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Efficacy of Smart Burs and CARISOLV in caries removal in comparison to conventional method: A Randomized Controlled Clinical Trial

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ABSTRACT

This study was aimed to compare the effectiveness of three techniques of caries removal in primary molars; Smart Burs, Carisolv gel and Conventional Rotary Drill. A total of 60 carious primary mandibular molars were selected. They were equally assigned into three groups; Group 1: Carisolv gel, Group 2: Conventional Rotary Drill, and Group 3: Smart Burs. The time needed to excavate all caries and the pain level caused by each technique were evaluated. Mann-Whitney U test showed that the conventional method needed the least time to excavate all caries, followed by Smart burs and CariSolv, respectively with a statistically significant difference ($P < 0.05$). However, the Chi-Square test for pain values showed a significant difference between the groups in preference to Smart burs group ($P < 0.05$). It was concluded that the conventional method in removing caries needs the least time to excavate all caries, followed by smart burs and CariSolv respectively. In addition, it was concluded that smart burs cause the least pain among the three methods.



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1. INTRODUCTION

Rotary instrumentation was used as the most common method in caries excavation for decades. However, it comes along with many shortcomings such as thermal effects on pulp, excessive removal of intact dentin, and discomfort to the patients especially children [1], [2].

The mentioned factors are driving forces in the development of alternative methods that can overcome the disadvantages of the traditional technique in caries removal [1].

Chemo-mechanical caries removal systems (CMCR) are enzyme based agents, which play an important role in the softening of carious tissue in order to facilitate their excavation. Carisolv is one of those agents, which is composed of 0.95 % sodium hypochlorite solution added to three amino acids (leucine, lysine, and glutamic acid). The reaction of NaOCl with the mentioned amino acids advanced the degradation of collagen fibers in the carious dentinal tissue [3].

CariSolv is an effective method for removing caries with leaving healthy dental tissue intact according to many studies. CariSolv enables a minimal invasive therapy that selectively softens infected dentin and preserves healthy one. It has anti-inflammatory properties, which helps in causing less pain. After softening carious dentin, mechanical hand instruments are used to help in removing carious tissues [4].

Smart Burs are made of a polyether-ketone-ketone (PEKK) having polymer shaft and blades in three different sizes – 004, 006, 008 used in slow speed rotary handpieces at 500–800 rpm, which can easily remove soft carious dentin. The hardness of Smart Burs (50KHN) is higher than infected dentin (15-20KHN) and less than healthy one (68KHN), which helps in the selective removal of carious infected dentin without removal of the affected dentin. Smart burs blunt out when they touch the hard dentin, which avoids unnecessary removal of both affected and intact dentin [5], [6].

Smart burs are minimally invasive excavation tool that has the advantage of fewer dentinal tubules being cut and, thereby, less pain feeling being provoked compared to conventional burs. Smart burs look like conventional burs, but they are not manufactured from carbide, instead, they are processed from a special polymer material [7].

The most recent systematic review published in 2020 regarding the alternative methods of removing caries concluded that more studies are needed, comparing more than one alternative treatment simultaneously [8], [9]. Thus, this trial aimed to compare the effectiveness of different caries removal techniques in primary molars using the Carisolv system, Smart Burs and conventional technique in removing dentinal caries in primary teeth in children. The time needed to excavate all carious tissues and pain level were evaluated for different caries removal techniques. The null hypothesis for this trial was there are no differences between the three tested caries removal techniques regarding time and pain.

2. MATERIALS AND METHODS

2.1 Study design, Ethical approval and Setting

This trial was designed as a randomized, controlled, parallel-group clinical trial to compare the efficacy of Smart Burs and Carisolv in removing active dentin caries to the conventional rotary tools in primary molars in children. The study was conducted in accordance with the Declaration of Helsinki and ethical approval was obtained from the Institutional Review Board in Damascus University. CONSORT statement for reporting randomized controlled trials was applied in this study. The study was conducted between 2019 and 2021 in Pediatric dentistry department at Damascus University.

2.2 Sample size, Participant recruitment, Inclusion and exclusion criteria

The sample size was determined using G*Power 3.1.9.7 software (University of Düsseldorf, Germany). The alpha and beta levels were set at 0.5 and 80% consecutively. Previous study showed that an estimated 15 carious lesions in each group were required to demonstrate an effect size of 0.4. Thus, the total sample size was raised by 20% to avoid the adverse effect of the possible drop rate (20 teeth in each group).

