in conservative management of very deep carious lesions by selective caries removal clinically and by digital radiography over 24 months follow up period.

Materials and methods: 99 teeth of patients who fulfilled the inclusion criteria were selected to participate in the study. All the selected teeth were divided in three groups (Fuji IX), (MTA) and (Theracal) groups. Teeth with deep caries undergone selective caries removal with hand or rotary instrument after rubber dame isolation and the tested lining materials were placed in the base of the cavity then composite were placed over as a final restoration. Postoperative pain (using thermal, percussion and palpation tests) and periapical pathosis (using digital periapical radiograph) were tested initially at (T_0), after one week (T_1), after three months (T_3), after six months (T_6), after 12 months (T_{12}) and after 24 months (T_{24}). After follow up period only 90 teeth were statistically analyzed using R statistical analysis software version 4.3.1 for Windows1.

Result: the success rate after overall assessment (clinical and radiographic) of the three lining materials Fuji XI, RetroMTA, Theracal LC, was: 53.3, 73.3, and 60 % respectively. The differences between groups were not statistically significant ($p>0.05$).

Conclusions: the three lining materials (Fuji XI, RetroMTA, TheraCal LC) have almost the same clinical and radiographic success rate after 2 years follow up period. Both RetroMTA and Theracal LC have favorable and comparable success rates when used in partial caries lining in very deep carious lesions.

KEYWORDS: Dental caries, Glass Ionomer, TheraCal LC, Fuji XI, selective caries removal.

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INTRODUCTION

Unfortunately, Dental caries is a destructive disease; hence, deep carious lesions treatment is a significant challenge to the clinicians for approaching a healthy pulp. The use of minimally invasive dentistry in the treatment of carious lesions is the outcome of a paradigm shift grounded in a research-led approach. ***(Clarkson et al., 2021)*** When treating deep cavitated carious lesions, conservative operative techniques that preserve both soft and hard tissues are included in the concept of minimally invasive dentistry. ***(Banerjee 2013)***

Non-selective caries removal, which includes removing all carious tooth structure to sound enamel and dentine that raise the risk of pulp vitality loss, was the recommended method of treatment decades ago ***(Martignon ,2019).*** Thus, using a technique known as selective caries removal, it is possible to remove carious tissue from an operating room while still being effective without having to eliminate every single organism.

Throughout the journey of deep carious lesion management, the pulp tissues health assessment is mandatory several months after the pulp tissue repair process. In such clinical situations, the biocompatibility of the material that used for replacing the dentine is the main deciding factor in choosing the posterior restoration to obtain pulpal tissue healing. ***(Koubi et al., 2013).***

Decades ago, conventional glass ionomer (GIC) was used on a wide scale in dentistry. This material has the main advantage; its adhesive property as it chemically bonds to the tooth structure also it aids in stopping the caries progression due to its fluoride release intra orally. In addition, it has biocompatibility with the pulpal tissues.

GIC has an 83.3% clinical success rate, according to Hashem et al. (2015). However, despite this clinical success, postoperative pain was noted in some cases after treatment with GIC as an indirect pulp capping material, and ranged from mild to severe. Additionally, some teeth required endodontic treatment following the capping procedure, so a more biocompatible material is needed for capping that has a higher rate of clinical success in terms of postoperative pain and biocompatibility with the pulpal tissues.

