

Evaluation of Caries Removal Efficacy Using BRIX 3000 and Atraumatic Restorative Treatment in Primary Molars: A Clinical Comparative Study

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ABSTRACT

Aim: The aim of the present study was to compare and evaluate the efficacy of two minimally invasive methods in the removal of infected carious dentin in primary molars.

Materials and methods: Eighty primary molars with class I occlusal caries involving dentin were selected and allocated to either of the two groups using convenient sampling. Group A ($n = 40$) caries were excavated using BRIX 3000 and in Group B ($n = 40$) atraumatic restorative treatment (ART) caries were excavated using hand instruments only. In both groups, caries removal efficacy was evaluated clinically using caries detection dye (Sable and Sleek), and the patient's discomfort level was noted using the Wong-Baker faces pain rating scale (WBFPS).

Results: The results indicated that BRIX 3000 was effective in the removal of caries from primary molars with a significant difference. While there was no statistically significant difference seen in pain perception on caries excavation using both the methods. Although, a mild discomfort was noted in Group B.

Conclusion: Comparing the two minimally invasive techniques, the new chemomechanical solution (BRIX 3000) was an effective method for the removal of caries from primary molars. So, it can be considered an alternative to the conventional caries removal method in treating pediatric dental patients.

Clinical significance: BRIX 3000 gel is effective in the removal of caries in children who are anxious and apprehensive as it is a noninvasive method of treatment in the pediatric age group.

Keywords: Atraumatic restorative treatment, BRIX 3000, Caries-detector dye, Wong-Baker faces rating scale.

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INTRODUCTION

Dental caries is fundamentally a preventable chronic health disease. It is characterized by the dissolution of enamel and dentin by acidogenic bacteria and fermentable carbohydrate which aids in bacterial penetration into the dentinal tubules. Recent global reports suggest that oral health has not improved in the last 25 years, with 573 million children with untreated dental caries in primary teeth.¹ While there have been constant efforts to decrease its prevalence, it is still widespread, especially in lower socio-economic classes and pediatric groups.

Minimal invasive dentistry ("prevention for extension") was developed to overcome these constraints, particularly in the pediatric age group, and instill a positive dental attitude by permitting maximal preservation of sound dental tissue that has the capability of remineralization. In contrast, using traditional rotary instruments to remove caries in children can result in excessive loss of healthy dental tissues, overextended cavities, and harmful heat to the vital pulp.² Moreover, the need for water coolant to prevent heat during the use of arotor increases the aerosol transmission and risk of contamination with bacteria, fungi, and viruses including coronavirus disease-2019 (COVID-19).³

Over the years, different techniques have been used to remove caries, including the use of arotor, aluminum oxide, air-abrasion, sono-abrasion, and polymer burs. The disadvantage with these materials was the potential loss of sound tooth structure and less tactile sensation.⁴

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Atraumatic restorative treatment has long been practiced in community-based set-ups and was developed in Tanzania in the mid-1980s. It is based on the principle of removal of caries using sharp sterile hand instruments and then filling them with an adhesive restorative material.⁵

Chemomechanical caries removal on the other hand bears promising and a viable alternative to the standard procedure in pediatric and medically compromised patients.⁶ This technique involves the use of a chemical product to soften the carious dentin or the degraded collagen followed by removal with gentle excavation.^{2,7}

In 1975, Habib et al. were the first to use 5% sodium hypochlorite to remove carious lesions. In later times various chemical compositions have been used as chemomechanical caries removal agents. These include GK-101, Caridex, Carie-care, Carislov, and Papacarie. Although Carisolv proved efficient in the removal of infected carious tissue, it could not be a practical alternative for drilling as it required a special instrument and preheating of the solution.⁸

In 2016, the name BRIX 3000 was given to one of the most recent modifications in the papain-based gel. This gel has high enzymatic activity due to a high proportion of papain (3000 U/mg) and bio-encapsulation (EBE) technology, which delivers the gel with the optimal pH to immobilize the enzyme at the moment of activating proteolysis in collagen, thus increasing its activity, which results in increased proteolysis of collagen fibrils, ultimately increasing its enzymatic activity.⁹

Various studies had been conducted to assess the efficacy of other chemomechanical methods. However, there are limited studies conducted on BRIX 3000. Hence the present study was conducted to compare and evaluate the efficacy of a chemomechanical method (BRIX 3000) and ART in removing infected carious dentin in primary molars.

