



Primary Teeth Caries Removal Using the Carisolv Chemomechanical Method: A Clinical Trial

Katerina Kavvadia, DDS, MDentSc, Drodont Vassiliki Karagianni, DDS, MSc
Argy Polychronopoulou, DDS, MSc, ScM, ScD Lisa Papagiannouli, DDS, MSc, DrOdont

Dr. Kavvadia is lecturer and Dr. Papagiannouli is professor and chairman, Department of Pediatric Dentistry; Dr. Polychronopoulou is assistant professor, Department of Community and Preventive Dentistry, University of Athens School of Dentistry, Athens, Greece.

*Dr. Karagianni is in private practice, Patras, Greece.
Correspond with Dr. Kavvadia at kavad@dent.uoa.gr*

Abstract

Purpose: The purpose of this controlled clinical trial was to compare the working time for caries removal in primary teeth, the need for local anesthesia and patient cooperation, when the chemomechanical Carisolv or the conventional mechanical method were used.

Methods: The sample consisted of primary teeth of children who had occlusal or buccal carious lesions into dentin. High speed and/or low speed were used as the conventional mechanical method of caries removal. The efficiency in caries removal was judged on the basis of clinical criteria. Length of working time, need of local anesthesia, and level of patient cooperation were recorded for both methods. Statistical analysis was performed using the student's *t* test and chi-square test.

Results: Working time with the chemomechanical method was much more prolonged than with the mechanical method ($P < .001$), but it did not negatively affect children's cooperation. Furthermore, the chemomechanical method reduced the need for administration of local anesthesia for Class V cavity preparations.

Conclusions: The chemomechanical method, although more prolonged, is effective in caries removal in primary teeth, does not influence children's cooperation and may reduce the need of local anesthesia in Class V restorations. (*Pediatr Dent.* 2004;26:23-28)

KEYWORDS: CHEMOMECHANICAL CARIES REMOVAL, CARISOLV, CLINICAL TRIAL, PRIMARY TEETH

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Chemomechanical dentinal caries removal is an alternative method to other caries removal systems such as mechanical, lasers,¹ kinetic cavity preparation,² and atraumatic restorative treatment.³ The first report of a chemomechanical system for caries removal was published in 1975,⁴ and was marketed under the trade name of Caridex (National Patent Medical Products, New Brunswick, NJ). However, lengthy working time and noneffective instruments prevented Caridex from achieving clinical success.

A new chemomechanical caries removal system, Carisolv (MediTeam Dentalutveckling AB, Savedelen Sweden) that has been recently introduced in Europe,⁵ seems to be more promising. This system consists of a gel and specially designed hand instruments. The gel is an aqueous mixture of 2 parts: part I contains sodium hypochlorite; part II contains 3 amino acids (glutamic acid, leucin, and lysine),

sodium hydroxide, erythrocin, and methylcellulose.⁶ When the 2 parts are mixed just prior to the procedure, amino acids get chlorinated and, when applied, interact with dentin, degrading only decayed collagen fibers,⁷ making them brittle and facilitating decay removal with the hand instruments. This method may be desirable in pediatric dentistry since it allows minimally invasive techniques to be applied, considered to be less painful, is noise and vibration free, and patients were more comfortable than with the mechanical technique.

The first in vitro investigation on the use of Carisolv, in primary and permanent teeth was published in 1998.⁸ It was reported that Carisolv was effective in caries removal. Since then, the use of Carisolv has been compared in controlled clinical trials in permanent teeth to the conventional mechanical method^{6,9-10} and the removal of decay by hand

instruments.¹¹ Carisolv was found to need significantly longer working time than the conventional method, but, similar to the hand instruments, minimized the need for local anesthesia and patients reported much less discomfort when compared to the other 2 methods. For the primary teeth, however, there has been only one clinical study that found similar results regarding working time. However, that study reported that children disliked the taste and did not prefer the use of Carisolv, as compared to the conventional mechanical method.¹² Comparison of patient cooperation between the 2 methods has not been studied.

The purpose of the present controlled clinical trial was to compare in primary teeth the working time for caries removal, need for local anesthesia, and patient cooperation when the chemomechanical Carisolv or the conventional mechanical method were used.

Methods

Study design

A prospective controlled clinical trial design was used in this investigation. The study design included a pretreatment examination, caries removal with either Carisolv or the conventional mechanical method, clinical evaluation of caries removal, and tooth restoration. Informed consent was obtained from patients parents prior to the procedure.

Sample

Patients were examined clinically prior to treatment with a mirror and an explorer. Patients' inclusion was based on the occurrence of at least 1 open carious lesion into dentin, on occlusal or buccal anterior surfaces, so the lesion could be easily accessed by a hand-excavating instrument. In some cases, however, minimal occlusal preparation of the enamel with a high-speed handpiece was necessary before chemomechanical treatment to access the dentin with chemomechanical hand instruments.

