

ORIGINAL RESEARCH

Evaluation of Papacarie®, Carie-Care™, BRIX3000™ and conventional hand instrumentation for caries removal in primary teeth: a randomized control study

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Abstract

In the current odontological era, carious lesions are removed while tooth tissue is preserved. Most of these ideals are met by chemomechanical caries removal (CMCR) methods, which are easy and comfortable to use, differentiate and eliminate infected tissues, minimize pressure, vibration and heat, and are cost-effective. This study examines the efficacy of commercially available CMCR agents, namely Papacarie®, Carie-Care™ and BRIX3000™, and a conventional hand instrumentation method for caries removal in deciduous molars in terms of time consumption, ease of application, and pain perception. For this randomized clinical trial, 120 children aged 4 to 9 years were selected and randomly allocated to four groups of 30 patients each. Time consumption, ease of application, and pain perception were evaluated at three intervals: pre-, during- and post-caries removal, using Wong-Baker FACES (WBF) Pain Rating Scale and the Face, Legs, Activity, Cry, Consolability (FLACC) scale. The results showed that among the compared materials and conventional hand instrumentation technique, Carie-Care™ was statistically found to be the least time-consuming with a *p*-value of 0.019, have the least pain perception with a *p*-value of 0.02, and was clinically the best with respect to manipulation and handling. While all three CMCR agents aid in the removal of carious tissue, Carie-Care™ was the most effective based on time consumption, pain perception and simplicity of administration.

Keywords

BRIX3000™; Carie-Care™; Chemomechanical caries removal; Pain perception; Papacarie®

1. Introduction

Dental caries, one of the most common oral diseases, has long been a source of concern for public health [1]. Initially, hand drills were used to remove caries, but in 1871, they were quickly surpassed by James Morrison's treadle instrument, which was based on Isaac Singer's sewing machine mechanism. Surgical intervention for the removal of the carious lesion has been utilized for over a century since there was little understanding about the "preservation of the remaining tooth structure" [2]. Sir G.V. Black's "extension for prevention" strategy was required at the time because no other viable option existed. However, due to the disadvantages, there is a growing demand for treatments or materials that aid in caries management without extending into the affected area. Thus, it is apt to switch approaches, from "extension for prevention" to "prevention of extension". As M. M. De Van once quoted,

"Our goal should be the perpetual preservation of what is left rather than the meticulous restoration of what is missing" [3]. As a result, a novel concept known as chemomechanical caries removal (CMCR) has emerged.

CMCR was initially developed with the use of 5% sodium hypochlorite solution (NaOCl-based CMCR agents) in 1970; then, GK 101 was employed in 1972 and GK 101e in 1975, the latter of which was patented in the United States as Caridex and authorized by the Food Drug Administration in 1984. Swedish researchers developed Carisolv in 1998, while Bassadori *et al.* [4] produced Papacarie® in Brazil [5]. Moreover, Carie-Care™ was introduced in India in 2010 [6], while Brix3000™ was created in Argentina in 2016 [7].

Papacarie®, Carie-Care™ and BRIX3000™ are all enzyme-based CMCR agents. They also have abrasive and antibacterial properties. Moreover, chemomechanical therapy for carious dentin is as effective as standard caries removal and contains

the enzyme papain. This enzyme holds a vital role similar to that of NaOCl in NaOCl-based agents. Gulzar *et al.* [8] also revealed that CMCR agents have antibacterial properties [9].

Papacarie® is as successful as conventional techniques yet less painful. However, Almaz *et al.* [10] in 2016, Anegundi *et al.* [11] in 2012, and Hegde *et al.* [12] in 2016 all underscored that Papacarie® took longer to remove caries than conventional surgery, while Matsumoto in 2013 [13] and Motta *et al.* [14] in 2014 found no difference [14, 15]. Furthermore, Papacarie® treatment cost is another factor to consider. Due to their high cost and limited shelf life, chemomechanical techniques may be less practical than traditional treatments. Some research, nevertheless, indicates that Papacarie® is a cost-effective alternative for conservative caries treatment in young patients. This enzymatic CMCR method reduced excavation time while potentially enhancing the morphological features of residual dentin for subsequent bonding [16].