MATERIALS AND METHODS

An *in-vivo* study was conducted in the Department of Pedodontics and Preventive Dentistry, Sri Siddhartha Dental College and Hospital, Tumkur, India. The study duration was 12 months. A written consent form was procured from the parent/guardian after being informed about the nature of the study. Ethical clearance was approved by the Institute's ethics and review committee (SSMC/Dent/IEC-6/October 2019), where 40 children were selected with bilateral caries. Sample size was calculated using the following formula: N (sample size) = $\frac{2 \times \{Z_{(1-\alpha/2)} + Z_{(1-\beta)}\}^2 \times \sigma^2}{d^2}$ and the total sample obtained was 40 in each group.

The inclusion criteria were healthy and co-operative children between 4 and 10 years of age, children with no history of any systemic disease, and patients with bilateral class I occlusal carious lesions in primary molars (Ekstrand et al. score 3). The exclusion criteria were the teeth with developmental anomalies, deep dentinal caries which are symptomatic (mobility, fistula, abscess), teeth that have already been restored or fractured, medically compromised and with a multisurface carious lesion.

A total of 80 primary molars with class I occlusal caries involving dentin as confirmed using intraoral periapical radiograph using paralleling technique were selected for the study.

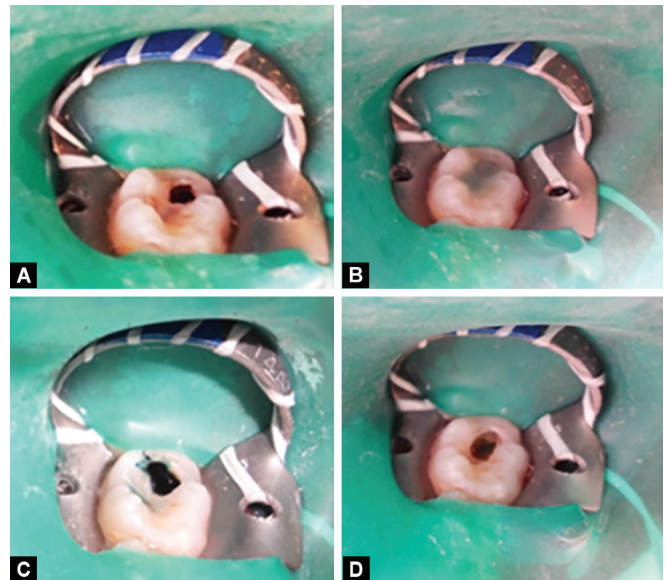
The selected teeth were allocated to either of the two groups using convenient sampling.

- *Group A* ($n = 40$): BRIX 3000 gel—caries was excavated using BRIX 3000.
- *Group B* ($n = 40$): ART technique—caries was excavated using a hand instrument.

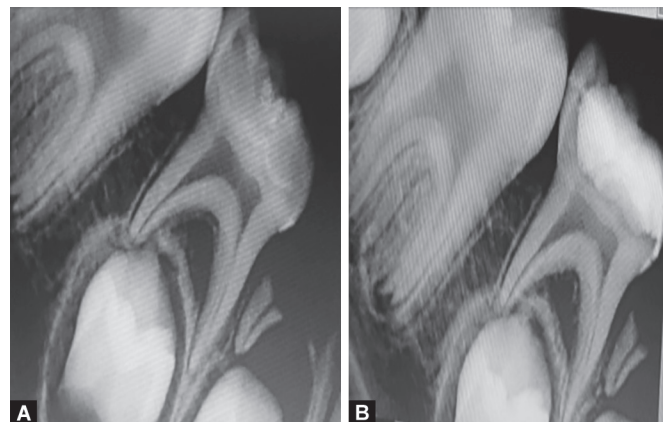
All the clinical procedures were carried out by two operators. The kappa for intraexaminer agreement and interexaminer reliability was 0.80.

