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Clinical randomized controlled trial of chemomechanical caries removal (Carisolv™)

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Summary. *Objectives.* The purpose of this study was to compare the chemomechanical caries-removal system (Carisolv™) with high-speed excavation in cavitated occlusal caries of primary molars.

Design and setting. The study was a randomized controlled, clinical trial in which the two techniques were compared in each subject. Participants were chosen from public schools, in Maracaibo County, Zulia State, Venezuela.

Sample and methods. The sample consisted of 80 primary molars selected from 40 children (mean age 7·7 ± 0·7 years). Each patient had at least two contralateral primary molars with cavitated occlusal caries and approximately equal-size access to lesions. The outcome variables were: clinically complete caries removal, size of the opening of the cavity, volume of carious tissue removed, pain during caries removal, anaesthesia requested by the patient, caries-removal time, and behaviour and preference of patients.

Results. All treated molars were clinically caries free whichever caries-removal procedure was used. When Carisolv™ was used the final cavity entrance sizes were smaller ($P < 0{\cdot}001$) and the estimated volume of tissue removed was less ($P < 0{\cdot}001$). The time taken for caries removal was three times longer (7·51 ± 1·83 min, $P < 0{\cdot}001$). Some pain was reported by seven (17·5%) participants when Carisolv was used, compared with 16 (40%) when high-speed excavation was used ($P < 0{\cdot}05$). Using the Carisolv method there was a higher proportion of patients with positive behaviour ($P < 0{\cdot}01$), and 71·0% ($P < 0{\cdot}05$) preferred this treatment.

Conclusion. Carisolv is an effective clinical alternative treatment for the removal of occlusal dentinal caries in cavitated primary molars; it is more conservative of dental tissue and appeared to be more comfortable for most patients, although the clinical time spent is longer than when using high-speed excavation.

Introduction

Conventional caries excavation involves the use of a high-speed drill on a handpiece to gain access to the carious lesion, and a low-speed handpiece to remove carious dentine [1]. Kidd *et al*. [2] have pointed out that judgement as to the termination of excavation varies according to the country, dental school, the individual teacher's idiosyncrasy, and the presumed proximity of the soft tissue to the pulp. For example, in some teaching programs, excavation continues until the cavity is stain free. A further issue is the extent to which high- and low-speed excavation is used. In some countries, like Venezuela, the current practice of caries removal in cavitated lesions consists of use of manual excavators for soft dentine and high-speed air turbine until the cavity becomes stain free. This is because conventional excavation techniques with low speed are believed to cause pressure and vibration, producing an increase in temperature. These thermal and vibratory stimulus are painful and, in most the cases, anaesthesia has to be used [1,3–5].

However, exclusive use of high-speed excavation with air turbine handpieces presents some disadvantages, since the drill removes both infected and non-infected dentine, it may cause an unnecessary weakness of the tooth structure, and also increases the possibilities of damaging pulpal tissue [2]. However, the principles of minimal intervention approach indicate the need to remove only dental tissue to the extent that is strictly necessary for treatment. The currently available restorative materials do not

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have the same physical, biological, aesthetic, and preventive properties as the tooth tissue that they replace [6–8].

The search for alternative systems to avoid, or at least minimize, the adverse effects produced by drilling instruments has continued for decades [9,10]. In 1999, a product from MediTeam group called Carisolv™ was marketed [1]. This contains sodium hypochlorite and three natural aminoacids: lysine, leucine, and glutamic acid. The amino acids are used for their effective interaction with the dentine, since they act on the different protein chains of denaturalized collagen, enhancing the effect of sodium hypochlorite on carious dentine, they also neutralize the action of the agent on healthy tissue and prevent degradation of healthy collagen, which can be remineralized. This product also includes methyl-cellulose as a means of improving viscosity, and a colour agent to make its visualization and clinical use easier. In contrast with conventional excavators and drills used for conventional excavation, carious dentine is removed using specially designed hand instruments, all of which reduce the risk of removing intact dentine [1].

