Removing Dentine Caries in Deciduous Teeth with Carisolv™: A Randomised, Controlled, Prospective Study with Six-Month Follow-up, Comparing Chemomechanical Treatment with Drilling

Jørgen Bergmann[a]/Jorge Leitão[b]/Christina Kultje[c]/Dorte Bergmann[a]/Maria João Clode[b]

Abstract: Dental fear is often associated with experience of pain, unpleasant sounds and uncomfortable vibrations caused by dental drills. Therefore patients welcome alternative, less painful excavating methods such as lasers, sandblasters and chemomechanical systems.

The aim of this study was to compare a chemomechanical caries removal system (Carisolv) to traditional drilling with regard to patient acceptance and time consumption as well as the six-month success rate of fillings.

Ninety-two primary teeth in 46 children were included in the study.

From this study, the following conclusions can be drawn: patient acceptance of Carisolv-treatment compared to drilling is excellent, since 65% would choose Carisolv and no one drilling when treated next time. The dentists rated patients' degree of pain significantly lower in Carisolv situations than in drill situations.

Time consumption is significantly higher when excavating with Carisolv (6,7 min.) than with drill (3,3 min.).

The durability of fillings six months after treatment is equal in the two groups.

Key words: caries, excavation

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Conventional treatment of caries involves cavity preparation by means of drilling. This is perceived as unpleasant by many patients (Ayer et al, 1983; Berggren and Meynert, 1984) and local anaesthesia is frequently needed. Drilling may also induce removal of uninfected dentine and cause unnecessary loss of tooth tissue.

An alternative method for preparation of the cavity is removal of the caries by chemo-mechanical means (Beeley et al, 2000; Bindslev, 2004). A patented method for chemo-mechanical caries removal has been developed (Carisolv™, MediTeam Dental AB). The active ingredients are sodium hypochlorite (NaOCl) and three naturally occurring aminoacids – glutamic acid, leucin and lysine. In addition, it contains methylcellulose to increase viscosity. The method also includes a new type of hand instruments with blunt edges, which reduce

[a] *Ryslinge-Ørbaek Community Dental Clinic, Ørbaek Fyn, Denmark*

[b] *University of Lisboa, Dental Faculty, Lisboa, Portugal*

[c] *AstraZeneca R&D, Mölndal, Sweden*

Reprint requests: *Jørgen Bergmann, Central Dental Clinic, Langemosevej 3, DK-5853, Ørbæk, Denmark. Phone +45 65 33 20 30. Fax +45 65 33 18 06. E-mail: tandpl@post7.tele.dk*

the risk of removing intact dentine, as compared to treatment with conventional excavators and drills.

The objective of this investigation was to evaluate the patient acceptance and efficacy (cavity caries free, time consumption as well as six-months success rate of fillings) of chemomechanical removal of caries with the Carisolv method on deciduous teeth. Conventional treatment by means of drilling served as control.

MATERIALS AND METHODS

In this prospective, randomised controlled, open investigation performed at two centres (Denmark, general public practice, and Portugal, university clinic) patients had dentine caries removed with Carisolv gel and instruments on one tooth and with the dental drill (high- and low-speed) on another. One and the same investigator treated all patients at each centre to avoid too much operator-related variability in treatment outcomes. Prior to the start of the study the investigators had treated at least 20 cases with Carisolv to feel comfortable with the method.

The study was conducted according to the Declaration of Helsinki and had obtained ethical committee approval. The legal guardian (mostly one of the parents) signed an informed consent form prior to including the child into the study.

All consecutive patients, five years or older, appearing for a regular dental examination and fulfilling the inclusion criteria, were invited to enter the investigation. Each patient presented at least two active dentine caries lesions in deciduous teeth after a routine examination. When the patient had two cavities or more, the choice of sites to be included in the investigation was determined by randomisation (randomisation envelopes). One site was allocated to the test group and one to the control group.

The investigation included a pre-treatment examination, randomisation, caries removal, cavity inspection and cavity restoration, operator rating of anxiety and pain before, during and after treatment, patient interview as well as a six-month follow-up visit.

Caries removal

Chemo-mechanical removal: If needed, the lesion was opened with a drill or hand instruments. The dentine caries was covered with Carisolv gel, which forms a viscous droplet. After approimately 30 seconds, the carious dentine was gently scraped with specially designed hand instruments to remove softened carious tissue. Fresh Carisolv gel is clear but becomes opaque or cloudy with debris removed from the lesion. When the gel was heavily contaminated with debris, it was removed with gentle suction or with a cotton roll or pellet. Fresh gel was applied. The procedure was repeated until the gel no longer became contaminated with debris.

