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CLINICAL AND RADIOGRAPHIC EVALUATION OF 2.25% SODIUM HYPOCHLORITE GEL AND BRIX 3000 IN CARIES REMOVING OF DECIDUOUS TEETH

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ABSTRACT

Objective: Evaluation the efficacy of 2.25% sodium hypochlorite gel and Brix 3000 in caries removal of deciduous teeth. **Subjects and methods:** Thirty-six primary molars (class 1) with depth of caries not more than the coronal two thirds of dentine thickness. The children were aged 4-7 years and randomly divided into three equal groups based on the method of caries removal. The time of caries removal in each tooth was calculated using a stopwatch and the mean time of each method was obtained. The physical pain was also assessed by asking the children to choose the face that express their feeling using the Wong-Baker FACES analysis scale. The children were recalled for clinical and radiographic evaluation after 1 and 6 months. **Results:** The conventional method showed the shortest time $(2.82\pm0.477 \text{ min.})$ of caries removal followed by Brix 3000 (5.47 ± 1.35 min.) and 2.25% sodium hypochlorite gel (7.24 ± 1.45 min.). Concerning pain sensation; the conventional methods. The results showed no significant difference between 2.25% sodium hypochlorite gel and Brix 3000. The clinical and radiographic evaluation showed that there was no significant difference after 1 and 6 months between all groups. **Conclusion:** 2.25% sodium hypochlorite gel and Brix 3000 are effective chemomechanical caries removing agents.

KEYWORDS: 2.25% sodium hypochlorite gel, Brix 3000, chemomechanical caries removing agents.

INTRODUCTION

Dental caries is the most common destructive disease that lead to loss of tooth structure so dealing with this disease should be done early as just as possible to prevent its complications and preserve the tooth structure ⁽¹⁾. The conventional technique of dental caries removal using high-speed rotary instruments has many disadvantages such as heat generation, pain sensation, extensive removing of dental tissues. Moreover, recently a research advocated that the air borne droplets generated during the conventional caries removal can cause cross- infection by air borne viruses ⁽²⁾. Minimally invasive dental caries removal techniques are a new concept which developed in dentistry to overcome the disadvantages of conventional caries removal these techniques were developed to conserve the dental tissues during dental caries removing process and using dental adhesive filling materials ⁽³⁾.

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The chemomechanical technique of dental carries removing is one of the techniques of minimally invasive dentistry which is based on application of Chemomechanical dental caries removing agent on the carious dental tissues for suitable time for softening and easy removing of carious tissues by hand excavators ⁽⁴⁾. Chemomechanical caries removing agents are available in dental market in different types and names. These agents can be classified into two categories according to their composition; the first category is sodium hypochlorite based Chemomechanical dental caries removing agents and the second category are enzyme based chemomechanical dental caries removing agents ⁽⁵⁾.

Sodiumm hypochlorite 2.25% gel is a recent sodium hypochlorite-based chemomechanical caries removing agents which prepared in gel form by the action of carboxy methyl cellulose for viscous consistency of the agent to be more controllable during the application on the dental carious lesions ⁽⁶⁾. Brix 3000 is also a recent enzyme based Chemomechanical dental caries removing agent. It based mainly on papain enzyme which prepared by E.B.E (Encapsulating Buffer Emulsion) technology that allowing the highest possible concentration of the papain enzyme which equal 3000 U/mg⁽⁷⁾. Thus, the present study was directed to evaluate the efficacy of both 2.25% sodium hypochlorite gel and Brix 3000 in dental caries removing of deciduous teeth and pain sensation assessment of the children during this procedure in compare to the conventional method of dental caries removal.

SUBJECTS, MATERIALS AND METHODS

Study design:

Prospective randomized controlled clinical study.

Study setting and population:

Outpatients clinic department of faculty of Dental Medicine, Cairo, Al-Azhar University.

Sample size:

Based on previous study investigating the effect of Brix 3000 on caries removing of deciduous teeth; 30 teeth were selected as a sample size ⁽⁸⁾. This sample size was calculated using G*power Program version 3.1.9.4. This sample showed effect size =1.17, with α error = 0.05 and power = 80.0%. The recommended calculated sample size will be 10 in each group and by adding 20% to compensate for possible drop out then the total calculated sample size will be 12 in each group hence the total investigated teeth were 36.