Moreover, according to previous studies, Carie-Care™ is less expensive than Papacarie® and has a longer shelf life. Although it is also less painful, it has a lengthier process time and its caries removal efficacy is comparable to conventional techniques [17–22]. As for Brix3000™, it has a good shelf life and has improved antibacterial, antifungal and antiseptic properties. This agent is also effective in removing caries and is less painful; however, it has a lengthy process time [7, 23–25].

CMCR is a minimally invasive method that assists in the removal of damaged dentin by using a chemical agent rather than a drill. To preserve more tissue, the infected rather than the affected layer is removed. Due to its simplicity, researchers suggest that the adoption of this procedure for children who are fearful of dental treatment is promising [26, 27]. According to Appukuttan DP, the most dreaded dental treatment events are cavity cutting, anesthesia induction and tooth extraction. Hence, the CMCR approach is preferred for individuals who have dental anxiety [28]. Furthermore, CMCR agents have numerous advantages over traditional drilling methods, including reduced pain perception, effective caries removal in uncooperative patients, no pulpal irritation, as well as reduced anxiety and fear, resulting in less distress in pediatric patients; they are also useful in physically challenged patients and those with infectious diseases [5]. Any clinical process that is guaranteed to be less frightening, anxiety-provoking, and time-consuming may be extremely beneficial not only to the patients but also to the operator.

This study aims to determine the best method for removing carious lesions in pediatric patients since they are the most fearful of dental treatment. Hence, it intends to evaluate the efficacy of currently available CMCR agents: Papacarie®, Carie-Care™ and BRIX3000™, in primary teeth caries removal in terms of ease of manipulation, time consumption, and pain perception. This study's null hypothesis is that there is no difference in the three agents' efficacy.

2. Materials and methods

2.1 Study design

The parents were provided with detailed information about the goals, study design, and possible benefits associated with the trial before their children being included in the study. Using the sequentially numbered opaque-sealed envelope technique, a randomized, controlled experiment was designed and carried out among children aged 4 to 9 years who visited the department for the research.

2.2 Sample size estimation

A sample size of 120 teeth was estimated, with 30 in each group.

$$\text{Sample Size } (n) = \frac{p \times q \times Z^2}{e^2}$$

Where,

Z = standard normal variate at 95% confidence level = 1.96;

e = anticipated level of accuracy/level of precision in percentage = 5%;

p = relative portion of the population with the desired characteristic to be evaluated = 8.5%;

q = 100 – p = 100 – 8.5 = 91.5;

n = (8.5)² × 91.5 × (1.96)² / (5)² = 119.5.

2.3 The study's inclusion and exclusion criteria

Inclusion Criteria:

1. Children aged 4–9 years.
2. Broad cavitated occlusal lesion with dentinal involvement (Black's Class I cavity) and occlusal access.
3. Radiograph showing dentinal caries up to two-thirds of the dentinal thickness.
4. The consistency of carious lesions ranges from soft to medium hard.
5. Color ranges from light yellow to brown.

Exclusion Criteria:

1. Cases requiring restorative treatment that is not of the Class I variety.
2. Extensively damaged teeth.
3. Radiograph showing dentinal caries of more than two-thirds of the dentinal thickness.
4. Caries involving pulp or extending below the gingiva.
5. Medically or developmentally compromising conditions.

2.4 Sample preparation

A total of 120 carious deciduous teeth fulfilling the inclusion criteria were randomly divided into four groups: Group A (Carie-Care™ (Ecodentalworks India Pvt Ltd, Bengaluru, India)), Group B (BRIX3000™ (Brix Medical Science Carcanã, Argentina)), Group C (Papacarie® (Fo'rmula and Ac aõ, Saõ Paulo-Brazil)), and Group D (Control group (Atraumatic restorative treatment group) (Fig. 1—Flow Chart). A thorough case history was taken along with a caries risk assessment prior to the initiation of the procedure. A single-blinded examiner for the caries removal technique evaluated each case

