

REVIEW ARTICLE

## Comparison of Carisolv system vs traditional rotating instruments for caries removal in the primary dentition: A systematic review and meta-analysis

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### Abstract

**Objective.** The purpose of this systematic review and meta-analysis was to evaluate the reliability of the Carisolv system with respect to drilling regarding the full removal of decayed hard tissues in primary dentition. A systematic review of the literature was conducted to identify controlled trials, randomized controlled trials and clinical trials that compared the Carisolv system to the traditional mechanical caries removal in the primary dentition. **Materials and methods.** The main relevant databases were searched: MEDLINE via PUBMED, Web of Science and SCOPUS. Complete caries removal, length of working time and need of local anesthesia were the outcomes evaluated. **Results.** A total of 195 studies were identified and complete analysis of 28 studies was performed; finally, 10 papers were included. The trials included involved a total of 348 patients for 532 treated teeth. There was no significant difference in terms of clinical efficacy between the Carisolv and the rotary instrument ( $z = 0.68$ ,  $p = 0.50$ ), whereas the treatment with Carisolv was significantly longer in terms of time with respect to the rotary instruments ( $z = 10.49$ ,  $p < 0.01$ ). The chemo mechanical technique reduces the need for local anesthesia, with a difference between two types of treatment near to statistical significance ( $z = 1.91$ ,  $p = 0.06$ ). **Conclusions.** This systematic review indicates that the clinical efficacy of chemo-mechanical removal with Carisolv seems as reliable as the rotary instruments. However, the results should be interpreted cautiously due to the heterogeneity among study designs and to the shortage of available data. Further large-scale, well-designed randomized controlled trials are needed.

**Key Words:** *carisolv, chemo mechanical caries removal, dental caries, primary dentition, rotating instruments*

### Introduction

According to the World Health Organization [1], dental caries is defined as a localized, post-eruptive, pathological process of external origin, involving softening of the hard dental tissues and proceeding to the formation of a cavitation. Dental caries is one of the most commonly occurring diseases worldwide and its treatment has considerable implications in term of economic resources and biological costs [2].

In the past, carious lesions operative treatment was related to the knowledge of the disease pattern and the restorative materials that were available at that

time [3]. In the late nineteenth century, the principle of ‘extension for prevention’ was proposed: cavity preparation required the loss of sound tissue, extending to anatomical sites that might otherwise encourage plaque accumulation [4]. Due to a deeper knowledge of the caries evolving processes and the coming of adhesive restorative materials, the approach to the disease switched from the ‘broaden to prevent’ era to ‘minimally invasive dentistry’ [5]. Modern restorative dentistry offers alternatives to the traditional tissue removal using drilling instruments: a possible alternative is the chemo mechanical removal.

In 1976, the possibility of removing decayed material chemically, using N-monochloroglycine, was reported [6]. A few years later, the Caridex system was introduced as the first chemo mechanical method for caries removal [7]. The chemo mechanical method allows for saving of healthy tissue, providing, at the same time, the patient's comfort [8].

In 1998, a gel-based system used with specially designed non-cutting hand instruments was developed, its name is Carisolv<sup>®</sup>. This product selectively removes infected carious dentine. When the 53 mM of the amino acids in gel form (lysine, leucine and glutamic acid) and the liquid containing 270 mM hypochlorite are mixed, amino acids bind chlorine and form chloramines at a pH of 11. This chlorination affects the secondary and/or quaternary structure of the collagen, by disrupting hydrogen bonding and, thus, brings about proteolytic reaction. It does not affect healthy dentine because amino acids act as homing devices for active chlorine. The chlorine atom of hypochlorite is transferred to the amino group of each amino acid and in this way it is made less reactive and less aggressive to healthy tissue [9]. The chemo mechanical method of caries removal is considered useful, especially in pediatric dental practice, reducing the noise, vibration and pain produced by the use of high- and low-speed rotary instrument [10]. Other products for the chemo mechanical caries removal based on papaya plant extract (Papacarie and Carie-care) were launched on the dental market, but scarce scientific data are present on these products [11–13].

Few *in vivo* studies evaluate Carisolv<sup>®</sup> efficacy: the results seem to support the reliability of the chemo mechanical caries removal [9,10,14–18].

Therefore, this study aimed at systematically evaluating the current literature by means of a meta-analysis. The primary outcome variable of interest was the clinical efficacy in primary caries removal and secondary parameters were the clinical efficiency (treatment time) and patient's comfort (need of local anesthesia).

## Materials and methods

This systematic review was performed following the guidelines of the Transparent Reporting of Systematic Reviews and Meta-Analyses (PRISMA) [19].

### Focused PICO question

In primary dentition, what is the efficacy of Carisolv in caries removal rate (clinically appreciated) compared to the traditional drill technique, the clinical efficiency (treatment time) and patient's comfort (need of anesthesia)?