Group A: Caries Removal by Chemomechanical Method (BRIX 3000)

BRIX 3000 gel (Argentina, BRIX SRL) was applied using a blunt spoon excavator and allowed to work for 3 minutes (Figs 1 and 2).



Figs 1A to D: BRIX 3000 procedure: (A) Class I occlusal caries on 85; (B) BRIX 3000 gel applied; (C) Caries detector dye applied; (D) Cavity after removal of caries detector dye



Figs 2A and B: BRIX 3000 procedure: (A) Preoperative; (B) Postoperative radiograph on 85

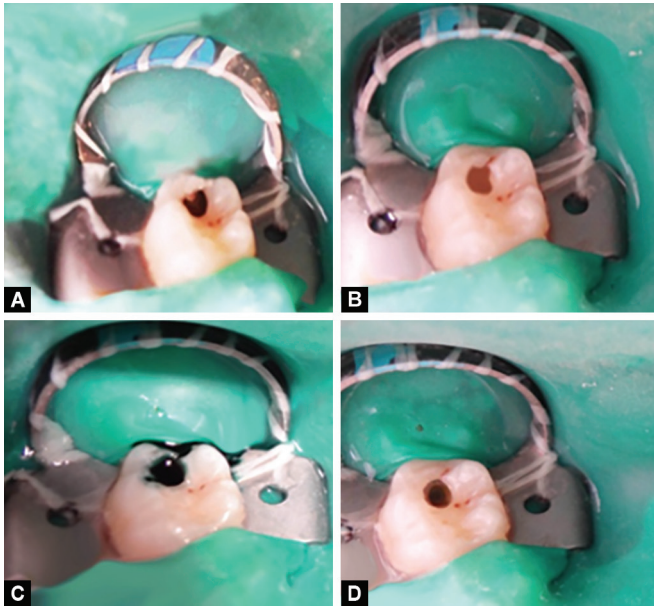
After 3 minutes of application, the caries was excavated gently with the blunt spoon excavator in a pendulum motion. BRIX 3000 gel was initially clear, but as a result of its effect (carious lesion decomposition), it darkened (turbid). The decomposed dentin was then softened and scraped away with a blunt spoon excavator under no pressure. The BRIX 3000 gel was applied 2–3 times until the healthy dentin was obtained.

Group B: Caries Removal by Atraumatic Restorative Treatment

Caries was removed using a sterile sharp spoon excavator until the point where hard dentin was obtained; later it was detected with the help of a probe at the base of the cavity (Figs 3 and 4).

Clinical Evaluation

In both groups, the cavity was inspected by tactile sensation and visual inspection to ensure that the carious lesion had been completely removed (Banerjee et al., 2000). The absence of any dentin discoloration was used as a visual criterion, while the smooth passage of the explorer without any catch or “tug-back” sensation



Figs 3A to D: ART procedure: (A) Class I occlusal caries on 75; (B) ART done 75; (C) Caries detector dye applied; (D) Cavity after removal of caries detector dye

was used as a tactile criterion. Additionally, caries detector dye (stable and sleek) was used to verify caries removal efficacy and was scored based on Munshi et al. criteria the dye was applied to the cavity with the help of a cotton pellet for 10 seconds and then rinse with saline.

After complete removal of caries in both the groups, the cavities were filled with type IX glass ionomer cement according to the manufacturer's directions. After the procedure was completed, the high points were checked with articulating paper. For protection, the restoration was coated with petroleum jelly.

