Original Research

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Evaluation of effectiveness and efficiency of caries removal by chemo-mechanical versus atraumatic restorative technique: an in-vitro experimental study

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Abstract:

Introduction: Advancement in minimally invasive dentistry in restorative dentistry have led to a giant leap in innovation. However, the effectiveness and efficiency of these methods require further scientific exploration to be incorporated into clinical practice.

Material and Methods: The study included 50 extracted human permanent molars with Class I carious lesions, characterized by distinct cavities extending into dentin (ICDAS score 5). Each sample was sectioned through the center of the carious lesion to obtain two equal halves. These halves were randomly allocated into two groups: Group I – ART (n = 50) and Group II – CMCR (n = 50). Caries removal was performed following standardized protocols for both groups. The efficiency was measured by recording the time required for complete caries removal, while the effectiveness was assessed using a caries detector dye.

Results: CMCR (4.69 ± 1.22 min) was more efficient than ART (5.89 ± 1.27 min) in complete caries removal ($p<0.05$). Single use of CMCR was required for complete caries removal in 80% of the specimens, while only 52% of the specimens were deemed caries free after single attempt of ART ($p<0.05$). There was statistically significant difference in effectiveness of caries removal between the groups.

Conclusion: CMCR is an effective and efficient technique that may serve as a viable alternative in minimally invasive dentistry for management of dental caries.

Keywords:

Atraumatic restorative treatment; papain; Caries affected dentin; Dental caries

Introduction:

The Global Burden of Disease Study 2019 reported that around 3.5 billion people worldwide are affected by oral diseases, with dental caries in permanent teeth being the most common (1). In light of this, the paradigm on caries management has shifted toward more convenient, biological, and minimally invasive approaches (2). Efforts to enhance access to and utilization of dental care have significantly increased interest in delivering effective treatments within community-based settings that often face resource limitations, posing major challenges (3). These approaches rely on minimal intervention, the use of portable handheld instruments, and more experienced or subjective clinical assessments by practitioners (4).

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Date of Receiving:14 October 2025

Date of Revision:13 April 2026

Date of Acceptance: 20 April 2026

DOI: https://doi.org/10.69491/kpmp8541

The concept of Minimally Invasive Dentistry (MID) emphasizes "a systematic respect for the natural tissue" (2). In restorative dentistry, the primary objective is tissue preservation, which involves preventing or halting active disease through non-operative and/or minimally invasive methods (2,5,6). In dental caries, two distinct dentin layers can be observed macroscopically: the outer *infected layer*, which is contaminated with microbes and has irreversibly degraded dentinal collagen, and the inner *affected layer*, which contains collagen capable of remineralization and should be conserved to protect the pulp (7,8). Clinically, it is critical to differentiate between these two layers to ensure conservative caries removal (2). To address the aforementioned limitations, several strategies include manual instrumentation utilizing Atraumatic Restorative Technique (ART) and/or Chemo-mechanical Caries Removal (CMCR) have been introduced (6,9). ART, being the conventional minimally invasive approach, relies exclusively on manual instruments to remove caries without the use of local anesthesia, followed by restoration with a fluoride-releasing material (10). As an advancement to ART, CMCR was introduced to complement manual excavation by employing chemical agents that soften infected dentin, facilitating easier removal while preserving the affected dentin for potential remineralization (11). Since 1975, multiple CMCR agents have been developed, broadly categorized into natural and synthetic agents, such as sodium hypochlorite (NaOCl) or enzyme-based formulations (12). A more recent agent incorporates the proteolytic enzyme papain (derived from papaya), which exhibits antibacterial and anti-inflammatory properties

like the human enzyme pepsin. It specifically targets partially degraded collagen, as the infected tissue collagen lacks alpha-1-antitrypsin, thereby aiding caries removal while enhancing antimicrobial activity (13).

A recent study by Souza *et al.* observed better effectiveness when ART was aided by CMCR (9). However, Kitsahawong *et al.* found chemo-mechanical agents were less effective and efficient than conventional method (14). The effectiveness as well as efficiency of CMCR is therefore contentious and requires further exploration in minimally invasive dentistry to be incorporated into dental services. The aim of this study was to evaluate efficiency and efficacy of CMCR using a novel papain-based gel versus ART in the removal of caries in freshly extracted human permanent teeth. The null hypothesis for this study was that CMCR will exhibit greater effectiveness and efficiency as compared to ART in caries removal.