### Eligibility criteria

The studies included in the present review are Clinical Trials, Randomized Clinical Trials and Controlled Trials assessing the efficacy on the primary dentition of Carisolv compared to traditional mechanical caries removal (control) with drilling instruments. Only studies where total caries removal in each group was completed using Carisolv systems or rotary instruments used without any time limit were considered eligible. The studies including other experimental groups in addition to Carisolv and drilling were also included in this review. Studies assessing the complete caries removal different from clinical criteria (i.e. using a sharp probe) were excluded.

### Search strategy

For the identification of studies to evaluate for this review, a unique search strategy to be applied for each database research was developed (Figure 1). The following key words were used: Carisolv and Chemo mechanical Caries Removal. No Mesh term match was found. The terms were searched following the Boolean term 'OR' for a total of three inquiries.

Database research:

- MEDLINE via PUBMED (from 1948 to December 2014);
- Web of Science (from 1948 to December 2014); and
- SCOPUS (from 1969 to December 2014).

A comparison of the different searches was carried out to delete the repeated studies. Then, two authors (GL and CLC), on charge to evaluate the eligibility of the studies, examined independently all abstracts of the selected papers. If an abstract didn't supply enough information to determine if the paper met the inclusion criteria, the full report was obtained. All studies which appeared to meet the inclusion criteria were obtained in the full text format. The two authors assessed the papers independently, to establish whether or not the studies met the inclusion criteria. Disagreements were resolved by discussion. If not possible, other authors were consulted.

### Data analysis

The outcomes considered in the studies were: the caries removal rate clinically appreciated (binary yes/no), the time required to complete the tissue removal (continuous) and the pain threshold during the procedure, assessed through the need for local anesthesia by patients (binary yes/no). When raw data was not available in the text, tables or graphs, single authors were contacted to obtain such information. To compare dichotomous data, a calculation of the Odd Ratio

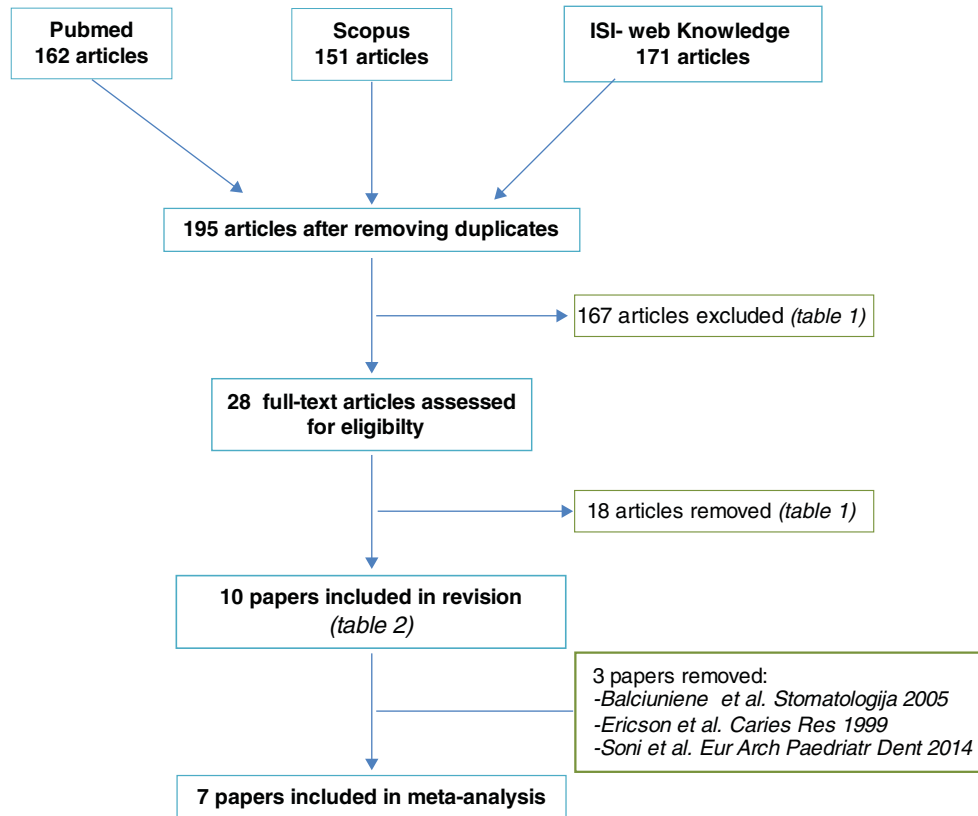


Figure 1. Flowchart of search strategy.