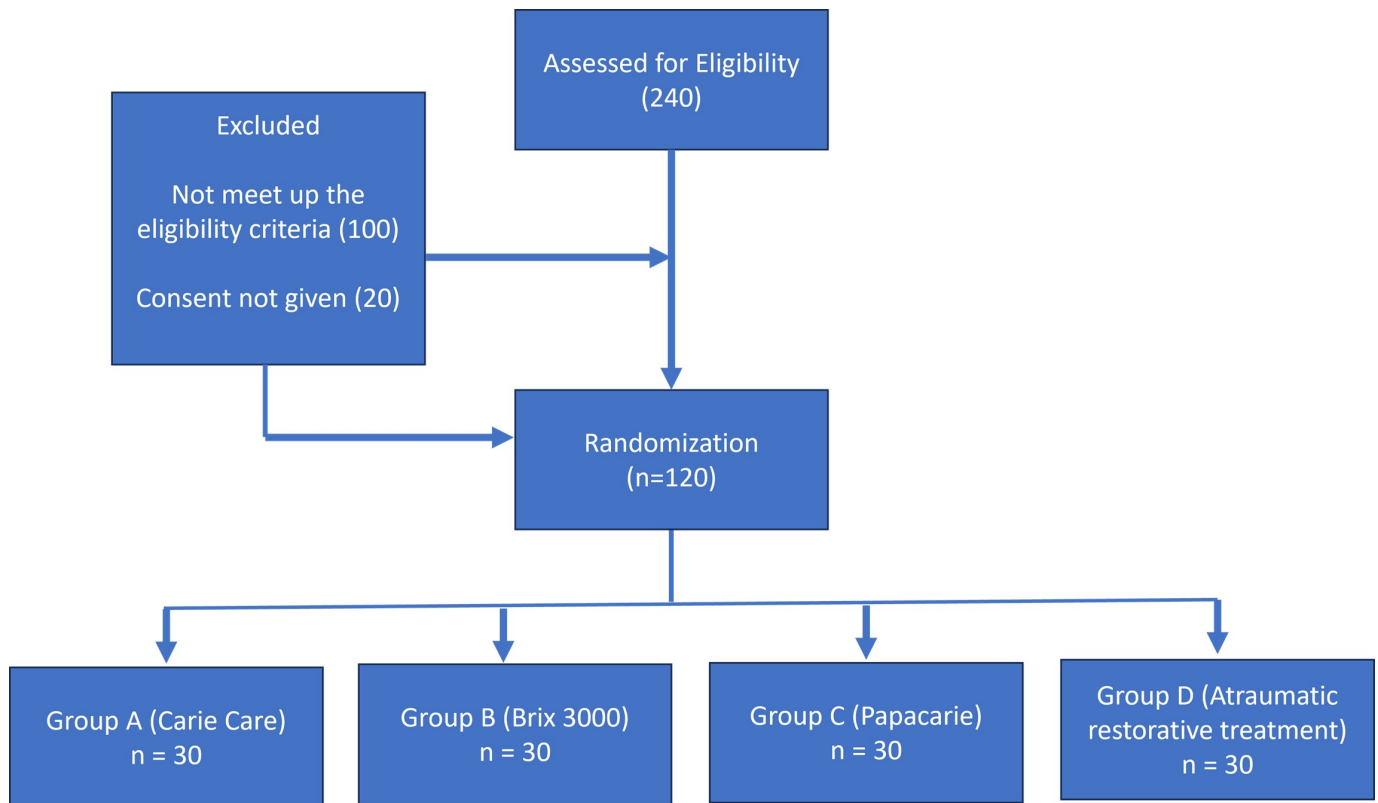


FIGURE 1. Flow chart. n = 30.

for complete removal. This eliminated any element of bias in the study. The process began with the child seated in the dental chair, and to make them comfortable, the entire procedure was explained to them using the Tell-Show-Do technique. Before the start of the procedure, rubber dam isolation was done for each group; this was then followed by caries excavation based on group assignment.

2.5 Procedure

In Group A, Carie-Care™ was dispensed in the cavitated area for 60 seconds. As the gel appeared to be cloudy, the gel and infected dentin were scraped out with a spoon excavator without pressure. A second application of the gel was made as needed until healthy dentin was visible.