Clinical Study: This clinical study was carried out on thirty-six carious primary molars without pulp involvement. The children teeth were selected from outpatient's clinic Pedodontics and Oral Health department Faculty of Dental Medicine, Cairo, Al-Azhar University.

Ethical consideration:

This study was approved by Ethical Committee of Faculty of Dental Medicine, Boys, Cairo, Al-Azhar (code: 305/2799). All parents will sign an informed written consent form (Attached copy) before treatment beginning.

Eligibility Criteria (6,9,10):

Inclusion criteria:

The ages of children should be 4-7 years, should have open cavitated primary molars class 1 not extended more than the coronal two thirds of the crown, intact lamina dura and normal periodontium.

Exclusion criteria:

Teeth showing pulp involvement, sever tooth destruction (unrestorable), obliteration of the pulp or root canal, presence of bone loss, physiologic or pathologic root resorption either internal or external and radiolucency at the furcation or periapical region.

Procedures:

The selected 36 teeth from 30 patients were classified according to method of caries removal into three equal groups;

- **1. Group** (**A**): Dental caries was removed by using 2.25 % sodium hypochlorite gel.
- **2. Group (B):** The caries was removed by using Brix 3000.
- **3. Group(C)** (**Control group):** Dental decay was removed by using conventional technique.

Intervention (6, 9, 10)

- 1. Personnel data collection.
- 2. Medical and dental history taking.
- 3. Clinical and radiographic examination.
- 4. EMLA 5% Anesthetic cream (AstraZeneca Biopharmaceutical Company, England) was applied for five minutes on the gingiva which surround the carious tooth of the study.
- 5. The rubber dam clamp was applied on the intended tooth supragingivaly without injection of local anesthesia.
- Caries detecting dye (Sable seek, Ultradent Products Company, USA) was used for identifying the carious tissues.
- 7. Dental caries removing according to the technique of each group:
 - 2.25% sodium hypochlorite gel (Group A) 2.25% sodium hypochlorite gel was applied for two minute (for standardization) on carious tissues then spoon shaped hand excavator was used in bandolym movement away from the dental pulp for dental caries removing. Dental probe and dye were used to detect any residual carious tissues. The procedure was repeated till complete dental caries removal.

- Brix 3000 (Group B): Brix 3000 (Brix medical science company, Argentina) was applied for two minutes (according to manufacturer's instruction) on carious tissues then spoon shaped hand excavator was used in bandolym movement away from the dental pulp for dental caries removing. Dental probe and mirror were used to detect any residual carious tissues. After dental caries removing the caries a detecting dye was applied several times post caries removal till complete dental caries removal.
- Conventional technique (Group C): High speed round bur (BR-40EF, MANI Inc Company, Japan) revolved at high speed contra angled hand piece was used for dental caries removing. Dental probe and mirror were used to detect any residual carious tissues. After dental caries removing the caries detecting dye was used for insuring of complete dental caries removing of the tooth. These steps were being repeated until complete dental caries removal.
- 8. A stop watch was used for calculating the required time of complete dental caries removing starting from the beginning of dental caries removing until insurance of complete dental caries removing.
- Immediately after complete caries removal, the children were asked to select the face of Wong-Baker FACES analysis scale that best illustrates the physical pain they are experiencing.
- Adhesive final restoration (Medifill IX forte AC, Promedica Dental Material GmbH Company, Germany) was used immediately after dental caries removing for restoring these cavities.
- 11. The child was recalled for clinical and radiographic examination after one month and six months.

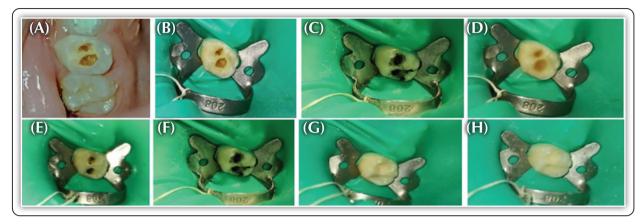


FIG (1) Clinical procedure of chemomechanical caries removal (A): Preoperative clinical picture. (B): Rubber dam application. (C): Caries detecting dye application. (D): Application of chemomechanical caries removing agent. (E): Beginning of caries removing by hand excavator. (F): Reapplication of caries detecting dye. (G): Complete caries removal. (H): Final restoration.