A single Investigator (K. N) screened 100 children for eligibility, depending on the following inclusion and exclusion criteria. Inclusion Criteria of participants: Healthy children aged 6 to 8 years willing to co-operate.

Inclusion Criteria of teeth: 1- Clinically: Each participant had at least one active lesion with dentin exposed on an asymptomatic primary mandibular molar based on the ICDAS II (“Code 5: dentin cavity easily visible with the naked eye where the surface of cavity feels soft or leathery on gentle probing”) [10].

2- Radiographically: Tooth was included if there was a clear band of healthy dentin between the pulp and the caries on the X-ray.

Exclusion criteria: The tooth was excluded if it had symptoms of pulpitis, pulp exposure, abscess/fistula, sensitivity to percussion or discoloration related to tooth non-vitality. Also, it was excluded if there were any radiographic signs of pulp necrosis.

Written informed consent and an invitation letter that describes the scope and purpose of the research was sent to parents and guardians of eligible children. Children who were enrolled in this study had brought back a signed consent before the initiation of the trial.

2.3 Randomized Allocation of Participants

A total of 60 carious primary mandibular molar in 60 children aged between 6-8 years were selected for the study. Each participant was assigned a number between 1 to 60 and Randomizer.org webpage was used to create the randomization list. Those selected subjects were randomly assigned into one of the three groups according to the caries removal technique as following:

- Control group (Caries removed using conventional rotary tools)
- Smart Burs group
- Carisolv group

The Consort diagram that describes participant flow is outlined in Figure 1.

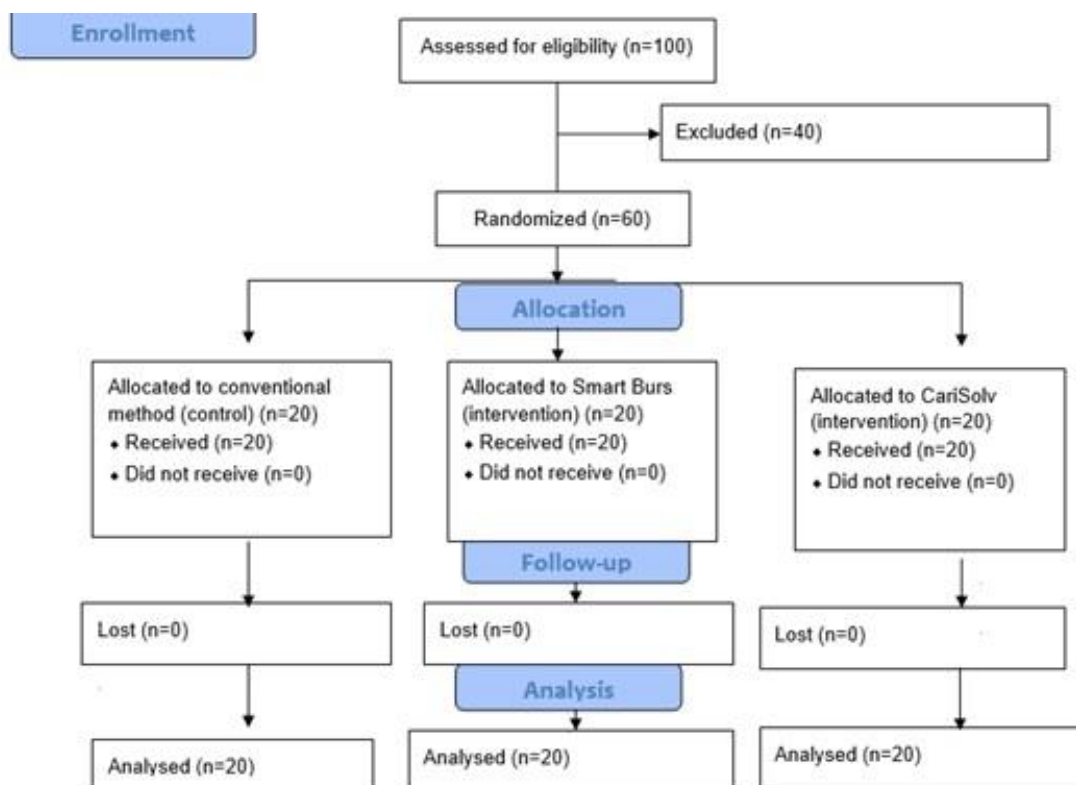


Figure 1- CONSORT flowchart of participants

2.3.1 Protocol:

Clinical examination was carried out by a single experienced investigator (KN) using a disposable blunt probe and mirror. Firstly, carious lesions activity were assessed based on ICDAS II criteria. Teeth that scored Code 5 on ICDAS II were considered active cavitated lesion. Then, a periapical x-ray were taken to ensure that there was a 0.5 mm of healthy band of dentin between the pulp and the caries.

