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ORIGINAL ARTICLE

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Evaluation of the chemomechanical removal of dentine caries in vivo with a new modified Carisolv gel

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Abstract Carisolv is a minimally invasive method for softening and removing dentine caries. A new, modified Carisolv gel has been developed in order to optimise the efficiency if its chemical caries dissolution. The aim of the present study was to compare the caries removal efficiency of the original gel with that of the new gel, which contains almost double the concentration of sodium hypochlorite. Ten dentists treated 202 cavities in 170 patients; 104 cavities were randomised to the new gel and 98 to the original gel. Their mean treatment times for caries removal were 6.7±4.1 min and 7.6±4.2 min, respectively ($P>0.05$). In close-to-pulp lesions, constituting 32% of the cavities, the mean times for caries removal were 9.0±7.0 min and 11.6±4.4 min for the new and original gels, respectively ($P<0.01$). Questionnaires revealed that 81% of the patients preferred chemomechanical treatment to drilling. In conclusion, the improved efficiency of the modified Carisolv gel did reduce the time for caries removal in deep lesions. However, it still needs more time than conventional drilling.

Keywords Chemomechanical caries removal · Clinical trial · Dentine caries · Patient perception · Treatment time

Introduction

Carisolv is a chemomechanical, minimally invasive method for softening and removing dentine caries which is used in combination with hand instruments. In comparison with drilling, the method is often more time-consuming [4, 8, 9, 12, 13, 19]. To optimise the efficiency and effectiveness of Carisolv gel with respect to chemical caries dissolution and minimal effect on healthy dentine, a new, modified gel has been developed.

The original Carisolv red gel contains three differently charged amino acids which are mixed with sodium hypochlorite prior to treatment. The new gel has no colour agent. It contains half the concentration of amino acids and a higher concentration of sodium hypochlorite, 0.475%, almost twice the 0.250% in the original Carisolv gel. Special hand instruments are also included in the Carisolv system for the removal of dissolved carious dentine. The aim of this study was to evaluate the new modified Carisolv gel for the chemomechanical removal of dentine caries and to compare it with the original gel in terms of efficiency and safety.

Material and methods

Study design

This was a prospective, open, single-blind, randomised, and controlled multicentre study. Consecutive patients at nine Swedish dental clinics (four private practitioners, four community dental clinics, and two dentists at a university clinic), who came for regular dental checkups and presented at least one active carious lesion on a vital tooth, were asked to enter the study. All ten dentists participating in the study were highly experienced in using the Carisolv caries removal method.

Inclusion/exclusion criteria

Pretreatment examination involved medical history and clinical examination, with a dental mirror, explorer, and radiographs as part of the standard routine. Patients with extreme caries activity and conditions which might cause loss of the treated tooth within a 1-year follow-up period were excluded. Special attention was paid to excluding teeth that presented pulp or soft-tissue pathology and pathological processes of the dentine tissues other than caries that would affect the performance and results of the treatment, such as signs of erosion.

Informed consent was obtained prior to the start. The study was approved by the Ethics Committee at Gothenburg University (Dnr: Ö097-01) and performed according to the guidelines of the Declaration of Helsinki.

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Randomisation

After the pretreatment information was retrieved and the patients were found to fulfil the entry criteria, including the agreement to participate, the carious lesions were randomised using the following procedure. For each procedure, a consecutive randomisation envelope was opened. It contained information about which of the two treatments was to be given, either the new (test) or the original Carisolv gel (control). If the patient had more than one active dentine carious lesion, the randomisation envelope also gave information about which of the lesions were to receive which treatment. The patients were not informed about the gel that was used.

Lesion characteristics

The lesions were recorded as 'not deep at all' if carious dentine involved less than the outer third of the dentine, as 'close to pulp' if the lesion involved the inner third of the dentine, and as 'medium' for regions in between. The consistency of the lesions was assessed using a standard probe and recorded as soft if the probe readily entered the dentine, as medium if the probe entered the dentine with some resistance, and as hard if the dentine was not entered when the probe was firmly pressed. In most lesions, the consistency of the dentine involved combinations of two of these assessments and was then recorded according to the softest part.