(OR) along with 95% Confidence Intervals (CIs) was used, whereas, for continuous data, the Mean Difference (MD) with 99% Confidence Intervals (CIs) was calculated. Also, for each comparison the Z-test was used. A random-effect model was applied to reassess all data extracted from the included studies.

Analysis was performed using Review Manager 5.3 software provided by the Cochrane Collaboration [20].

## Results

A total of 195 studies published from 1999–2014 were identified and assessed (Table I). Twenty-eight papers were analyzed and 10 studies met the eligibility criteria (Table II).

The trials included in the review involved a total of 348 patients and 532 treated teeth. In three studies [14,16,21] it was not possible to extract the number of patients treated and so these studies were excluded.

From the selected studies, two were conducted in India [9,21], one in Venezuela [18], two in Greece [10,22], one in Lithuania [16], one in Serbia [15], one in Sweden [14], one in the US [23] and one in both Denmark and Portugal [17]. Two of the papers reported data from multi-center (Sweden; Denmark and Portugal) studies.

One of the studies had a crossover design [18], three were split mouth [16,17,22] and six had a parallel group design [9,10,14,15,21,23].

Most studies compared the Carisolv system [7] with the conventional rotary drill excavation for caries removal, but in three papers four different methods were reported [9,14,21].

In two studies no details about the operator and co-investigator were reported [9,21], in another two studies there was Testo one operator and one co-investigator [15,16], while in another one there was one operator and two co-investigators [18], in another one [10] two operators but no co-investigator and, finally, in two studies there was only one operator [21,23]. In one of the two multi-center studies there was one operator and one co-investigator for each center [14,17].

Six of the trials included only primary teeth [9,10,17,18,22,23] with participants' ages ranging from 28 months to 11 years. Four trials were carried out on permanent teeth also [14–16,21] and the ages of the subjects ranged from 30 months to 85 years.

In five trials [10,14–17] the teeth involved in the studies were molars and anterior primary teeth; in four studies [9,18,22,23] only primary molars with occlusal caries were treated; while in one study [21] primary molars were treated, but it was not mentioned which surfaces were treated.

Table I. List of excluded studies.

Authors	Year	Journal	Reason for exclusion	Authors	Year	Journal	Reason for exclusion
Ammari et al.	2014	Braz Oral Res	Microbiological study	Amaral et al.	2011	Am J Dent	In vitro study
Boob et al.	2014	Int J Clin Pediatr Dent	In vitro study	Chang et al.	2011	Journal of Southern Medical University	Chinese language
Bussadori et al.	2014	Oral Health Prev Dent	In vitro study	Gugnani et al.	2011	J Conserv Dent	No group with Carisolv
Bussadori et al.	2014	J Contemp Dent Pract	No group with Carisolv	Imbrunito et al.	2011	Int J Periodontics Restorative Dent	In vitro study
Garcia-Contreras et al.	2014	In vivo	In vitro study	Kochhar et al.	2011	J Clin Pediatr Dent	Evaluation with caries detector
Geetha Priya et al.	2014	J Indian Soc Pedod Prev Dent	No clinical evaluation	Li et al.	2011	J Dent	In vitro study
Gil-Montoya et al.	2014	Clin Oral Investig	Only permanent teeth	Neves Ade et al.	2011	J Dent	In vitro study
Hamama et al.	2014	Aust Dent J	Review	Neves Ade et al.	2011	Dent Mater	In vitro study
Hamama et al.	2014	J Endod	In vitro study	Neves Ade et al.	2011	J Dent	In vitro study
Jingarwar et al.	2014	J Clin Diagn Res	Review	Shabzendeddar et al.	2011	J Contemp Dent Pract	In vitro study
Li et al.	2014	J Oral Rehabil	Review	Zawaideh et al.	2011	Pediatr Dent	In vitro study
Motta et al.	2014	J Appl Oral Sci	No group with Carisolv	Banerjee et al.	2010	J Dent	In vitro study
Pradeep Kumar	2014	Int J Pharma Bio Sci	No group with Carisolv	Gianini et al.	2010	Am J Dent	In vitro study
Schwendicke et al.	2014	J Dent	Review	Tsanova et al.	2010	Folia Med	In vitro study
Aggarwal et al.	2013	Aust Dent J	In vitro study	Yamada et al.	2010	J Clin Pediatr Dent	In vitro study
Banerjee	2013	Br Dent J	Review	Allaker et al.	2009	Int J Antimicrob Agents	Review
Bijle et al.	2013	J Contemp Dent Pract	Statistical survey	Bertassoni et al.	2009	Scanning	In vitro study
Cecchin et al.	2013	Braz J Oral Sci	In vitro study	Fure et al.	2009	Oral Health Prev Dent	No control group
Goomer et al.	2013	J Int Oral Health	Clinical eval caries detector	Kotb et al.	2009	J Clin Pediatr Dent	No group with Carisolv
Gupta et al.	2013	J Clin Pediatr Dent	No group with Carisolv	Martins et al.	2009	J Dent Child (Chic)	In vitro study
Hamama et al.	2013	Aust Dent J	In vitro study	Pai et al.	2009	J Conserv Dent	In vitro study
Juntavee et al.	2013	Int J Clin Pediatr Dent	In vitro study	Prabhakar et al.	2009	Pesqui Bras Odontopediatria Clin Integr	In vitro study
Kathuria et al.	2013	J Clin Diagn Res	In vitro study	Topaloglu-Ak et al.	2009	Clin Oral Investig	No control, no clin eval
Moldovanu et al.	2013	Rev Chim	In vitro study	Abdelnur et al.	2008	J Dent Child	Case report
Zenen et al.	2013	Cumhuriyet Dent J	In vitro study	Barata et al.	2008	J Appl Oral Sci	Study in permanent teeth