Recently, as a hydraulic bioceramic a new material is presented which is Retro MTA (BioMTA, Seoul, Korea) it includes carbonate calcium salts, aluminum oxide, silicon dioxide and hydraulic calcium andzirconia. (***Pornamazeh, T. et al., 2017)***

MTA is a bioactive component that may promote healing by stimulating remineralization. Over partially demineralized collagen matrices, the material may release an ion that might cause precipitation or the production of apatite crystals. MTA possesses strong alkaline pH, anti-bacterial activity, biocompatibility, and very good closure qualities. It can also connect with dentine during intrafibrillar deposition. (***Pratiwi, A.R., et al., 2017)***

TheraCal LC, a light-cured Tricalcium-silicate, was introduced in 2011 by BISCO Dental Products, Schaumburg, IL, USA. It can solve the drawbacks of MTA, which are important factors to take into consideration in preventative dentistry, notably the lengthy setting time and challenging handling. ***(Menon, N.P et al., 2016)***. Furthermore, TheraCal's release of calcium ions stimulates cell division and growth as well as the synthesis of secondary dentin. Compared to MTA and other common materials, TheraCal releases more calcium ions, is easier to handle, flows from a syringe, and is less soluble. Using TheraCal avoids the need for pressing, mixing, and triturating. After that, it can be immediately attached and carefully placed on deep cavities. ***(Arandi, N.Z. and Rabi, T., 2018).***

The aim of this study is to compare postoperative pain of calcium silicate cement and resin-based tricalcium silicate (TheraCal LC) versus chemically cured Glass Ionomer in conservative management of very-deep carious lesions by selective caries removal clinically and by digital radiography over 24 months.

MATERIALS AND METHODS

Randomized Controlled Trial, single blind parallel arm design was conducted at the Faculty of dentistry, Cairo University, Cairo, Egypt from january2021- January2023.

99 teeth of participants who met the inclusion requirements were chosen to take part in the trial **(Figure.7)**. Before the trial started, each patient's consent was obtained. Teeth were divided into 3 main groups by utilizing simple random sampling method each group was 33 participants. A power analysis was designed to have adequate power to apply a statistical test of the null hypothesis that there is no difference would be found between different tested groups regarding postoperative pain. By adopting an alpha (α) level of (0.05), a beta (β) level of (0.2) (i.e. power=80%) and an effect size (?) of (0.341) calculated based on the results of a previous study; the predicted sample size (n) was a total of (84) cases (i.e. 28 cases per group). Sample size was increased by (20%) to compensate for possible drop-out during different follow up intervals to be a total of (99) case (i.e. 33 cases per group). Sample size calculation was performed using G*Power version 3.1.9.7

Intervention procedures

Fuji XI was used as the control in group (A1), which included the chosen participants, while Ret-roMTA was used as the first intervention (A2) and Theracal was used as the second intervention (A3).

- Eligibility criteria:

Eligibility Criteria of participants:

Inclusion Criteria of participants:

1. Patients older than 18 years with no difference in gender
2. Deep carious lesion reaching three-quarters or more into the dentine as appeared in the peri-apical (PA) radiograph.
3. Clinically (according to International Caries Detection and Assessment System) (ICDAS II) score 4
4. With (cold test) the pulp response positive to thermal stimulation
5. No Peri-apical changes screened on PA radiograph

Exclusion Criteria of participants:

1. Any signs of endodontic inflammation (spontaneous pain)
2. Detecting o fistulas or swelling
3. Tooth mobility or pain to percussion
4. Aesthetic area
5. Pregnancy
6. Patients less than 18 y
7. Patients cannot give consent

Exclusion criteria of the teeth:

Teeth that exhibit signs of irreversible pulpitis, such as dull throbbing pain that doesn't go away, sharp pain that appears suddenly, or pain that gets worse when you lie down, won't be considered. Patients who experience pulp exposure during the baseline operative intervention will also be removed from the study.

-Intervention procedures:

Pre-operative clinical assessment:

1. Thermal testing using Refrigerant spray (Endo Frost, Roeko, Langenau, Germany)
2. Percussion test.
3. Palpation and clinical examination for the signs of inflammation (pain, abscess, sinus tract, and mobility).
4. PA radiographs using digital radiograph will be taken at baseline (T0) and will be assessed to exclude any signs of irreversible pulpitis (widening of periodontal ligament [PDL] or PA lesions).