An important advantage of using Carisolv is that anaesthesia is no longer needed during the treatment because the procedure is not as painful. The reduction of pain and the lack of need for anaesthesia during the treatment are thought to foster a positive attitude from patients [1,4,11–14]. Compared with conventional excavation, the main disadvantage of using Carisolv is that more time is needed to remove caries [1,11,13–15].

The purpose of this study was to compare the chemomechanical caries-removal system (Carisolv) with the used high-speed excavation in cavitated occlusal caries in primary molars, with respect to: caries removal, volume of removed tissue, caries-removal time, reported pain severity, patient preference, need for anaesthesia, and behaviour.

Materials and methods

Sample

The sample consisted of 80 primary molars, selected from 40 children (20 female, 20 male; average age $7{\cdot}7 \pm 0{\cdot}7$ years; range, 7–9 years), students at the Children School, in Maracaibo County, Zulia State, Venezuela. Patients included had at least two contralateral cavitated primary molars, with occlusal caries having approximately equal-sized cavity openings (diameter ≥ 2 mm). Exclusion criteria included patients who were not very cooperative during the selection process, as well as those who presented molars with clinical or radiographical signs and symptoms of irreversible pulpitis, or molars with radicular resorption involving more than half the radicular length. Guardians responsible for each of the children were fully informed of the details of the study, and asked to sign a consent form authorizing their child's participation in the study, in agreement with the ethical principles of the Helsinki declaration.

Experimental design

The study was a clinical randomized controlled trial with cross-over design, where the two techniques were compared in each individual. An independent co-investigator (M.Q.) was responsible for randomization. A coin was flipped to decide the treatment type in each tooth and the sequence of the procedure. The study included the following steps: a pre-treatment examination, a dental medical history, randomization, caries removal, cavity inspection, restoration, and patient interview. Both treatments were carried out in the same session. Patients were offered local anaesthesia during caries removal. All treatments were performed under rubber dam isolation using no. 00 or 02 Hu-Friedy clamps with topical application of anaesthesia by same trained operator (M.L.). The cavity inspection for successful removal of caries was performed by an independent co-investigator (H.G.) who was blinded to the method of caries removal. All cavities were restored using Brilliant Dentine/Enamel (Coltène™).

Caries removal

For molars treated with Carisolv, the dentine caries was covered with Carisolv gel and after 30 s, the carious dentine was gently scraped away with the specially designed hand instruments supplied by the manufactures to remove softened carious tissue. The procedure was repeated until the gel became clear and the surface was hard when touched with the instruments. After complete caries removal, the remaining gel was rinsed away with water.

For molars treated with high-speed excavation, the caries was removed using a machine KaVo 604 (speed 380·000–450·000 r.p.m. with water cooling), N°. 330 burs and no. 2 and 4 round burs, depending

on the extent of the caries at the floor of the cavity, until it was found to be clinically caries free.

Efficiency of caries removal

Irrespective of the removal method used, each cavity was checked by the operator for remaining caries with an explorer. The completeness of clinical caries removal was judged on the basis of clinical criteria, i.e. the explorer should not stick in the dentine, not give a tug-back sensation, and the cavity must be stain free. If carious dentine remained, the procedure was repeated. The efficiency of the removal of caries was evaluated later by an independent co-investigator using the same criteria. If the case was regarded as a failure, i.e. caries excavation was not complete as judged by the examiner, the caries-removal procedure was repeated with the same method.

Cavity entrance size

The greatest diameter of the entrance size of the lesion was estimated in whole millimeters with a metallic structured caliper before removing the caries. In the same way, after removing the caries, the entrance of the cavity was measured again to compare both the initial and the final size of the cavities. Two blinded co-investigators (O.Z. and H.G.) measured the entrance of the cavities on both occasions. The inter-examiner reproducibility was measured and expressed as kappa = 0·89.