Table I. (Continued).

Authors	Year	Journal	Reason for exclusion	Authors	Year	Journal	Reason for exclusion
Rajakumar et al.	2013	J Clin Pediatr Dent	No group with Carisolv	Bussadori et al.	2008	J Clin Pediatr Dent	Case report
Ramamoorthi et al.	2013	J Conserv Dent	In vitro study	Corra et al.	2008	J Clin Pediatr Dent	In vitro study
Venkatraghavan et al.	2013	J Int Oral Health	Review	Corra et al.	2008	Eur Arch Paediatr Dent	In vitro study
Viral et al.	2013	J Clin Pediatr Dent	In vitro study	Guar et al.	2008	Spec Care Dentist	No clinical evaluation
Yildiz et al.	2013	Eur J Paediatr Dent	In vitro study	Gurbuz et al.	2008	Eur J Dent	In vitro study
Zhang et al.	2013	Aust Dent J	In vitro study	Hosein et al.	2008	J Coll Physicians Surg Pak	Only permanent teeth
Ahmed et al.	2012	Caries Res	In vitro study	Piva et al.	2008	Braz Oral Res	In vitro study
Anegundi et al.	2012	Contemp Clin Dent	No group with Carisolv	Perić et al.	2008	Srpski Arhiv za Celokupno Lekarstvo	No data
Arora et al.	2012	Eur Arch Paediatr Dent	In vitro study	Rupf et al.	2008	J Dent Res	In vitro study
Avinash et al.	2012	J Indian Soc Pedod Prev Dent	In vitro study	Subramaniam et al.	2008	J Clin Pediatr Dent	Microbiological study
Azzouz et al.	2012	SJKFU	Only permanent teeth	Tachibana et al.	2008	Lasers Med Sci	In vitro study
Banerjee	2012	Ann R Australas Coll Dent Surg	Review	Yamada et al.	2008	J Dent	In vitro study
Bhardwaj et al.	2012	RJPBCS	No clinical study	Corra et al.	2007	J Clin Pediatr Dent	In vitro study
El-Tekeya et al.	2012	Pediatr Dent	In vitro study	De Oliveira et al.	2007	Journal of Adhesion	In vitro study
Galuscan et al.	2012	Rev Chim	Clin evalu with caries detector	Giza	2007	Ann Acad Med Stetin	Polish language
Kumar et al.	2012	Indian J Dent Res	No control group	Inglehart et al.	2007	J Am Dent Assoc	No clinical evaluation
Schlafer et al.	2012	J Nat Prod	In vitro study	Kirzioglu et al.	2007	Clin Oral Investig	No control group
Singhal et al.	2012	Indian J Dent Res	In vitro study	Okida et al.	2007	Braz Oral Res	In vitro study
Sirin Karaarslan et al.	2012	J Dent	In vitro study	Pandit et al.	2007	J Indian Soc Pedod Prev Dent	No control group
Verma et al.	2012	J Indian Soc Periodontol	In vitro study	Peric T et al.	2007	Eur J Paediatr Dent	In vitro study
Yamada et al.	2012	J Clin Pediatr Dent	In vitro study	Topaloglu-Ak	2007	J Appl Oral Sci	Endodontic study
Zhao et al.	2012	Chinese Journal of New Drugs	No clinical evaluation	Topaloglu-Ak et al.	2007	J Appl Oral Sci	No control group
Yamada et al.	2007	J Clin Pediatr Dent	In vitro study	Kakaboura et al.	2003	Quintessence Int	Only permanent teeth
Antonio et al.	2006	J Oral Sci	Study on the bovine	Kinoshita et al.	2003	J Clin Laser Med Surg	In vitro study
Bonsor and Pearson	2006	Dent Update	Microbiological study	Lager et al.	2003	Caries Res	In vitro study

Table 1. (Continued).

