

COMPARISON OF TWO AEROSOL-FREE CARIES REMOVAL METHODS: A SPLIT-MOUTH RANDOMIZED CLINICAL TRIAL

ABSTRACT

Objectives: The management of deep caries lesions in immature permanent molars can be challenging in clinical practice, but minimally invasive caries removal methods can maintain apexogenesis by preventing extensive tissue loss. Here we compare a chemo-mechanical caries removal (CMCR) gel and polymer bur in terms of time spent on caries removal, patient acceptability, and clinical success.

Materials and Methods: The teeth of 30 children were randomly divided into two groups. The duration of each method, the level of cooperation during each method, and the child's choice of caries removal method were recorded. Patients were followed at six-month intervals for at least two years.

Results: The difference between the patients' preferences was not statistically significant, while the average caries removal time of the polymer bur method was significantly shorter (p<0.05) than the CMCR method. The rates of apical closure without pathology in the CMCR and polymer bur groups were 63.2% and 73.7%, respectively; 10% of each group underwent further treatment due to their clinical and/or radiographic pathology.

Conclusions: These methods were thought to serve as an interim treatment in managing immature permanent teeth with deep caries. Furthermore, these methods, which do not involve water cooling, can minimize the risk of contamination and cross-infection.

Keywords: Dental atraumatic restorative treatment; Permanent; Pain; Papain; Polymer bur.

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INTRODUCTION

Dental caries is a disease with a high prevalence worldwide.¹ According to Takao Fusayama's 1980 description, the carious lesion consists of two layers. The 'outer layer' is an acidic, irreversibly demineralized, touch sensitive layer that contains high levels of bacteria, and therefore can be removed without the need for local anaesthesia. The 'inner layer' is a partially demineralized, less contaminated layer that contains collagen fibrils in the dentinal tubules. Because the dentine preserves the inner layer's structural integrity, it cannot be removed without local anaesthesia. The use of rotary instruments in the treatment of dental caries results in the removal of extra tooth tissue.² Traditional caries removal methods have other disadvantages as well, such as decreased patient comfort due to pressure and heat and the need for during local anaesthesia the procedure.³ Furthermore, the need for water coolant to prevent heat during the use of a high speed hand piece increases the aerosol transmission and the risk of contamination with bacteria, fungi, and viruses, including COVID-19.4

Pain, heat, and pressure felt during treatment with traditional methods can cause dental anxiety, especially in paediatric patients, and the persistence of this anxiety may cause people to avoid dental treatment in adulthood.⁵

Contemporary restorative dentistry has moved away from the traditional, surgical method of managing dental caries based on the operative concepts of G.V. Black of more than a century ago and towards a 'minimally invasive' approach.⁶ The minimally invasive principle aims to preserve the maximum of healthy tooth tissue with remineralization capacity by removing as little tooth tissue as possible, thus allowing pulp integrity to be preserved.¹ Minimally invasive dentistry continues to gain importance, especially in the treatment of permanent teeth with deep caries lesions and immature roots. Advanced endodontic treatments in these patients include complex root tip closure treatments such as apexification.⁷ It has been reported that the apical closure of vital young permanent teeth can be successfully completed with appropriate indirect vital pulp treatments⁸ and

that avoiding the complete removal of carious lesions close to the pulp reduces the risk of pulp exposure.⁹

The chemo-mechanical caries removal (CMCR) method, one of the minimally invasive caries removal methods, was first described in 1975 by Habib et al., who used 5% sodium hypochlorite. In the following years, GK-101, Caridex systems, and Carisolv systems were developed and used. Due to these system's disadvantages, such as short shelf life, high corrosion effect, the requirement of special equipment, and high cost, in 2003 a new formulation was created in Brazil by Bassadori et al.¹⁰ Subsequently, a new CMCR agent, containing papain, chloramine, toluidine blue, water, salt, and thinner, was introduced with the commercial name Brix3000 (Brix Srl Argentina).¹¹ Papain is a proteolytic enzyme that consists of the pulp of the fruit, leaves, and rubber of the Carica papaya tree, which is grown in tropical regions such as Brazil, India, South Africa, and Hawaii. It is similar to human pepsin and has bactericidal, bacteriostatic, and anti-inflammatory properties. With its antibacterial effect, it can prevent the proliferation of both Gram negative and Gram positive organisms. Papain also acts as an antiinflammatory, debriding agent that does not damage healthy tissue and accelerates the cicatricle process. Chloramines, which are amines containing at least one chlorine atom bonded directly to a nitrogen atom, are formed during the reaction between chlorine and ammonia. They have bactericidal and disinfecting properties and are used chemically to soften carious dentine. Toluidine blue is an antimicrobial agent. Papain, chloramine T, and toluidine blue, which form the papain-containing gel, create a synergistic effect and facilitate the removal of caries.¹² In sum, papain-containing gel is a biomaterial that allows the protection of maximum healthy tooth tissue, is easy to apply, and does not require special equipment.¹⁰