The lesion consistency was judged by the tactile sensation of an explorer as follows⁹:

1. hard=if the dentin was not entered when firmly pressing the explorer;
2. medium=if the explorer entered the dentin with some resistance;
3. soft=if the explorer readily entered the dentin.

After removal of the decay, the depth of the lesion was recorded as medium or deep. Medium was recorded when the decay reached the dentin just into the dentinoenamel junction and deep was recorded when the decay reached deeper into dentin.

A total of 31 children—15 boys and 16 girls ages 28 months to 9 years old, mean age=4.2±1 years, all patients of the Pediatric Dentistry Department at the University of Athens, Greece, participated in this study, with a total of 92 primary teeth.

Table 1. Sample Size by Method and Class of Preparation

Method	Class I	Class V	Total
Conventional mechanical	10	17	27
Chemomechanical*	22	43	65
Total	32	60	92

*Material used for the chemomechanical method: Carisolv (MediTeam Dentalutveckling AB, Savedelen Sweden).

Method

After the selection of teeth as described, color slides of the lesions were taken. Local anesthesia was administered before caries removal only in Class I lesions that radiographically penetrated more than one third into dentin to prevent the child from feeling any pain. In Class V lesions, no anesthesia was administered before caries removal. However, in those types of lesions, anesthesia was given during caries removal if the child perceived any pain. Teeth were then isolated with cotton rolls or a rubber dam if anesthetized and were treated as follows: approximately, for every tooth assigned to the conventional method, 2 consecutive teeth were assigned to the chemomechanical method. An effort was made to retain the above ratio within class of preparation to eliminate any possible confounding effect.

Chemomechanical Carisolv method

The material used in the teeth treated with this method was Carisolv (MediTeam Dentalutveckling AB, Savedelen Sweden), which was applied as it has been previously published.⁶

Thirty seconds after placing the Carisolv gel and using the appropriate hand excavator, careful removal of the soft carious dentin was performed, using firm cyclical abrasion movements. If further excavation was deemed necessary, more gel was placed onto the surface of the cavity and the procedure continued until the gel remained clear and a clinically hard cavity surface was attained upon checking with a probe. If the patient felt any pain during the decay removal, local anesthetic was then administered.

Conventional mechanical method

In the control group, caries removal was carried out using conventional mechanical means, which are high speed and/or low speed, until the cavity was found to be caries free.

Evaluation of the caries removal

When the cavity was considered caries free, a water spray cleaning was performed, followed by careful examination for the presence of caries using clinical criteria, visual examination, and a sharp probe. To prevent the probe from sticking into dentin, the efficiency in caries removal was

Table 2. Mean Total Time in Minutes for Caries Removal With Use of Conventional Mechanical as Compared to Chemomechanical Method, by Class of Preparation

	Conventional mechanical		Chemomechanical		Student's <i>t</i> test <i>P</i> value
	N	Time (min) mean±SD	N	Time (min) mean±SD	
Class I	10	3.1±1.7	22	10.3±5.4	< .001
Class V	17	2.6±2	43	7.0±4.9	< .001
Total	27	2.8±1.9	65	8.1±5.3	< .001

judged on the basis of clinical criteria.^{9,13} If the cavity was not caries free, then the same procedure was repeated, either with the chemomechanical or mechanical method.

Recording of working time

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

Restoration

After cavity preparation by either method, the teeth were restored with composite resin in the customary manner, except those Class I lesions prepared with the conventional mechanical method that were restored with amalgam.

Operators

Two operators, calibrated with regard to the use of technique and removal of caries, performed caries removal. Prior to this study, the 2 operators were trained in the technique and calibrated in 12 teeth regarding their agreement in clinical evaluation of caries removal.

Cooperation

Patient cooperation was recorded before and during the procedure as follows:

1. A was allocated to patients who were cooperative before and during the procedures.
2. B was allocated to patients who were cooperative before and became uncooperative during the procedures.
3. C was allocated to patients who were uncooperative both before and after the procedures.

Statistical methods

Standard statistical methods for continuous, ordinal, and

qualitative variables were used for data description and analysis.¹⁴ For comparison of total working time between the 2 methods, the student's *t* test was performed, whereas, for the evaluation of need of local anesthesia and patient cooperation, chi-square methods were used. For sparse quantitative data, Fisher's exact test was applied. Data analysis was

conducted using the SAS statistical package (SAS Institute Inc, Cary, NC).

Results

From the total of 92 primary teeth—60 anterior and 32 posterior, which comprised the study sample—65 were treated with the chemomechanical method and 27 with the conventional mechanical method (Table 1). Just prior to this study, calibration of the 2 operators regarding caries removal was performed using 12 teeth and agreement was found to be 91%. The mean age by treatment was 4.2±0.7 months for the conventional mechanical method and 4.2±1.1 for the Carisolv.