Observation:

The required time of complete dental caries removing: starting from the beginning of dental caries removing and includes all steps of residual dental caries detection were recorded and tabulated.

Pain sensation assessment: Wong-Baker Faces analysis scale which consists of six pictures of the facial expressions ranged from smiling to crying and has numbers zero, two, four, six, eight and ten was use for children assessment of pain sensation that they experienced during caries removal process. The child is asked to select the picture of the facial expressions that best illustrates the physical pain they are experiencing during the treatment (Fig.2).

Clinical and radiographic follow up: The children teeth were assessed after one month and six months clinically to detect any abnormal condition as Pain, Swelling, Palpation sensitivity, periapical lesions, widening of periodontal space, internal or external resorption and alveolar bone loss.

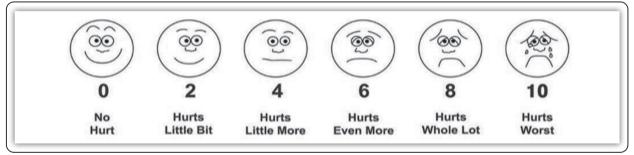


FIG (2) Wong-Baker Faces Pain Rating Scale.



FIG (3) Radiographic follow up (A) Preoperative x-ray. (B): Immediate post-operative x ray. (C): One Month later. (D): Six months later.

Preparation of 2.25% sodium hypochlorite gel:^(6,11)

Distilled water (130 ml) was added to 30 ml of 12% sodium hypochlorite solution for producing 160 ml of 2.25% sodium hypochlorite solution according to the chemical equation C1(concentration) V1(volume)=C2(concentration) V2(volume).

Carboxy methyl cellulose was added to the solution of 2.25% sodium hypochlorite Slowly during continues slow mixing for producing the gel form of 2.25% sodium hypochlorite by the action of the magnetic stirrer device for homogenous distribution and proper mixing the gel components.

Statistical analysis

The collected data was revised, coded, tabulated, and analyzed using SPSS program software, version 22.0. One Way ANOVA test was used to compare between the quantitative data with normal distribution. Statistical significance level was set at 5% (p<0.05 is considered statistically significant).

RESULTS

These primary molars were classified randomly into three equal groups (n=12) according to the

method of dental caries removing. The age of children in this study was ranged from 4-7 years. The mean ages were age 4.5 ± 0.45 , 4.91 ± 0.79 , and $4.75 \pm 0.62y$ for groups A, B & C respectively. On comparing the children's ages it was found that there are no statistically significant differences (*P*>0.05) between the three groups (Table1).

Also, it found that the number of girls was 18(50%) while number of boys was 18(50%). Group A has 7(58.3%) males and 5(41.7%). Group B has 5(41.7%) males and 7(58.3%). Group C contains 6(50.0%) males and 6(50.0%) females. Also on comparing the children's gender it was found that there are no statistically significant differences (*P*>0.05) between the three groups (Table1).

The required time of complete dental caries removing

This study demonstrated that the mean of required time of complete dental caries removing for groups (A, B and C) were $2.82\pm0.477, 5.47\pm1.35$ and 7.24 ± 1.45 respectively. The results showed statistically high significant difference between all groups of the study (Table 2).

Character	Conventional method n=12	Brix 3000 n=12	2.25% Sodium hypochlorite gel n=12	Significance
Age/years	6.39±1.8	6.51±1.02	6.45±0.58	P1=0.425
Mean±SD				P2=0.214
				P3=0.312
Gender	N(%)	N(%)	N(%)	P1=0.68
Male	7(58.3%)	5(41.7%)	6(50.0%)	P2=0.68
Female	5(41.7%)	7(58.3%)	6(50.0%)	P3=0.414

TABLE (1) Comparison of the subjects' demographic data in each group.

One Way ANOVA-test *Significant at $P \le 0.05$

**High significant difference at $P \le 0.01$

P1: Comparison of Conventional method and Brix 3000.

P2: Comparison of Conventional method and 2.25% Sodium hypochlorite gel.

P3: Comparison of Brix 3000 and 2.25% Sodium hypochlorite gel.