In 2003, polymer burs with the commercial name SmartBur (SS White, Lakewood, N.J., USA) were developed in Boston as an alternative to traditional caries removal methods. Used with lowspeed rotary tools, these single-use burs that specifically remove infected dentine and abrade when it comes to affected dentine.²

The aim of this study was to preserve pulp vitality and provide apical closure physiologically by using minimally invasive methods in vital permanent teeth with incomplete root development. The two minimally invasive methods, CMCR (BRIX 3000) and the polymer bur (SmartBur), were compared in terms of time spent on caries removal, patient acceptability, and clinical success.

MATERIAL AND METHODS

This prospective study received approval from the Human Research Ethics Committee of Biruni University (Turkey) under process number 2015-KAEK-43-18-08 and was conducted in the Department of Pediatric Dentistry of the same university.

The sample size was calculated by G*Power 3.1.9.2 software (Dusseldorf, Germany), keeping alpha at 0.05 and power at 80%. A total number of 30 healthy children in the age group 7-11 years old were selected for this randomized and controlled clinical trial with a 'split-mouth' design. The investigation was designed, analysed, and interpreted according to the Consolidated Standards of Reporting Trials (CONSORT).

Inclusion Criteria:

• Bilateral class 1 deep carious lesion on permanent molars with incomplete roots

• No pulpal involvement as evident on a radiograph

• No clinical signs or symptoms of irreversible pulpitis.

Exclusion Criteria:

• Pulpal exposure or bleeding during the excavation procedure

- Presence of underlying systemic diseases
- Lack of compliance.

One researcher completed the clinical procedures, while another researcher recorded the data. Follow-up evaluations were performed by a third researcher who was blind.

Procedure:

The procedure was explained in detail to the parents, and written informed consent was obtained before the study.

The teeth were randomly divided into two groups: Group I (CMCR agent) and Group II (polymer bur). Randomization of the groups was performed by lots, using numbered tiles to determine the tooth and the treatment that would be done first. The other tooth in the same subject was automatically submitted to the other form of treatment. During the clinical procedure, the duration of each method and the child's choice of caries removal method were recorded. The cooperation levels of the patients were evaluated according to the Frankl Behavior Rating Scale.¹³

Group I: The teeth with a sufficient amount of hard tissue were isolated with a rubber dam, while for the teeth with extensive tissue loss and the teeth of uncooperative patients, relative moisture control using cotton wool rolls and suction was performed. BRIX 3000 gel was applied to the cavity and allowed to work for 120 seconds. The softened carious dentine was then removed with a round tip excavator, as recommended by the manufacturer. The application was repeated until the colour of the gel did not change. Finally, the cavity was washed with water spray and dried with moisture- and oilfree air.

Group II: The teeth with a sufficient amount of hard tissue were isolated with a rubber dam, while for the teeth with extensive tissue loss and the teeth of uncooperative patients, relative moisture control using cotton wool rolls and suction was performed. After isolation, the caries excavation was done with a Smart Bur using a low speed hand piece (500– 800 rpm) in circular movements starting from the centre to the periphery of the carious lesion. Visibly abraded Smart Burs were replaced. The procedure was continued until complete caries excavation was achieved.

The restorations were performed with glass ionomer cement (Equia Forte, GC®). All patients were followed clinically and radiographically at 6month intervals until the root development was completed and for at least 2 years. Teeth whose root development was completed without any pathology were recorded as successful treatments. Root canal treatment was applied to teeth with pain, intraoral or extra oral abscess formation, fistula formation, or periapical lesions on radiography during follow-up and were recorded as unsuccessful treatments.

IBM SPSS Statistics 22 for statistical analysis (SPSS IBM, Turkey) programs were used for statistical analysis, and the compliance of the parameters to the normal distribution was evaluated with the Shapiro-Wilk test. While evaluating the study data, in addition to descriptive statistical methods (mean, standard deviation, and frequency), the Mann-Whitney U test was used for comparing parameters between two groups. Fisher's exact chi-squared and Fisher-Freeman-Halton tests were used to compare qualitative data. Significance was evaluated at the p < 0.05 level.

RESULTS

This split-mouth designed study was conducted on 60 teeth of 28 children aged between 7 and 11 years old. Nineteen females (63.3%) and 11 males (36.7%) with a mean age of 7.93 ± 1.14 years participated in the study. The majority of the teeth (90%) were the first permanent molars of the patients aged from 7 to 9 years old. The second permanent molars of three patients who were 10 or 11 years old were included. The research flow chart is shown in Figure 1.