Results of this study showed that teeth treated with the chemomechanical technique needed statistically significantly more time than teeth treated with the conventional mechanical method (Table 2, *P*<.001). The same was true within the 2 types of the cavity preparation (Class I: *P*<.001, Class V: *P*<.001). Mean total time with the chemomechanical technique was 8.1 minutes, and 2.8 minutes for the conventional mechanical method (Table 2). For chemomechanically

Table 3. Mean Total Time in Minutes for Caries Removal With Use of Conventional Mechanical as Compared to Chemomechanical Method, by Depth of Lesion into Dentin

Depth into dentin						
		Medium		Deep		Student's <i>t</i> test <i>P</i> value*
		N	Time (min) mean±SD	N	Time (min) mean±SD	
Conventional mechanical	Class I	5	2.0±0.7	4	4.2±1.7	<.05
	Class V	12	2.7±2.3	5	2.2±1.3	NS
	Total	17	2.5±2	9	3.1±1.8	NS
Chemo- mechanical	Class I	8	7.0±3.3	14	12.0±5.6	<.05
	Class V	25	7.7±5.6	18	6.1±3.7	NS
	Total	33	7.5±5.1	32	8.7±5.5	NS

*NS=nonsignificant.

Table 4. Mean Total Time in Minutes for Caries Removal With Use of Conventional Mechanical as Compared to Chemomechanical Method, by Consistency of the Lesion

Consistency of the lesion						
Soft				Medium/hard		
		N	Time (min) mean±SD	N	Time (min) mean±SD	Student's <i>t</i> test <i>P</i> value*
Conventional mechanical	Class I	5	2.4±1.1	5	3.8±2	NS
	Class V	10	1.8±2	7	3.5±1.8	NS
	Total	15	2±1.7	12	3.6±1.8	<.05
Chemo- mechanical	Class I	5	6.6±2.4	17	11.3±5.6	NS
	Class V	16	4.5±2.8	27	8.5±5.3	<.05
	Total	21	5±2.8	44	9.6±5.6	<.001

*NS=nonsignificant.

treated teeth, Class I cavities needed more working time than typical Class V ($P<.05$, not shown).

Further investigation explored the possible associations of working time with the cavity depth, as presented in Table 3. This parameter was found to be significant for both methods tested, but only for Class I preparations where deep cavities needed statistically significant longer working time than medium ones ($P<.05$).

Working time for the chemomechanical method was also associated with the consistency of the lesion (Table 4), both for the conventional mechanical ($P<.05$) and chemomechanical method ($P<.001$). As expected, mean working time was prolonged for medium/hard consistency lesions as compared to soft lesions. When the association was examined by class of lesion, the above finding was mainly observed for Class V preparations, treated with the chemomechanical method ($P<.05$).

Table 5. Need of Local Anesthesia, by Use of Conventional Mechanical as Compared to Chemomechanical Method, for Class V Preparations

Class V preparations					
Need of local anesthesia	Conventional mechanical		Chemomechanical		Fisher exact <i>P</i> value
	N	%	N	%	
Yes	4	24	1	2	<.05
No	13	76	42	98	
Total	17	100	43	100	

Comparison for the need of administration of local anesthesia between the 2 methods could be safely performed for the Class V preparations only, since, in some of the Class I preparations, anesthesia was given beforehand to prevent the feeling of pain. In the Class V lesions, the chemomechanical method reduced the need for local anesthesia significantly, $P<.05$, in up to 98% of the treated teeth with the chemomechanical method (Table 5).

The cooperation of patients treated with the chemomechanical technique was similar to the patients treated with the conventional

mechanical method (Table 6). The aforementioned analysis was also conducted with age stratification. The results suggested that prolonged treatment time did not greatly influence behavior, at any age. The 2 groups of children did not show a significant difference in cooperation with respect to the administration of local anesthesia.

Discussion

Results of this study clearly show that the chemomechanical method of Carisolv, although it takes much longer, is as effective a method for caries removal in primary teeth, under clinical criteria, as the conventional mechanical method. These criteria have been previously used and tested in permanent teeth.^{6,9,15} The efficacy of caries removal by this chemomechanical method has been documented in in vitro studies using electrical caries monitoring,⁶ and scanning electron microscopy.¹⁵ Clinical working time with the chemomechanical method was much more prolonged than

Table 6. Patient Cooperation When Conventional Mechanical was Compared to Chemomechanical Method, at Different Cooperation Levels

Cooperation levels	Conventional mechanical		Chemomechanical		Trend test <i>P</i> value*
	N	%	N	%	
A	12	44	26	40	
B	6	22	15	23	NS
C	9	34	24	37	
Total	27	100	65	100	

*NS=nonsignificant.

that with the conventional mechanical method as this has been previously found for permanent teeth^{6,10} and in a limited sample of primary teeth.¹² However, no data exists for primary teeth comparing the removal of caries by the chemomechanical method to the removal of caries by hand instruments alone, constituting a limitation of the present investigation.