Anaesthesia

Prior to the excavation and restorative treatment procedures, the patients were asked to choose whether they wanted local anaesthesia. They were also informed that, if they wanted to start without anaesthesia, it could still be administered on request at any time during the treatment.

Treatment procedures

Drill or hand instruments provided access to the carious lesion as needed. The carious dentine was then covered with test or control Carisolv gel (MediTeam Dentalutveckling, Sävedalen, Sweden), which formed a viscous droplet on the tooth surface. After 30 s, the carious dentine was gently scraped away using a specially designed hand instrument (MediTeam) to remove softened carious tissue [8]. The procedure was repeated until the gel was no longer contaminated with debris.

All clinical procedures such as rubber dam, rotary instruments, and water coolant were those normally employed by the operator. The circumstances and results of the treatment were noted. If the cavity had to be treated with direct pulp capping or step-by-step excavation, no special action was taken. The total caries excavation time was recorded, and the cavities were followed 1 year after the first treatment as standard routine.

Efficacy and efficiency

After treatment, the cavities were checked for remaining caries using a probe. The completeness of caries removal was judged on the basis of normal clinical criteria, i.e. the probe should neither stick in the dentine nor give a 'tug-back' sensation. If carious dentine remained, the procedure was repeated. The time for complete caries removal was then recorded.

Restoration

After caries removal with the gel, the cavity outlines were adjusted with a drill or hand instruments as necessary. Suitable restorations using a tooth-coloured material were placed according to the manufacturer's instructions.

Patient questionnaire

Patient evaluation of the procedures was carried out immediately after the treatment using an interview based on a questionnaire. The questionnaire was filled in by the operator and related to pain and comfort. The patients were requested to contact the investigator immediately if any complications were experienced or unexpected problems localised to the treated teeth occurred during the following 12-month period. Any finding and/or additional treatment was reported.

One-year follow-up

One year after the removal of caries and restoration of the cavities, the fillings/teeth were evaluated as part of the regular follow-up. The examination involved recording secondary caries and a vitality test. Visual inspection, probing, and radiographs, when appropriate, diagnosed secondary caries. The patients were also asked about possible adverse effects associated with the treatment.

Statistical analysis

Descriptive statistical analyses were primarily performed. The time taken for caries removal was compared using Student's two-sample *t*-test (two-tailed). The nonparametric Kruskal-Wallis test was used if there were any differences in treatment times between the clinics. Fisher's exact test was used for comparisons of frequency distributions between the two treatment groups (test and control). The statistical analyses were performed with the aid of SPSS computer software (SPSS, Chicago, Ill., USA).

Results

Subjects

Ten dentists treated a total of 202 cavities in 170 patients, 95 females and 75 males. At the time of treatment, the patients were between 19 and 85 years of age, with mean ages of 43 in the test group and 42 in the control group. The treatments were performed between November 2001 and June 2002. Clinical follow-up after 1 year was performed at the respective dental clinics.

Lesions

Of the 202 carious lesions, 104 were randomised for treatment with the test gel and 98 to the control gel. The lesions in the two groups were comparable in terms of type of tooth, location, consistency, and depth (Table 1). When all the lesions were taken together, 54% of the cavities were of medium depth, 32% were close to the pulp, and 14% were not deep at all. Two teeth in the test group were treated with pulp capping, and step-by-step excavation was performed on two teeth, one in each group. No negative reactions or adverse effects were reported from any treatment session.