Table 1. The time required for caries removal	
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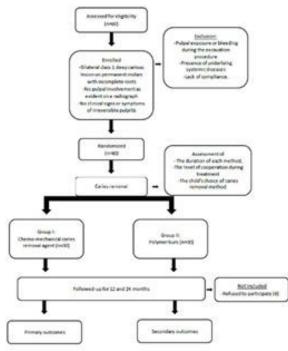


Figure 1. Research flow chart

Subsequent to the procedure, when patients were asked about their favourite between the two methods, 46.7% of the participants chose the polymer bur, while 43.3% preferred the CMCR agent. The proportion of children who were undecided was 10%.

The average caries removal time of the polymer bur method was statistically significantly shorter than the CMCR agent method (p<0.05)(Table 1).

	Time (second)			
Method	Mean±SD	Median		
CMCR gel	476.3±223.4	425		
Polymer bur	100.8±54.2	81		
р	0.000*			

No statistically significant difference was found between the caries removal method and the level of cooperation. The method used and the level of cooperation are shown in Table 2.

		Method		
	-	CMCR Gel	Polymer Bur	р
		n (%)	n (%)	
Cooperation Level	Definitely negative	5 (16.7%)	6 (20%)	¹ 0.985
	Negative	9 (30%)	8 (26.7%)	
	Positive	6 (20%)	6 (20%)	
	Definitely positive	10 (33.3%)	10 (33.3%)	

¹Fisher Freeman Halton Test p<0.05

At the end of the first year, the failure rates of both study groups were 10%, and apical closure was detected in 33.3% of each group. Details of the first year clinical evaluation are shown in Table 3. Eight patients (16 teeth) were excluded due to nonattendance at the second year appointments due to the COVID-19 pandemic. Table 3 shows the data from the second year follow-up appointments.

 Table 3. 12- Month and 24- Month Clinical and Radiographic Evaluation

			Method				
		CMCR Gel 12 Month	CMCR Gel 24 Month n (%)	Polymer Bur 12 Month	Polymer Bur 24 Month	P 12 month	P 24 Month
Dain	N.	n (%)		n (%)	n (%)	11.000	
Pain	No	27 (90%)	19 (100%)	27 (90%)	19 (100%)	$^{1}1.000$	
	Yes	3 (10%)	0 (0%)	3 (10%)	0 (0%)		
Infection	No	29 (96.7%)	19 (100%)	27 (90%)	17 (89.5%)	¹ 0.612	¹ 0.486
	Yes	1 (3.3%)	0 (0%)	3 (10%)	2 (10.5%)		
Radiographic Pathology	No	27 (90%)	17 (89,5%)	27 (90%)	18 (94.7%)	$^{1}1.000$	$^{1}1.000$
	Yes	3 (10%)	2 (10.5%)	3 (10%)	1 (5.3%)		
Apical Closure	No	20(66.7%)	7(36.8%)	20(66.7%)	5(26.3%)	$^{1}1.000$	¹ 0.728
	Yes	10(33.3%)	12(63.2%)	10(33.3%)	14(73.7%)		

¹Fisher's Exact Test

DISCUSSION

The management of deep carious lesions in paediatric patients can be challenging for clinicians. The maintenance of pulp vitality should be a priority in permanent teeth which are asymptomatic; however, conventional caries removal methods lead to the loss of healthy tooth structure and may result in pulp exposure and the need for endodontic treatment.^{6,14} Furthermore, in the case of performing apexification procedures, proper root development cannot be achieved, and the tooth may be more susceptible to fracturing.¹⁵

Previous studies have reported numerous minimally invasive caries removal methods with the purpose of reducing noise, vibration, fear, excessive removal of uninfected dentine, and pain.^{14,16–18} For example, carbon steel, tungsten carbide, or polymer burs, hand instruments (excavators, chisels), air

abrasion, air polishing, ultrasonics, sono-abrasion, CMCR agents, lasers, photo-active disinfection (PAD), or ozone were used for selective caries removal.¹⁹ Papain-based CMCR agents were reported as an effective method for caries removal by previous studies.^{11,12,20} Similarly, studies investigating the efficiency of polymer burs were conducted.^{2,21–23} Although there are few in vitro and in vivo studies comparing these two methods in the previous literature, to our knowledge no clinical study has been conducted on young permanent molars regardless the patients' level of cooperation.^{2,24–26} To evaluate the effect of vibration sensation on patient acceptability, these two methods, one of which involves the use of a rotary instrument, were chosen.