In Group B, BRIX3000™ was dispensed into the carious cavity for two minutes. The gel and the infected dentin were scraped using a blunt spoon excavator while employing a pendulum motion and no pressure. A second gel application was made as needed until healthy dentin was visible.

In Group C, Papacarie® was dispensed into the carious cavity for 30 to 40 seconds. The infected dentin was scraped using the opposite side of the spoon excavator while employing a pendulum motion. A second gel application was made as needed until healthy dentin was visible.

In Group D, the infected dentin was scraped away with a spoon excavator until all of the soft dentin was removed from the tooth.

The cavities were then checked for absolute caries removal using Ericson *et al.*'s [29] criteria from 1999, which included “visual inspection and tactile sensation”. When no tug-back sensations were detected while passing the explorer’s tip

smoothly over the prepared dentinal surface, caries was considered eliminated. The final restoration was done using glass ionomer cement (Shofu Inc., Japan).

The first parameter considered was the time taken by each procedure to entirely remove caries; this was logged using a stopwatch, starting with the initial application of the agent and ending with the complete removal of caries. The patients’ pain perception was also assessed; this was recorded using subjective (Wong-Baker FACES (WBF)) [30] and objective (FLACC scale) [31] scales before, during and at the end of the procedure. In 1988, Wong and Baker developed the WBF Pain Rating Scale. It is a “faces rating scale” with picture illustrations of six distinct facial expressions. These emotions span from a pain-free, happy countenance to one exhibiting intense distress. The child is asked to choose the face that best describes their pain. The major limitation of the facial rating scale, however, is that it is highly subjective. Also, young children may become confused by the facial expressions and may randomly select a face irrespective of the pain they are experiencing. Hence, an objective scale parameter, the FLACC scale, was also used for evaluation [9]. The last factor evaluated was the ease of use, which was described based on the operator’s assessment.

2.6 Statistical analysis

Analysis of Variance (ANOVA) was used to compare different groups, while the *post-hoc* Tukey’s test was employed for the pairwise comparison of the groups in order to perform statistical analysis on the obtained and tabulated data.

3. Results

A total of 120 teeth from children aged 4 to 9 years were evaluated in this study. Data revealed that all four groups shared demographic characteristics such as gender, mean age and tooth type. The mean time consumption for Groups A (Carie-Care™), B (BRIX3000™), C (Papacarie®) and D (spoon excavator) were 5.36 minutes, 7.5933 minutes, 6.2266 minutes and 6.7866 minutes, respectively. Carie-Care™ had a shorter meantime consumption than all the other materials used. A statistically significant difference in time consumption was also observed between the four groups ($F = 3.444$, $p < 0.05$) (Table 1). Moreover, there was a statistically significant difference ($p < 0.05$) in time consumption between Carie-Care™ and BRIX3000™ ($p = 0.012$); however, this was not the case ($p > 0.05$) when comparing Carie-Care™ and Papacarie® ($p = 0.618$), Carie-Care™ and spoon excavator ($p = 0.196$), BRIX3000™ and Papacarie® ($p = 0.233$), as well as Papacarie® and spoon excavator ($p = 0.864$) (Table 2). Furthermore, the ANOVA with *post-hoc* Tukey's test was employed to compare the four groups' time consumption. The *post-hoc* Tukey's test for within-group comparison found a statistically significant difference in time consumption between Groups A and B ($p = 0.05$).

ANOVA for between-group comparison revealed a statistically significant difference in pain perception, as measured by the WBF scale, during the treatment ($p = 0.021$), but not at pre-treatment ($p = 0.119$) or post-treatment ($p = 0.877$) (Table 3). Similarly, there was no statistically significant difference in pain perception, as measured by the FLACC scale, before ($p = 0.443$), during ($p = 0.433$), or after treatment ($p = 1$). Moreover, the *post-hoc* Tukey's test found a statistically significant difference in pain perception during treatment between Groups A and D, as well as between Groups C and D ($p < 0.05$). Also, there was a significant difference in pain perception between Groups A and B, Groups B and C, and Groups A and C (Table 4).

