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Clinical evaluation of a chemomechanical method for caries removal in children and adolescents

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Abstract

Objective. The purpose of this study was to make a clinical comparison of the chemomechanical method for caries removal and the conventional rotary instruments technique when used in children and adolescents. ***Material and Methods***. The study comprised 120 patients aged 3–17 years randomized into two groups: caries were removed chemomechanically in 60 patients and 60 patients received conventional treatment with rotary instruments. The outcome variables were: clinically complete caries removal, pain during caries removal, need for local anesthesia, treatment time, preferences of patients, and clinical success of the restorations during the 12-month evaluation period. ***Results.*** Complete caries removal was achieved in 92% of chemomechanically treated teeth and in all teeth treated with rotary instruments ($p > 0.05$). The chemomechanical method significantly reduced the need for local anesthesia ($p < 0.001$). Eighty-five percent of patients treated with Carisolv and 47% treated with rotary instruments were satisfied with the treatment ($p < 0.05$). The mean time for chemomechanical caries removal was 11.2 ± 3.3 min and 5.2 ± 2.8 min for caries removal with rotary instruments ($p < 0.001$). At the end of the 12-month evaluation period, there was no observed influence of the caries removal method on the survival of the restorations. ***Conclusions.*** The chemomechanical caries removal technique is an adequate alternative to the conventional rotary instruments method and is advantageous in pediatric dentistry.

Key Words: *Chemomechanical removal, clinical trial, dentine caries*

Introduction

Although dental materials and equipment have progressively improved in recent decades, problems associated with rotary instruments for caries removal have remained unresolved. Conventional caries removal has potential adverse effects on the pulp, owing to heat, pressure, and vibration [1]. This approach always results in extensive removal of healthy tooth tissues [2]. Moreover, drilling often causes pain and requires local anesthesia, procedures that are usually perceived as unpleasant, especially in children and patients with dental anxiety. Modern restorative dentistry offers numerous options for caries removal developed to replace rotary instruments. One of these methods involves chemomechanical caries removal.

Carisolv (MediTeam Dental AB, Gothenburg, Sweden) is the latest product for chemomechanical caries removal. Its active components are three natural amino acids (leucine, lysine, and glutamic acid) and sodium hypochlorite (NaOCl). When amino acids are added to NaOCl, its proteolytic action is aimed more specifically at denatured proteins – carious dentine – so that sound and carious dentine become readily separable [3,4]. During treatment, several reactions act in concert to disrupt the fiber structure of collagen and have a softening effect on the carious tissue. Owing to the selective attack of the solution solely on denatured collagen fibers, the chemomechanical method affects neither sound dentine [5,6] nor healthy or carious enamel [7]. Specific hand instruments are designed to remove softened carious dentine without damaging the healthy dentine.

The majority of clinical trials of the chemomechanical method for caries removal were carried out on the permanent dentition [8–13]. A general conclusion was that the chemomechanical method was an adequate alternative to conventional techniques of caries removal. It is claimed that this method

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reduces the need for local anesthesia, and decreases the use of rotary instruments, and high acceptance of patients was also pointed out. The perception is that children's tolerance of dental procedures is lower in comparison to that of adults. In addition, there are considerable differences in cooperation among young children, schoolchildren, and adolescents. The purpose of this study was to make a clinical comparison between the chemomechanical method for caries removal and the conventional rotary instruments when used in children and adolescents and to determine patient acceptance of a new method.

Material and methods

This prospective, controlled, clinical trial included the following steps: a pretreatment examination, randomization, caries removal, cavity inspection, restoration, and a patient interview. Patients were treated at the Clinic for Pediatric and Preventive Dentistry of the University of Belgrade between April 2006 and June 2007. The study was conducted in accordance with the guidelines of the Declaration of Helsinki and approved by the local ethics committee.