Time of dental caries removing /minutes	Conventional method n=12	Brix 3000 n=12	2.25% Sodium hypochlorite gel n=12	Significance
Mean±SD	2.82±0.477	5.47±1.35	7.24±1.45	P1=0.001** P2<0.001** P3<0.001**

TABLE (2) Comparison between the three groups regarding to the time of caries removal/minutes.

**High significant difference at $P \le 0.01$

P₁: Comparison of Conventional method and Brix 3000.

P₂: Comparison of Conventional method and 2.25% Sodium hypochlorite gel.

* Significant at $\mathbf{P} \leq 0.05$.

P₃: Comparison of Brix 3000 and 2.25% Sodium hypochlorite gel.

Pain sensation assessment

One Way ANOVA-test

The data of pain sensation assessment in group A showed that just one child (8.3%) was select grade (6), five children (41.7%) were select grade (8) and six children (50%) were select grade (10). While in Group B, one child (8.3%) was select grade (2), seven children (58.3%) were select grade (4), three children (25%) were select grade (6) and one child (8.3%) was select grade (8). Furthermore, pain assessment in Group C children demonstrated that one child (8.3%) was select grade (2), five children

(41.7%) were select grade (4), four children (33.3%) were select grade (6) and two children (16.7%) were select grade (8). On comparing the data of selected grades in all group, it was found that the conventional method was the most painful method followed by 2.25% sodium hypochlorite gel group and Brix 3000 group methods respectively. Moreover, it showed high significant with the two chemomechanical methods of caries removal. At the same time there was no statistical significant difference between Brix 3000 group and 2.25% sodium hypochlorite gel group (Table 3).

TABLE (3) Comparison of pain sensation among the children in each group.

Pain Sensation	Conventional method N=12(%)	Brix 3000 N=12(%)	2.25% Sodium hypochlorite gel N=12(%)	significance
Mean±SD	8.8333±1.33712	4.6667±1.55700	5.1667 ± 1.80067	$P_1=0.000**$ $P_2=0.000**$ $P_3=0.433$

One Way ANOVA-test * Significant at $P \le 0.05$

** High significant difference at $P \le 0.01$

P₁: Comparison of Conventional method and Brix 3000.

P₂: Comparison of Conventional method and 2.25% Sodium hypochlorite gel.

P₃: Comparison of Brix 3000 and 2.25% Sodium hypochlorite gel.

Clinical follow up:

Absence of pain

Concerning pain presence, it was found that in group A at one month follow up none of the treated children complained of pain, only child complained of pain at six months. In group B no child came with pain at one month follow up while at six months there was only one child suffering from pain. However, all group C children showed no pain complaint all over the study periods of clinical follow up. However, although group C showed the highest success rate than that of groups A and B concerning pain complaints but there are no significant differences between the groups in regard to pain presence (Table 4).

Absence of swelling

According to swelling presence, no molar of all groups came with periapical swelling at one month or six months follow up. Subsequently, there were no differences between all groups depending on swelling presence (Table 4).

Absence of palpation sensitivity

After one month and six months of clinical follow up, the conventional method group and Brix3000 group showed that all the treated molars had no palpation sensitivity. Meanwhile, group C showed that only child complained of palpation sensitivity at six months. However, although group C showed the lowest success rate than groups A and C concerning palpation sensitivity complaints, there are no significant differences between the groups (Table 4).

Character	Interval		Group A n=12		Group B n=12		Group C n=12		Sign.
			Ν	%	Ν	%	Ν	%	
Absence of pain —	<u> </u>	NO	0	0.0	0	0.0	0	0.0	
	One month	Yes	12	100%	12	100%	12	100%	
	Six months	No	1	8.3%	1	8.3	0	0.0	P ₂ =1.0
		Yes	11	91.7%	11	91.7%	12	100%	$P_3 = 1.0$
Absence of	One month -	No	0	0.0	0	0.0	0	0.0	
		Yes	12	100%	12	100%	12	100%	
	Six months	No	0	0.0	0	0.0	0	0.0	
		Yes	12	100%	12	100%	12	100%	
Absence of palpation – sensitivity	<u> </u>	No	0	0.0	0	0.0	0	0.0	
	One month	Yes	12	100%	12	100%	12	100%	P ₃ =1.0
		No	0	0.0	0	0.0	1	8.3	$P_2 = 1.0$ $P_3 = 1.0$
	Six months	Yes	12	100%	12	100%	11	91.7%	

TABLE (4) Comparison between the clinical follow up of all groups of the study.