Volume of carious tissue removed

The volume of tissue removed was estimated by calculating the difference between final and initial sizes of the cavity; these were categorized in mm^3 to account for the cavity width and depth (three-dimensional estimation). The linear measurements of the cavity entrance size were measured to the nearest 0·5 mm, so the average value for the cavity size was first estimated. For example: a measured opening sizes of the cavity of 2 mm was taken to indicate that the actual width of the opening could be between 2 and 2·49 mm so an average of 2·25 mm was taken. The final cavity size in mm^3 was computed using the formula $\pi\ (d/2)^2\ h$, where π is a constant with a value 3·142, d is the average diameter of the entrance of the cavity and h is the depth of the cavity that was taken to be equal to the average diameter of entrance size of the cavity. For this example the volume measured will be: $3{\cdot}142 * (2{\cdot}25/2)^2 * 2{\cdot}25 = 8{\cdot}95\ mm^3$ [16].

Caries-removal time

The preparation time for each caries-removal technique was evaluated using a stopwatch. For the Carisolv group, the time was taken from the beginning of gel application until the end of the caries-removal procedure, including the time required for providing anaesthesia, when requested by patients.

Pain, preference, and anaesthesia

After the removal of caries was completed in each tooth, a brief interview, adjusted for the age of the patient, was used to evaluate whether she or he had felt any pain during the procedure. The options were no pain, some pain and unspecified. The patient was asked which treatment he or she preferred. It was also recorded whether or not the patient requested local anaesthesia.

Behaviour

The degree of cooperation by the patient during caries removal was evaluated according to behaviour categories of Frankl *et al*. [17].

Rating 1: Definitely negative: refusal of treatment, crying forcefully, fearful, or any other overt evidence of extreme negativism.

Rating 2: Negative: reluctant to accept treatment, uncooperative, some evidence of negative attitude but not pronounced, i.e. sullen, withdrawn.

Rating 3: Positive: acceptance of treatment, at times cautious, willingness to comply with the dentist, at times with reservation but patient follows co-operatively the direction of the dentist.

Rating 4: Definitely positive: good rapport with the dentist, interested in the dental procedures, laughing, and enjoying the situation.

Statistical analysis

Data for interval/ratio: cavity entrance sizes, volume of carious tissue removed, and caries-removal time were tested for normality; following this analysis parametric statistics was used for volume and time (*t*-test), and nonparametric statistic for cavity entrance sizes (Wilcoxon signed ranks test), pain during treatment (McNemar test), behaviour (sign test),

Table 1. Cavity entrance sizes and volume of removed tissue according to the removal system used.

Removal system	Initial cavity entrance size media ± SD mm	Final cavity entrance size media ± SD mm	Removed tissue volume media ± SD mm^3
Carisolv	2·78 ± 0·93	3·18 ± 1·00[a]	11·48 ± 14·16[c]
High-speed excavation	2·48 ± 0·45	4·09 ± 0·82[b]	52·71 ± 39·75[d]

a ≠ b ($P < 0·001$) Wilcoxon signed ranks test.
c ≠ d ($P < 0·001$) *t*-test.

and treatment preferred by patients (binomial test) and Mann–Whitney's test for association between order of treatment and behaviour of patients The statistical analyses were performed with aid of the SPSS 10·0 computer software. (SPSS Inc., Chicago, IL, USA).

Results

Using conventional criteria, the blinded examiner considered that all the lesions treated with Carisolv and high-speed excavations became clinically caries free. One case of pulp exposure occurred in a molar treated using high-speed excavation.

The mean of the initial and final opening sizes of cavity and the estimated volume of carious tissue removed from the cavities in each technique are shown in Table 1. There was no statistically significant difference between the mean value for initial opening sizes of the cavities from both treatment groups; nevertheless, when final opening sizes of the cavities were compared, a statistically significant difference between the two groups was found ($P < 0·001$). In the same way, the volume of carious tissue removed was significantly smaller ($P < 0·001$, CI = 1·24–1·98) in Carisolv treated molars.

The mean time ± SD for complete caries removal with high-speed excavation was 2·47 ± 1·83 min, whereas the mean time for the Carisolv group was 7·51 ± 2·10 min; this difference was statistically significant ($P < 0·001$, CI = 1·04–1·49). Using high-speed excavation, 77·5% of the patients required a treatment time of less than 3 min; whereas using Carisolv, 70·0% of the patients needed a treatment time of more than 6 min.