One hundred and twenty patients of both genders (56 girls, 64 boys) were included in this study. The mean (SD) age of the individuals was 8.7 (3.0) years (range 3–17). All patients were consecutive patients of the clinic who attended regular dental examinations where it was determined whether they met the inclusion criteria. The patients included in the study had one primary carious lesion. Teeth with development disorders, pulp or adjacent soft tissue pathology, i.e. spontaneous or provoked pain, pulp necrosis, or swelling, were excluded. All patients had experience of conventional caries therapy (rotary instruments) 3 to 12 months earlier. Participants were healthy individuals with no history of allergies or sensitivity to any drugs, medications, food, or other antigens. The children and the parents were fully informed of the purpose of the investigation, therapy procedures to be performed, and the possible benefits and potential risks involved. Informed parental consent was obtained in writing prior to the child's participation in the study, and informed assent was obtained from the child.

The patients were randomized into two groups using a table of random numbers. Sixty patients underwent chemomechanical caries removal and 60 patients received conventional treatment with rotary instruments. The same technician, who had experience in chemomechanical caries removal, performed all the treatments. An independent co-investigator, blinded to the method of caries removal, determined the efficiency of the caries removal after the cavity preparation. The completeness of caries removal was judged according to standard clinical criteria, i.e. the probe did not stick in the remaining dentine.

The consistency of the lesions was judged by the tactile sensation of a probe and recorded as "soft" if the probe entered the dentine or as "hard"" if the dentine was not entered when firmly pressing the explorer. After removal of carious dentine, the depth of the lesion was recorded as "superficial" if the lesion reached the dentine just into the dentinoenamel junction, as "close to pulp" if the lesion reached the inner third of dentine, and as "medium" for regions in between.

Prior to the clinical procedure, all patients were offered local anesthesia and were also informed that it could be given upon request at any time during the treatment.

Carisolv gel for the chemomechanical caries removal was prepared as per the manufacturer's instructions and applied to the surface of the carious lesion. After 30 s, the superficial softened layer was removed with specially designed hand instruments. The procedure was repeated until the gel no longer turned cloudy and the surface was hard, as judged by clinical criteria (probing and visual inspection). Of 60 lesions treated with Carisolv, 57 were characterized as "open lesions" and directly accessible for the chemomechanical technique. When complete caries removal was impossible with the chemomechanical method, the remaining caries was removed with rotary instruments. For teeth treated with drilling, caries was removed using rotary instruments until the cavity was found to be clinically caries free. Time taken for caries removal with either method was recorded in minutes for each tooth.

Glass-ionomer cement, composite, or amalgam was used according to the manufacturer's instructions to restore the cavity. A calcium hydroxide lining material (Calcimol self-curing paste; VOCO GmbH, Cuxhaven, Germany; Calcimol LC paste; VOCO GmbH) was applied for indirect pulp protection when indicated. For glass-ionomer cement, the cavity was conditioned with 10% polyacrylic acid for 20 s (GC Dentin Conditioner; GC Int., Tokyo, Japan); the material (GC Fuji IX GP Capsule; GC Int.) was placed into the prepared cavity and coated with varnish (GC Fuji Coat LC, GC Int.) which was light cured for 10 s to protect the material from moisture and desiccation. For composite restoration, the cavity was conditioned with 37.5% phosphoric acid gel (Gel Etchant; Kerr Dental, Orange, Calif., USA) using a total-etch technique. A bonding agent (OptiBond Solo Plus; Kerr Dental) was applied and polymerized utilizing a visible light for 20 s after a 20 s interval. Composite material (Point 4; Kerr Dental) 2 mm in thickness was placed in the cavity using the layer method and exposed to the light for 40 s. For amalgam (Dentam Dental Amalgam Capsules; Dentam Scitem Ltd., Fujairah, UAE), the protective base was applied prior to the placement

of restorative material. Restorations were evaluated after 7 days, 6, and 12 months. After 7 days, we noticed possible adverse effects (postoperative sensitivity, soft tissue reaction). Examinations after 6 and 12 months included recording the integrity of the restorations (intact restoration/fractured, mobile or missing restoration), secondary caries (evidence of caries contiguous with the margin of the restoration when assessed by visual inspection and probing), and signs of pulp pathology (sensitivity, pain, or swelling).

