Chemomechanical Caries Removal in Primary Molars : Evaluation of Marginal Leakage and Shear Bond Strength in Bonded Restorations" – An *in Vitro* Study

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Objectives : To evaluate and compare the efficiency, marginal leakage and shear bond strength of Carisolv and Papacarie in primary molars. **Method:** Freshly extracted 60 human carious primary molars were randomly divided into two experimental groups - Group I [caries removal by Carisolv] and Group II [caries removal by Papacarie]. The amount of time taken for complete caries removal was recorded using a stopwatch. After bonded restorations, both the experimental groups were further randomly subdivided into four experimental groups and subjected to marginal leakage and shear bond strength evaluation. **Results :** Papacarie [337.67 ± 18.13] was clinically more efficient than Carisolv [461.33 ± 27.76] in removing caries with respect to time in seconds. 66.7% of teeth treated with Carisolv did not show any marginal leakage as compared to 20% with Papacarie. The mean [\pm SD] shear bond strength of Carisolv [9.67 ± 3.80] treated teeth was slightly more when compared to Papacarie [8.36 ± 4.51]. **Conclusion :**Papacarie was clinically more efficient in caries removal but showed significantly more marginal leakage than Carisolv.

Keywords: Carisolv, Papacarie, clinical efficiency, marginal leakage, shear bond strength.

INTRODUCTION

hemomechanical method of caries removal was first introduced in 1975 by Habib *et al*¹ by using 5% sodium hypochlorite, which was followed by introduction of GK – 101, Caridex system,^{2,3} and Carisolv,⁴ consisting of sodium hypochlorite, glutamic acid, leucine and lysine. But because of their certain disadvantages like short shelf life, high corrosiveness, requirement of specialized instruments and high cost, in 2003, a research project in Brazil by Bussadori *et al*⁵ led to the development of new formula to universalize the use of chemomechanical method for caries removal which is commercially known as Papacarie6, that contains 10% papain, 0.5% chloamine – T, toluidine blue and a thickening agent.

The failure in the interaction between adhesive system and tooth substrate yields poor marginal sealing with consequent marginal leakage, which may lead to early loss of the restoration, post operative sensitivity, discoloration, marginal deterioration and secondary caries, ultimately leading to displacement of the restoration and pulpal damage. It is known when Carisolv is used, it will lead to the removal of organic material as well as the smear layer. Conse-

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quently the dentin becomes more permeable, which facilitates adhesive system penetration and may increase resin composite bonding to the tooth. Due to micromorphologic alterations, after the use of chemomechanical agents marginal leakage and variations in shear bond strength may occur. The effectiveness of adhesive material bonding after the use of Papacarie, however is unknown.⁷ There are few studies related to the efficiency of chemomechanical agents on carious primary dentin and its success with the bonded restorations. Hence the aim of the present study was to evaluate and compare the caries removal efficiency of the above two chemomechanical caries removal agents, marginal leakage and shear bond strength in bonded restorations in primary molars.

MATERIALS AND METHOD

The present study was carried out in the Department of Pedodontics and Preventive Dentistry, Rajarajeswari Dental College and Hospital, Bangalore, India, after getting approval from ethical committee of the same institution. Freshly extracted 60 human primary molar with occlusal caries extending into the dentin and accessible to hand instruments were collected. These teeth were extracted due to periodontal and/or orthodontic reasons. The patients for the same, were selected by random sampling technique. An informed consent was taken from the patient's parent/guardian prior to the extraction procedure. The primary molars with occlusal caries extending into dentin and the same confirmed through intraoral periapical radiograph were included in this study. Whereas teeth involving pulpal and/or periapical pathology, teeth involving multisurface carious lesions and teeth with developmental anomalies wee excluded. The surfaces of teeth were cleaned with Hufriedy universal scaler and no.11 blade for removal of calculus and remnants of periodontal ligament. These teeth were stored in formalin 2% [pH=7.0] for 14 days and subsequently in saline solution. Sixty primary molars were

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then randomly divided into two experimental study groups-

Experimental group I [30 teeth] - carious tissue removed by Carisolv.

Experimental group II [30teeth] – carious tissue removed by Papacarie.