The cavity was checked for remaining caries using a probe. The completeness of caries removal was judged by normal clinical criteria (i.e. the probe should not stick in the dentine, and should not give a "tug-back" sensation). If carious dentine remained, the procedure was repeated. Finally the remaining Carisolv gel was removed with a cotton pellet soaked in water, or by water-spray.

Drilling: The operator removed caries using rotary round drills following well known normal procedures.

The cavity was checked for remaining caries using a probe. The completeness of caries removal was judged the same way as after caries removal with Carisolv. If carious dentine remained, the procedure was repeated.

Cavity inspection

The independent co-investigator (one at each centre) evaluated the efficacy of the removal of caries (after the operator had done the same).

If the case could not be completed (no complete caries removal) due to the patient's reactions, it was regarded a failure and the reason for not completing was stated.

Cavity restoration

After caries removal the cavity outline was adjusted if necessary. Adhesive restorative materials were used, according to the manufacturer's instructions. If a temporary filling was made, this was followed closely in such a way that the cavity was continuously filled. Treatments to assure this were reported at the six-month follow-up.

Patients' experiences

Patient evaluation of the procedures was carried out shortly after the procedure through an interview

according to a standardised questionnaire, usually directly after the treatment was completed. The dentist rated the patients' level of anxiety and pain separately.

Follow-up

Six months after removal of the caries lesions and restoration of the cavities, the patients were evaluated. The examination involved examination of marginal discoloration and for recurrent caries. The patients were also asked for possible adverse effects associated with the treatment. If a patient experienced complications or unexpected problems within the first six months of follow-up, localised to the treated teeth, the patient was requested to contact the investigator.

Success criteria

Efficacy: The cavity judged free from remaining caries by both the treating dentist and the co-investigator.
Safety: No subjective or objective adverse patient effects.
At the follow-up visit: No recurrent caries and remaining (intact) restoration after six months. Vital teeth still vital.

If it was not possible to perform the second treatment, due to the patients reactions to the first treatment, even on another day, the first treatment was regarded a failure.

Withdrawals/drop-outs

If pulp exposure occurred in an included tooth during treatment, this was reported and the tooth was withdrawn from further reporting within the study.

Data analysis and statistical evaluation

Descriptive statistical evaluation was performed. Comparison of the two groups was performed by means of a Chi-square test or non-parametric statistics (Mann-Whitney test).

Table 1a Distribution of teeth

		Carisolv™	Drill
Maxillae	Incisor	0	1
	Molar	24	30
Mandible	Incisor	0	1
	Molar	22	14
Total		46	46

Incisor = tooth 53, 52, 51, 61, 62, 63 and 73, 72, 71, 81, 82, 83 respectively
Molar = tooth 55, 54, 64, 65 and 75, 74, 84, 85 respectively

RESULTS

Forty-six (46) individuals entered the study, 20 girls and 25 boys (for one child the sex was not reported). The patients were between four and 11 years old, with a mean age of eight years.

In the study 92 deciduous teeth were treated, 46 with Carisolv and 46 with the drill. Most patients had good or acceptable oral hygiene, although 18 patients had poor oral hygiene. The distribution of teeth is seen in Table 1a. The variation in cavity size and consistency is seen in Table 1b, showing more large lesions in the Carisolv teeth than in the drill teeth in spite of randomisation.

In the Carisolv group one tooth received local anaesthesia and in the drill group two did. The reason was that the patient anticipated that the treatment would hurt or (in one of the drill cases) felt that it hurt. Rubber dam was not applied in any of the cases. In the Carisolv group access to the lesion was made with the drill in 37 cases, with hand instruments in seven cases and not needed in two.

All cavities became caries free according to the co-investigator, irrespective of treatment method, except for one in the drill group where the pulp was exposed.

The mean time for caries excavation was 6,7 minutes (+/– 2,9) in the Carisolv group and 3,3 minutes (+/– 2,3) in the drill group. Mean total treatment times, including anaesthesia, filling etc was 10,9 (+/– 4) and 7,6 (+/– 3,6) minutes respectively (Table 2). These differences were significant ($p < 0.001$ in both cases).