Furthermore, in this investigation, the comparison and statistics between conventional mechanical and chemomechanical treatment was conducted, taking into account the category of the preparation and depth and consistency of the caries. When reporting working time, most of the related literature did not analyze for the category of the preparation in chemomechanically treated teeth since this could greatly influence the result. For example, in the present investigation, Class I preparations needed much longer time than Class V. The consistency of decay could also influence working time,¹⁷ and soft lesions needed less time than medium or hard ones.

Studies in permanent teeth suggest that the use of the chemomechanical method minimizes the need of local anesthesia.¹⁰⁻¹¹ This has been found in a limited sample of primary teeth, medium depth occlusal lesions, and in older children¹² where cooperation may be better than among the young children used in this study. Results of the present investigation suggest that the chemomechanical method can reduce the need of local anesthesia in Class V preparations in primary anterior teeth, in children ages 2.5 to 9 years. It should be noted that a limitation of the study design was the absence of data for the Class I lesions.

An interesting finding of this investigation was that the chemomechanical method did not negatively affect children's cooperation, although removal of decay with this method was a much more prolonged procedure during which children could grow tired. The noise and vibration of the handpieces most often disturb small children; it is possible that the chemomechanical technique, a noise- and vibration-free technique, helped them sit through this long procedure undisturbed. There are no other studies examining the effect of the chemomechanical method on the cooperation of the patient. Previous studies have shown that the method is highly accepted by adults,^{5,10} although a study in a limited sample of primary teeth has shown that young patients disliked the taste and would not recommend it to their friends.¹² Children in the present investigation did not report disliking the taste.

If future research proves that the chemomechanical method can be used without local anesthesia, then the total working time of this method as compared to the conventional mechanical method will be diminished by the time needed for the administration of local anesthesia in small children, let alone the inconvenience caused by the administration itself. In this way, the difference in time between the 2 procedures will not be as significant. Working time may be further reduced by using an improved Carisolv gel

that contains 0.95% sodium hypochlorite instead of 0.5%, in combination with the motor driven instruments (350-450 rpm/minutes) both recently introduced.

This chemomechanical method of caries removal could be useful for the pediatric dental practice in reducing the use of the noise-producing, vibration-producing, and pain-inducing high- or low-speed conventional mechanical methods. This method, however, cannot fully replace the conventional methods, and its use is limited to specific cases such as small children with open cavities into dentin where minimum preparation is needed to access or perfect the cavity before the restoration of the tooth. The chemomechanical method might also be useful with needle phobics and when local anesthesia is contraindicated, such as with immunocompromised patients or patients with a bleeding disorder. Additionally, the chemomechanical treatment could be of help in treating hypoplastic teeth, where it is difficult to achieve a good level of local anesthesia.

Conclusions

Although it necessitated much longer treatment time than the conventional mechanical method, the Carisolv chemomechanical method of caries removal in primary teeth did not seem to negatively affect the cooperation in children. Furthermore, it reduced the need of local anesthesia when treating buccal lesions in anterior teeth.

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ABSTRACT OF THE SCIENTIFIC LITERATURE



A COMPARISON OF 2 ORAL FORMULATIONS OF MIDAZOLAM

The aim of this study was to compare 2 available oral formulations of midazolam, with respect to sedation score and plasma midazolam levels in pediatric surgical patients 2 to 10 years old. Patients were randomized to receive 0.5 mg/kg of either the commercially available Versed syrup orally or a mixture of the IV midazolam preparation in Syrpalta syrup as an anesthetic premedication. Observer's assessment of alertness/sedation (OAAS) scores were obtained by a blinded observer at 15 and 30 minutes after drug administration, and plasma midazolam levels were acquired exactly 45, 60, and 90 minutes after administration. Patients receiving an IV formulation mixed in Syrpalta had a significantly lower median OAAS score at 30 minutes and significantly higher mean plasma midazolam levels at all 3 acquisition times. This study concluded that IV midazolam mixed in Syrpalta syrup yields more reliable sedation and correspondingly higher plasma levels than an equivalent dose of the commercially formulated and marketed preparation.

Comments: The finding of this study is interesting because, since Roche Laboratories released Versed syrup, many pediatric dentists use the commercially available midazolam syrup instead of the IV formulation for oral sedation procedures. **HA**

Address correspondence to Keith K. Brosius, MD, Children's Healthcare of Atlanta at Egleston, 1045 Clifton Rd., NE, Atlanta, GA 30322. keith_brosius@emoryhealthcare.org

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