Experimental group 1: Carisolv (Mediteam) gel was used through the Multimix Syringe Dispenser. The gel was dispensed onto a dappen dish. It was then applied onto the dentinal carious lesion using a plastic filling instrument. The lesion was completely covered by the gel for thirty seconds. On application, the gel was clear, but became opaque or cloudy when it was contaminated with the debris during removal. Following this, the softened dentin was gently excavated using Star 1 and Star 3 double ended excavator (Mediteam) as per manufacturer's instructions. The soften carious dentin was scraped and not cut, so that it does not promote any kind of stimulus or pressure. The material was re-applied for another thirty seconds till complete removal of caries was achieved. The cavity was wiped with a moistened sterile cotton pellet and rinsed.

Experimental group II: Papacarie (Formula and Acao) gel was dispensed onto a dappen dish. It was then applied onto the dentinal carious lesion using a plastic filling instrument. The lesion was completely covered by the gel for thirty seconds. When the gel was cloudy, it was removed gently by scrapping with the spoon excavator without applying pressure. The softened tissue was scrapped, but not cut. The gel was re-applied for another thirty seconds till the cavity appeared vitreous which indicated that the cavity was completely free of caries. The cavity was wiped with a moistened sterile cotton pellet and rinsed.

The complete removal of caries in both experimental groups was judged by visual and tactile methods.

Criteria for evaluation of complete removal of caries 8

- 1. The visual criteria- absence of any discoloration.
- 2. The tactile criteria- the smooth passage of the explorer and absence of a catch or a tug-back sensation.

The amount of time taken for complete removal of caries was recorded using a stopwatch. AdaperTM easy one self etch adhesive (3M) was applied and restored with composite Z250 [3M], as per the manufacturer's instructions. After restorations, both exper-

 Table 1. Comparison of amount of time required for complete removal of caries between experimental group I and group II.

Time required to	Group I	Group II
remove caries in		[Papacarie]
seconds.	(11 = 30)	(11 = 30)
Minimum time	410	310
Maximum time	520	360
Mean time	461.33	337.67
Median time	460.00	340.00
SD	27.76	18.13
	Significantly less time was required to	
Inference remove the caries in Group II c		Group II compared
	to Group I with $p < 0.001$.	

imental groups were stored in saline at 37° C for 72 hours separately and on removal were polished with abrasive rubber cup in slow speed handpiece in order to remove the saline remnants. Both experimental groups were subjected to thermocycling in distilled water at 5°C and 55°C ($\pm 2°$ C), for 100 thermal cycles for 30 seconds.

Both the experimental groups were further randomly subdivided into the following subgroups-

Experimental group I A (15 teeth) - Carisolv treated teeth undergoing marginal leakage test.

Experimental group I B (15 teeth $\,$ - Carisolv treated teeth undergoing shear bond strength test.

Experimental group II A (15 teeth) - Papacarie treated teeth undergoing marginal leakage test.

Experimental group II B (15 teeth) - Papacarie treated teeth undergoing shear bond strength test.

Marginal leakage test

Experimental group I A and group II A received two coats of nail varnish on the entire tooth surface except for the restoration and a 1mm rim of tooth structure around the restoration and was allowed to air dry. The apices up to the furcation were sealed with sticky wax. Both the experimental groups were then immersed in basic fuchsine 2% dye for 8 hours separately. After 8 hours teeth were washed in tap water for 10 minutes and air dried. This was followed by longitudinal sectioning of teeth in two sections at the centre of the restoration with diamond disc in slow speed handpiece and water coolant. Stereomicroscope (40X) was used to evaluate the amount of marginal leakage. Scores from 0 - 3 was assigned depending upon the amount of dye penetration.

Scores for evaluation of marginal leakage: -7

- 0- No penetration.
- 1- Penetrate only in the surround enamel.
- 2- Penetrate into dentin.
- 3- Penetrate into cavity floor.

Scores of both sections were evaluated and the worst score was recorded.



Graph 1. Comparison of amount of time required for complete removal of caries between experimental group I and group II.

Marginal leakage	Group IA [Carisolv] (n=15)	Group IIA [Papacarie] (n=15)
No penetration	10 (66.7%)	3 (20.0%)
Penetration at surrounding enamel	3 (20.0%)	3 (20.0%)
Penetration in dentin	2 (13.3%)	7 (46.7%)
Penetration into cavity floor	0	2(13.3%)
Inference	Marginal leakage was significantly more in Group II A as compared to Group I A with p = 0.032.	