Materials and methods:

The present in-vitro experimental study was carried out in accordance to the CRIS guidelines (Checklist for Reporting In-vitro Studies) and World Medical Association Declaration of Helsinki (2008) at the dental clinics and laboratory at Aga Khan University Hospital, Karachi, Pakistan, after ethical approval was obtained from ethical review committee (2022-8112-23012) (15,16).

The sample size was calculated using open epi software version 3.0 (open-source statistics for public health, *www.openepi.com*) using the module for comparing two means (17). According to a study by Konde *et al.,* the mean and standard deviation (SD) values for time taken for CMCR and convention technique were 11.2 ± 5.959 seconds and 14.5 ± 5.367 seconds, respectively (18). Keeping the confidence interval at 95% with power of 80%, the sample was calculated to be 47 per group, which was rounded off to 50.

Inclusion criteria: Freshly extracted human permanent molars with class I carious lesions visible in dentin i.e., International Caries Detection and Assessment System (ICDAS) score 5 were included after clinical and radiographic assessments with the minimum width of 2mm.

Exclusion criteria: Teeth with caries confined to enamel, deep lesion with potential for pulp exposure or pulp exposure, fractured teeth and teeth with development anomalies were excluded from the study.

Data collection: A total of 50 teeth that fulfilled the inclusion criteria were collected via non-probability purposive sampling technique. The teeth included in the study were collected after obtaining verbal consent from patients who opted for extractions or were advised extractions during routine dental clinics. After obtaining a freshly extracted tooth, it was adequately debrided using an ultrasonic scaler (EMS 250 Piezon, Switzerland) to remove remnants of periodontal ligament or calculus. Each tooth was numbered and sectioned from the centre of the carious lesion (either mesio-distally or bucco-lingually) using diamond bur attached in high-speed handpiece under copious irrigation. This was carried out to ensure equal distribution of carious lesions in both halves, each of which was assigned to either of the two groups; ART (n=50 specimens) or CMCR (n=50 specimens) (Figure 1). The data was collected by primary author (SAT), who was trained and calibrated by two restorative dentists. Fleiss' kappa was used in order to determine the agreement on the caries removal score. As a final analysis, all three examiners were assessed on three samples each in a separate room so that they could not influence the decision of other examiner. Fleiss' kappa revealed that the operators' judgements were in good agreement (0.825 (95% CI, 0.820 to 0.829), p = 0005).

Figure 1: Each tooth was mesiodistally sectioned from center of carious lesion so that two halves will have equal size of carious lesions

Group I: ART

Excess moisture from the cavity was removed with a dry cotton pellet. Thereafter, following the principles of ART, carious dentin was removed using excavators #127/128 (SurgiMac, USA).(19) The cavity was deemed caries-free upon reaching a non-sticky leathery-hard texture felt on tactile sensation with an explorer and no longer stained with caries detector dye (Visucarie; Maquira, Brazil). The process was repeated if caries were detected.

Group II: CMCR

The papain-based gel in CMCR was smeared on the carious dentin using a microbrush on the teeth sections. The gel was retained in the cavity for 2 minutes as per manufacturer's instructions. After 1 minute, the gel changed colour from a transparent green solution to a hazy mixture. This was due to the production of oxygen during the dissolution process. The chemically treated tissue was then curettage; first from the surrounding cavity walls followed by the pulpal floor. The procedure was carried out repeatedly until the gel no longer changed colour and the cavity was hard and non-sticky on tactile sensation using an explorer (Figure 2). The process was repeated if caries were detected.

Figure 2: Protocol for CMCR. A: Section of tooth with carious lesion; B: Application of CMCR according to manufacturer instructions; C: Conditioning time for 2 minutes; D: caries excavation with spoon shaped excavator followed by rinsing with distilled water and drying with cotton pellet; E: application of caries-disclosing dye (Visucarie; Maquira, Brazil) with micro-applicator followed by rinsing with distilled water; F: after caries removal.

Outcome Assessment:

• Effectiveness of Caries Removal

The effectiveness of removal of carious dentin in both groups was determined by caries indicator dye under 3.5x magnification loupes (Univet, Italy) according to the scoring criteria by Ericson *et al.* (Figure 3) (18). The outcome assessment was performed by two blinded restorative dentists who were not the part of the study.