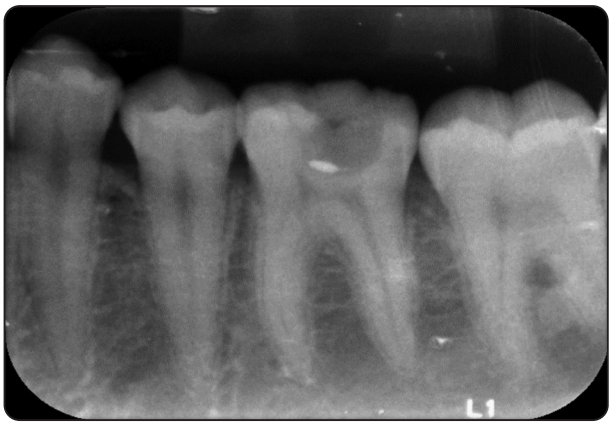

Fig. (1): Baseline Digital radiograph (T0) deep caries lesion before Fuji XI application

Fig. (2): Follow up Digital radiograph at 24 months (T24) after selective caries removal and application of Fuji IX.

Fig. (3): Baseline Digital radiograph (T0) deep caries lesion before application of RetroMTA.

Fig. (4): Follow up Digital radiograph at 24 months (T24) after selective caries removal and application of RetroMTA.

Fig. (5) Baseline Digital radiograph (T0) deep caries lesion before TheraCal application.

Fig. (6) Follow up Digital radiograph at 24 months (T24) after selective caries removal and application of TheraCal.

These tests were carried out at baseline, pre-operatively, and at 1 month, 3, 6, 12 and 24-months in post-operative follow-up visits

Selective Caries removal procedure:

The patient will be given local anesthesia, followed by total isolation of the tooth (with the inclusion criteria) using rubber dam. If necessary, the operator (15 years experienced operator in deep caries manrgment), will use a high-speed hand piece to open the enamel. (NSK, NSK America Corp,USA) with high speed diamond round bur (Standard shank Ø1.6mm x 19mm FG. Diamond medium grit) (komet Rock Hill, SC, United States) under copious irrigation. Next, in the elimination of wall caries Steel-carbon rose-head bur (komet Rock Hill, SC, United States) in low speed hand piece (W&H DentalwerkBürmoos GmbH, Bürmoos, Austria). At the end, the deeper caries will be removed using excavator (no 49, 61 or 73, Dentsply,Maillefer) leaving the last layer firm leathery dentine without any direct pulp exposure (**Clarkson et al., 2021**). Then the interventions were applied according to the manufacture instructions (Fuji IX titrated in the amalgamator for 10 seconds then loaded in the gun and applied to the cavity), (retro MTA mixed and applied) and (theracal applied and light cured for 20 seconds) Finally the resin composite material was used as a final restoration in all groups.

Clinical outcome measures

This study was conducted over a twenty-four-month period. (T). The primary outcome was Postoperative pain it was tested by cold testing (Endo Frost, Roeko, Coltène/Whaledent, Germany) percussion and palpation tests. The secondary outcome was detecting the presence of the periapical pathosis that was tested by digital periapical parallel radiograph at the baseline (T_0), after one month (T_1), after three months (T_3), after six months (T_6), after twelve months (T_{12}) and twenty-four months (T_{24}). (**Table 1**)

TABLE (1) Outcomes criteria, measuring devices, scores, characteristics, measuring unite:

Criterion	M. device	Score	Characteristics	M. unit
Postoperative pain (1^{ry} outcome)	Endofrost	a =1	Normal Response to cold	Binary
		b=2	Exaggerated response	
		c =3	No response to cold	
	Percussion	a =1	Normal	Binary
		b =2	Pain on percussion	
	Palpation	a =1	normal	
		b =2	Tenderness	
Periapical pathosis (2^{ry} outcome)	Digital radiograph	D_1 =1	Normal periapical area	Binary
		D_2 =2	Widening of LD or periapical radiolucency	

Data management

Baseline data collection

For all the patient medical and dental history were recorded. Examination records were fulfilled.