One Way ANOVA-test * Significant at $P \le 0.05$

** High significant difference at $P \le 0.01$

P1: Comparison of Conventional method and Brix 3000.

P2: Comparison of Conventional method and 2.25% Sodium hypochlorite gel.

P3: Comparison of Brix 3000 and 2.25% Sodium hypochlorite gel.

Radiographic follow up:

Absence of external or internal resorption/Absence of alveolar bone loss

Regarding the external or internal resorption and alveolar bone loss, surprising all groups gave the same results. At one month and six months assessment, no molar of all groups came with alveolar bone loss or external or internal resorption. Consequently, there was no difference between all groups regarding presence of external or internal resorption and alveolar bone loss (Table 5).

Absence of periapical lesion

Concerning periapical lesion, it was found that none of the treated children in groups A and C showed lesion at periapical region at one month follow up. Only one child complained of periapical lesion at six months in both groups. While in group B, no child came with periapical lesion at one month or six months follow up. However, although Brix 3000 group showed the highest success rate than that of groups A and C concerning periapical lesion complaints, there are no significant differences between the groups (Table 5).

Absence of widening of the periodontal membrane

All teeth in group A and C showed normal periodontal membrane space at 1 and 6 months follow up. While one tooth in group B showed widening of the periodontal membrane at 6m follow up only. However, although group B showed the lowest success rate than that of groups A and C concerning widening of periodontal membrane, there are no significant differences between the groups (Table 5).

TABLE (5) Comparison between the radiographic follow up of all groups of the study.

Character	Interval		Group A n=12		Group B n=12		Group C n=12		Sign.
			Ν	%	Ν	%	Ν	%	
Absence of	One month	No	0	0.0	0	0.0	0	0.0	
		Yes	12	100%	12	100%	12	100%	
periapical lesion	<u> </u>	No	1	8.3%	0	0.0	1	8.3%	$P_1 = 1.0$ $P_3 = 1.0$
	Six months	Yes	11	91.7%	12	100%	11	91.7%	
		No	0	0.0	0	0.0	0	0.0	
Absence of external	One month	Yes	12	100%	12	100%	12	100%	
or internal	Six months	No	0	0.0	0	0.0	0	0.0	
resorption		Yes	12	100%	12	100%	12	100%	
Abaanaa of	One month	No	0	0.0	0	0.0	0	0.0	
Absence of widening of periodontal space		Yes	12	100%	12	100%	12	100%	
	Six months	No	0	0.0	1	8.3	0	0.0	P ₁ =1.0
		Yes	12	100%	11	91.7%	12	100%	$P_{3}^{1}=1.0$
Absence of alveolar bone loss		NO	0	0.0	0	0.0	0	0.0	
	One month	Yes	12	100%	12	100%	12	100%	
	Six months	No	0	0.0	0	0.0	0	0.0	
		Yes	12	100%	12	100%	12	100%	
One Way ANOVA-test *Sign		ificant at	$P \le 0.05$		** High s	ignifican	t difference	at $P \le 0.01$	

P2: Comparison of Conventional method and 2.25% Sodium hypochlorite gel.

P3: Comparison of Brix 3000 and 2.25% Sodium hypochlorite gel.

^{**} High significant difference at $P \le 0.01$

P1: Comparison of Conventional method and Brix 3000.

DISCUSSION

Dental caries is the most dangerous disease worldwide which can destroy the dental tissues and affect their function. Dental caries treatment techniques should be improved and be less destructive to keep the vitality and integrity of the remaining dental tissues ⁽¹²⁾. For many years conventional rotary method is the most common reliable method of caries removal due to its effectiveness and Time consuming. However, it has multiple complications such as pain sensation, excessive loss of tooth structures, heat generation and psychological trauma for many patients. So in the last years, Chemomechanical caries removing technique was developed to overcome these shortages ⁽¹³⁾.

This study was reported the Brix 3000 is effective in dental caries removing of primary Molars and that is agree with the study of Srinath et al., 2021⁽¹⁴⁾ who reported Brix 3000 is effective chemo mechanical dental caries removing agent for occlusal caries removal of the extracted primary teeth. Also the clinical trial of prabhav et al., 2019⁽¹⁵⁾ reported the Brix 3000 is effective minimally invasive chemo mechanical dental caries removing agent for the primary teeth.