Figure 3: Scoring Criteria for Caries Removal as proposed by Ericson et al (18).

Scores	Definition
0	Complete removal of caries
1	Residual caries at the base of cavity
2	Residual caries at the base and/or wall of cavity
3	Residual caries at the base and/or two walls of cavity
4	Residual caries at the base and/or >2 walls of cavity
5	Residual caries at the base, walls, and margins of cavity

• Efficiency of Caries Removal:

The total time taken (minutes) and number of applications/ attempts to fully remove caries was also noted in a self-administered proforma.

Statistical Analysis:

The Statistical Package for the Social Sciences (SPSS) version 23.0 was used to analyze the data. The Shapiro Wilk test was used to determine the normal distribution of data. A Mann-Whitney U test and an independent t test were performed, respectively, to compare the scores and attempts made to remove cavities between the two groups. Cohen's d correlation was utilized to calculate the effect size. The significance level was held at 0.05.

Results:

The results of the present study revealed that the meantime taken for caries removal was 4.69 ± 1.22 min for CMCR and 5.89 ± 1.27 min for ART. To compare the efficiency, the independent *t*-test revealed a significant difference between the meantime taken for caries removal in both groups, revealing that CMCR was slightly more efficient than ART group ($p<0.05$) (Table 1).

Table 1: Comparison of time taken in minutes for caries removal in both groups.

Groups (n)	Minimum (min)	Maximum (min)	Time (min) Mean ± SD	*p-value*	Cohen's d effect size
ART (50)	4.1	9.15	5.89 ± 1.27	0.003*	0.963
CMCR (50)	3.08	7.01	4.69 ± 1.22		

**Independent t-test, level of significance p < 0.05; SD= Standard deviation*

Table 2: Comparison of initial and final scores for caries removal in both groups.

Score	First attempt		Second attempt	
	ART (50)	CMCR (50)	ART (24)	CMCR (10)
	n(%)	*n(%)*	*n(%)*	*n(%)*
0	26 (52)	40 (80)	24 (100)	10 (100)
1	20 (40)	6 (12)	0 (0)	0 (0)
2	4 (8)	4 (8)	0 (0)	0 (0)
3	0 (0)	0 (0)	0 (0)	0 (0)
4	0 (0)	0 (0)	0 (0)	0 (0)
5	0 (0)	0 (0)	0 (0)	0 (0)

p-value	0.061*	0.687*

**Mann Whitney U test, level of significance p < 0.05; SD= Standard deviation*

Conferring to the findings of Mann-Whitney U test, there was a significant difference in the effectiveness scores and number of applications/attempts required for complete caries removal with CMCR revealing superior results ($p<0.05$). Initially 80% of the specimens deemed caries free in CMCR compare to 52% in ART group only in single attempt to caries removal($p<0.05$) (Figure 3). There was no statistically significant difference in effectiveness between the two groups ($p > 0.05$) (Table 2).

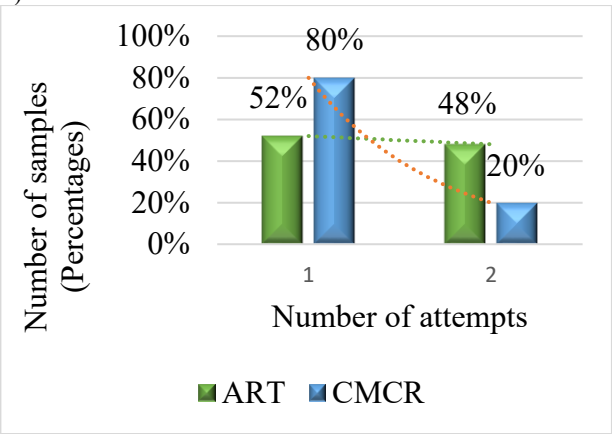

Figure 3: Percentages of number of applications in study groups.