After the randomized allocation of participants into the three groups, cavity was cleaned using disposable micro brush, then the tooth was isolated using cotton rolls and saliva ejectors. After that, caries detecting agent Nishikas (Caries Detector: containing 1% acid red in propylene glycol) was applied using an applicator tip and left for one minute then cavity was washed with water. After that, Caries were removed depending on the group as following:

In Control group, caries were removed using a conventional round tungsten carbide bur size 4 (H1 SE 204) with a low speed contra-angle handpiece (NSK, Japan) with an approximate speed of 1300 rpm without water coolant. Endpoint of caries excavation was determined using two methods which was evaluated by an experienced blinded pediatric dentist not related to this study. First, it was verified using the same caries detecting agent which was applied in the same manner as mentioned above. The second method was tactile sensation which was examined using a sharp tip explorer (dental probe DA 410R; Aesculap, Tuttlingen, Germany). Dentin was considered hard if the explorer wasn't able to penetrate the tissue under firm pressure. If either method showed active caries or soft dentin, a second round of caries removal was done and endpoint of caries removal was re-evaluated by the same examiner using the same techniques.

In Smart Burs group, caries were removed using a Smart bur size 004 with a low speed contra-angle handpiece (NSK, Japan) with an approximate speed of 1300 rpm without water coolant. Carious dentin was removed with circular movements from the periphery to the center of the lesion. Endpoint of caries excavation was

similar to control group.

In Carisolv group, Carisolv gel was applied to the carious lesion with the help of specially designed multistar instrument. After 30 seconds, the area treated with Carisolv gel showed a cloudy appearance. After that, Carisolv gel was removed with a wetted cotton pellets and softened carious dentin was excavated using spoon excavator. Endpoint of caries excavation was similar to control group.

Thenceforth, teeth in the 3 groups were restored with Glass ionomer cement (Fuji IX, GC, Japan).

2.4 Outcome measures: Time and Pain

Time required to fully remove the carious dentin lesion and pain experienced by the children during caries removal were considered the main outcome measures in this study.

2.4.1 Time:

Needed time to excavate the carious dentin in each group was recorded using a timer device. Timer was started when the Investigator started with caries removal process (t0) and it was stopped when the endpoint of excavation was reached (t1). It's worth to be noted that the timer was stopped during the evaluation of cavity for hard dentin and it was started again if further rounds of caries removal were needed.

2.4.2 Pain:

For pain assessment in children, a video was recorded only during the removal of caries in the 3 groups, then two external investigators used SEM scale to evaluate the pain intensity. The objective scale of pain SEM scale (sound, eye and motor) was used in this study, in order to monitor the external signs that appear on the children to link them with the intensity of pain. SEM scale has 4 grades that focuses on the changes in the patient's voice, eyes and movement to assess the patient's comfort and pain during treatment [11] (figure 2) [19]. To assess intra-rater reliability, 10% of the total sample was randomly re-assessed after two weeks.

Parameters	Comfort (Score 1)	Mild discomfort (Score 2)	Moderate discomfort (Score 3)	Painful (Score 4)
Sound	No sound	Non-specific sound	Verbal complaint, louder sound	Verbal complaint shouting, crying
Eye	No sign	Dilated eye without tears (anxiety sign)	Tears, sudden eye movements	Crying, tars all over the face
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defense, turning the head the opposite site

Figure -2- Sounds, Eyes, Motor (SEM) Scale

2.5 Statistical Analysis

Data were analyzed using IBM SPSS version 23 (IBM Corp., Armonk, USA). Descriptive results, including minimum, maximum, mean, and standard deviation, were obtained for the tested groups.

After using Kolmogorov-Smirnov test to determine if data were molded by a normal distribution, the test showed that data were distributed normally. Kruskal-Wallis test was used to determine significant differences in the time required to fully remove the carious dentin lesion between the three groups. Chi-Square test was used to show the significant difference among the three groups regarding the pain level resulted.

