

Clinical Evaluation of Papacarie in Primary Teeth

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*The change in the concepts of cavity preparation and the development of reliable adhesive materials lead to the development of alternative methods of caries removal. Chemo-mechanical caries removal (CMCR) involves the chemical softening of carious dentin, followed by its removal with gentle excavation. **Objective:** The present study was conducted to evaluate clinically the efficiency of caries removal using a new chemo-mechanical agent (Papacarie) compared to the conventional drilling method including the need for local anesthesia, the need for drill, duration of the treatment and the pain reaction. **Study design:** This study was split mouth design. The study was performed on thirty seven bilateral open carious lesions. They were divided into two equal groups according to method of caries removal. In Group I, caries was removed using the Papacarie system and in Group II, caries was removed with the conventional drill. **Results:** The results showed that the Papacarie was as efficient as the drill in caries removal from open carious lesions with no significant difference in the operating time. The new CMCR agent also reduced significantly the need for local anesthesia and the use of drill. In addition, Papacarie was also more comfortable than the traditional rotatory instruments. **Conclusions:** It was concluded that Papacarie could be an effective caries removal method to treat children, particularly those who present with early childhood caries or management problems.*

Keywords: Chemo-mechanical caries removal; Papacarie; Dentin caries; Primary teeth; Pain
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INTRODUCTION

Studies on dental anxiety have revealed that injection and drill were reported to be the most highly stressful factors in producing pain during dental treatment.¹ Hence, a painless technique is one of the keys to avoid dentally fearful and uncooperative patients, and a skill every pediatric dentist should strive to master.²

Chemo-mechanical caries removal involves the chemical softening of carious dentin, followed by its removal with gentle excavation. It involves the selective removal of

degraded collagen fibrils in carious dentin lesion, while preserving the affected demineralized dentin layer.³

Development of a clinically effective caries removal reagent which is harmless to healthy tissue and biocompatible to the pulp is fundamentally difficult. Since the 1970s, many chemical compositions have been used for chemo-mechanical caries removal. These included: GK-101, Caridex, Carisolv and enzymes.³

Although the last product, the Carisolv, was effective in removing infected carious tissue, it did not prove to be a practical alternative to drilling. This was mainly because of its high cost, need of special instruments and more time consumption. Also children dislike its chlorine taste and odor.⁴

Papacarie[®] (Fórmula & Ação (F & A), São Paulo (SP) – Brazil) is a chemo-mechanical caries removal product composed of papain, chloramine, toluidine blue, salts and a thickening vehicle.⁵ It obtains a synergistic action from each of its components that facilitates the removal of the decay with highly antimicrobial properties.⁶ Papain is a proteolytic enzyme similar to the human pepsin. It is a cheap raw material that comes from the latex of the leaves and fruits of the green adult papaya “*Carica papaya*.”⁷ Papaya is widely used in the biomedical area due to its healing and its anti-inflammatory potential.^{8,9,10}

Regarding its application in the field of dentistry, researches were limited to its use in toothpastes as a non-abrasive whitening agent.^{11,12} Few studies were done to

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evaluate its efficiency in caries removal.^{5,13,14}

The aim of this study was to evaluate clinically the efficiency of caries removal using a new chemo-mechanical agent (Papacarie) compared to the conventional drilling method.

MATERIALS AND METHODS

This study is a clinical controlled trial (split mouth) where two methods of caries removal were compared in the same patient.

The study included a total of 37 healthy children aged 5-9 years. Each child had two contralateral primary teeth, showing comparable open carious lesions. A total of 74 primary teeth were included (60 teeth that required Class V cavity preparations and 14 molars that required Class I cavity preparations).

Selection criteria

Teeth were selected according to the following criteria.^{15,16}

- 1–Bilateral open carious lesions with dentin involvement, but not involving the pulp. The access opening of the carious lesion had to be large enough to allow the penetration of the excavator.
- 2–No proximal caries as evidenced by bitewing radiographs.
- 3–Asymptomatic vital teeth, without clinical or radiographic evidence of pulp, furcation or periapical pathoses.

Teeth were divided into 2 groups according to the method of caries removal. Each group consisted of 37 teeth. *Group I*: the test group, caries was removed using the chemo-mechanical agent (Papacarie). *Group II*: the control group, caries was removed using the conventional drilling method.