Discussion:

Contemporary approaches in minimally invasive dentistry have now been developed that aid in preservation of native tissue in cariology (2). The present study investigates effectiveness and efficiency of two different minimally invasive caries removal protocols using conventional ART and CMCR with a recently introduced papain-based gel 'BRIX3000'. The results of this study revealed CMCR to be more efficient than ART in terms of time and number of applications required to fully remove the infected carious dentin. However, both techniques were equally effective at removing caries completely. Pertaining to the findings, the study resulted in partial acceptance of the null hypothesis. It is speculated that CMCR using novel papain-based gel could be considered as viable alternative in minimally invasive dentistry in the management of dental caries.

In this study, no significant difference was observed between the effectiveness of the two groups. These findings are in agreement with the recent study conducted by Gupta *et al.* that reported papain-based gel to be an effective method for caries removal in comparison to ART (20). Similarly, studies by Pandit *et al.* and Soni *et al.* reported greater effectiveness of caries removal by CMCR using a different debriding agent, using the same scoring criteria (21,22). As claimed by manufacturers, the volume of papain used in recently introduced gel (3,000 U/mg in a concentration of 10%) and the fact that it is bio-encapsulated using Encapsulating Buffer Emulsion (EBE) technology separates this product from other enzyme-based CMCR agents (23). Therefore, the pH of this gel is ideal for immobilizing enzymes that enhance proteolytic action on collagen fibrils in carious dental tissues.(24) The active lesions in carious dentin have a more acidic environment with a lower mean pH (pH = 4.9), whereas arrested lesions have a higher mean pH (pH = 5.7). As a result, this innovative bio-encapsulation has a neutral pH (pH = 7) that allows the solidification of proteolytic enzymes, which permits stability as well as rapid release in the midst of an acidic environment with disrupted collagen strands, thereby inducing hydrolysis (23).

This study found a significant difference between the efficiency for caries removal for both the groups with CMCR required less time than ART (p <0.05). These findings are in agreement with Inamdar *et al.*, that reported papain-based gel to be efficient method of caries removal compared to conventional rotary instrumentation (11). Contrary to this, Hedge *et al.* reported that CMCR using other chemical compositions, though time consuming, were definitely superior compared to conventional techniques (25). The plausible ground for differing efficiency could be due to different compositions of agents, techniques and operator-related factors that lead to variable outcomes.

The number of interventions required was determined by the consistency of the carious enamel and dentin. A single application almost eradicate 70-80% of caries limited to the outer layer. Two applications were necessary at caries confined to or near DEJ and the cavity's base. Arkansas dental sharpening stones were used to sharpen the excavators for each application. Caries detector dye did not stain sound dentin or arrested dentin, but rather aided discern between soft dentin and sound dental structure. Under 3.5x magnification loupes (Univet, Italy), caries excavation was carried out for both groups effectively. Pertaining to the findings of the current study, it was found that 80% of the specimens required only a single application of CMCR as compared to 52% required for ART group. The average time taken in ART group is 0.963 standard deviation as compare to average time taken in CMCR group as reported in Cohen's d computation.

The randomization technique employed in the current study was carried out to reduce selection bias and minimize inherent effect modifiers. This study utilizes conventional caries-detector dye, which stains the denatured dentine and aids in decision-making (26). However, literature reported the sensitivity of 70-75% and specificity of 100% of propylene-glycol dyes, that have a tendency to stain unaffected circumpulpal dentin and sound dentin in the area of the amelo-dentinal junction (27). A substantial amount of evidence suggests that traditional visual-tactile techniques provide adequate assessment of caries status during cavity excavation (28). Furthermore, the redundant use of a caries-detector dye of concern might result in excavation of native tooth structure.

This study is subjected to some inherent limitations. No dimensional assessment or laboratory based microbial analysis were performed for caries affected lesion. As an in vitro investigation, variables such as patient pain during caries excavation could not be evaluated, and the clinical importance of these findings can only be verified with further research evaluating the clinical trials of these chemo-mechanical approaches in caries excavation.

Conclusion:

The results of the study concluded that the CMCR utilizing novel papain-based gel was found to be effective and efficient measure and could be considered as viable alternative in minimally invasive dentistry in the management of dental caries. However, to support the outcome of the current study, a large-scale, well-designed randomised controlled clinical trials are required.

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Conflict of interest: Author declares no conflict of interest.
Funding Disclosure: Nil

Author's Contribution:
Syeda Abeerah Tanveer: Substantial Contribution, Content, Drafting and Final version approval
Robia Ghafoor: Final approval and Accountability