Outcome data collection

At baseline, two assessors conducted the sensitivity tests and the radiographic evaluation of the teeth. After one week, three months, six months, twelve months, and twenty-four months of evaluation, if the results differed, the assessors discussed it and, if they could not agree, a third assessor resolved the conflict.

Statistical analysis

Categorical data were presented as frequency and percentage values and were analyzed using chi-square test followed by pairwise comparisons

utilizing multiple z-tests with Bonferroni correction for intergroup comparisons and Friedman's test followed by Nemneyi post hoc test. Age data were presented as mean and standard deviation values. They were analyzed for normality using Shapiro-Wilk test and were found to be normally distributed. They were analyzed using one-way ANOVA followed by Tukey's post hoc test. The significance level was set at $p<0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.3.1 for Windows1.

RESULT

Demographic data

From 99 enrolled patients; 90 teeth were included in the study. The flow chart of the patients through the study followed the CONSORT flow diagram is presented in **(Figure.7).**

The study was conducted on 90 cases that were randomly and equally allocated to each of the studied groups (i.e. 30 cases each)

Age, Gender and tooth distribution in all groups

There were 13 males in MTA group and 17 females, while in other groups there were 12 males and 18 females. The mean age of the cases in MTA group was (32.17±8.50) years, in Fuji XI group it was (33.80±11.27) years, while in Theracal group it was (31.83±9.11) years. There was no significant difference between tested groups regarding sex ($p=0.955$) and age ($p=0.705$). Demographic data are presented in table (2).

Outcome results

Primary outcome (postoperative pain)

a- Endofrost test

Within all intervals, there was no significant difference between tested groups regarding response to Endofrost ($p>0.05$). For Fuji XI group, there was a significant difference between responses measured at different intervals, with significantly higher percentage of cases having normal responses at T12 in comparison to T0 ($p=0.005$). For other groups, the difference was not statistically significant ($p>0.05$).

b- Percussion test

At T1, there was a significant difference between tested groups with percentage of cases in MTA group with normal response being significantly higher than Theracal group ($p=0.016$). Within other intervals, the difference was not statistically significant ($p>0.05$). For all groups, there was a significant difference between responses recorded at different intervals ($p<0.001$). For MTA and Fuji XI groups, post hoc pairwise comparisons showed percentage of positive cases to be significantly higher in T0 in comparison to other intervals ($p<0.001$). While for Theracal groups are showed percentage of positive cases to be significantly higher in T0 and T1 in comparison to other intervals ($p<0.001$).

c- Palpation test

Within all groups and intervals, all cases were free.

TABLE (2) Intergroup comparisons and summary statistics of demographic data

Parameter		*MTA*	*Fuji XI*	*Theracal*	*Test statistic*	*p-value*
Sex [n(%)]	***Male***	13 (43.3%)	12 (40.0%)	12 (40.0%)	**0.09**	**0.955**
	Female	17 (56.7%)	18 (60.0%)	18 (60.0%)		
Age (Mean±SD) (years)		32.17±8.50	33.80±11.27	31.83±9.11	**0.35**	**0.705**