Table 1 Distribution of lesions for the test (n=104) and control (n=98) treatments in terms of type of tooth, location, lesion, consistency, and depth. Mean±SD times for caries removal are given in min

	Test teeth			Control teeth		
	N	%	Mean±SD	*N*	%	Mean±SD
Incisors and canines	16	15	4.4±1.9	16	16	7.1±2.4
Premolars and molars	88	85	7.5±5.5	82	84	7.7±4.3
Location						
Coronal	73	70	7.2±4.3	77	79	7.7±4.3
Root	24	23	7.1±7.8	20	20	6.9±3.5
Coronal + root	7	7	4.1±1.2	1	1	10.0±0.0
Type of lesion						
Primary	52	50	6.2±3.5	51	52	7.8±3.9
Recurrent	52	50	7.8±6.4	47	48	7.4±4.4
Consistency						
Hard-medium	15	14	6.9±4.9	25	26	7.6±4.4
Medium-soft	54	51	5.5±2.8	42	43	7.1±3.7
Soft	35	34	9.3±7.1	31	32	8.2±4.6
Depth of lesion						
Not deep at all	13	12	5.9±4.6	15	15	4.9±2.3
Medium	54	51	5.8±3.1	55	56	6.2±2.7
Close to pulp	37	36	9.0±7.0	28	29	11.6±4.4

Table 2 Time for caries removal (min) in terms of test (n=104) and control (n=98) treatments

	Test	Control	*P* value
Mean±SD	6.7±4.1	7.6±4.2	N.S.
Range	2.0–20.0	2.0–20.0	
Median	5.0	6.0	N.S.
Total treatment time including filling etc.	21.3±10.4	22.0±10.9	N.S.
Time for caries removal as a percentage of total treatment time	31%	35%	
Mean±SD for caries removal in 'close to pulp' lesions (test n=37, control n=28)	9.0±7.0	11.6±4.4	<0.01

Treatment time

The mean treatment time per cavity for caries removal was 6.7 min for the test gel and 7.6 min for the control gel (Table 2). When comparing the mean times for caries removal, no statistically significant difference was found with Student's *t*-test. Using the nonparametric Kruskal-Wallis test, differences in treatment times between the clinics were analysed. Both when examining treatment times per clinic (caries excavation and total times) and when divided between test and control gel, there were significant differences between the clinics (P<0.001).

At five of the clinics, the treatment times were shorter than the total average, while they were longer at four. There was, however, a significant difference between clinics in terms of depth of lesion, with 'faster' clinics treating a larger number of shallow cavities and 'slower' clinics treating deeper cavities.

When testing for differences in treatment times including all the lesions, there were significant differences (P<0.001) in mean treatment times between the lesion depths of 'not deep at all', 'medium', and 'close to pulp', with time increasing, the deeper the lesion was. When comparing test and control mean excavation times for the three lesion depths, there were no statistically significant differences between the respectively two 'not deep at all' or 'medium' groups. For the two 'close to pulp' groups, there was, however, a significant difference (P<0.01), whereby the test group had shorter excavation time (Table 2).

Patient questionnaire

The questionnaires indicated that approximately half the patients did not mind going to the dentist, while the other half were everything from 'very afraid' to 'a little afraid'. Irrespective of treatment group, almost all the patients (97%) rated the gel treatment as 'pleasant' or 'acceptable' (Table 3); nor was there any difference between the groups when rating smell and taste, which were acceptable to almost everyone.

Anaesthesia

Thirty-two of 104 teeth in the test group and 30 of 98 in the control group underwent anaesthesia. The most common reason for the patients' choosing anaesthesia was that they usually had it and refused to have any treatment without it. Among patients who did not use anaesthesia, around 60% said that they experienced 'no pain' during the excavation, 39% experienced 'some pain', and two of the subjects in the control group without anaesthesia experienced 'severe pain' (Table 3). When the patients were asked about their wishes for future treatment, 81% said that they would prefer chemomechanical treatment if they

Table 3 Patient evaluation of the two gel treatments, in terms of treatment experience (test *n*=104, control *n*=97/98; information from one subject missing in terms of experience of treatment) and degree of pain in subjects without anaesthesia (test *n*=72, control *n*=68)

How did you experience the treatment?	Test *n*, (%)	Control *n* (%)
Pleasant	43 (41)	37 (38)
Acceptable	58 (56)	56 (58)
Unpleasant	3 (3)	4 (4)
Very unpleasant/awful	0 (0)	0 (0)
How did you find the taste?		
Acceptable	96 (92)	92 (94)
Bad	8 (8)	6 (6)
Very unpleasant/awful	0 (0)	0 (0)
How did you find the smell?		
Acceptable	101 (97)	95 (97)
Bad	3 (3)	3 (3)
Very unpleasant/awful	0 (0)	0 (0)
Degree of pain as rated by subjects without anaesthesia		
No pain	45 (63)	39 (57)
Some pain	27 (38)	27 (40)
Severe pain	0 (0)	2 (3)

could choose. Two per cent preferred drilling, and 17% of the patients did not mind either method.