In this study, the level of significance (P-Value) was set at 0.05 and the power of study was set at 80%. Intra-examiner reproducibility and inter-examiner reliability for pain level assessment was calculated by cohen's

kappa test. The kappa for intra-rater agreement and inter-rater reliability was 0.90, 0.88 correspondingly.

3. Results

Sixty participants were enrolled in this study (25 male and 35 female) with a mean age of 7.44 ± 1.31 years. (Table 1)

Table -1 Descriptive characteristics of the enrolled participants

Male		Female		Age
N	%	N	%	Mean \pm SD
41.6		58.4		7.44 ± 1.31

Descriptive data of the needed time to excavate the carious dentin in each group showed that CariSolv gel required the longest time to excavate all carious dentinal tissues, followed by Smart Burs, and then conventional method. The mean of minutes needed to excavate all caries were as follows (4.5, 2.2, and 1.05 min respectively) (Table 2).

Table -2 The descriptive results of Kruskal-Wallis test regarding the time required for caries removal (min).

	Minimum	Maximum	Mean \pm SD
CariSolv	4 minutes	5.1 minutes	4.55 ± 0.8
Smart Burs	1.8 minutes	2.6 minutes	2.2 ± 1.1
Conventional	0.8 minutes	1.3 minutes	1.05 ± 0.6

Kruskal-Wallis test showed that there was a significant differences regarding the time needed for caries removal between the three groups ($P=.000$) In the binary comparison, Mann-Whitney U test showed a statistically significant difference between each two groups. (Table 3).

In order to assess the pain level while using the different techniques tested in this trial, SEM scale (sound, eye and motor) was used. The following scores were given from 0-3: no pain, mild pain, moderate pain and severe pain.

Table -3 Pairwise Comparison of Mann Whitney U test.

Comparison	Difference of Means	Standard Deviation	P-Value
CariSolv – Smart Burs	-14.332	3.123	.001*
CariSolv – Conventional	-16.103	3.546	.000*
Smart Burs – Conventional	-17.221	2.109	.002*
*statistically significant difference			

The obtained data were subjected to Chi-Square test accomplished by Fisher's Exact Test.

Descriptive pain level data among the three studied groups showed the best value in favor of the smart burs group and the lowest value in favor of the conventional method group. (Table 4).

Fisher's Exact Test was used to show where the difference between the three groups is. It revealed that there was a statistically significant difference between each two groups.

Table 4 – Descriptive data of the pain level in the studied groups.

Pain score	CariSolv	Smart Burs	Conventional	P-Value
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0	15	19	2	.000*
1	2	0	3	
2	3	1	15	
3	0	0	0	
*statistically significant difference.				

4. DISCUSSION

The journey of Caries removal covers the ground so far from conventional tools to ultra-conservative methods constantly improving in quality. However, Certain drawbacks such as increased time consumption, cost factor, and limited availability compared to the highly efficient, cost-effective high-speed drills make it difficult for dentists to choose these recent advancement in caries removal in their clinical practice [12].

On the other hand, caries removal by conventional procedures is accomplished with high-speed rotary equipment. However, they have multiple disadvantages such as causing dental anxiety due to the need of local anesthesia, excess removal of tooth structure, removal of both infected and affected dentin, which can lead to adverse effects to the pulp due to the heat generated at the cutting ends [13].

With the recent advancement of G.V Black's concept from "Extension for prevention" to Conservation for prevention", conserving the healthy tooth structure is considered mandatory in daily dental practice. Thus, Minimal invasive dentistry have been introduced which involved the use of new methods in caries removal such as Chomo-mechanical removal of caries via Carisolv and Brix 3000 and Polymer Smart burs [14], [15].

This study was conducted to compare two minimally invasive techniques for caries removal using smart burs and carisolv gel compared with conventional technique.

International Caries Detection and Assessment System (ICDAS II) criteria have been applied in the inclusion assessment in this study. These criteria have been widely studied, and it was shown that ICDAS II criteria are reliable, valid, and reproducible in assessing the activity of primary caries. Also, only Class 1 (ICDAS II code 5) lesions were included to facilitate the accessibility of caries removal techniques that have been used in this study to avoid the need of drills to modify the cavity [10], [16- 19].