 Table 2.
 Comparative evaluation of marginal leakage between group
 I A and II A.
 II A.<

Shear bond strength test

Experimental group I B and group II B were stored in distilled water for 2 days after thermocycling. The teeth were then mounted on acrylic resin blocks and subjected to Lloyd testing machine (LR50K) with a crosshead speed of 1mm/minute. To evaluate shear bond strength values were recorded in MPa.

Statistical Analysis

The data obtained was tabulated and subjected to statistical analysis. Unpaired 't' test was used for assessing caries removal efficiency and shear bond strength where as Chi Square test and Fischer Exact test were used to assess marginal leakage.

RESULTS

Table 1 and Graph 1 shows superior clinical efficiency of Papacarie [(337.67 ± 18.13 seconds), when compared to Carisolv (461.33 ± 27.76 seconds) with respect to total amount of time required for

complete removal of caries. Table 2 and Graph 2 show significant amount of marginal leakage with Papacarie treated teeth (80%) when compared to those treated with Carisolv (33.33%). Table 3 and Graph 3 shows slightly higher mean (\pm SD) shear bond strength for Carisolv (9.67 \pm 3.80 MPa), when compared with Papacarie treated teeth (8.36 \pm 4.51 MPa).

DISCUSSION

In order to conduct the investigation under the conditions of daily clinical practices, the efficiency of caries removal was judged by standard clinical criteria. It has been suggested that conventional visual and tactile criteria are sufficient to ensure the removal of most infected dentin.⁹ Dyes were not used, as their use does not provide a complete objective method for 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 especially in primary teeth because primary dentin is more porous.¹⁰ At the same time, the extracted teeth may respond to caries excavation differently than the teeth in function, since an outward flow of fluid has been reported in vivo dentin.¹¹ This was partly ameliorated by using freshly extracted teeth.

In the present *in vitro* study, the clinical efficiency of Papacarie was found superior when compared to Carisolv with respect to total amount of time required to remove caries (Table and Graph No 1). Various studies have reported that Carisolv and Papacarie took longer time for caries removal when compared to rotary instruments.^{1,12-25} The mean time taken for complete removal of caries by Carisolv and Papacarie was 7.68 minutes and 5.60 minutes respectively which was in accordance with the studies conducted by various authors.^{12,13,15,23,24,25}

The possible reason for Papacarie, being more clinical efficient in removing caries with respect to time could be due to its mechanism of action. Papacarie acts by breaking the partially degraded



Graph 2. Comparative evaluation of marginal leakage between group I A and II A.

Shearbond strength in MPa	Group IB [Carisolv] (n=15)	Group IIB [Papacarie] (n=15)
Minimum strength	3.42	2.46
Maximum strength	15.47	20.44
Mean strength	9.67	8.36
Median strength	8.05	7.62
SD	3.80	4.51
Inference	Mean shearbond strength was not statis- tically significant between two groups with p = 0.396.	

 Table 3.
 Comparative evaluation of shear bond strength between group I B and group II B.

collagen molecules, contributing to the degradation and elimination of the fibrin 'mantle' formed by the carious process. The attack causes cleavage of the polypeptide chains and hydrolyses the cross links of collagen fibrils. After the degradation, oxygen is freed, and this explains the appearance of bubbles on the surface and blearing of the gel during the clinical procedure. These signs demonstrated that the removal process has been started. 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 lack or do not show anti trypsin which inhibits protein digestion.5 Whereas Carisolv's proteolytic action is aimed at denatured proteins present in carious dentin, so that sound and carious dentin become readily separable. During its application on carious lesions, several reactions act in concert to disrupt the fiber structure of collagen and have a softening effect on carious tissue,25 which might explain the long duration of time taken for complete caries removal, when compared to Papacarie.

The depth of carious lesions is an important parameter for the excavation time.^{15,16,18} The operator found that pulpal caries on the floor was easier to instrument than the caries on the walls of the preparation. This could explain why Carisolv was less efficient with respect to time required for complete removal of caries, inspite of specially designed instruments with their neutrally angled blade that allowed for scrapping action in two or more directions in contrast to spoon excavator used for Papacarie removal of caries, which only had one working direction.