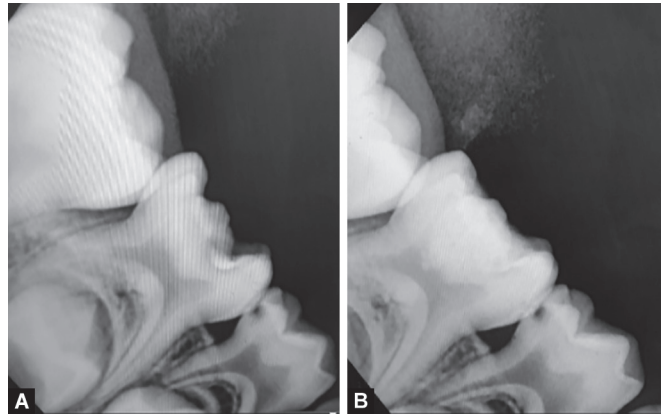
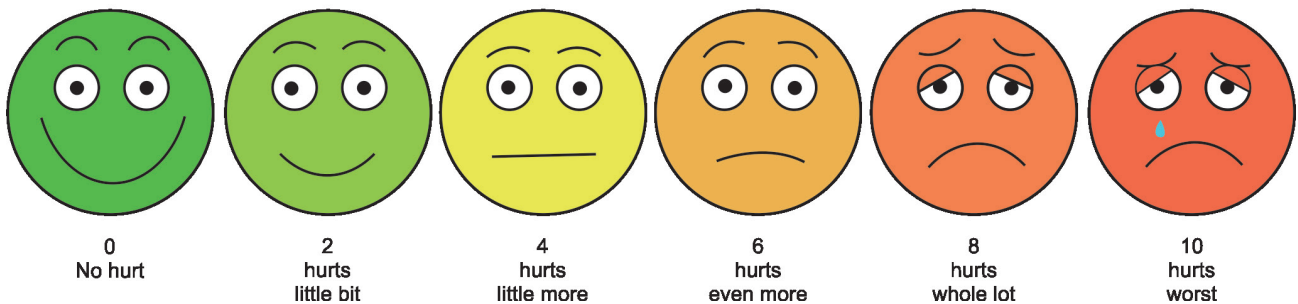
- 0 Caries removed completely
- 1 Caries noticed—at the base of the cavity
- 2 Caries noticed—at the base and/or one wall of the cavity
- 3 Caries noticed—at the base and/or two walls of the cavity
- 4 Caries noticed—at the base and/or more than two walls of the cavity
- 5 Caries noticed—at the base, walls, and margins of the cavity

Scoring criteria by Munshi et al.¹⁰

Pain Perception

Immediately after the treatment, Wong-Baker faces pain rating scale (WBFPS) was used for subjective evaluation of pain assessment in both the groups. It was done by asking the patient to choose a face that was similar to their own pain.

Wong-Baker faces pain rating scale



Figs 4A and B: ART procedure: (A) Preoperative; (B) Postoperative radiograph on 75

Statistical Analysis

Data were entered into an Excel sheet and statistical analysis was performed using the Statistical Package of Social Sciences (New York, version 21). The frequency and percentage of age were calculated for each group. For categorical data analysis, Pearson's Chi-square test was used. *p*-values <0.05 were considered statistically significant.

RESULTS

The sample consists of 40 children aged 4–10 years (Table 1 and Fig. 5). Table 2 and Figure 6 show frequency values of caries removal efficacy of chemomechanical caries removal agent (BRIX 3000) and ART in primary molars. The clinical assessment was done based on the scoring criteria starting from 0 to 5. Overall, a significant difference was noted when comparing the clinical efficacy of both groups. In BRIX 3000 group, 50% (score 0 and 1) of the teeth had caries removed, whereas in the ART group 14% (score 0) showed complete removal of caries was observed. Score 1 was observed in 13% of the teeth in the ART group. Comparison between both the groups gives a Chi-square value of 15.544 which shows a statistically significant difference of 0.001* (*p* <0.05).

Wong-Baker's pain rating scale showed no significant difference between the groups. The comparison of pain perception between both the groups gives a Chi-square value of 3.837 which showed no statistically significant difference of 0.147 (*p* <0.05) (Table 3 and Fig. 7).