One-year follow-up

When it came to restoration, cavity etching, bonding, and some kind of composite had been used in 90% of the cases in both groups. Of the 202 teeth involved in the study, 177 (88%) were examined after 1 year, 90 in the test group (*t*) and 87 in the control group (*c*). Reasons for dropping out were that the patients had died (one *t*, one *c*), moved from the district (four *t*, three *c*), or were not interested in attending the reexamination (nine *t*, seven *c*).

No complications or adverse effects which could be associated with the Carisolv treatment were reported during the follow-up year. All teeth except three were found to be sensitive when tested with an electric pulp tester and water coolant (Table 4). In one of the nonvital teeth, pulp capping had been performed. The other two teeth had been treated endodontically during the follow-up period because of deep lesions, but this did not involve the lesions treated with Carisolv. One filling had been lost, and nine (five *t*, four *c*) were affected by secondary caries.

Discussion

The main reason for using a chemomechanical caries removal system is the desire to remove adequate quantities of carious dentine and at the same time preserve healthy dental tissue [4, 5]. However, compared with most other methods of carious dentine excavation, such a procedure is more time-consuming [4, 8, 9, 11]. In order to optimise the efficacy and efficiency of the Carisolv system, the concentration of amino acids in the new gel is half that in the original gel, and the concentration of sodium hypochlorite has been almost doubled.

When including all cavities, no significant difference was found between the test and original gels in terms of the time spent for caries removal. It could be argued that the sample size was too small to reveal significant differences between the two gels. It is also difficult to produce identical study groups in this type of clinical trial, since it is impossible to find two completely equivalent lesions. These factors must be taken into consideration when evaluating our results. The lesions were, however, randomised and comparable in terms of location, type of lesion, consistency, and depth.

For the 'close-to-pulp' lesions, excavation time using the test gel was found to be significantly shorter than with the original gel. This is an important finding, as deep lesions are one of the main occasions for using a chemomechanical caries removal system. Such excavation still probably requires more time than conventional drilling. When it comes to preserving the vitality of the pulp, however, the longer time required for Carisolv treatment than for drilling is definitely justified.

The mean time used for caries removal was around 7 min, with a range of 2 to 20 min. The excavation time was in accordance with that in other studies of the chemomechanical removal of carious dentine [5, 8, 9, 11, 14, 15, 16]. Compared with drilling, the chemomechanical excavation time was shown to be significantly longer in some of those studies [4, 8, 9, 11]. In a recent study of contralateral primary molars of 7- to 9-year-old patients, 16 teeth were treated with the Carisolv method and 16 with the traditional air motor bur [13]. The Carisolv

Table 4 Sensitivity and condition of restoration in the 170 teeth included in the 1-year follow-up examination

Condition	Test[a]			Control			Total
	N not deep + medium	*N* close to pulp	*N* total	*N* not deep + medium	*N* close to pulp	*N* total	
Intact filling, vital tooth	58	25	83	58	23	81	164
Intact filling, not vital tooth	1	1	2	1	0	1	3
Lost filling, vital tooth	0	0	0	1	0	1	1
Secondary caries, vital tooth	2	3	5	2	2	4	9
Total	61	29	90	62	25	87	177

[a] No significant differences between the test and control groups (Fisher's exact test)

method did not remove decay completely within 15 min in six of the 16 teeth, and the mean excavation time for those completed was 6 min 51 s. Owing to the longer treatment time, only less than one third of those children would recommend Carisolv to their friends rather than drilling. This is not in agreement with the findings in this study and previous studies of chemomechanical caries removal in adults, where 70–97% would prefer this method instead of drilling [2, 9, 16, 21].