Authors	Year	Journal	Reason for exclusion	Authors	Year	Journal	Reason for exclusion
Clementino-Luedemann et al.	2006	Dent Mater J	In vitro study	Lumbau et al.	2003	Minerva stomatol	No clinical evaluation
Damaschke et al.	2006	Aust Dent J	Study on the rats	Rafique et al.	2003	Caries Res	Only permanent teeth
De Magalhães et al.	2006	Braz Dent J	In vitro study	Sakoolnamarka et al.	2003	Am J Dent	In vitro study
Grisi et al.	2006	Braz Dent J	In vitro study	Tonami et al.	2003	J Med Dent Sci	In vitro study
Lennon et al.	2006	Oper Dent	In vitro study	Yazici et al.	2003	J Oral Rehabil	In vitro study
Lenters M et al.	2006	Eur Arch Paediatr Dent	Full text not available	Arvidsson et al.	2002	J Dent	In vitro study
Marquezan et al.	2006	Braz Oral Res	Review	Arvidsson et al.	2002	Biomaterials	In vitro study
Meller et al.	2006	Eur J Paediatr Dent	In vitro study	Damaschke et al.	2002	J Dent	Study on the rats
Mhaviile et al.	2006	Eur Arch Paediatr Dent	Clinical evaluation with RX	Kubo et al.	2002	Oper Dent	In vitro study
Roeleveld et al.	2006	Eur Arch Paediatr Dent	No clinical evaluation	Nemes et al.	2002	Fogorvosi szemle	Review
Saboia et al.	2006	Oper Dent	No clinical evaluation	Sakoolnamarka et al.	2002	Aust Dent J	In vitro study
Bussadori et al.	2005	J Clin Paediatr Dent	No group with Carisolv	Yazici et al.	2002	Oper Dent	In vitro study
Damaschke et al.	2005	Acta Odontol Scand	In vitro study	Arvidsson et al.	2001	Gerodontology	In vitro study
El-Kholany et al.	2005	J Adhes Dent	In vitro study	Beeley et al.	2001	Ned Tijdschr Tandheelkd	Review
Fickiger et al.	2005	J Dent	In vitro study	Damaschke et al.	2001	J Dent	Study on the rats
Hosoya Y et al.	2005	J Dent	In vitro study	Hosoya et al.	2001	J Dent	In vitro study
Hu et al.	2005	Med J Wuhan Uni	In vitro study	Ilewicz et al.	2001	Acta Pol Toxicol	In vitro study
Lima et al.	2005	J Appl Oral Sci	Microbiological study	Maragakis et al.	2001	Int Dent J	Review
Morrow et al.	2005	Am J Dent	In vitro study	Munshi et al.	2001	J Clin Pediatr Dent	No control group
Rahman et al.	2005	Int Endod J	Study on the ovine	Nadanovsky et al.	2001	Caries Res	Only permanent teeth
Sakoolnamarka et al.	2005	Aust Dent J	In vitro study	Splieth et al.	2001	Clin Oral Investig	In vitro study
Sonoda et al.	2005	J Dent	In vitro study	Yamada et al.	2001	J Clin Laser Med Surg	In vitro study
Yamada et al.	2005	J Clin Paediatr Dent	In vitro study	Young et al.	2001	J Dent	Study on the rats
Yazici et al.	2005	Quintessence Int	In vitro study	Banerjee et al.	2000	J Dent	In vitro study
Zesewitz et al.	2005	Schweizer Monat fr Zahnmedizin	German language	Beeley et al.	2000	Br Dent J	Review
Ziskind et al.	2005	Quintessence Int	Review	Fure et al.	2000	Caries Res	Only permanent teeth
Arvidsson	2004	Acta Odontol Scand	In vitro study	Haak et al.	2000	Eur J Oral Sci	In vitro study

Table I. (Continued).

