

Clinical evaluation of carisolv® in the chemico-mechanical removal of carious dentin

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The Chemo-mechanical caries removal technique involves the application of chemical agents, to cause a selective softening of the carious dentine and facilitate removal by gentle excavation. Carisolv® is one such new chemical agent used in this minimal invasive technique of carious dentine removal. The present study was, therefore, undertaken to evaluate the efficacy of Carisolv® in the chemo-mechanical removal of carious dentine, the time taken for caries removal, the perception of the treatment by the patient, and to evaluate the restorations, radiographically. Accordingly, fifty primary and permanent molars with dentinal carious lesions were excavated using this technique of caries removal. The chemo-mechanical caries removal technique using Carisolv® proved to be an effective atraumatic treatment modality with potential interest for use in clinical pediatric dentistry.

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INTRODUCTION

Pain during the invasive treatment of dentinal caries is quite a common phenomenon often inducing fear and anxiety in children.¹ The minimal removal of infected carious dentine, together with the use of a therapeutic restorative material is a fundamental requirement of modern operative dentistry. Minimal intervention dentistry eliminates the pain associated with the removal of carious dentine, thereby providing a gentle introduction to dental treatment in children.

In recent years, with the advent of adhesive restorative materials and the subsequent developments in minimal cavity design, the widely accepted principle of "Extension for Prevention" proposed by G.V. Black, in the operative treatment of carious lesion has been challenged and is now considered too destructive a method for caries removal.²

The other techniques used in carious dentine removal include the mechanical rotary or non-rotary instruments, chemo-mechanical caries removal system and lasers. The non-rotary, non-invasive techniques include air-abrasion, air-polishing, ultrasonic and sono-abrasion. The chemo-mechanical caries removal system, based on the principle of minimal invasive dentistry involves the application of substances like Caridex® and Carisolv®.^{2,3}

In the 1980's, the chemo-mechanical caries removal system involving the application of Caridex™ was tried. But use in clinical practice was limited because of the need for increased volumes of the solution, prolonged period of time to complete the procedure, and a short shelf-life.⁴

To overcome these limitations, a new product for chemo-mechanical caries removal named Carisolv® was launched with renewed interest. It selectively removes carious dentine, thereby avoiding the painful removal of sound dentine. It involves the chemical softening of carious dentine within a short period after application, followed by removal with gentle excavation.⁵

The present study was, therefore, conducted with the following:

Aims and Objectives

1. To clinically evaluate the efficacy of Carisolv® in the removal of carious dentine.
2. To evaluate the time taken for caries removal.
3. To evaluate perception of the treatment by the patient.
4. To radiographically evaluate the restorations, immediately and after a period of six months.

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Figure 1. The new Carisolv® twin Multimix Syringe Dispenser.

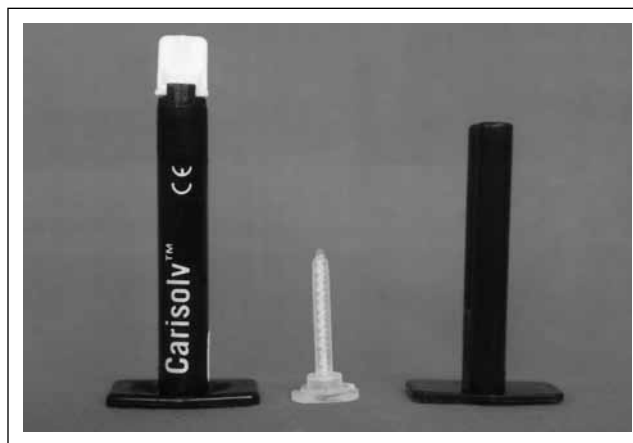


Figure 2. The parts of the new Carisolv® twin Multimix Syringe Dispenser: syringe, static mixer, plunger.

MATERIALS AND METHODS

This study was designed to evaluate the effectiveness of CARISOLV® in the chemo mechanical removal of carious dentine.