Table 1b Size and consistency of lesion

Size of lesion	Carisolv™	Drill	Consistency	Carisolv™	Drill
Large	19	7	Hard	1	4
Medium	19	26	Medium	26	31
Small	8	13	Soft	19	11
Total	46	46	Total	46	46

Table 2 Treatment times (minutes)

	Carisolv™	Drill
0–10 min	43 (23)	46 (35)
11–20 min	3 (22)	0 (11)
> 20 min	0 (1)	0 (0)
Total	46 (46)	46 (46)

	N	Minimum	Maximum	Mean	Std. Dev.
Carisolv™	46	2 (5)	15 (23)	6,7 (10,9)	2,9 (4,0)
Drill	46	1 (3)	10 (15)	3,3 (7,6)	2,3 (3,6)
				p < 0.001	

Numbers in brackets correspond to total treatment times including anaesthesia, fillings, etc)

The final cavity form was obtained using hand instruments in 2/3 of the Carisolv cases. In 21 cases (Portugal) cavity etching and bonding was used as well as some type of isolation before filling with composite. In 25 cases (Denmark) no etching or bonding was used before filling with resin reinforced glas ionomer cement (Table 3).

About one quarter of the patients had never been to the dentist before, while more than half had been there many times (mostly Danish patients). The patient questionnaire indicated that approximately half of the patients were relaxed about dentistry while the other half was differing from very afraid to a little afraid. More patients rated Carisolv treatment rather than drill treatment good or OK ($p < 0,05$) (Fig 1a), and this corresponded well to the dentists' rating of patient anxiety (Fig 1b). In both treatment groups there was an increase in anxiety during treatment rated by the dentist. More patients were afraid during drilling than during Carisolv treatment ($p < 0,05$). The degree of pain, as rated by the dentist, was less for the Carisolv treatments compared to drilling ($p < 0,05$), and again this corresponded to the patients' own ratings, however here the differences between the treatments was not significant ($p > 0.05$) (Fig 1c). If the patients could choose the treatment method next time, 65% would choose Carisolv, no one drilling and 13% did not mind either. The remaining 22% did not know which they would prefer.

At the six-month follow-up two cases of secondary caries were reported in the Carisolv group and one in the drill group. For one of each also a lost/fractured filling was reported. Three and two teeth respectively had exfoliated during the follow-up period (Table 4). There were no differences

Table 3 Cavity restorations

Final cavity form	Carisolv™	Drill	Filling material	Carisolv™	Drill
Not needed	3	1	Glas ionomer	25	24
Drill	12	44	Composite	21	21
Hand instrument	31				
Total	46	45*	Total	46	45*

* 1 withdrawn

	Cavity etched		Bonding used		Isolation used	
	Carisolv™	Drill	Carisolv™	Drill	Carisolv™	Drill
Yes	21	21	21	21	22	22
No	25	24	25	24	24	23
Total	46	45*	46	45*	46	45*

Table 4 Status of filling and marginal discoloration at six months

	Carisolv™	Drill	Total
Intact filling	40	42	82
Secondary caries	2°	1°	3
Tooth exfoliated	3	2	5
Other complications	1**	0	1
Total	46	45*	91
	Carisolv™	Drill	
No discoloration anywhere at the margin	39	41	
Discoloration present at the margin	3	2	
Filling not valuable	4	2	
Total	46	45*	

* 1 withdrawn
° 1 each in combination with fractured/lost filling
** abscess, originally deep cavity, tooth extracted at follow-up

in marginal discoloration between the groups (Table 4). No severe side-effects were noted either at caries removal or during the six-months follow-up period.

DISCUSSION

The randomised, paired design of this study is believed to give reliable, comparative results. By

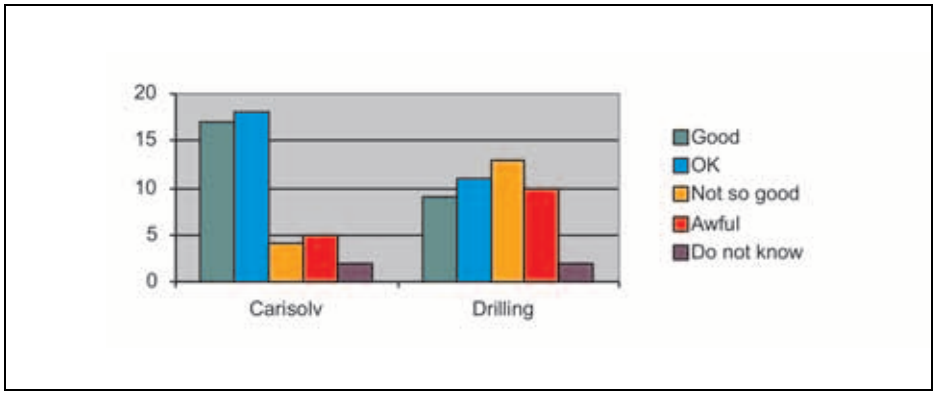

Fig 1a Patient reaction – patients' rating.