The difference between children and adults might be explained by the fact that children are less tolerant about being kept in the dental chair for a longer time. Another recent study on anxious children aged between 4 and 10 years achieved, however, an acceptance rate of over 90% for chemomechanical caries removal [1]. The average time for caries removal was 10–15 min. Only four out of 60 restorative procedures required local anaesthesia, and there were no complaints about the length of time involved. As pointed out by the authors, when adding the time required to achieve local anaesthesia, conventional treatment would probably takes as long in anxious paediatric patients.

The patient evaluation revealed no differences between the original and test gels in terms of taste, smell, or pain. The majority, i.e. more than 90%, found the taste and smell acceptable, and around 60% felt no pain. These results are in line with those of previous studies of the original Carisolv gel [8, 9, 14, 15, 16]. In the study of primary molars, only seven of the 16 children (44%) found the taste of the Carisolv gel 'OK', while seven said it was bad and two terrible [13]. Correlation analysis revealed, however, that the older children had higher acceptance of the taste. Furthermore, local anaesthesia was required in all bur-treated lesions but none of those excavated with Carisolv in that study. This indicates that the children experienced less pain when treated with the chemomechanical method.

Questions have been raised about whether the Carisolv method effectively removes carious dentine. The efficacy of Carisolv excavation was not tested separately in this study. Carisolv gel is supposed to act on and dissolve the outer carious dentine layer with substantially degraded collagen but not to affect the inner layer with remineralisable dentine affected by caries. Previous studies using an explorer to determine the completeness of caries removal have found that the Carisolv method is effective for caries removal in most teeth [5, 8, 9, 11, 14, 15].

In vitro evaluation using autofluorescence to compare the efficacy of carious dentine excavation between five alternative methods revealed that the Carisolv method removed adequate quantities of tissue [4]. Bur excavation was fastest but overprepared the cavities, whereas sonic abrasion tended to underprepare. Another in vitro study using methyl red dye to distinguish between active and inactive caries in affected dentine found that using Carisolv left about 50 μm more remineralisable carious dentine in the inner, caries-inactive layer than drilling [17].

In a recent in vitro study on bacterial presence, bacteria were detected in one out of 14 bur-excavated lesions and in three of 14 lesions excavated with Carisolv. Besides, a few bacteria at the dentinoenamel junction were found in three lesions treated with Carisolv [19]. Contrary to these findings, a recent in vivo study detected fewer viable bacteria after Carisolv excavation than after drilling [12]. The authors discussed the clinical importance of these remaining bacteria, and clarification needs further investigation.

There was no difference found regarding safety or comfort when comparing the two gels. No negative or adverse reactions associated with the treatment were recorded during treatment or localised on the treated teeth during the 1-year follow-up period. Most of the fillings in the reexamined teeth were intact after 1 year. Nine of 177 teeth were affected by secondary caries and, there also, no significant difference was found between the two types of Carisolv gel. Most of these cavities extended to the root surfaces, and the fillings had been difficult to perform.

Five of the secondary lesions found had been treated by one dentist, who reported that there had been problems finishing the cavity margins in some of these cavities. Therefore, one possible explanation for the high secondary caries rate may be insufficient caries removal at the cavity margin, and another that marginal discolourations were misjudged for secondary caries. The endodontic treatment of two teeth had been occasioned by lesions apart from those treated with Carisolv. For the third tooth that was found to be not vital, pulp capping had been performed, and residual bacteria in the pulp tissue was probably the reason for pulp necrosis. Studies of the original Carisolv system have shown that the gel has no or only a weakly adverse effect on oral mucosa, sound enamel, dentine, and pulp tissue [3, 6, 7, 10, 13, 18, 20].

Conclusions

It can be concluded from this study that no difference regarding efficacy and safety could be seen when comparing the new Carisolv gel with the original gel. The time required for caries removal was shorter with the new gel in deep lesions. The results indicate that the new, chemomechanical Carisolv method offers an interesting alternative for caries removal, as it was preferred over drilling by the majority of the patients.

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