Authors	Year	Journal	Reason for exclusion	Authors	Year	Journal	Reason for exclusion
Azrak et al.	2004	Int J Paediatr Dent	Microbiological study	Morrow et al.	2000	Dent Update	Full text not available
Berto et al.	2004	Gen Dent	Study on the rats	Yamada et al.	2000	J Clin Laser Med Surg	In vitro study
Bulut et al.	2004	J Dent	In vitro study	Cederlund et al.	1999	Acta Odontol Scand	In vitro study
Erhardt et al.	2004	Quintessence Int	In vitro study	Cederlund et al.	1999	Int J Periodontics Restorative Dent	In vitro study
Fure et al.	2004	Clin Oral Investig	Only permanent teeth	Hannig	1999	Clin Oral Investig	In vitro study
Grbz T	2004	Pain Clinic	No clinical evaluation	Banerjee et al.	2000	Caries res	In vitro study
Hahn et al.	2004	Caries Res	In vitro study	Banerjee et al.	2000	Br Dent J	In vitro study
Sepet et al.	2004	J Dent	In vitro study	Wennerberg et al.	1999	Eur J Oral Sci	In vitro study
Al-Kilani et al.	2003	Int Endod J	In vitro study	Lai	1990	Rivista italiana di odontoiatria infantile	
Ansari et al.	2003	J Oral Rehab	No clinical evaluation	Bianchi et al.	1989	Dental Cadmos	In vitro study
Beyth et al.	2003	Refiat Hapeh Vehashinayim	Review	Bianchi et al.	1989	Dental Cadmos	Only permanent teeth
Burrow et al.	2003	Aust Dent J	In vitro study	Scheutzel	1989	Deutsche zahnärztliche Zeitschrift	German language
Cehreli et al.	2003	J Dent	In vitro study	Goldman et al.	1988	J Pedod	In vitro study
Chaussain-Miller et al.	2003	Clin Oral Investig	Only permanent teeth	Anusavice et al.	1987	J Dent Res	No clinical evaluation
Fritz	2003	J Orofac Orthop	Review	Morlot	1986	Le Chirurgien-dentiste de France	Full text not available
Hossain et al.	2003	Oper Dent	In vitro study				

Table II. Summary of the characteristics of the included study.

Author (year)	Patients characteristics	Interventions				Outcomes (Carisolv/drill)		
		Carisolv/drill	Study design	Carisolv	Drill	Clinical efficacy	Time taken	Need for anesthesia
Soni et al. (2014)	120 patients (4–14 years); 120 primary and permanent teeth.	30/30	RCT parallel group	30 Carisolv/special hand instrument until cavity was hard on probing	Rotary instruments until the cavity clinically caries free			
Bohari et al. (2012)	120 patients (5–9 years); 120 primary teeth. Lesion dentine/occlusal surfaces	30/30	RCT parallel group	30 Carisolv/special hand instrument until cavity was hard on probing	Rotary instruments until the cavity clinically caries free	474.7–43.0 s (30)/ 206.7–22.1 s (30)		
Peric (2009)	120 patients (3–17 years); 74 primary teeth. At least one primary carious lesion	40/34	RCT parallel group	30 Carisolv/special hand instrument until cavity was hard on probing	Rotary instruments until the cavity clinically caries free. The cavity checked by an operator	648–162 s (40)/ 432–84 s (34)		
Peters et al. (2006)	50 patients (6–11 years); 50 primary molars. One primary occlusal carious lesion for each tooth.	26/24	RCT parallel group	30 Carisolv/special hand instrument until cavity was hard on probing. Time limit was 15 min	Rotary instruments until the cavity clinically caries free. Time limit was 15 min	604.2–227.5 s (26)/80.7–84 s (24)		
Lozano-Chourio (2006)	40 patients (7–9 years); 80 primary teeth. At least two caries in primary molars	40/40	RCT cross-over design	30 Carisolv/special hand instrument until cavity was hard on probing. The cavity checked by an operator	Rotary instruments until the cavity clinically caries free. The cavity checked by an operator	450.6–109.8 s (40)/ 148.2–126 s (40)	100% (40 of 40)/ 100% (40 of 40) caries free	0% (0 of 40)/ 5% (2 of 40)
Balciuniene (2005)	30 patients. (2.5–13 years); 60 primary and permanent teeth. At least two lesions	30/30	Controlled clinical trial split mouth design	30 Carisolv/special hand instrument until cavity was hard on probing. The cavity checked by an independent examiner	Rotary instruments until the cavity clinically caries free. The cavity checked by an independent examiner			

Table II. (Continued).

Author (year)	Patients characteristics	Interventions				Outcomes (Carisolv/drill)		
		Carisolv/drill	Study design	Carisolv	Drill	Clinical efficacy	Time taken	Need for anesthesia
Kavvadia et al. (2004)	31 patients (28 months–9 years); 92 primary teeth. At least one primary carious lesion	65/27	Controlled clinical trial parallel group	30 Carisolv/special hand instrument until cavity was hard on probing. The cavity checked by two operators	Rotary instruments until the cavity clinically caries free. The cavity checked by two operators	100% (65 of 65)/100% (27 of 27) were caries free	486–318 s (65)/168–114 s (27)	2.3% (1 of 43)/23.5% (4 of 17) requested anesthesia
Bergmann et al. (2005)	46 patients (4–11 years); At least two active dental caries lesions in primary teeth	46/46	RCT split mouth design. A multi-center study	30 Carisolv/special hand instrument until cavity was hard on probing. The cavity checked by an operator one for each center	Rotary instruments until the cavity clinically caries free. The cavity checked by an operator one for each center	100% (46 of 46)/97.8% (45 of 46) were caries free	402–174 s (46)/198–138 s (46)	
Maragakis et al. 2001	16 patients (87–109 months); two contralateral primary molar with occlusal primary decay	16/16	Controlled clinical trial split mouth design	Application of Carisolv/special hand instrument until cavity was hard on probing. The cavity checked by an operator. Time limit was 15 min	Rotary instruments until the cavity clinically caries free. Time limit was 15 min			
Ericson et al. (1999)	137 patients. (3–85 years). At least one active dental primary caries	16/1	RCT parallel group multi-center study	20 Carisolv/special hand instrument until cavity was hard on probing. The cavity checked by an operator	Rotary instruments until the cavity clinically caries free. The cavity checked by an operator		618–336 s (16)/no data	