Chaussain Miller *et al* reported that the chemomechanical method is of less interest for small cavities because of lack of visibility and access.¹⁶ However in the present study cavities selected were open and readily accessible to hand instruments. In clinical practice, carious lesions can often be difficult to reach and additional use of rotary instruments may be needed.

In the present study significant amount of marginal leakage was seen with Papacarie treated teeth (80%) than those treated with Carisolv (33.33%) (Table and Graph 2; Figures 1 - 4). Carisolv is capable of decreasing marginal leakage after composite resin restorations. The highly irregular surfaces or high roughness without a smear layer in Carisolv cavities could provide a suitable surface for good adhesion or strong bonding with restorative materials.⁷ According to Feda, it is not known whether Carisolv treatment prevents smear layer formation or whether a smear layer is produced



Graph 3. Comparative evaluation of shear bond strength between group I B and group II B.

during the scrapping of carious dentin, which Carisolv treatment then removes, leaving patent dentinal tubules.²⁶ Whereas according to Doglas, caries removal with Carisolv does not produce smear layer, resulting in greater opening of the dentinal tubules, which optimizes the penetration of the adhesive system.²⁷ Hosoya reported that Carisolv is more effective in removing the smear layer and smear plugs in primary dentin than in permanent dentin.²⁸

According to Michelle, use of Papacarie for caries removal, led to irregular surfaces with the predominance of an amorphous layer in flakes covering the dentinal tubules. In some areas, locations similar to the presence of smear layer were observed, but with microfractures. This could be the reason for high amount marginal leakage seen in Papacarie treated teeth.²⁹ Another possible reason could be presence of an effervescent surface activity following excavation using Papacarie, which could be an indication of oxygen release, potentially affecting the polymerization of the bonding mechanism.³⁰

Self etch adhesive system do not completely resolve or remove the smear layer, but rather partly integrate into the hybrid layer and they have relatively high bond strength to enamel and dentin and have been designed to simplify clinical procedures and hence used in this study.³¹ Self etching system lacks the rinsing step and thus the smear layer is not removed. Due to this, partially demineralized remnants of the gel could be stagnated on the dentin surface, and could potentially interfere with the bonding mechanism.³⁰

Evaluation of shear bond strength between Carisolv and Papacarie did not show any statistically significant difference in our study. The mean (\pm SD) shear bond strength for Carisolv was found to be 9.67 \pm 3.80 MPa, whereas Papacarie showed 8.36 \pm 4.51 MPa. This result was in accordance with the study conducted by Michelle ,who reported a mean shear bond strength of 10.87 \pm 5.97 MPa between Papacarie treated demineralized slabs and resin composite.²⁹ Feda, reported a mean shear bond strength of 6.69 \pm 4.08 MPa between Carisolv treated primary carious dentin and resin composite. Bond strength values depend on laboratory equipment and instrumentation, reflecting specimen geometry, sample preparation, surface area, storage protocols, strain used to debond specimens and operatory variability.²⁶ This study used thermocycling to mimic the 24- hour intraoral environment. The specimens were ther-



Figure 1. Specimen (experimental group I A) showing no penetration of dye.



Figure 3. Specimen (experimental group II A) showing penetration of dye into dentin.

mocycled 100 times, since more than 100 cycles have been shown to be unnecessary.³²

The marginal leakage and shear bond strength are independent parameters to evaluate the quality of adhesion between restorative materials and dental tissues.³³ The use of natural lesions in the present study, did not allow standardization of all variables of sample, eg: shape of lesions, activity status of the lesions, location, type of lesions, consistency and the depth. Hence long term clinical studies are required to critically evaluate the relevance of these *in vitro* results.

CONCLUSION

From the present study following conclusions were drawn

- Papacarie showed high clinical efficiency when compared to Carisolv, with respect to total amount of time required for complete removal of caries.
- Papacarie showed more marginal leakage when compared to Carisolv in bonded restorations.

Shear bond strength of Carisolv and Papacarie did not show any statistically significant difference.



Figure 2. Specimen experimental group I A) showing penetration of dye in the surrounding enamel.



Figure 4. Specimen (experimental group II A) showing penetration of dye into the cavity floor.

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