The present study reported that 2.25% sodium hypochlorite gel was effective as caries removing agent for primary molars. These results were in agreement with Alkhouli et al., 2020⁽⁶⁾ study who stated that 2.25% sodium hypochlorite gel is effective and well-tolerated method of primary teeth caries removal. However, this study was in disagreement with the study of Dammaschke et al., 2005⁽⁶⁾ who reported that sodium hypochlorite gel (0.5%) is not effective in dental caries removing as Carisolv. While Alkhouli et al., 2020⁽⁶⁾ stated that the method, concentration and quality of sodium hypochlorite gel have direct effects on the efficacy of sodium hypochlorite gel in dental caries removing.

Our study reported that the mean of required time of complete caries removing of the conventional method was lower than Brix 3000 and the highest mean of required time of complete caries removing is owned to 2.25% sodium hypochlorite gel this result was in agreement with the study of Alkhouli et al., 2020⁽⁶⁾ who reported the shortest time for dental caries removing is carried out by the conventional method, followed by Brix 3000 and followed by 2.25% sodium hypochlorite gel. Also the study of Santos et al., 2020⁽⁸⁾ was in agreement with these results and reported the conventional method of dental caries removing has shorter time than Brix 3000.

The results of this study showed statistically significant differences between pain sensation assessment of the children between the conventional method of dental caries removing and chemo mechanical dental caries removing agents (Brix 3000 and 2.25% sodium hypochlorite gel). Also the results showed no significant difference in pain sensation assessment between the two chemo mechanical dental caries removing agents. These results were in agreement with the study of Alkhouli et al., 2020⁽⁶⁾ who used Wong-Baker Faces analysis scale for pain sensation assessment. Also the study of Dogra et al., 2021⁽¹⁶⁾ who used Wong-Baker Pain Scale for pain sensation assessment and reported that was significant difference of pain perception between the conventional method and chemomechanical caries removal technique. Also, this study results were in agreement with the study of Cardoso et al., 2020⁽¹⁷⁾ who reported that the chemo mechanical dental caries removing agent Papacaire had less pain and superior acceptance by patients in compare to the conventional method of caries removal.

The clinical and radiographic success rates of conventional method group after six months follow up in this study was 91.7% and this result was in agreement with the study of Peric et al., 2009⁽¹⁸⁾ that reported 90% success rate of the conventional caries removing technique after one-year clinical follow-up in 3-17y old patients.

However, the clinical and radiographic success rate of Brix 3000 group was the same of the conventional technique success rate (91.7%) after six months evaluation. This result was compatible with Bussadori et al., 2014⁽¹⁹⁾ who investigate a similar composition substance [Papacarie (papain enzyme based chemomechanical caries removing agent)] and achieve 88.1% success rate in 3-5y old children primary teeth after one year follow up.

The current study reported 91.7% success rate in 2.25% sodium hypochlorite gel group after six months of evaluation. This result was compatible with Ali et al., 2020⁽²⁰⁾ study that reported 76.6% success rate in badly decayed permanent teeth treated with carisolv (NaOCl based chemomechanical caries removing agent) after 2 years follow up.

In comparing between the three groups, all groups showed the same success rate after 6 m of clinical and radiographic follow up. Also the results showed significant only between the conventional caries removal group and the other two groups of chemomechanical groups on regard to pain sensation. While on regard to caries removal time the conventional group came first then Brix 3000 group followed by 2.25% sodium hypochlorite gel group with highly significant differences between groups. Generally, these results in agreement with Alkhouli et al., 2020⁽⁶⁾, Santos et al., 2020⁽⁸⁾, Dogra et al., 2021⁽¹⁶⁾, Cardoso et al., 2020⁽¹⁷⁾, Peric et al., 2020⁽²⁰⁾

CONCLUSION

- 1. Both 2.25% sodium hypochlorite gel and Brix 3000 were effective in dental caries removing and should be considered effective chemome-chanical dental caries removing agents.
- Chemomechanical caries removing agents had lower pain sensation effect hence it is more acceptable for children than the conventional method of dental caries removing so it can be used as painless caries removal technique.

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