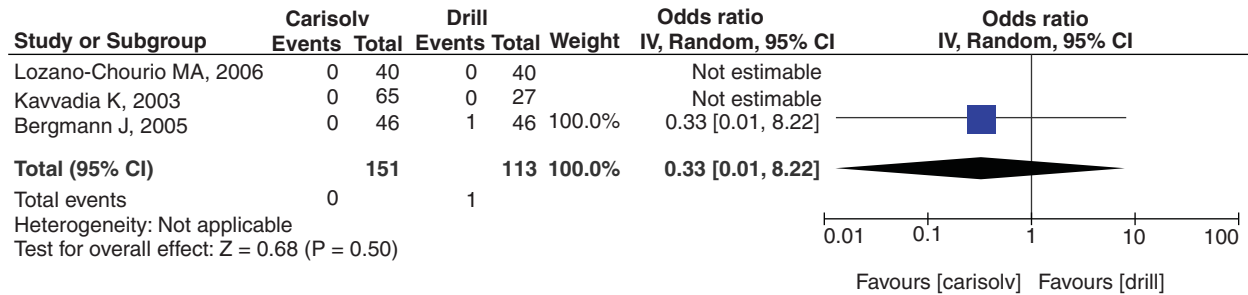


Figure 2. Forest plot of comparison: Individual and overall Odds Ratio in the comparison of clinical efficacy between the Carisolv group and the rotary instrument group.

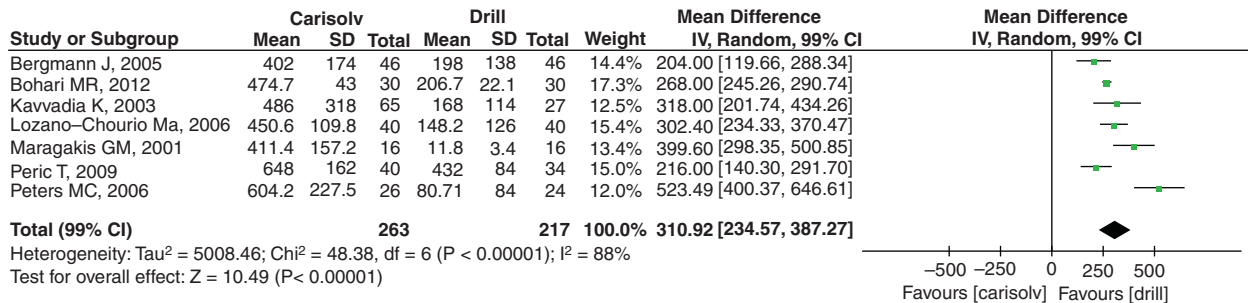


Figure 3. Forest plot of comparison: Individual and overall Mean Difference in the comparison of time taken between the Carisolv group and the rotary instrument group.

Data regarding the clinical efficacy in decayed tissue removal of the Carisolv system vs a control group were obtained from three papers [10,17,18], with a total of 264 analyzed teeth. Complete caries removal was obtained in 100% (151 of 151) of the teeth using Carisolv and 99.2% (112 of 113) using the drill. When data were combined in meta-analysis, the summary OR was 0.33 (99% CI = 0.00–22.65). On the basis of the available evidence, there was no statistically significant difference in caries removal between the chemo mechanical system (Carisolv) and the rotary instruments ( $z = 0.68$   $p = 0.50$ ) (Figure 2).

Data on the time required (seconds) to complete the procedure (mean  $\pm$  SD) was obtained from seven studies [9,10,15,17,18,22,23] with a total of 480 teeth involved. The maximum time required for caries removal was 648 s for Carisolv and 206.7 s for the rotary instrument, whereas the minimum time of treatment was 402 s for the chemo mechanical removal and 80.7 s with the use of drills. The chi-square value was 48.38, with six degrees of freedom (df) and  $p < 0.01$ . The treatment with Carisolv required a statistically significant greater time amount than that required with the use of rotary instruments. The z-test for overall effect for the Carisolv group vs rotary instruments was  $z = 10.49$ ,  $p < 0.01$  (Figure 3).