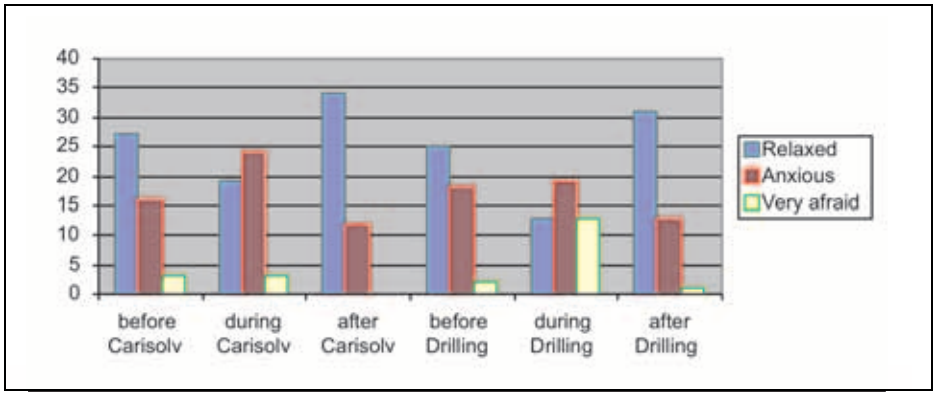

Fig 1b Patient reaction – dentists' rating of anxiety.

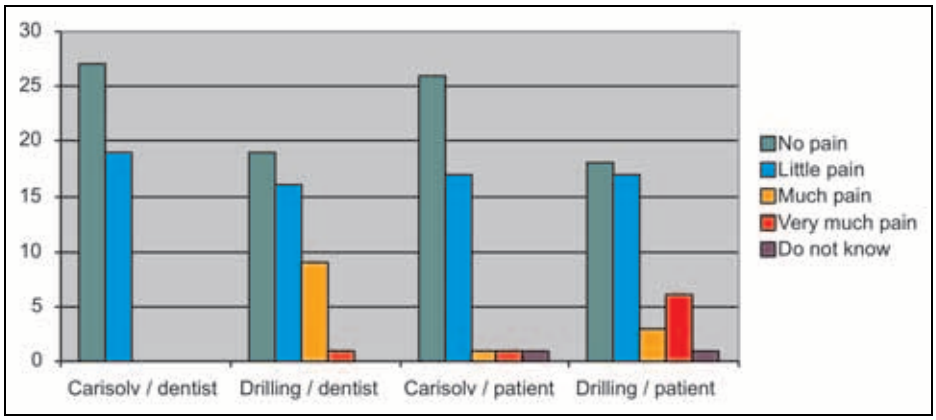

Fig 1c Patient reaction – dentists' and patients' rating on pain.

having the same operator at each centre to perform both kinds of treatment, inter-operator variability was excluded as a thread to the validity of the study.

Time consumption: in spite of randomisation there were more large cavities in the Carisolv-teeth than in the drill-teeth. This might be a partial explanation of the longer treament time in the Carisolv group, but other studies support the conclusion that use of Carisolv is more time consuming than use of drill (Ericson et al, 1999; Kakaboura et al, 2003).

Patient reaction: even though there were more large cavities in the Carisolv teeth, the findings were clearly in favour of the Carisolv treatment. It could be interpreted that bias from dentist or positive expectations from patient might be a reason for these positive findings, but as it is impossible to make a blind study design in a clinical situation, where instruments can be seen and felt, we are not able to judge the value of this. We should keep in mind, of course, that patients – especially young ones – often want to please their dentist and be positive to his new methods.

Excavation-quality: it must be mentioned that one of the operators on later radiographs in a few cases has seen Carisolv-treated teeth showing a thin, radiolucent zone under the filling. Even though this zone looked like recurrent caries, it did not progress and was probably a result of a slight under-excavation compared to the over-excavation that is often a risk when a drill is used. Several other studies confirm that Carisolv is able to remove caries sufficiently (Fure et al, 2000; Maragakis et al, 2001; Munchi et al, 2001; Cederlund et al, 1999).

CONCLUSIONS

1. Carisolv™ has value both as an alternative and as a complement to drilling. No side-effects have been demonstrated.
2. Patient acceptance of Carisolv-treatment compared to drilling is excellent since 65% would choose Carisolv and no one drilling when treated next time. The dentists rated patients' degree of pain significantly lower in Carisolv situations than in drill-situations.
3. Time consumption is significantly higher when excavating with Carisolv (6,7 min.) than with drill (3,3 min.).
4. Durability of fillings six months after treatment is equal in the two groups.

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