Clinical procedures

Treatment was carried out according to the following steps:

- No local anesthesia was given, unless required.
- Partial isolation was done using cotton rolls and saliva ejector.⁵
- Caries removal was performed using either of the two methods:

Group I: Using the chemo-mechanical method⁵ (Figures 1-8)

The Papacarie[®] was taken out of the refrigerator ten minutes before treatment to reach room temperature. The carious cavity was filled with Papacarie[®], and the gel was allowed to work for 60 seconds. The fresh gel is clear, but after its application, the gel denatured the non-structured collagen fibers of the carious lesion and became turbid or darkish in color. The softened decayed dentin was scraped away with a blunt excavator in a pendulum movement. The softened tissue was scraped away but not cut within. The gel was reapplied whenever a darkish color was evident. This indicates that the decomposition of the decayed tissue is still in process. The procedure was repeated until the gel

appeared clear and reached an unchanged light color indicating that the infected carious dentin was removed. Cavity was examined by visual inspection and tactile sensation¹⁵ using a mirror and an explorer to assess caries removal. Caries was considered removed when the explorer did not stick in dentin and did not give a tug-back sensation. The remaining gel was removed with a cotton-pellet soaked in water.

Group II: Using conventional drilling method

Caries was removed using a high speed hand piece under cooling system with a #330 carbide bur. The cavities were checked for remaining caries using the same criteria used for the chemo-mechanical caries removal.

After caries removal by either method, cavities were restored using composite resin according to the manufacturer’s instructions.

Assessment procedures

For each patient, the following was recorded:

Pain reaction using Sound, Eye and Motor scale (SEM) according to Wright *et al.*¹⁷

It is an objective method for pain assessment where measurement of comfort was taken according to three types of observations; sound (S), eyes (E) and motor (M). The level of response for each observation, according to Table 1, was given a numerical value (score) and these values were averaged to obtain the comfort level.

Table 1. Sound, Eye and Motor scale (SEM) according to Wright *et al*

Observation	Comfort or pain level			
	Score 1 Comfort	Score 2 Mild discomfort	Score 3 Moderately painful	Score 4 Painful
Sounds	No sounds indicating pain	Non-specific sounds; possible pain indication	Specific verbal complaints, e.g. "OW", raises voice	Verbal complaints indicates intense pain, e.g. scream , sobbing
Eyes	No eye signs of discomfort	Eye wide, show of concern, no tears	Watery eyes, eyes flinching	Crying, tears running down face
Motor	Hands relaxed; no apparent body tenseness	Hands show some distress or tension; grasps chair due to discomfort, muscular tension	Random movement of arms or body without aggressive intention of physical contact grimace , twitch	Movement of hands to make aggressive physical contact e.g. punching, pulling head away

The need for local anesthesia which was given if the patient scored more than 2 in any of the Sound, Eye and Motor pain scale (SEM).¹⁷

In the chemo-mechanical treatment group, the selective use of a drill to either complete caries removal or to finish the enamel margins was recorded.

The total working time, taken for caries removal and cavity preparation with either method, was recorded in minutes

using a stopwatch. When anesthesia was given, time was recorded twice:

1- The total working time of caries removal including

time of anesthesia administration.

2- Only the operative time of caries removal excluding time of anesthesia administration.



Figure 1. A preoperative photograph of a 5½ year old child with cervical caries in the mandibular primary canines.



Figure 4. Cloudy appearance of the gel indicating the decomposition of the decay tissue.



Figure 2. Application of the Papacarie gel in the mandibular right primary canine.



Figure 5. Scraping away the carious dentin from the mandibular right primary canine using a blunt excavator.



Figure 3. Clear appearance of the fresh applied gel.



Figure 6. The color of the reapplied gel appears unchanged after complete caries removal.



Figure 7. The appearance of the cavity after complete caries removal using the Papacarie gel.



Figure 8. A postoperative photograph of the same patient in Figure 1 after composite resin restorations of the mandibular canines.

RESULTS

Table 2 and 3 show the distribution of the sample according to age, gender, location and consistency of the carious lesion.