Carisolv® is a gel based chemo-mechanical caries removal system, marketed by Mediteam, Co (Sweden). It consists of two basic components. One is a **transparent liquid** containing 0.5% sodium hypochlorite. The other component is a **red gel** containing 0.1M mixtures of three amino acids, leucine, lysine and glutamic acid. Carboxymethylcellulose enhances the viscosity. Erythrosine dye stains the carious dentine. Sodium hydroxide provides a pH of 11. Sodium chloride and purified water act as a vehicle.

The delivery system is termed as the “new Carisolv® twin Multimix Syringe Dispenser” (Figure 1). It mixes the two components in equal proportions, resulting in the active gel, which is then applied onto the carious lesion. It consists of 3 parts (Figure 2): (1) a syringe containing the dual components of Carisolv®, (2) static mixer that mixes the two components and (3) a plunger to dispense the mixed gel.

INCLUSION CRITERIA

Children, who presented to the Department of Pedodontics and Preventive Dentistry, A.B. Shetty Memorial Institute of Dental Sciences, Deralakatte for routine dental examination and treatment were included in the study. They ranged in age between three years to twelve years and were otherwise healthy. Parental consent was obtained prior to the procedure.

All the subjects were given a routine oral examination. Accordingly, fifty primary and permanent molars having dental caries into dentine were restored using this technique of excavation of carious dentine. Any pulpal involvement was ruled out by intra oral periapical radiographic evaluation.

THE CHEMOMECHANICAL CARIES REMOVAL METHOD

After isolation of the involved tooth, the Carisolv® gel was mixed using the Multimix Syringe Dispenser. The “active” 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 sixty seconds. Following this, the softened dentine was gently excavated using a ‘Hu-Friedy’ spoon excavator.

On application, the gel was clear, but became opaque or cloudy when it was contaminated with the debris during removal. When the gel was heavily contaminated with the debris, it was removed using a small cotton pellet and fresh gel was applied. The procedure was repeated until the gel was no longer contaminated with the debris and the cavity surface was felt hard with the excavator. The cavity was checked for remaining caries using an explorer.

THE EVALUATION CRITERIA

The efficacy of caries removal was then evaluated by the visual and tactile criteria.⁶ The visual criteria included the absence of any discoloration. The tactile criteria included the smooth passage of the explorer and absence of a catch or a “tug-back” sensation. The efficacy of caries removal was graded as complete, partial, and incomplete⁶ and numerically scored 0, 1, 2, 3, 4, 5 (Table I). The time taken for the removal of carious dentine, beginning from the application of the gel until the completion of the procedure was evaluated using a stopwatch. (Nikon Co).

The perception of the treatment by the patient was evaluated through a questionnaire. “Did you experience any pain or discomfort during the treatment?”

Following the placement of a restoration, an intra-oral periapical radiograph was taken for immediate evaluation. After a period of six months, the longevity of the restorations and the presence of secondary caries at the restoration-dentine interface were evaluated radiographically, using the criteria proposed by Frenken J. *et al.*⁷ (Table II).

Table I. Presents the definition of the caries removal status scores.

Score	Definition
0	Caries removed completely.
1	Caries present in the base of the cavity.
2	Caries present in the base and/or one wall.
3	Caries present in the base and/ or two walls
4	Caries present in the base and /or more than two walls
5	Caries present in the base, walls and margins of the cavity.

Table II. Presents the definition of the radiographic evaluation scores of the restorations.

Score	Criteria
0	Restoration present. No gap between the wall and the base.
1	Gap and/or restoration present partly. No signs of caries.
2	Gap and/or restoration present partly. Signs of caries.
3	Restoration not present. No signs of caries.
4	Restoration not present. Signs of caries.

STATISTICAL ANALYSIS

The data thus collected was subjected to statistical evaluation. The comparison of the caries removal status scores and the time taken for caries removal, between the soft and arrested carious dentine were assessed by the Mann—Whitney ‘u’ test. The difference between the radiographic evaluation scores on immediate and six-month follow-up examination, if any were assessed by the Wilcoxon Signed Rank Sum Test.