The materials' ease of use is a subjective parameter. The assessment was also based on the difficulties observed by the operator during the procedure. To evaluate the ease of operation, the following criteria were used: Score 1—easy to apply, easy to manipulate; Score 2—easy to apply, difficult to manipulate; Score 3—difficult to apply, easy to manipulate; Score 4—difficult to apply, difficult to manipulate. Fig. 2 depicts the frequency of the above-mentioned scores among the three CMCR agents. Carie-Care™ was found to be the best material in terms of ease of application, with a maximum score of 1, comparable to Papacarie®.

4. Discussion

CMCR, a game changer in pediatric dentistry, was launched in the 1970s, but the concept was not widely explored. Nonetheless, it has gained popularity in recent years, particularly after the global pandemic. The said scenario caused by SARS-CoV-2 (COVID-19) was challenging for conventional dental techniques due to the potential risk of cross-infection during caries removal. Thus, rotatory instruments were avoided, reigniting interest in methods with low aerosol production,

TABLE 1. Mean time consumption.

	N	Mean (Minutes)	Standard Deviation
Group A Time Consumption	30	5.3600	1.7908
Group B Time Consumption	30	7.5933	3.5798
Group C Time Consumption	30	6.2266	3.2833
Group D Time Consumption	30	6.7866	2.0474
ANOVA		$F = 3.444$; $p = 0.019$	

ANOVA: Analysis of Variance.

TABLE 2. *Post hoc* Tukey's test within group comparison.

Tukey HSD			
(I) Groups	(J) Groups	Mean Difference (I-J)	<i>p</i> value
Group A			
	Group B	-2.24000*	0.012
	Group C	-0.87333	0.618
	Group D	-1.43333	0.196
Group B			
	Group A	2.24000*	0.012
	Group C	1.36667	0.233
	Group D	0.80667	0.676
Group C			
	Group A	0.87333	0.618
	Group B	-1.36667	0.233
	Group D	-0.56000	0.864
Group D			
	Group A	1.43333	0.196
	Group B	-0.80667	0.676
	Group C	0.56000	0.864

*The mean difference is significant at $p < 0.05$ level. Tukey HSD: Honestly Significant difference.

such as CMCR. Some research evaluated the effectiveness of CMCR compounds and air rotors with burs in removing caries from deciduous teeth. It has been discovered that the cavities made by the CMCR approach are equivalent to those created by the air-rotor method, and the restoration's sustainability is likewise comparable.

CMCR agents work by destroying the permanently damaged collagen fibers in infected dentin, thus aiding in its easy removal while keeping the healthy affected dentin in its place. This process is accomplished mainly by chlorination, which involves hydrolysis of the cross-links between tropocollagen units and/or cleavage of the polypeptide chains within the triple helix. In NaOCl-based CMCR agents, the chlorination process is the main mechanism of action, while in enzyme-based agents, the mechanism of action is based on papain.

TABLE 3. Post hoc Tukey’s test within group comparison Tukey HSD (Wong Baker’s Scale).

(I) Groups	(J) Groups	<i>p</i> value (pre)	<i>p</i> value (during)	<i>p</i> value (post)
Group A				
	Group B	0.196	0.96	0.899
	Group C	0.899	1.00	0.899
	Group D	0.899	0.038	0.899
Group B				
	Group A	0.196	0.96	0.899
	Group C	0.196	0.96	0.899
	Group D	0.196	0.124	0.899
Group C				
	Group A	0.899	1.00	0.899
	Group B	0.196	0.96	0.899
	Group D	0.899	0.038	0.899
Group D				
	Group A	0.899	0.038	0.899
	Group B	0.196	0.124	0.899
	Group C	0.899	0.038	0.899
ANOVA		<i>F</i> = 1.9863	<i>F</i> = 3.361	<i>F</i> = 0.2275
		<i>p</i> = 0.1199	<i>p</i> = 0.021	<i>p</i> = 0.8771

*The mean difference is significant at the 0.05 level. ANOVA: Analysis of Variance.