Table 2. Distribution of the sample according to age and gender

Age	Min- max	5- 9.2
	Mean ± SD	6.5 ± 4.2
Gender	Male: N (%)	17 (45.9)
	Female: N (%)	20 (54.1)

Table 3. Distribution of the sample according to location and consistency of the carious lesion

CHARACTERISTICS		PAPACARIE N (%)	CONVENTIONAL METHOD N (%)
		Total No = 37	Total No = 37
Class	Class I: N (%)	7 (18.9)	7 (18.9)
	Class V: N (%)	30 (81.1)	30 (81.1)
Lesion location	Upper	16 (43.2)	16 (43.2)
	Lower	21 (56.8)	21 (56.8)
Tooth	Canine	30 (81.1)	30 (81.1)
	First molar	3 (8.1)	3 (8.1)
	Second molar	4 (10.8)	4 (10.8)
Lesion consistency	Soft	4 (10.8)	4 (10.8)
	Medium	33 (89.2)	33 (89.2)

Table 4. Comparison between test and control as regards the need for local anesthesia in different lesion classes

LESION CLASS	NEED FOR ANESTHESIA	PAPACARIE N (%)	CONVENTIONAL METHOD N (%)	TOTAL N (%)	P VALUE OF MCNEMAR TEST
Class I	Without anesth	7 (100)	0 (0)	7 (50)	0.02*
	With anesth	0 (0)	7 (100)	7 (50)	
	Total	7 (50)	7 (50)	14 (100)	
Class V	Without anesth	30 (100)	9 (30)	39 (65)	<0.0001*
	With anesth	0 (0)	21 (70)	21 (35)	
	Total	30 (50)	30 (50)	60 (100)	
Total	Without anesth	37 (100)	9 (24.3)	46 (62.2)	<0.0001*
	With anesth	0 (0)	28 (75.7)	28 (37.8)	
	Total	37 (50)	37 (50)	74 (100)	

anesth: local anesthesia administration; *: Statistically significant; No statistically significant difference between Class I and Class V in conventional method group as regards need for anesthesia (P value of Fisher exact test P= 0.16).

In the present study, the new chemo-mechanical caries removal method (Papacarie) was as efficient as the conventional method in caries removal in all cases. The explorer passed smoothly over the remaining dentin surface and there was absence of a catch and tug-back sensation.

Table 4 shows a comparison between test and control groups as regards the need for local anesthesia in different lesion classes. In the chemo-mechanical group, no cases received local anesthesia. However, in the conventional group, local anesthesia was given in 28 out of 37 cases (75.7%) with significant difference between the two groups (P <0.0001). Table 5 shows the frequency distribution of the use of drill in the Papacarie group according to the two classes. In 97.3% of the Papacarie cases, the drill was not needed.

Table 6 shows the mean time for caries removal (in minutes) in both test and control groups according to cavity preparation when time of anesthesia administration was excluded in the drill group. The mean time was 4.89 ± 1.05 for the Papacarie group, and 4.50 ± 1.83 for the drill group. When time of anesthesia administration was included, the mean working time significantly increased as shown in Table 7.

Sound, eye and motor scale for pain assessment is presented in table 8 as well as figure 9. In the Papacarie group,

Table 5. Frequency distribution of the use of drill in the Papacarie group according to the two classes

USE OF DRILL	CLASS I N (%)	CLASS V N (%)	TOTAL N (%)
Not used	6 (85.7)	30 (100)	36 (97.3)
Used	1 (14.3)	0 (0)	1 (2.7)
Total	7 (100)	30 (100)	37 (100)
P value of Fisher exact test	0.19 NS		

NS: Not statistically significant

Table 6. Mean time for caries removal (in minutes) in both test and control groups according to cavity preparation when time of anesthesia administration was excluded in the drill group.

LESION	PAPACARIE MEAN ± SD	CONVENTIONAL METHOD MEAN ± SD	PAIRED T TEST	P VALUE
Class I	6.05 ± 0.73	5.75 ± 3.24	0.23	0.83 NS
Class V	4.66 ± 0.96	4.25 ± 1.36	1.66	0.11 NS
Total	4.89 ± 1.05	4.50 ± 1.83	1.35	0.19 NS
T test	3.38	1.12		
P value	0.002*	0.31 NS		

*: Statistically significant

NS: Not statistically significant

Table 7. Mean time for caries removal (in minutes) in both test and control groups according to cavity preparation when time of anesthesia administration was included in the drill group.