OBSERVATIONS

Table III shows the number of the soft and arrested carious lesions, with the respective mean caries removal status scores. The comparison between the scores indicated a very highly significant statistical result. Of the soft carious lesions 83.3% showed the complete removal of soft carious dentine. Of the arrested carious lesions 70% showed a partial removal of the carious dentine.

Table IV represents the values of the time taken for the removal of carious dentine and the comfort on excavation, respectively.

Table V shows the immediate and six-month follow-up radiographic evaluation scores of the restorations. On immediate radiographic evaluation, 75% of the soft carious lesions, showed the absence of a gap between the restoration–dentine interface and 25% showed the partial presence of the gap. After a six month radiographic examination, 53.6% of the soft carious lesions, showed the presence of the restoration, 35.7% showed the partial presence of a gap between the restoration dentine interface and 10.7% showed the absence of the restoration. None of the treated lesions showed the presence of secondary caries.

Of the arrested carious lesions 22.2% showed the presence of the restoration and the absence of a gap between the wall and the base of the cavity and 77.8%

Table III. Shows the comparison of the caries removal status scores between the soft and arrested carious lesions.

Consistency of the Carious Lesion	No. of the Lesions Representing the Caries Removal Scores						Mean ± S.D. (Score)	Mann-Whitney ‘U’ Test Statistical Score
	Score	Score	Score	Score	Score	Score		
	0	1	2	3	4	5		
Soft n=30	25	4	1	-	-	-	0.17±0.38	Z = 6.33 at P = 0.000 *VHS
Arrested n=20	0	2	4	14	-	-	2.6±0.68	

* VHS = Very highly significant

Table IV. Presents the time taken for caries removal and the patient comfort on caries excavation.

Soft carious dentine	Time taken in minutes	Comfort on excavation	Arrested carious dentine	Time taken in minutes	Comfort on excavation
1	5M	ND*	1	4 M	MD**
2	5M	ND	2	7M 30S	MD
3	4 30S	ND	3	5M 25S	MD
4	4M	ND	4	6M 60S	ND
5	4M	ND	5	6 M	MD
6	5M	ND	6	7 M	MD
7	5M 10S	ND	7	6 M	ND
8	4M	ND	8	5 M	ND
9	4M	ND	9	5M 10S	ND
10	8M	ND	10	6M 20S	ND
11	5M	ND	11	5 M	MD
12	7M 10S	ND	12	6M 15S	ND
13	6 M	ND	13	7 M	ND
14	4M 30S	ND	14	6 M	ND
15	4M 30S	ND	15	6M 30S	MD
16	5M	ND	16	7 M	MD
17	5M	ND	17	8 M	MD
18	5M	ND	18	6 M	MD
19	4M	ND	19	8 M	MD
20	6M	ND	20	6 M	ND
21	5M 25S	ND	Mean±S.D. = 6.10±1.04		
22	5M	ND	↑ Time taken for the removal of arrested carious dentine = 6.10±1.04 minutes Time taken for the removal of soft carious dentine = 4.56±0.58 minutes ↓		
23	6M	ND			
24	5M 10S	ND			
25	4M	ND			
26	4M	ND			
27	4M	ND			
28	4M 25S	ND			
29	4M 10	ND			
30	5 M	ND			
Mean±S.D.=4.56±0.58					
			*ND = No Discomfort **MD = Mild Discomfort		

showed the partial presence of a gap at the restoration–dentine interface, on immediate radiographic evaluation. After six months, 11.1% showed the presence of the restoration, 61.1% showed the partial presence of the restoration and 27.8% showed the absence of the restoration. None of the treated lesions showed the presence of secondary caries formation, on radiographic evaluation.