After the treatment, all of the 40 participants were asked if they had felt any pain during the caries-removal procedure, some pain degree was reported by seven (17·5%) participants when Carisolv was used, compared with 16 (40·0%) when high-speed excavation was used, these differences were statistically significant ($P < 0·05$).

During caries removal with Carisolv, no patient requested the use of local anaesthesia (0/40); whereas two patients (2/40) requested anaesthesia for high-speed excavation procedure, these results did not allow further statistical analysis. In one patient, who required anaesthesia, a vital pulpotomy was carried out because a pulpal exposure had occurred during the high-speed excavation.

Carisolv treatment was carried out first in 24 pairs, whereas high-speed excavation (HSE) was carried out first in 16 pairs. There was no evidence of association between order of treatment and behaviour of patients in either group (HSE $P = 0·65$ and Carisolv $P = 0·34$).

In relation to the behaviour of patients during the procedure, six (15%) patients showed very negative behaviour, with some differences in favour of the Carisolv treatment. Positive behaviour was seen in 16 patients (40%) during the treatment with Carisolv but six (15%) of these had negative behaviour during high-speed excavation. Seventeen patients (42·5%) had very positive behaviour with Carisolv and 13 patients (32·5%) with high-speed excavation. Only one (2·5%) patient showed better behaviour in favour of high-speed excavation. These results showed a difference in favour of the Carisolv system, and was statistically significance ($P < 0·01$; Table 2).

Of all of the participants (40) when asked about which treatment they preferred, 27 (71·0%) said that they preferred the Carisolv method. The difference

Table 2. Paired comparison of patient behaviour during caries-removal procedure.

	Carisolv				
High-speed excavation	Very negative	Negative	Positive	Very positive	Total *n* (%)
Very negative	3	3	–	–	6 (15)
Negative	–	–	6	–	6 (15)
Positive	–	1	10	4	15 (37·5)
Very positive	–	–	–	13	13 (32·5)
Total *n* (%)	3 (7·5)	4 (10)	16 (40)	17 (42·5)	40 (100)

Sign test ($P < 0·01$).

in proportion was statistically significant ($P < 0{\cdot}05$, CI = 0·54–0·84), two patients were excluded from this part of the statistical analysis because they where not able to answer.

Discussion

In this study, all cavities were found to be clinically caries-free, after being treated with Carisolv; these results agree with the results of clinical studies reported by Ericson *et al*. [1], and Fure *et al*. [11] concerning the effectiveness of Carisolv. *In vitro* investigations conducted by Moran *et al*. [18] and Braun *et al*. [19] also reported complete caries removal using Carisolv and Haffner *et al*. [20] reached 94% efficiency when evaluating 100 teeth, in the same way Fluckiger *et al*. [21] also reported efficiently of the Carisolv for caries removal in primary teeth. The results of this investigation contrast with those reported by Maragakis *et al*. [5] in a clinical study with paediatric patients, who reported only 62·5% (10/16) efficacy of using Carisolv. This was probably because a limit of 15 min was set as maximum time for treatment, and because the caries-free cavity criteria used were those according to Kidd *et al*. [22,23], which were complete removal of all soft and stained dentine, stopping only when dentine was hard to sharp explorer, irrespective of staining. These criteria differed from the ones used in this investigation where criteria for clinically caries free teeth were that the explorer should not stick in the dentine, not give a tug-back sensation, and where the cavity had to be stain free at the end of the excavation.

The results of this study suggested a smaller mean cavity size for the Carisolv technique, a finding that is in contrast with the results reported by Fure *et al*. [11]. This was probably at least partly a result of differences in: lesion location, instruments used for measuring the opening size of the cavity, speed of drilling machine, and the kind of burs used, although Fure *et al*. [11] did not report the speed or the kind of burs used in their investigation. Estimates of the mean volume of tissue removed suggest that amounts were significantly lower when Carisolv was used, offering evidence of the minimal intervention effect of Carisolv in removing carious tissue. An important subject was the criteria for clinically caries free teeth used, which are likely to have considerably influenced the difference in volume of tissue removed between the groups.