DISCUSSION

Dental caries is one of the common pathoses seen in all age groups. The emphasis on the management of carious lesions has shifted to a biological and less-invasive approach. Therefore, the ultimate goal

Table 1: Distribution of children in the sample according to age

Age	N	(%)	Cumulative (%)
5	1	(2.5)	(2.5)
6	4	(10)	(12.5)
7	13	(32.5)	(45)
8	10	(25)	(70)
9	11	(27.5)	(97.5)
10	1	(2.5)	(100)
Total	40	(100)	

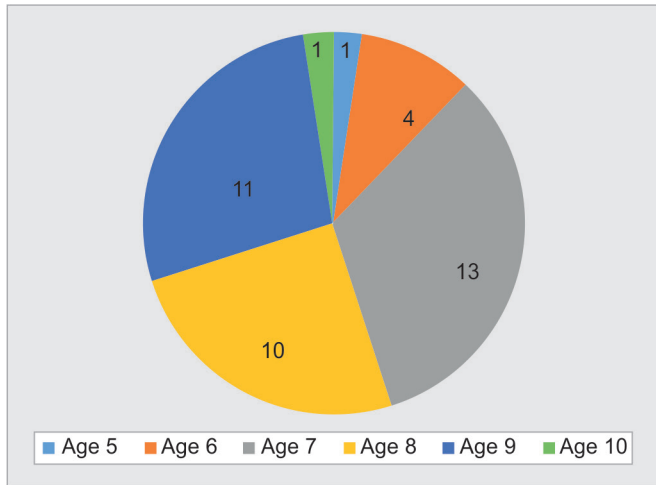


Fig. 5: Distribution of children in the sample according to age

Table 2: Caries removal efficacy of BRIX 3000 and ART based on the clinical assessment in primary molars

Scoring criteria	BRIX 3000	n (%)	ART	n (%)	Chi-square value	p-value
0	20	(50)	14	(35)	15.544	0.001*
1	20	(50)	13	(32.5)		
2	0	0	12	(30)		
3	0	0	1	(2.5)		
4	0	0	0	0		
5	0	0	0	0		

*p < 0.05 significant

of conservative restorative dentistry has been to remove infected dentin without compromising healthy dentin, which has the ability to remineralize.⁷

Macroscopically, two distinct layers are visible: the outer or infected layer, which cannot be remineralized due to microbial and organic matter contamination, and the inner or healthy layer, which has the ability to remineralize due to limited collagen degradation, and this layer should be preserved. The rationale for superficial caries removal is that proper restoration prevents the progression of bacteria by limiting the external nutrient supply for the bacteria, and gentle excavation prevents inadvertent removal of sound carious teeth.¹¹

A modern approach called minimal invasive dentistry (MID) has now been developed that follows the same principles of identifying, protecting, and restoring the tooth. The minimally invasive technique which has been used in this study is one of the recent concepts of caries removal. In the literature, the clinical applicability of BRIX 3000

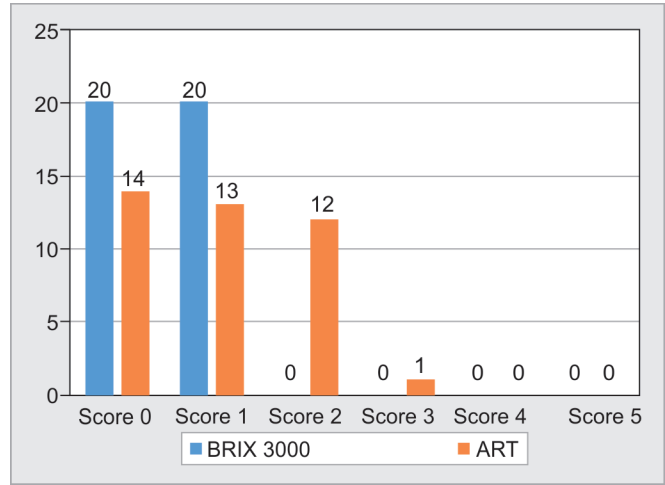


Fig. 6: Comparison of caries removal efficacy of BRIX 3000 and ART based on the clinical scoring in primary molars

Table 3: Perception of pain by the patient during caries removal using BRIX 3000 and ART in primary molars