Preoperative and postoperative questionnaires were completed by the independent co-investigator who was blinded to the method of caries removal. Before the treatment, we took note of dental fears, dislikes, and opinions about drilling and local anesthesia. After completion of the procedure, the children reported the intensity of pain during the treatment and their impressions of the caries removal method. Parents helped them to fill in the questionnaires, when needed. To compare patients' attitudes and cooperation, they were divided into three age groups: young children (≤ 6 years), schoolchildren (>6, <14 years), and adolescents (≥ 14 years).

Descriptive statistical analyses were primarily implemented, and the Fisher exact test and chi-squared test were used for comparisons of frequency distributions between the two treatment groups. For data with non-homogeneous repartition, a non-parametric test was used (Mann-Whitney test, Kruskal-Wallis or Wilcoxon tests). The level of significance was set at $p < 0.05$ and the data were processed using statistical software S-Plus for Windows.

Results

Of the 120 patients, 50 were young children, 54 were schoolchildren, and 16 were adolescents. The mean (SD) age was 8.5 (2.7) years for the chemomechanical technique (range 4–17 years) and 9.1 (3.6) years for the conventional method (range 3–15 years).

In the preoperative questionnaire, 92 patients (77%) reported that they did not mind going to the dentist. All patients had previous experience of conventional caries therapy with rotary instruments, but only 48 patients (40%) reported a positive attitude to this procedure. Thirty-nine patients (33%) did not like the drilling and 16 patients (13%) associated rotary instruments with pain. Seventeen patients (14%) could not answer the question. A negative attitude to the rotary instruments was more frequent in boys than in girls and in young children than in schoolchildren and adolescents ($p < 0.05$, the Fisher exact test). Ninety-six patients (80%) had previous experience of local anesthesia. Of these, 56 patients (58%) reported that they liked the anesthesia because of painless and more comfortable treatment. Nineteen patients (20%) explained a negative attitude because of pain during the application of the local anesthetic, 7 patients (7%) did not like the "unpleasant feeling" after the application, and 9 patients (10%) reported a strong fear of needles. Five patients (5%) could not define their attitude. Regarding gender and age, there were no differences in patients' attitudes to local anesthesia (the Fisher exact test).

All selected carious lesions were localized on the dental crown. The lesions in the two treatment groups were comparable in terms of dentition, type of tooth, location, depth, and consistency (Table I).

According to the independent examiner's assessment, complete caries removal with Carisolv was reached in 55 cases (92%). In 5 cases (8%), remaining caries was found at the dentinoenamel junction. We found no significant differences in terms of dentition, type of tooth, location, and depth of the lesion (the Fisher exact test). All 60 teeth treated with drilling became caries free, as judged by the clinical criteria. No case of pulp exposure occurred.

Combined use of rotary instruments and Carisolv was necessary in 12 cases (20%): in 3 cases to gain access to the caries lesion, in 4 cases to adjust the periphery of the cavity, and in 5 cases to remove residual caries at the dentinoenamel junction.

The chemomechanical method significantly reduced the need for local anesthesia ($p < 0.001$, the Fisher exact test; Table II). The reason for using an anesthetic before the chemomechanical treatment was the patient's strong fear of pain. During the treatment, local anesthesia was given because of the pain or unpleasant sensations. Of the patients not receiving anesthetics, significantly fewer experienced pain in the Carisolv group ($p < 0.05$, chi-squared test; Table III).