DISCUSSION

Philosophies of dental treatment change with time and now there is more than ample evidence provided by research for a reappraisal of the traditional, approaches to caries treatment.⁷ The minimal intervention technique of chemo- mechanical caries removal, using Carisolv® represents one such new approach to restorative

dentistry. Results from the initial laboratory based experiments testing effectiveness, have shown this technique to be a more selective method of removal of carious dentine.^{4,5} However, no study has been attempted to evaluate the efficacy of Carisolv® in the removal of carious dentine in the primary teeth and the perception of this technique by children.

The dentinal carious lesion can be distinguished into two zones. An outer layer of infected dentine, in which the collagen fibres are partially degraded and cannot be remineralized, and an inner layer of affected dentine, which is partially demineralized with intact collagen fibres and can be remineralized.⁵ A chemo-mechanical caries removal system, acts by causing further degradation of the partially degraded collagen, in the infected dentine.⁸ The mechanism of action of Cari-

Table V. Presents the comparative radiographic evaluation scores of the restorations on immediate and six months follow-up radiographic examination.

Consistency of the carious lesion	No. of the carious lesions representing the immediate radiographic scores						Wilcoxon signed rank sum test statistical value	No. of the carious lesions representing the six months radiographic scores						Wilcoxon signed rank sum test statistical value
	Score 0	Score 1	Score 2	Score 3	Score 4	Mean ± S.D.		Score 0	Score 1	Score 2	Score 3	Score 4	Mean ± S.D.	
Soft n=28	21	7	0	0	0	0.25±0.44	Z = 2.762 at p = 0.006 HS*	15	10	0	3	0	0.678±0.945	Z = 2.46 at p = 0.014 S**
Arrested n=18	4	14	0	0	0	0.778±0.428		2	11	0	5	0	1.44±1.042	

* HS - Highly Significant

** S - Significant

solv®, satisfies this criteria in the chemo-mechanical removal of carious dentine.

The active ingredient in Carisolv® is sodium hypochlorite. When mixed with amino acids, it generates chloramines. This results in the chlorination of the partially degraded collagen, and the conversion of hydroxyproline to pyrrole - 2 - carboxylic acid, which initiates the disruption of collagen fibres and a selective softening of the outer layer of carious dentine.⁸ Due to a high pH of 11, only the organic phase of dentine is affected. The high viscosity of Carisolv® facilitates accurate placement and decreases the volume of the material needed.⁶

In this study, 83.3% of the soft carious lesions showed complete removal of the soft carious dentine, and 70% of the arrested carious lesions indicated partial removal of the carious dentine. Although Carisolv® did not completely remove the arrested carious dentine, there is strong evidence to support the concept that the partly demineralized, minimally infected inner carious dentine can be safely left behind, provided that the bonding of the restorative material to the tooth surface is adequate.⁷ Also, due to the high pH of Carisolv®, only the organic phase of dentine is affected, thereby rendering the arrested carious dentine, less susceptible to removal.⁶ The time taken for the removal of soft carious dentine and arrested carious dentine was 4.56±0.58 minutes and 6.10±1.04 minutes respectively. These values are in conformity with the result obtained in a study by Ericson *et al.*⁶

Since the technique does not require the use of local anaesthesia, it avoids the induction of pain and anxiety, that is caused due to the trauma during the injection procedure and the fear of the needle. In our study, none of the patients experienced any discomfort on excavation. Thus, it is a virtually painless, non-invasive procedure with an added advantage of patient cooperation during treatment. Additionally, this technique has also proved to be safe in preventing the progress of the carious lesions as noted in our six month follow-up of the restorations, through clinical and radiographic evaluation.

Though directly not evaluated in our study, the toxicity of Carisolv® has been investigated in experimental animals and was considered to be safe for use in the oral cavity.⁹

Hence, the Chemo-mechanical caries removal technique using Carisolv® can be considered as an effective atraumatic treatment modality.