TABLE 4. Post hoc Tukey’s test within group comparison Tukey HSD (FLACC).

(I) Groups	(J) Groups	<i>p</i> value (pre)	<i>p</i> value (during)	<i>p</i> value (post)
Group A				
	Group B	0.634	0.899	0.899
	Group C	0.634	0.899	0.899
	Group D	0.899	0.486	0.899
Group B				
	Group A	0.634	0.899	0.899
	Group C	0.899	0.899	0.899
	Group D	0.634	0.486	0.899
Group C				
	Group A	0.634	0.899	0.899
	Group B	0.899	0.899	0.899
	Group D	0.634	0.646	0.899
Group D				
	Group A	0.899	0.486	0.899
	Group B	0.634	0.486	0.899
	Group C	0.634	0.646	0.899
ANOVA		<i>F</i> = 0.8992	<i>F</i> = 0.9206	<i>F</i> = 0
		<i>p</i> = 0.4439	<i>p</i> = 0.4333	<i>p</i> = 1

*The mean difference is significant at the 0.05 level. ANOVA: Analysis of Variance.

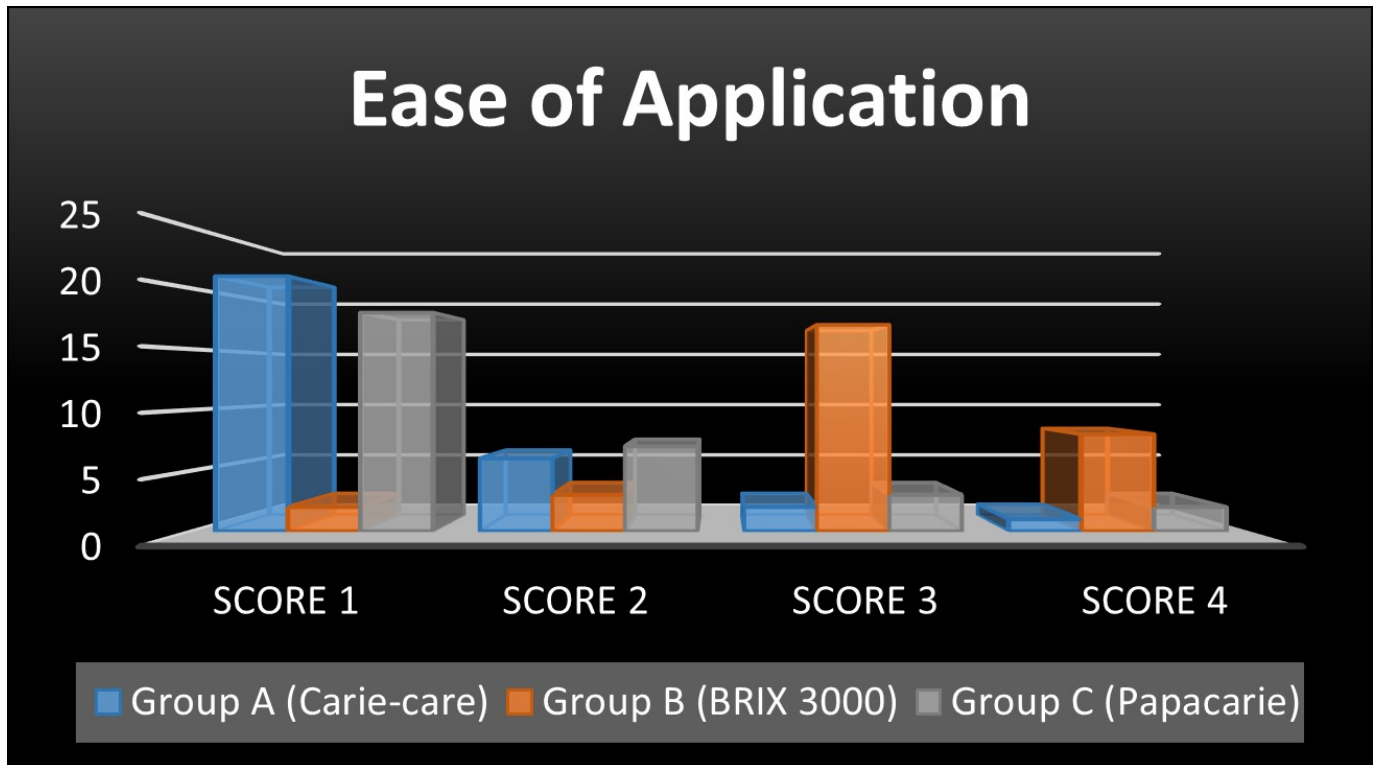


FIGURE 2. Ease of application.