Fifty-one patients (85%) treated with Carisolv and 28 patients (47%) treated with drilling were satisfied with the treatment ($p < 0.05$, the Fisher exact test). The majority of the patients in the Carisolv group preferred the chemomechanical method compared to the conventional one (48 patients – 80%). Seven patients (12%) did not experience any differences between the two caries removal methods: 3 children (5%) qualified the methods as equally pleasant, while 4 children (7%) considered the methods equally unpleasant. Patients who preferred rotary instruments (5 patients – 8%) were mainly adolescents who objected to the prolonged treatment time ($p < 0.05$, the Fisher exact test). There were no complaints about the smell and the taste of the Carisolv gel.

The mean (SD) time for chemomechanical caries removal was 11.2 (3.3) min and 5.2 (2.8) min for caries removal with rotary instruments ($p < 0.001$, Mann-Whitney test; Table I). Time needed for caries removal in the Carisolv group differed between class

Table I. Distribution of lesions for a Carisolv and a drilling group and time taken for caries removal.

	Carisolv			Rotary instruments		
	n	%	Mean (SD) (min)	*n*	%	Mean (SD) (min)
Teeth						
Deciduous[b]	40	67	10.8 (2.7)	34	57	3.7 (1.4)
Permanent[c]	20	33	12.0 (4.2)	26	43	7.2 (3.0)
Incisors	1	2	7.0	–	–	
Canines[b]	29	48	10.5 (2.6)	20	33	2.3 (0.8)
Premolars[d]	3	5	10.3 (1.5)	6	10	8.2 (3.2)
Molars[b]	27	45	12.2 (3.8)	34	57	5.3 (1.9)
Class						
I[b]	11	18	10.7 (3.8)	13	22	4.7 (1.0)
II[c]	19	32	12.7 (3.5)	20	33	7.8 (3.0)
III[b]	28	47	10.7 (2.5)	23	38	2.4 (0.6)
IV	2	3	6.5 (0.7)	–	–	
V	–	–		4	7	2.0 (1.4)
Depth of lesion						
Superficial[d]	2	3	13.5 (2.1)	6	10	3.5 (1.4)
Medium[b]	52	87	10.9 (3.2)	48	80	4.4 (1.9)
Close to pulp[c]	6	10	13.5 (3.8)	6	10	9.2 (2.5)
Consistency						
Soft[b]	55	92	11.0 (3.2)	56	93	5.4 (2.7)
Hard[d]	5	8	13.8 (2.8)	4	7	2.0 (1.4)
Total[a]	60	100	11.2 (3.3)	60	100	5.2 (2.8)

[a]$p < 0.001$ (Mann-Whitney test) when comparing Carisolv and drilling mean excavation times; [b]$p < 0.001$ (Wilcoxon test) when comparing Carisolv and drilling mean excavation times; [c]$p < 0.05$ (Wilcoxon test) when comparing Carisolv and drilling mean excavation times; [d]impossible to carry out a statistical analysis due to the small number of teeth.

I, II, and III cavities and class IV cavities ($p < 0.05$, Kruskal-Wallis test). Treatment time was prolonged for hard consistency lesions as compared to soft lesions ($p < 0.05$, Wilcoxon test). For teeth treated with rotary instruments, mean treatment times differed in terms of dentition ($p < 0.001$, Wilcoxon test), group of teeth ($p < 0.001$, Kruskal-Wallis test), localization of the lesion ($p < 0.001$, Kruskal-Wallis test), and depth of the lesion ($p < 0.05$, Kruskal-Wallis test).

We found no adverse reactions of adjacent soft tissues during or after the contact with Carisolv. In both treatment groups, no postoperative sensitivity was recorded. All re-examined teeth were without signs of endodontic complications. At the end of the 12-month experimental period, the overall success rate was 95% and 90%, respectively, for chemomechanical and mechanical methods ($p = 1$, the Fisher exact test). In the Carisolv group, 1 glass-ionomer restoration was lost in the 6th month; at the end of the 12-month follow-up period, 2 glass-ionomer restorations were lost in each group. In addition, 2 glass-ionomers and 2 composite restorations were with secondary caries.