The time spent in caries removal using Carisolv was comparable to that spent in previous investigations reported by Ericson *et al*. [1], Nadanovsky *et al*. [4], Maragakis *et al*. [5], and Fure *et al*. [11], although the timings varied between. Variation may have been related to the differences in type and size of the cavities, type of teeth, and ages of the patients. Treatment time for Carisolv in this study was three times longer than with high speed excavation (380·000–450·000 r.p.m.). Maragakis *et al*. [5], using low-speed machine (4·000 r.p.m.), reported that time spent was still 36 times longer when Carisolv was used.

Pain during removal of dentinal caries is a commonly reported phenomenon when using rotating instruments. It is claimed that the chemomechanical systems eliminate this painful symptomatology [1,9,11,24]. In this study, when using Carisolv, a significantly greater proportion of patients reported no pain during the removal procedure, a result similar to those of other studies. Other for example, Ericson *et al*. [1] stated that 42·3% of a group of patients reported very little pain and that no patient reported much pain when using Carisolv. Chaussain *et al*. [24] similarly indicated in their study that 39·2% of their patients reported an acceptable degree of pain when being treated using Carisolv; whereas Munshi *et al*. [9] reported that none of their patients experienced any kind of pain during caries removal using Carisolv. Differences between results may be due to the subjective nature of pain when reported by patients, as well as variability of the pain threshold in each individual. In the present study, the ages of participants limited the possibility of obtaining a more complete description of the kind of pain felt during the caries-removal procedure.

Previous studies [1,5], using low speed for the conventional excavation technique, showed a large difference in favour of the Carisolv regarding use of local anaesthesia during the caries-removal procedure. In this study, only two patients requested local anaesthesia when using more conventional high-speed excavation. This may be due at least partly to the speed used. More revolutions per minute produce less pressure and thermal and vibratory stimulus, and the patients felt less pain in consequence [1,5]. Some studies [4,11] have revealed that the most frightening moments experimented by patients during dental treatment are when the drill is used and when local anaesthesia is given to them. Caries removal by a chemomechanical system,

without using a drill and without applying local anaesthesia, should therefore allow patients to be more comfortable and relaxed during their visit to the dentist.

During caries removal, the majority of patients showed positive behaviour regardless of the treatment method used. However, the highest percentage of positive behaviours was seen when using Carisolv. It is important to note that the exclusion criteria included non-cooperative patients during the initial patient selection. All patients had received an introduction to dental treatment before the study that may also have influenced behaviour. The size and depth of the cavities may also have influenced these results.

Regarding preferences related to the caries-removal technique, most of the patients chose Carisolv, contrasting with the results reported by Maragakis *et al*. [5], who claimed that only 31·25% of their paediatric patients preferred Carisolv. Reasons for preferring Carisolv were 'less noise', 'no drilling', or 'no tooth scratching'. In the study of Maragakis *et al*. [5], 69% selected the air-motor because 'it was quicker', 'it tasted better', and also 'they finished sooner'. In the present research, the patients who preferred high-speed excavation were those from whom the time taken for caries removal was less than 3 min. The time factor may be crucial for acceptance of the treatment by some patients, especially children, since it constitutes an important source of discouragement for them [5].

What this paper adds

- This study shows that the amount of tissue removed when using Carisolv may be less than when using high-speed excavation for caries removal in occlusal caries in primary molars.
- Using Carisolv to remove caries took longer than a conventional mechanical method.

Why this paper is important for paediatric dentists

- The use of Carisolv is an alternative means of caries removal.
- The procedure takes longer but may be preferred by some children and result in more positive behaviour.

Conclusion

In conclusion, the results of this study suggest that Carisolv is an effective clinical alternative of treatment for the removal of occusal dentinal caries in cavitated primary molars. It helps to preserve dental tissue, appeared to be more comfortable for most paediatric patients, although the clinical time spent in the treatment is longer than that spent when using high-speed excavation.

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