This enzyme breaks down the partly degraded collagen and helps in the disintegration and extinction of the fibrin mantle produced by the carious process without damaging the unimpaired collagen fibrils. The infected dentin becomes softer and easier to remove as a result of the lack of alpha-1-antitrypsin, a plasmatic protease inhibitor, in infected dentin [32].

Many *in vivo* and *in vitro* studies [2, 6, 33, 34] have been conducted in which the traditional drilling method is individually compared to various CMCR agents. However, there have been very few studies that compare the various CMCR agents altogether. Therefore, this study's main objective was to compare popular CMCR agents in terms of time consumption, pain perception, and ease of application.

The first aim of the present investigation was to estimate the mean time required to remove caries using the conventional technique (spoon excavator) and the three CMCR agents. Carie-Care™ had the lowest meantime consumption of the three agents tested. The data was found to be clinically and statistically significant. According to Dogra *et al.* [33], removing caries with Carie-Care™ takes longer than with an air rotor. Although the air rotor removes caries faster than any other CMCR agent, their lack of tactile sensibility causes them to remove the majority of the tissue quickly and with less control, resulting in excessive cavity preparation. By employing a carbide or diamond bur, the dentist ultimately excavates the healthier dentin and is unable to find the last location that needs to be removed. This exposes the healthier dentin, which is more permeable. Aswathi KK *et al.* [34] also examined the efficiency of removing caries using a polymer bur and Carie-Care™, concluding that both techniques are equally effective and take about the same amount of time.

Furthermore, Cardoso M *et al.* [1] compared the clinical effectiveness of CMCR utilizing Carisolv and Papacarie® and found that the latter took less time to completely remove all caries; their research produced clinically significant results. In the present study, findings were consistent with those of Deng Y *et al.* [35], who examined ten studies on Papacarie® and concluded that the traditional approach took longer than Papacarie® therapy.

Alkhouli MM *et al.* [7] also found parallel results when comparing standard drilling techniques to the use of two distinct CMCR agents: 2.25% sodium hypochlorite and BRIX3000™. According to Ismail MM *et al.* [36], although BRIX3000™ takes longer, it is still a great substitute for removing decay, with the same effectiveness as the traditional drilling approach.

In contrast to our results, Kotb *et al.* [37] found that Papacarie® was just as effective as the drill at removing caries from open carious lesions, with no discernible increase in time required to complete the task. As a direct consequence of the newly created CMCR agent, the use of drills and local anesthesia was used far less frequently. In addition, Papacarie® was far more pleasant to use than the conventional rotatory instruments.

This study also compared the patients' pain perception after employing the three CMCR agents and the conventional hand instrumentation method. The results were clinically and statistically significant. Similar results were found among various studies worldwide. According to Shashikala *et al.* [6],

in 2017, despite similar efficacy and patient compliance, the CMCR method outperforms the Carie-Care™ and air rotor groups. This is because it masks the sound intensity and boosts enthusiasm in young children who are otherwise susceptible to the dental setup's sonority. They asserted that the CMCR approach reduces noise, protects the dental structure, and promotes children's cooperative behavior. It could be a better option than the typical caries eradication technique [6].

In 2011, Kochhar GK *et al.* [38] underlined that using air rotors caused the most unpleasant feelings, which were determined to be least in Papacarie®, followed by Carisolv [38]. According to Boob *et al.* [39], cutting or removing carious dentin generated minimal to no feelings, whereas the cutting of sound dentin caused some discomfort and sensitivity. Hegde *et al.* [18] also indicated similar outcomes. For Ismail MM *et al.* [36], BRIX3000™ was more acceptable than the ceramic bur because it used less local anesthesia and air rotor; they revealed that when measuring anxiety during the ongoing treatment period, the use of the ceramic bur resulted in a higher percentage of negative behavior than the CMCR method. There was no discernible difference between the two approaches' acceptability levels.