Table II. Use of local anesthetics.

	Carisolv		Rotary instruments	
Anesthesia	*n*	%	*n*	%
None	53	89	24	40
Before treatment	5	8	34	57
During treatment	2	3	2	3
Total	60	100	60	100

Local anesthesia was used significantly less frequently in the Carisolv group ($p < 0.001$, the Fisher exact test).

Discussion

In most cases, the children in this study did not show a negative attitude to the dentist. However, the patients clearly demonstrated that some of the therapeutic procedures, i.e. caries removal with burs and application of a local anesthetic, were very unpleasant. Scott et al. [14] estimated that about 80% of the population experienced some degree of dental anxiety. Dental procedures that patients fear the most are drilling, application of a local anesthetic, and tooth extraction [15]. Children's attitudes to the dentist may depend on age, gender, medical condition, oral health, previous dental interventions, general tendency to fear, parents' influence, social milieu, etc. During their first visits to the dental surgery, children are usually upset because of the fear of the unknown and fear of pain. Dentists and parents should methodically help the child to overcome his/her fears. Introduction of less traumatic therapeutic procedures may play an important role in this process.

In order to conduct the investigation under the conditions of daily clinical practice, the efficacy of caries removal was judged by standard clinical criteria – visual inspection and probing. It has been

Table III. Intensity of pain during caries removal.

	Carisolv			Rotary instruments		
	Anesthesia		Total	Anesthesia		Total
	No *n* (%)	Yes *n* (%)	*n* (%)	No *n* (%)	Yes *n* (%)	*n* (%)
Painless	46 (77)	7 (12)	53 (89)	10 (17)	34 (57)	44 (74)
Low	5 (8)	0 (0)	5 (8)	10 (17)	2 (3)	12 (20)
High	2 (3)	0 (0)	2 (3)	4 (6)	0 (0)	4 (6)
Total	53 (89)	7 (11)	60 (100)	24 (40)	36 (60)	60 (100)

Patients in the Carisolv group experienced significantly less pain than those in the drilling group ($p < 0.05$, chi-squared test).

suggested that conventional optical and tactile criteria are sufficient to ensure the removal of most infected dentine and that other aids, e.g. caries detector dyes, should not be routinely used [16]. Results of the present study are in accordance with those of earlier clinical investigations of the Carisolv system [8–10,17–19] which showed high success of the chemomechanical method in caries removal in both permanent and primary teeth. Occasionally, clinical evaluation of the efficiency of chemomechanical caries removal can be difficult because of the dull appearance of dentine after the cavity preparation [11]. In view of the fact that clinicians may have a different definition of what is a caries-free cavity, the efficacy of the chemomechanical caries removal method is probably more clearly demonstrated in various *in vitro* studies [2,7,20–23] which showed that the method removes adequate quantities of carious dentine and does not have a tendency to underprepare the cavity.

In this study the chemomechanical method failed to remove caries from the dentinoenamel junction in 8% of cases. Histological studies [24,25] showed that the Carisolv method tends to leave carious dentine close to the dentinoenamel junction. Kakaboura et al. [11] reported difficulties in caries removal at the posterior teeth and at the cavity undercuts, owing to the limited accessibility and the design of the hand instruments. Most of the cavities selected for the present investigation were readily accessible with hand instruments. In clinical practice, carious lesions can often be difficult to reach and additional use of rotary instruments may be needed. That is why it is important to set an appropriate indication for chemomechanical caries removal. We agree with the results of Chaussain-Miller et al. [12] who reported that the chemomechanical method is of less interest for small cavities because of the lack of visibility and access. However, owing to selective removal of carious dentine, this technique reduces the risk of an iatrogenic perforation of the pulp chamber in deep lesions. It has been pointed out that Carisolv gel does not penetrate the healthy dentine [26] and does not damage the pulp tissue, even after direct exposure to the gel [27,28].