Scoring criteria	BRIX 3000	n (%)	ART	n (%)	Chi-square value	p-value
0	25	(59.5)	30	(70)	3.837	0.147*
2	12	(30)	5	(12.5)		
4	3	(7.5)	5	(12.5)		
6	0	0	0	0		
8	0	0	0	0		
10	0	0	0	0		

*p < 0.05 significant

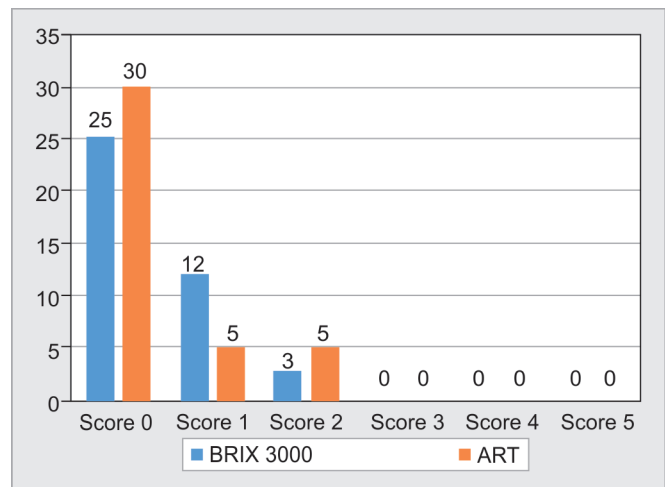


Fig. 7: Perception of pain by the patient during caries removal using BRIX 3000 and ART in primary molars

has been reported with conventional rotary instruments.⁹ Both ART and chemomechanical methods are based on a minimally invasive approach, aiming at minimal removal of dental tissue. ART has shown to be effective in cavitated caries lesion removal. Therefore, open carious lesion has been considered in this study. Conversely, chemomechanical technique uses chemicals to remove soften caries tissue with blunt manual instruments. The blunt instruments make the child less phobic as it does not cause any unnecessary pressure

on the affected dentin.¹² Anusavice et al.¹³ stated that the removal of infected dentin does not elicit any pain but when introduced into sound intact dentin creates unnecessary pain. This technique has been recommended for patients with special needs, phobic infants, and adults since it does not cause pain.

Papain gel, marketed as Papacarie[®], was first developed in 2003 in Sao Paulo, Brazil, as a chemomechanical caries removal agent. The papain protein interacts with collagen that has been exposed, leading to its breakdown. As a result, it softens diseased dentin thus making excavation easier. The most recent modification seen in papain gel is BRIX 3000 which was introduced in 2016. The enzymatic activity of this gel is claimed to be the highest when compared to other chemomechanical agents. The main component of this product is papain which helps in faster and more efficient degradation of collagen and it does not require any special armamentarium.⁹

Cohen's kappa test calculated intraexaminer reproducibility and interexaminer reliability for examination. The kappa for intraexaminer agreement and interexaminer reliability was 0.80. In the present study, pain perception was assessed in the age group of 4–10 years since child undergoes the stage of concrete operations in their cognitive behavior, and measurement of self-assessment pain is common in this age group. Hence, the reliability of this technique is adequately assessed in this study.¹⁴ It shows that low pain response was seen while using a chemomechanical gel which may be due to the papain content of the gel which acts only on the dead infected cells leaving behind undamaged healthy tissue. This was according to Ericson et al., who showed that chemomechanical approach is more comfortable than the traditional method. The presence of papain compound has a debriding anti-inflammatory effect that does not damage the healthy dental tissue. It helps in breaking the collagen but not to cut the dentin but to scape in pendulum motion, whereas in ART the operator tends to “dig” an excavator into the hard dentin, thereby opening more dentinal tubules which induce pain.^{15,16}

Kleinknecht et al.¹⁷ reported that dental anxiety mainly results from invasive dental procedures such as “injections and drilling”, while these are not needed with the use of CMCR agents. Abdul et al.¹⁸ stated that chemomechanical caries removal involves less pain than ART. This could be due to the BRIX 3000 group's use of blunt spoon excavators for caries excavation. Carlos et al.¹¹ had a similar opinion that the children who underwent chemomechanical caries removal showed lower pulse compared to those that underwent ART. However, both techniques showed minimal or absence of perceived pain. On the contrary, Adham et al.¹⁹ stated that patients reported more discomfort on caries excavation using the chemomechanical method when compared to ART which was not in accordance with the present study.