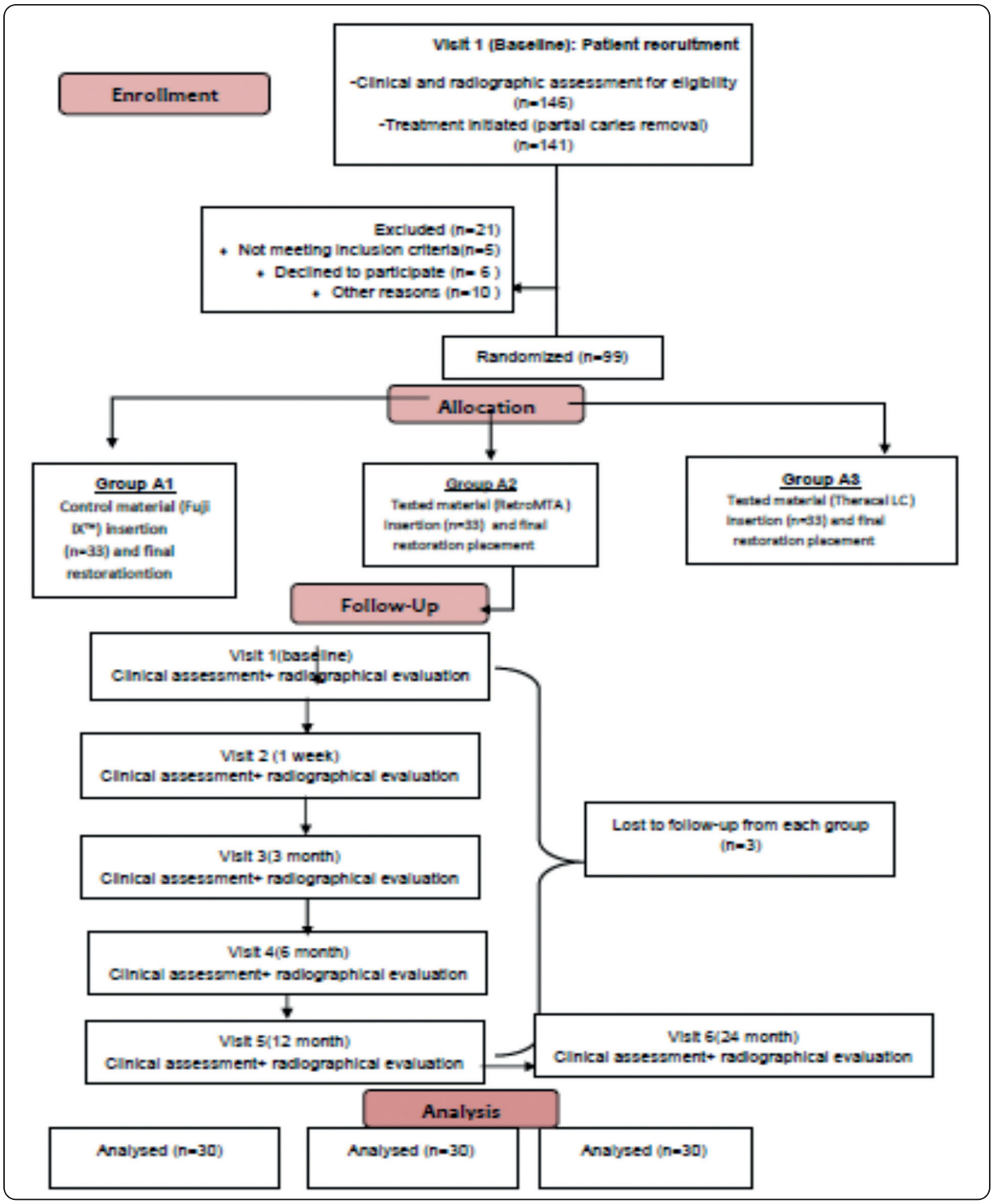

Fig. (7) Flow diagram indicating patient recruitment and follow-up adapted from CONSORT flow diagram 2010

Secondary outcome (periapical pathosis detection using digital periapical radiograph)

Within all intervals, there was no significant difference between tested groups regarding digital radiographic inspection (p>0.05). For all groups, there was a significant difference between inspections measured at different intervals, with a significantly higher percentage of cases showing positive signs at T12 in comparison to other intervals (p<0.001) (for Fuji XI the difference between T12 and T24 was not statistically significant (p>0.05).