The age of participants was chosen to be between 6 to 8 years old, since this age group might be more prone to cooperate more than younger children.

Numerous methods are documented in the literature to evaluate the efficacy of caries excavation such as tactile method, Caries-disclosing Dyes, Fluorescence-aided Caries Excavation, DIAGNOdent, and Micro-CT evaluation. In this study, the endpoint of excavation was determined with help of both Caries-disclosing dye and tactile method. According to the literature, both methods are equally effective in detecting caries [20-22]. Hence, to standardize the endpoint of caries excavation, both techniques were utilized in this study by an experienced investigator.

One of the most important aspects in pediatric dentistry is to provide a painless and less time consuming treatment for children. Thus, time required to fully remove the carious dentin lesion and pain experienced by the children during caries removal were considered the two main outcome measures in this study.

Pain perception during caries removal was evaluated by the Sounds, Eyes, and Motor (SEM) scale. SEM

scale was implemented in this study because it evaluated the relationship between pain and the reactions, taking in mind that the sensation of pain generates in the patient's eyes, bodily movements and verbal expressions of discomfort and also it is able to record the degree of intensity of the sensation of pain. SEM was considered as a valid and a reliable tool to evaluate pain perception in children during dental treatments [23], [24].

In this study, the mean of needed time to remove all caries with the CariSolv, Smart Burs and conventional method were 4.55 min, 2.2 min and 1.05, respectively.

Therefore, CariSolv required the longest period to excavate all caries. This can be justified by the fact that CMCR agents are enzymatic ones that soften carious tissue to facilitate their removal by working on the degradation of collagen rather than the mechanical removal of caries. For that reason, CariSolv require more time than other techniques.

Those results are in accordance with Kavvadia's study, which revealed that CariSolv required more time in removing caries of primary molars than that of conventional method [25].

Moreover, the findings of the present study was consistent with the randomized controlled clinical trial done by [26], which showed that the meantime for caries removal using CMCR (5 min) was significantly higher than the conventional method (1.6 min).

Smart burs needed more time to excavate all caries in the present trial than the conventional method. However, they required less time than CariSolv group. Those results were similar to those that found by [27], [28]. The mentioned studies referred the longer excavation period of smart burs to the reduced hardness of them in comparison to tungsten carbide burs.

In addition, the findings of the present study was in accordance with the trial conducted by [29] on primary molars, which compared between CMCR, Smart Burs and conventional method regarding the time needed to remove caries. Smart Burs was faster in excavating caries than CMCR in the aforementioned study, in agreement with our study.

Despite the consistence between our study and the other ones, there was a difference in the meantime of caries removal, which could be attributed to the higher quantity of carious tissues included (which was ICDAS II code 5) within selected teeth of the present trial.

SEM scale (sound, eye and movement) was used to evaluate the pain level while using the different techniques studied in this trial. The present study showed that the best acceptable technique for children was the smart burs and that the worst one was the conventional method. This can be attributed by the higher hardness of tungsten carbide burs that can cause more discomfort to the patient than the smart burs.

Moreover, smart burs are unique rotary instruments that are designed to selectively remove infected dentine without cutting healthy one. This characteristic is based on the hardness of the instrument that is lower than the hardness of the healthy dentine. This give the advantage of cutting fewer dentinal tubules and thus, less pain sensation and discomfort being stimulated [30].

In the present study, CariSolv caused more discomfort than Smart Burs. This can be justified by the unacceptable smell and taste of the CariSolv, which contains sodium hypochlorite. In addition, the longer

time needed to excavate all caries in CariSolv group may be one of the reasons that children accept it in a lower manner.

[31] revealed that CariSolv was the least painful method for caries excavation followed by smart burs. This result run against our findings and they attributed their results to the sound resulted from using Smart Burs, which can affect the anxiety level of children. Later on, this can cause more pain during the procedure.

The results of this study was in agreement with the findings of the study conducted by [28], as they found that smart burs can cause less pain than that of conventional method of removing caries by using tungsten carbide burs.

Limitations of the present trial was the small sample size and the absence of an objective method in the assessment of the remaining dentinal caries.

5. CONCLUSIONS

Within the limitations of this study, it was concluded that the conventional method in removing caries needs the least time to excavate all caries, followed by smart burs and CariSolv respectively.

In addition, it was concluded that smart burs cause the least pain among the three methods.

Conflict of Interest

Authors declares there is none.

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