LESION	PAPACARIE MEAN ± SD	CONVENTIONAL METHOD MEAN ± SD	PAIRED T TEST	P VALUE
Class I	6.05 ± 0.73	9.69 ± 2.45	3.56	0.02*
Class V	4.66 ± 0.96	8.19 ± 4.53	4.66	<0.0001*
Total	4.89 ± 1.05	8.44 ± 4.26	5.46	<0.0001*
T test	3.38	0.78		
P value	0.002*	0.44 NS		

*: Statistically significant

NS: Not statistically significant

Table 8. Comparison between test and control as regards Sound, Eyes and Motor scale for pain assessment

LOCATION	SCORES	PAPACARIE N (%)	CONVENTIONAL METHOD N (%)	Z OF WSRT P VALUE
Class I	Score 1 (comfort)	2 (28.6)	-	2.43
	Score 2 (mild discomfort)	5 (71.4)	-	
	Score 3 (moderately painful)	-	5 (71.4)	0.02*
	Score 4 (painful)	-	2 (28.6)	
	Median score	2 (mild discomfort)	3 (moderately painful)	
Class V	Score 1 (comfort)	17 (56.7)	1 (3.3)	4.87
	Score 2 (mild discomfort)	13 (43.3)	8 (26.7)	
	Score 3 (moderately painful)	-	9 (30)	<0.0001*
	Score 4 (painful)	-	12 (40)	
	Median score	1 (comfort)	3 (moderately painful)	
Total	Score 1 (comfort)	19 (51.4)	1 (2.8)	5.41
	Score 2 (mild discomfort)	18 (48.6)	8 (21.6)	
	Score 3 (moderately painful)	-	14 (37.8)	<0.0001*
	Score 4 (painful)	-	14 (37.8)	
	Median score	1 (comfort)	3 (moderately painful)	

WSRT: Wilcoxon signed ranks test

*: Statistically significant

No statistically significant difference between Class I and Class V scores of Papacarie (Z of Mann Whitney U test= 1.32, P= 0.19), and in conventional method group (Z of Mann Whitney U test= 0.43, P= 0.67)

51.4% of the cases demonstrated comfort and 48.6% mild discomfort. The median score of SEM scale in this group rated comfort during the treatment procedure. In the drill group, 2.8% of the cases demonstrated comfort and 21.6% mild discomfort during drilling, while 37.8% of the cases complained of moderate pain and 37.8% of intense pain. The SEM median score of this group rated moderately painful with a significant difference between the two groups (P < 0.0001).

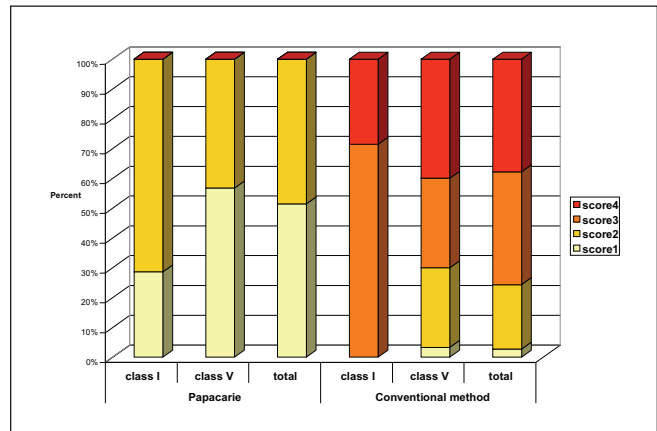


Figure 9. Pain scores distributed according to cavity preparations in both methods of caries removal

DISCUSSION

The development of caries removal techniques in restorative dentistry is progressing towards a more biological and conservative direction. The chemo-mechanical caries removal technique became an area of interest in dental researches due to its concept of tissue preservation. As only carious dentin is removed, the painful removal of sound dentin is avoided and hence, the need for local anesthesia is minimized.³

The latest production of chemo-mechanical caries removal "Papacarie" has been developed in Brazil in order to overcome the clinical limitations of other products. The present study was performed to assess the efficiency of this new product to remove carious lesion in primary teeth.