Treatment outcome:

The success rate after overall assessment (clinical and radiographic) of the three lining materials Fuji XI, RetroMTA, Theracal LC, was: 53.3, 73.3, and 60 % respectively. After two years of follow-up, the differences between groups were not statistically significant (p>0.05). Treatments' outcomes are presented in table (3) and in figure (8).

TABLE (3) Intergroup comparisons and summary statistics for assessments' outcomes

Assessment	*Outcome*	*n(%)*			χ^2	*p-value*
		MTA	***Fuji XI***	***Theracal***		
Clinical	***Success***	24 (80.0%)	21 (70.0%)	21 (70.0%)	**1.02**	**0.600**
	Failure	6 (20.0%)	9 (30.0%)	9 (30.0%)		
Radiographic	***Success***	27 (90.0%)	23 (76.7%)	25 (83.3%)	**1.92**	**0.383**
	Failure	3 (10.0%)	7 (23.3%)	5 (16.7%)		
Overall	***Success***	22 (73.3%)	16 (53.3%)	18 (60.0%)	**2.56**	**0.266**
	Failure	8 (26.7%)	14 (46.7%)	12 (40.0%)		

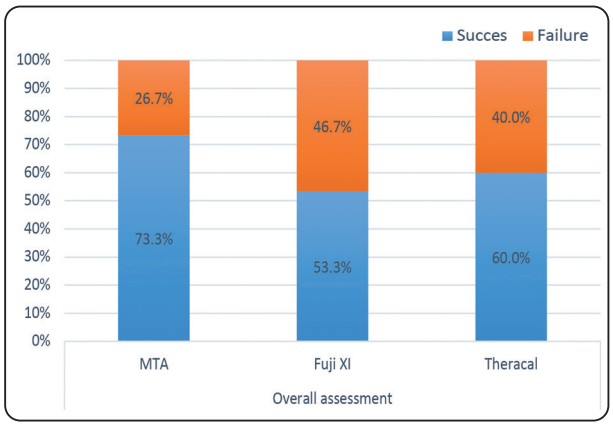

Fig. (6) Follow up Digital radiograph at 24 months (T24) after selective caries removal and application of TheraCal.

DISCUSSION

Because a tooth cannot be healthy unless its pulp remains intact and healthy, conservative dentistry aims to protect and maintain pulp vitality. By promoting the development of reparative dentin and limiting pulp inflammation, conservative dentistry aimed to achieve this objective. Our study focused primarily on more conservative technique of managing deep carious molar pulp with more compatible lining materials. In this study, we used three different biocompatible lining materials Fuji IX, RetroMTA and Theracal after selective caries removal in very deep carious lesions in teeth with

reversible pulpitis to preserve their pulp vitality, with a follow-up period of 24 months. To the end of our knowledge, the present study is the first to compare these three lining materials together in lining partial caries in very deep cavities. The caries removal approach (one-step excavation) used in this study was completed in a single visit. Therefore, to lower the danger of exposing the pulp, this is done. According to Maltz et al. (2012), one-step excavation survival rates were 98% and 91% after one and three years, respectively, while treatment success rates were 97% and 90%. Compared with stepwise excavation, partial removal of carious tissue had similar survival rates; however, within three years, this technique had a lower failure rate compared to the stepwise technique.

Glass-ionomers (GI) first appeared in the 1960s credited to Alan Wilson. Wilson and Kent have discovered that the glass ionomer interacted chemically with tooth structure. According to ***McCabe et al., 2009***, its primary benefit was its ability to adhere directly to the tooth structure without using a bonding agent. ***Yamakami et al.,2018*** 's Glass ionomers also have the advantages of releasing fluoride; as a result, ***Mount, 1994*** believes that glass ionomer cement will be clinically cariostatic.