The possibility of removing caries without the need for local anesthesia is one of the main advantages of the chemomechanical method. Although local anesthesia is part of the modern concept for painless dentistry, its use is not always indicated, and some procedures can be done without it. A correct psychological approach and gaining the patient's trust can often reduce the need for anesthesia. The fact that the Carisolv method can often be used without local anesthesia makes it well suited for use in the group of anxious and medically compromised patients [29].

Patients in the chemomechanical group had previously experienced caries removal with rotary instruments, so it was possible to make a comparison of the two methods. Finding that a new painless method allows treatment without drilling and anesthesia contributed to the positive attitude of most of the treated children. Earlier clinical investigations in adults [8,9,11] reported similar results. A study of chemomechanical caries removal in a group of anxious children [29] showed that 90% preferred the chemomechanical method. Lozano-Chourio et al. [18] reported significant differences in children's behavior when treated with Carisolv or high-speed excavation in favor of the Carisolv system. Kavvadia et al. [30] found no differences in cooperation among pediatric patients with regard to the caries removal method, whereas Maragakis et al. [31] stated that the chemomechanical method was not suitable for use in pediatric dentistry, since almost 70% of treated patients preferred rotary instruments. It has been reported that patients sometimes object to the unpleasant smell and taste of the Carisolv gel [8,9,11–13,29,31], but the present study does not confirm these findings. However, a dislike of the taste and/or smell of the solution probably will not dissuade patients from continuing with the treatment.

From the clinical viewpoint, the main disadvantage of the chemomechanical method is the prolonged treatment time. Caries removal with hand instruments, the period for the chemical reaction between the gel and tooth substrate, and multiple applications of gel may account for that. In the present study, class IV cavities took significantly less

time than class I, II, and III cavities, which is in accordance with the results of Ericson et al. [8]. This may be a reflection of lesion size and accessibility. However, this finding should be viewed reservedly, owing to the limited number of class IV cavities in the present study. Previous clinical investigations [12,13,30] found the depth of carious lesions to be an important parameter for the excavation time. Surprisingly, operating time did not correlate with cavity depth in our investigation. Regarding the consistency of decay, soft lesions often need less time than the harder ones.

Interesting data about patients' perceptions can be found in the literature: a significant number of adult patients did not feel that the time needed for chemomechanical caries removal was any longer than that for drilling, and some perceived that Carisolv was faster than drilling [8,9,12]. This was probably due to the experience of less discomfort because of the lack of unpleasant sounds, vibrations, and pain [8]. In the present study, the prolonged time for chemomechanical caries removal did not influence children's cooperation, which is in accordance with the findings of Ansari et al. [29] and Kavvadia et al. [30]. In contrast, Maragakis et al. [31] reported that 94% of children estimated that the Carisolv method lasted longer and the investigators explained this finding as the reduced tolerance of young children to dental procedures.

No complications or adverse effects associated with the chemomechanical method were recorded during the treatment or during the 12-month follow-up period. Studies of the Carisolv system have shown that the gel has no adverse effects on oral mucosa [32], sound tooth tissue [6,7,26], or restorative dental materials [33].

In this study, we found no influence of the caries removal method on survival of the restorations at the end of the 12-month evaluation period. In two studies, Fure et al. [9,13] found the majority of composite fillings placed in adult patients after the chemomechanical caries removal to be intact after one year (29 of 31, and 167 of 177, respectively). Kirzioglu et al. [19] evaluated the status of compomer restorations in primary molars after the caries excavation with Carisolv and reported 27 of 28 teeth to be clinically excellent or acceptable at the end of the experimental period.

Within the limitations of the present study, we find the chemomechanical caries removal method to be an adequate alternative to the conventional rotary instruments. This clinical procedure is efficient for caries removal, reduces the need for local anesthesia, and is well accepted by the pediatric patients. However, the greater time requirement represents a substantial barrier to its wider use by clinicians.

Declaration of interests: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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