Complete caries removal was assessed by the most widely used visual and tactile criteria according to Ericson.¹⁵ The color of the gel was another clinical indicator as no more turbidity was observed after complete caries removal.⁵ Dyes were not used, as their use does not provide a completely objective method for the assessment of caries removal. They deeply penetrate and stain carious infected dentin as well as the porous affected dentin. It has therefore been clearly demonstrated that dyes may lead to over preparation of the cavity^{18,19} especially in primary teeth because primary dentin is more porous.²⁰

The results of this study indicated that Papacarie is efficient in caries removal from open and accessible occlusal and buccal lesions. This finding is in agreement with Culquicóndor,⁶ Silva *et al*^{13,14} and Bussadori *et al*.²¹

In the present study, the Papacarie system reduced significantly the need of drill, where it was used in only one case to finish the enamel margins but not to complete the caries removal (Table 5). Papacarie acts by breaking the partially degraded collagen molecules, contributing to the degradation and elimination of the fibrin "mantle" formed by the carious process.^{5,6} The attack causes cleavage of the polypeptide chains and hydrolyses the cross-links of collagen fibrils. Right after the degradation, oxygen is freed, and this explains the appearance of bubbles on the surface and the blurring of the gel during the clinical procedure. These signs demonstrated that the removal process can be started.⁵ The chemical agent was found to have no ability to affect the sound collagen fibers in the inner affected and normal dentin, as papain can digest only dead cells because infected tissues lacks or do not show anti-trypsin which inhibits protein digestion.⁵

In the present study, the Papacarie system significantly reduced the need for local anesthesia compared to the conventional method (Table 4). This might be attributed to the fact that Papacarie softens only the infected layer of carious dentin, which is insensitive with no odontoblastic processes.^{22,23} Consequently, this softening reduces the pressure required for caries removal by excavation. Drills, on the other hand, can remove caries-infected and caries-affected dentin simultaneously, with possible extension into the underlying sound dentin, thereby opening more dentinal tubules. This is usually accompanied by pain and necessitates the application of local anesthesia during treatment,^{24,25}

In the test group, cases treated completely using the Papacarie gel were only considered in analysis of time required for caries removal, while the case, which was finished with the bur, was excluded. The operative time in this case was too high compared to the rest of the group. So it was an outlier that affected the mean. In this study, the working time was comparable in both methods of caries removal

when time of anesthesia administration was not included. A possible explanation is that carious lesions in this study were open and accessible for hand instruments and the drill was not used in almost all of the cases. Also, the lesion consistency was either soft or medium. Since the total chair time was found to influence the child's behavior,²⁶ the time taken for anesthesia administration was also recorded in this study and added to the working time in both groups. The results indicated that local anesthesia took additional time and significantly increased the total chair time needed for the drilling method to 8.44 ± 4.26 minutes (Table 7).

Pain is difficult to quantify in young children.²⁷ So, an objective scale was used to assess pain in this study. The SEM scale was used to measure sound, eye and motor components of the child's response to pain stimulation.¹⁷ The Papacarie group experienced significantly less discomfort compared to the drill (Table 8). This finding is probably due to lack of sound, vibrations and pain. Patients might also be content by the absence of anesthesia. This assumption is supported by the results of Bedi *et al*²⁸ and Locker *et al*²⁹ who reported that the patient's strongest fear are caused by injection followed by the drill.

CONCLUSIONS

From the results of the present study, it was concluded that:

- 1–Papacarie is efficient in removing caries from cavitated primary teeth.
- 2–The new chemo-mechanical caries removal agent appears to be more comfortable than the conventional method as it reduces the need for local anesthesia and the use of drill.
- 3–The working time with Papacarie in open lesions is comparable to that of drill when time of local anesthesia was not included.
- 4–The technique is simple and does not need training.

It appears from the results of the present study that the utilization of Papacarie as a mean for caries removal in opened dentinal lesions has presented encouraging outcomes. It can be an effective method to treat children, particularly those who present with early childhood caries or management problems. It could also be extended as an alternative treatment in a school dental service and homes for mentally and physically disabled. However, further studies and a strict analysis of the viability of its routine utilization are recommended.

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