However, GIC also had other flaws, like weak tensile and flexural strengths and significant solubility. A fast-setting reinforced glass ionomer was invented by ***Zoergiebe et al. in 2003,*** to increase strength, decrease solubility, and help accelerate setting time as well as preserve pulp vitality by being more compatible with low PH in initial setting (acid-base reaction). Assessment of the fast-setting conventional GIC (Fuji IX) revealed high strength and excellent marginal adaptation of this restorative material. (***Scholtanus et al., 2007 and Burke et al., 2007)***.

Concerning Retro MTA Tricalcium is a primary component that is bioactive and biocompatible. The calcium and hydroxyl ions that trigger hydroxyapatite crystals to form on the dentinal surfaces can be released by MTA. Dentine and MTA may interact during intrafibrillar deposition. Biocompatibility, high alkaline pH, antibacterial activity, radiopacity, and good closure properties are available in MTA. (***Pratiwi, A.R., et al., 2017)***

Regarding TheraCal's release of calcium ions encourages cell division and growth, as well as the synthesis of secondary dentin. Compared to MTA and other conventional materials, TheraCal releases more calcium ions and is easier to handle and flow from a syringe. It is also less soluble. ***(Arandi, N.Z. and Rabi, T., 2018).***

In this study the success rate after overall assessment (clinical and radiographic) of the three lining materials Fuji XI, RetroMTA, Theracal LC, was: 53.3, 73.3, and 60 % respectively. The differences between our groups were not statistically significant ($p>0.05$).

Our study's findings demonstrated that utilizing thermal test (endofrost), percussion test, palpation test and the postoperative pain for all the tested lining materials (Fuji IX, MTA,and Theracal), for treatment of very deep carious lesions after partial caries removal has no statistically significant differences. Additionally, no periapical pathosis was visible under the roots of either of the tested base materials on digital periapical radiographs.

For gender there was no statistically significant difference between all groups also for the treated tooth type there was no statistically significant difference. On the same track as our results, ***Hashem et al., 2015 and Hashem et al., 2018***, showed the same result for gender and tooth type. In contrary with our result, ***Baskaran et al., 2018,*** showed different results for gender and tooth type as they used biodentine (calcium silicate) for direct pulp capping in permanent teeth.

Also, our result for the primary outcome (Postoperative pain) using a thermal test (endo frost) depending on the principle of pulp sensibility showed. There was no significant difference between tested groups within all intervals, regarding

response to Endofrost. For Fuji XI group; the difference between responses measured at different intervals was significant, with significantly higher percentage of cases having normal responses at T12 in comparison to T0

We must explain the rationale behind cold testing in order to interpret our findings regarding postoperative pain using endofrost. Thermal tests cause fluid to move hydrodynamically within dentinal tubules, which activates the A-fiber and causes immediate impact is felt, but C fibers are not activated by thermal tests unless they cause pulpal injury. In order for the patient to feel pain, pulp tissue, including odontoblasts, are crucial. For the hydrodynamic mechanism to operate reliably, these odontoblasts must remain unharmed ***(Berman, L.H. and Hargreaves, K.M., 2015).*** One of the shortcomings of thermal testing, according to ***Pantera et al., 1992***, was that it necessitated opening dentinal tubules to allow the hydrodynamic movement of fluids, and in the case of tubule calcifications or the development of significant secondary dentine the thermal testing was inefficient.

We may provide a different explanation for the nearly the same result for both control (Fuji IX) and comparators (MTA and theracal) in the primary outcome over 24 months by outlining their different mechanisms of action. Although control and comparators belong to the same two groups of bioactive water-based cement-type restorative materials, they remineralize and interact with the underlying carious tissue in various manners. Glass ionomer is an acidic substance that could be harmful to the pulp tissues. The odontoblastic layer was observed to be disorganized following Fuji IX placement in the teeth, however after 3 days it rearranged again whereas the pulp displayed mild inflammatory reactions, according to ***Six et al., 2000***. According to all of the prior research, the initial pulp reactions to GIC seem to resolve over time, especially if there is a dentine barrier ***(Sidhu, 2011)***.