Caries detection dye (Stable and Sleek) has been used to confirm the effectiveness of caries removal in both groups. The visual and tactile criterion was used in this investigation since it is the most extensively used clinical criteria to assess caries removal. The difficulty of precisely and accurately diagnosing infected carious lesions by tactile and visual examination alone has been well-established, according to many systematic reviews and research.^{20–22} Although, such dyes have been demonstrated to be more effective than clinical evaluation in distinguishing between infected and partially demineralized dentin, they appear to stain the demineralized organic matrix rather than the bacteria. McComb claims that the dye lacks specificity and suggests that other clinical evaluation methods, such as visual and tactile examinations, should be used instead. As a result, the study combined all of the aforementioned evaluation approaches.²³

In the present study, 50% showed complete removal of caries while few showed caries remains still in the base of the wall. This is because the dye took up the maximum stain in the base compared to the wall, whereas in ART 32% of teeth showed incomplete removal of caries. Statistically, there was a significant difference in the efficacy of caries removal between chemomechanical and ART was seen (p -value 0.001).

Similar results were seen in the study conducted by Inamdar et al.⁷ where the efficacy of two chemomechanical methods Carie-care and BRIX 3000, and new smart bur was microbiologically assessed and concluded that among all the methods BRIX 3000 proves to be effective in the reduction of the bacterial count. This is due to the high papain concentration (3000 IU/mg). Santosh et al.²⁴ shared the same opinion on the efficacy of caries removal that Papacarie[®] as efficient as the conventional method in caries removal from open carious lesions with no significant difference. Sandra et al.⁶ also found that papain gel has been shown to be effective in the removal of caries by removing the need for anesthesia and the use of a bur, as well as lowering patient anxiety and preserving healthy tissue.

The proposed mechanism of action is that proteolytic action leads to chemical debridement by papain gel followed by degradation and elimination of fibrin mantle formed by the carious process. Later digesting the dead cells causes the breakdown of collagen molecules. Collagen molecules are broken down later when the deceased cells are digested. This damaged collagen is now chlorinated by chloramines, which also liberates oxygen, causing the gel to bubble and bleach. Chemically softened dentin is now excavated in a pendulum movement until the cavity looks clear, disrupting the hydrogen bond and affecting the secondary and quaternary structure.^{6,25}

BRIX 3000 is a biocompatible gel with antibacterial properties that reduces the need for anesthesia, removes just the affected tissue, and improves the preservation of healthy tissue. After using the gel, there is no evidence of the production of a smear layer. Without harming healthy tissue or creating pain, the gel combines an atraumatic treatment with antimicrobial qualities.²⁶

According to the findings of this study, BRIX 3000[®] is an effective method of caries removal and has shown to be a promising and successful treatment option for children of all ages. However, more tests involving microbiological validation are required to examine the outcomes of various excavation methods. This treatment has to be further studied to augment or complement existing ways of caries eradication in primary teeth.

Furthermore, in a country like India, the chemomechanical method of caries eradication is not cost-effective. Further studies to evaluate the feasibility and cost-effective method should be carried out in the dental program. However, since the outbreak of the COVID-19 pandemic, ongoing management through a minimally invasive approach will be required, as it exposes patients to a low risk of aerosol exposure, requires less local anesthesia, and can be completed in a short amount of time.

CONCLUSION

BRIX 3000 is a recent advancement in a chemomechanical agent that can replace the use of traditional instruments for caries excavation, especially in cases where children are anxious about the dental procedure. However, additional tests including microbiological validation are required and more research should be done on the cost-effective availability of chemomechanical caries removal agents for further use in pediatric dentistry.

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