In an environment, in which “*extraction is the rule rather than an exception*” as in the developing countries, unconventional tooth preserving approaches such as the atraumatic restorative treatment have an opportunity to evolve. Application of this approach, which does not rely on electricity or expensive dental equipment, makes it possible to provide a cost effective treatment for large populations.⁷

SUMMARY AND CONCLUSIONS

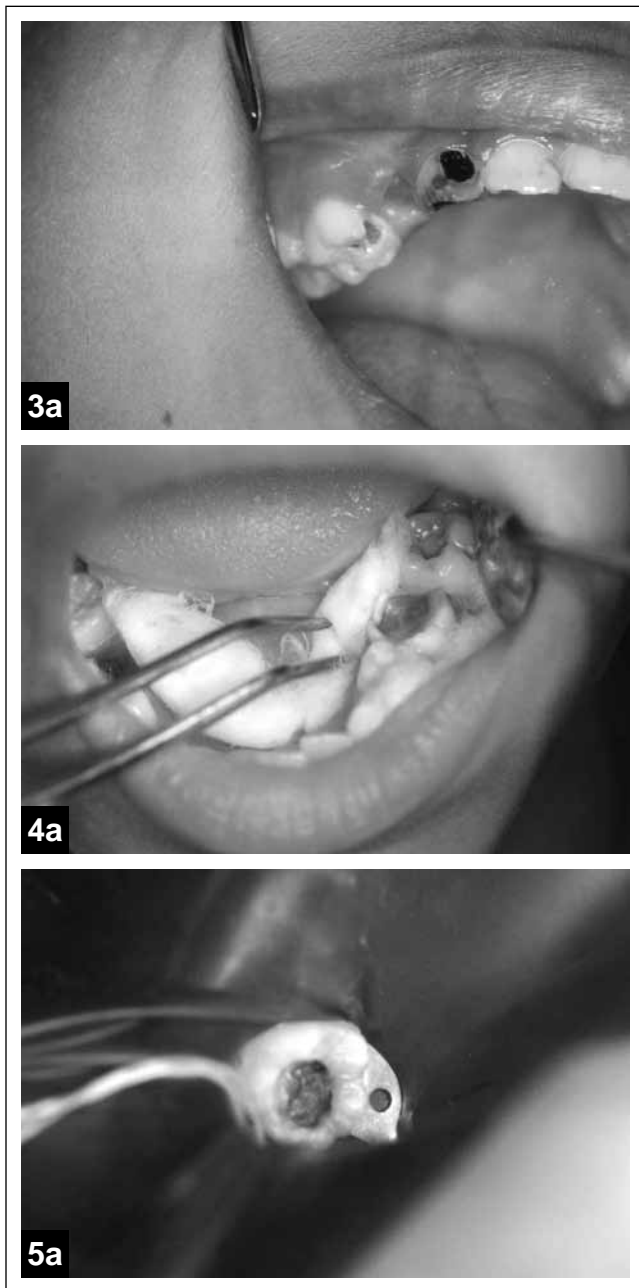
This study evaluating the efficacy of Carisolv® showed that:

1. The soft carious dentine was removed more effectively than the arrested carious dentine.
2. The removal of soft carious dentine required a shorter period of time, when compared to the removal of arrested carious dentine.
3. A high patient comfort on excavation was documented.
4. On radiographic evaluation of the restorations, none of the treated lesions showed the presence of secondary caries.