However, calcium silicate cement (RertoMTA and theracal) stimulated the synthesis of reparative dentin, probably as a result of a regulation of pulp cell transforming growth factor-b1 secretion. The results ***Laurent et al., 2012*** combined with our findings demonstrated that comparator particles were trapped in the newly formed clusters, and mineralization expressed as osteodentin. This finding raises the possibility that the material's physicochemical properties may enhance the mineralization process, as evidenced with MTA-based cement. According to ***Nowicka et al. 2013***, the tricalcium silicate, one of the primary components of both comparators, and the presence of both calcium and silicon ions may be correlated to the stimulation of cell proliferation and differentiation.

As a result of both theories, it can be hypothesized that glass ionomer can eventually cause indirect inflammatory reactions to the pulp, which may result in loss of sensibility along the first months. In contrast, loss of sensibility in calcium silicate groups may be attributed to the presence of a more radiopaque layer, which causes a recession to the pulp after application (along 3 months), which may indicate the formation of ostedentine. However, both hypotheses require further histological examination.

While, for the percussion test our result showed, no statistically significant difference between (T0), (T1), (T3), (T6), (T12) and (T24) groups in all lining materials. This was in agreement with the results of ***Gruythuysen et al., 2010***, who stated that the evaluation of indirect pulp capping in deep carious lesions on primary and permanent teeth does not always require the appearance of pain on percussion to determine whether a periapical lesion is present. Additionally, ***Pigg et al., 2017*** concurred with our findings when they said that the cold test was more reliable than the percussion test. The explanation for the potential cause of percussion discomfort is listed as an aspect of apical periodontitis and is predicated on the hypothesis that inflammation causes

sensory fibres outside the tooth to become more sensitive. However, even if the pulp inflammation is only mildly visible on the surface, periapical inflammatory alterations might still take place. In agreement with ***Reit et al., 2010,*** who had the same also for palpation test.

For secondary outcome (Digital radiograph) showed no statistically significant difference between (T0), (T1), (T3), (T6),(T12) and (T24) groups and this was in disagreement with the result of ***Hashem et al., 2015*** and ***Hashem et al., 2018*** as they used digital radiograph comparing between Fuji IX and Biodentine in indirect pulp capping. Also, they confirmed their results using cone beam computed tomography (CBCT) which gives more accurate results than a digital periapical radiograph.

Furthermore, we noticed a more radiopaque layer formed separating the base layer from the pulp cavity in some cases that were treated with both comparator groups after six to 12 months' evaluation by the digital periapical radiograph. The appearance of this layer may be explained by the tricalcium's previously indicated mechanism of action as an osteoinductive substance that can encourage the creation of reparative dentine. Prior research has assessed the nature of this tissue histologically ***(Parolia et al., 2010)*** and with microCBCT ***(Nowicka et al., 2015)*** following tooth extraction. We are unable to do this examination due to the patients' ethical rights and the lack of microCBCT in our nation. The material used for direct pulp capping determines the volume of reparative dentin bridges that are formed., according to ***Caicedo et al.,2006 and Nowicka et al.,2015*** evaluations of the reparative dentine formation after direct pulp capping with tricalcium silicate and other capping materials following tooth extraction and they reported that the volume of formed reparative dentin bridges depends on the material used for direct pulp capping. We may assume that our radioopaque layer is dentine-like structure that needs more histological evaluation.

CONCLUSIONS

The following conclusions were made in light of the findings, observations, and statistical analysis of this clinical and radiographic research

1. Clinically and radiographically, all three materials showed favorable outcomes in deep caries manegment in respect to success rate.
2. RetoMTA followed by theracal has more favorable result in the postoperative pain and this can make them more biocompatible to the pulp.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work.

Ethical approval

This research took the approval of the Research Ethics Committee (REC) Faculty of Dentistry, Cairo University no (26423).

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Trial sponsor: Faculty of Dentistry, Cairo University.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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