In their case studies, Felizardo *et al.* [40] and Prabhav C. *et al.* [41] concluded that BRIX3000™ was an effective alternative for caries eradication and aids in the maximum preservation of the tooth structure. In 2021, Oommen *et al.* [42], however, found no statistically significant difference in participants' pain response after BRIX3000™ and conventional surgical methods were used [42]. In a systematic review, Cardoso *et al.* [1] concluded that Papacarie® is a more effective agent for chemomechanical caries removal, with less pain and greater parental acceptance.

Air rotors, which are commonly used for cavity preparation and caries removal, may cause pain and suffering. This is a plausible explanation for dental anxiety. Painful sensations may be brought on by mechanical stimulation that puts pressure on the tooth, the presence of living pulp, thermal stimulation that causes high surface temperatures to form on cuts, as well as sound or vibration that reaches the bone. Nevertheless, since the CMCR compounds only affect denuded, demineralized dentin fibers, sound dentin is spared from harm and unpleasant sensations [43]. Bacteria cause the dentinal minerals to dissolve, exposing the collagen bundle fibers. Papain then interacts with the exposed collagen fibers to soften the diseased dentin, allowing the infected dentin to be removed without the necessity of burs or local anesthesia, using instruments devoid of cutting tips [4].

Lastly, this study examined the three CMCR compounds' ease of application. Although all three agents were found to be almost equally effective, Carie-Care™ was found to be the most user-friendly and successful in removing the carious lesion, whereas BRIX3000™ provided the least favorable results. This may be explained by the inclusion of a buffer emulsifier in BRIX3000™, which makes the gel extremely thick as well as challenging to apply and work within the cavity.

5. Strengths and limitations

This study explored the most recent concept of minimal intervention dentistry, especially in the post-COVID-19 scenario, where the use of conventional techniques has become a major challenge for dental treatment. This will help pediatric dentists in managing a child's behavior as well as efficiently delivering quality treatment. Also, there are many *in vitro* studies in the literature comparing various chemomechanical agents, but this research, being an *in vivo* study, has a major advantage and provides enhanced knowledge about the clinical application of CMCR agents.

As more CMCR products enter the market, our study was conducted to compare a few of them and determine which is superior. However, further research is still required to evaluate the same materials but with a larger sample size using a split-mouth design. There are also more attributing aspects to be investigated, as different oral cavities have different microflora, making them susceptible to higher caries index. Moreover, the agents discussed may have different effects on different microflora types. This topic could be further studied so that everyone could receive personalized treatment based on the condition of their oral cavity.

6. Conclusions

While all three agents were effective at removing caries, Carie-Care™ was found to be faster with statistically significantly less pain perception during treatment, as well as easy to apply and manipulate in the cavity. Even though these materials take longer to remove caries than the traditional drilling procedure, they are still advantageous in primary dentition. Moreover, CMCR may help with the treatment of early childhood caries, management issues, as well as immunosuppressed and medically vulnerable individuals. Additionally, there is no need for local anesthetic, and neither heat nor pressure will harm the pulp.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

NG, NM, AN, SV, NA, AA, KA, TD, FMM and PM—designed the research study. NG, NM, AN, SV—performed the research. SV, NA, AA, KA, TD, FMM and PM—provided help and advice for the research. NM, SV, TD, NM and PM—analyzed the data. NG, NM, AN, SV and PM—wrote the manuscript; NA, AA, KA, FMM and TD—reviewed and edited the manuscript; NM, AN, SV and PM—supervised all steps of the research. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Prior to initiation of the study, an informed ethical consent and assent was obtained from the parents of all the children who had enrolled for the study. This was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Mahatma Gandhi Dental College & Hospital, Mahatma Gandhi University of Medical Sciences & Technology, Jaipur, India vide letter no. MGDCH/Dental/2020/1305.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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