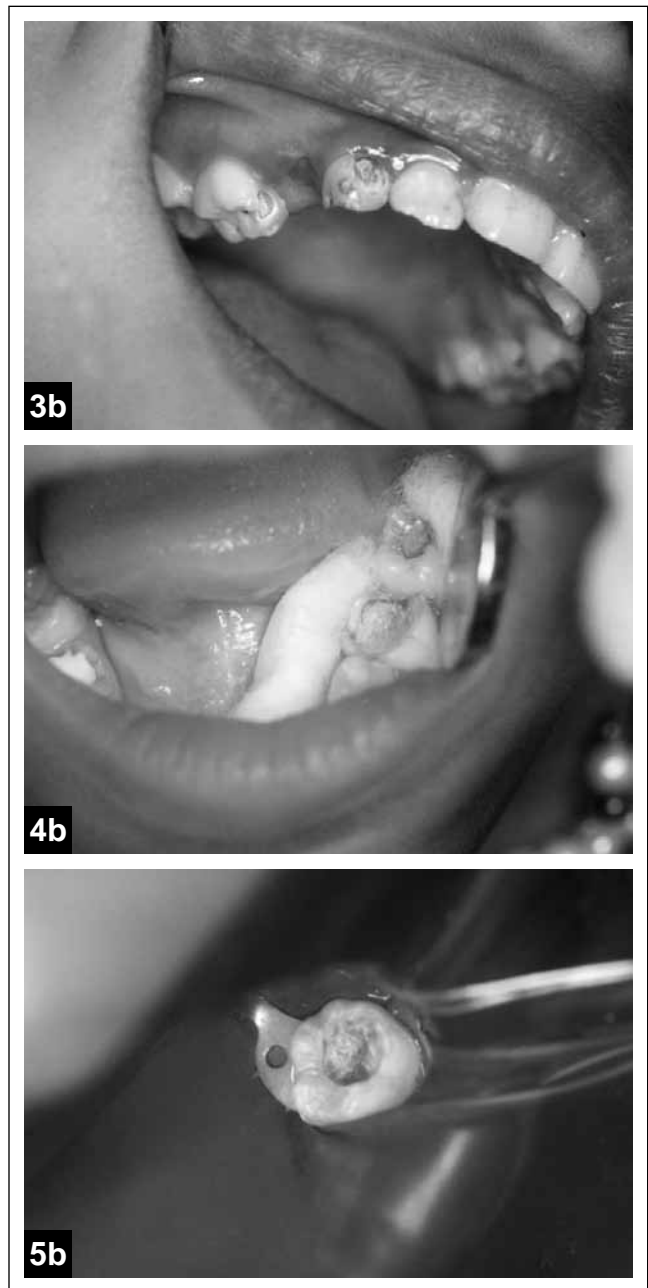
Hence, Carisolv® a virtually painless, non-invasive technique of caries removal appears to be of potential interest for use, in clinical pediatric dentistry and in combination with the atraumatic restorative treatment of dental caries in large populations.

REFERENCES

1. Rahimtoola S, Maher R. Pain related to treatment of caries lesion. J Dent Child 67: 123-127, 2000.
2. Elderton RJ. New approaches to cavity design with special reference to class II lesions. Br Dent J 157: 421-427, 1984



Figures 3a, 4a, 5a Carious lesion prior to excavation.



Figures 3b, 4b, 5b Following chemo-mechanical caries removal using Carisolv®

3. A.Banerjee A, Watson TF, Kidd EAM. Dentine caries excavation. A Review of current clinical techniques. *Br Dent J* 188: 476-481, 2000.
4. Vouigionklakis G, Parmosis D. The Caridex® system. *Hell Stomatol Chron* 32: 97-102, 1988.
5. Beeley JA, Yip HK, Stevenson AG. Chemomechanical caries removal. A review of techniques and latest developments. *Br Dent J* 188: 427-430, 2000.

6. Ericson D. Efficacy of a new gel for chemo-mechanical caries removal. *J Dent Res* 77: 1252. Abstract 360, 1999.
7. Frencken J. The A.R.T. - Review and global trends. *Community Dent and Oral Epidemiol* 27: 421- 453, 1999.
8. Goldman M, Kronman JH. A preliminary report on chemo-mechanical removal of caries. *J A D A* 93: 1149 -1153, 1976.
9. Dammaschke T, Stratman U, Ott K. Histocytological evaluation on reaction of pulp and dentin to Cavisolv®. Paper Presented at AFG - Jahrestagung Mainz, Jan 1999.