Finally, data regarding the pain threshold were obtained from four studies only [10,18,22,23] with a total of 222 teeth involved. With the Carisolv system, 4% of the children requested local anesthesia, while 26.8% used the conventional method. When

data were combined in meta-analysis, the summary OR was 0.09 (95% CI = 0.01–1.07) with a difference between two types of treatment near to statistical significance ( $z = 1.91$ ,  $p = 0.06$ ), with fewer patients who needed local anesthesia in the Carisolv group (Figure 4).

### Discussion

A multitude of technique and materials are proposed in the dental market to use in restorative dentistry and so the need of a strong scientific evidence for the ‘new’ methods is essential before their use in everyday practice.

Carisolv was introduced in the dental market (Sweden) in 1998 [9] and during the last 15 years it has been used almost exclusively in pediatric dentistry; as the use of Carisolv in clinical practice might be limited because of the material cost [24]. In the literature, there is no availability of systematic review on the efficacy of Carisolv system in caries removal in primary dentition. Hence, this meta-analysis review was performed in an attempt to gain further insight into the reliability of the Carisolv system. Seven studies were included, with a total of 450 primary teeth involved. The heterogeneity of the results generated by different studies on the use of Carisolv limits to obtain an overall correlation among outcome variables.

The parameter to evaluate the effectiveness of the Carisolv against rotary instruments was the caries removal rate, clinically appreciated. This evaluation

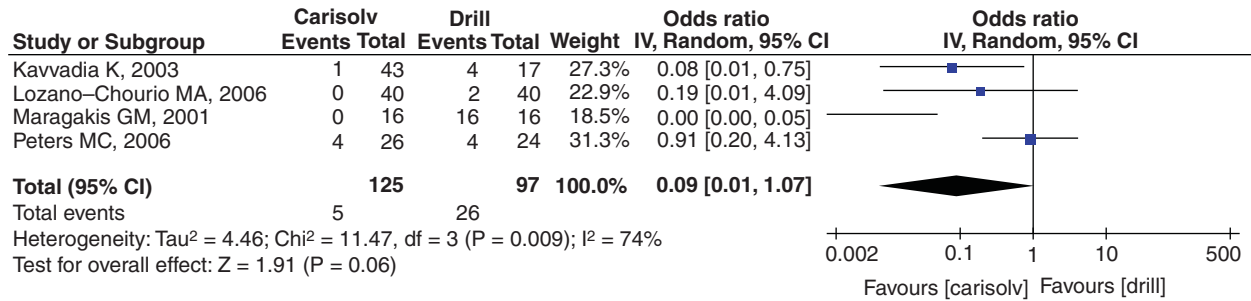


Figure 4. Forest plot of comparison: Individual and overall Odds Ratio in the comparison of need for anesthesia between the Carisolv group and the rotary instrument group.

method seems empirical and inaccurate, however it is the main and simple approach to check the caries removal [25]. This method only required a visual estimation and a tactile evaluation using a sharp probe. Other methods to evaluate the complete caries removal, like caries detectors, are a matter of controversy in the literature [26].

The comparison of the clinical evaluations data indicated that no statistically significant difference exists between the Carisolv group and the control group with rotary instruments in terms of caries removal efficacy.

Outcomes regarding the time required to complete the procedure were reported in five of seven studies selected. There was a significant difference regarding time required by the Carisolv procedure and the conventional drilling: treatment time was statistically significantly longer using Carisolv than drilling. This difference was related to the need of multiple applications of Carisolv gel, especially when big carious lesions were treated. Only one paper reported that the lesions in both groups were similar in terms of size, but the time taken for caries removal using Carisolv was 3-times longer [18]. A previous clinical investigation [27] found the depth of carious lesions was an important parameter for the excavation time with Carisolv.

Pain is a commonly reported phenomenon when removing dental caries and the use of local anesthesia is often required. Data on pain threshold or need of local anesthesia were reported in four papers. Carisolv seems to reduce the use of local anesthesia and this difference may be related to the use, together with Carisolv gel, of sharp hand instruments. However, it is necessary to consider that the four studies were heterogeneous in design and the Carisolv group was more numerous than the control group.

## Conclusion

Within the limitations of the available data, the clinical efficacy of chemo mechanical instruments in caries removal with Carisolv seems as reliable as that obtained using rotary instruments. Data analysis

suggests that the difference in terms of time taken was statistically significant: the Carisolv system takes more time than the traditional method to remove dental caries. Regarding patient's comfort, this systematic review indicates that the Carisolv system can reduce the use of local anesthesia. However, these results should be interpreted cautiously due to the heterogeneity among study designs and to the shortage of data usable. To confirm these conclusions there is the need of further large-scale, well-designed RCTs.

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