A split-mouth design was used due to its reported advantages in paediatric dentistry research.

A study's inconsistency or random error can be considerably reduced by performing within-patient instead of between-patient comparisons. In addition, a split-mouth design decreases the majority of intersubject variability in terms of the treatment effect, thus increasing research accuracy and power to detect real differences with fewer participants.²⁷

The duration of the procedures in paediatric dentistry practice has critical importance in terms of patient acceptance. As found in this study, the time taken for caries removal was less with a polymer bur (100.80 seconds) than with the CMCR gel (476.30 seconds). These results were consistent with those reported in the previous literature.^{25,28} The duration of caries removal with polymer burs was reported as 147.5 and 208.4 seconds in previous in vitro studies.^{29,30} Unlike in Divya *et al.*², the statistically significant difference in the duration of the two methods may be due to the 120-second waiting time of the CMCR agent we used. That the CMCR agent caries removal time was found to be 300 seconds in another study using the same product supports this idea.20

In the current study, children's choice rates were almost equal between the two caries removal methods. In the majority of the studies evaluating patients' selection or pain during the procedure, minimally invasive methods were compared with traditional methods, and conventional drilling methods were found to be less acceptable and more painful.^{22,31} Studies which compared patient acceptance of the two methods reported on in this study found that the polymer bur was more painful than the CMCR agent.^{25,28} In this context, although there is no study comparing the two methods in terms of patient choice, that 46.7% of the patients in this study had a 'definitely negative' or 'negative' level of cooperation for both methods may indicate that both methods are acceptable to the patients, especially since we had the opportunity to carry out the treatments in clinical conditions.

When we evaluate the methods in terms of clinical success, 10% of both groups underwent further treatment due to the clinical and/or radiographic pathology. On the other hand, apical closure was ensured properly in 50% of each group. This apical closure rate, low when

compared to a study that reported 96.8% success after a 24-month follow-up period, may be due to the differences in the developmental stage of roots at the time of treatment.³² The previous studies comparing the efficiency of these methods regarding the remaining amounts of bacteria after treatment reported that both methods were efficient and that there were no significant differences among groups.^{25,28}

The major limitation of this study was the high number of patients not attending the controls due to the pandemic. Additionally, standardizing root developmental levels would be useful for the clinical success assessment.

CONCLUSIONS

The use of a CMCR agent or polymer bur is recommended as a solution for the treatment of patients seeking an alternative to conventional methods. Additionally, these methods may serve as an interim treatment during the apexogenesis process in the management of immature permanent teeth with deep caries. Another advantage of these methods is that, since they do not involve water cooling, they can also minimize the risk of contamination and cross infection.

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This prospective study received approval from the Human Research Ethics Committee of Biruni University (Turkey) under process number 2015-KAEK-43-18-08 and was conducted in the Department of Pediatric Dentistry of the same university.

All authors gave final approval and agree to be accountable for all aspects of the work. The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

Aerosol İçermeyen İki Farklı Çürük Temizleme Yönteminin Karşılaştırılması-Bölünmüş Ağız Randomize Klinik Çalışma

ÖΖ

Amaç: Kök gelişimini tamamlamamış daimi azı dişlerinde görülen derin çürük lezyonlarının tedavisi klinik pratikte zorlayıcı olabilmektedir. Minimal girişimsel çürük temizleme yöntemleri, gereksiz doku kaybını önleyerek apeksogenezin sürdürülmesine

olanak vermektedir. Bu çalışmada, kemo-mekanik çürük temizleme jeli ve polimer frez, çürüğün tamamen uzaklaştırılması için harcanan süre, hasta kabul edilebilirliği ve klinik başarı açısından karşılaştırılmaktadır. Gereç ve Yöntemler: Otuz çocuk hastanın çift taraflı çürük azı dişleri rastgele iki gruba ayrılmıştır. Klinik prosedürlerin uygulanma süresi, işlem sırasındaki kooperasyon düzeyi ve çocuğun çürük temizleme yöntemi arasındaki seçimi kaydedilmiştir. Hastalar 6 aylık aralıklarla en az 2 yıl olacak şekilde takip edilmiştir. **Bulgular:** Hastaların tercihleri arasındaki fark istatistiksel olarak anlamlı bulunmamıştır, polimer frez ile çürük temizleme yönteminin ortalama süresi anlamlı olarak daha kısadır (p<0,05). Çürük temizleme jeli ve polimer frez gruplarında patoloji görülmeksizin kök ucu kapanma oranları sırasıyla % 63,2 ve % 73,7 iken, her grubun % 10'una klinik ve/veya radyografik patoloji nedeniyle ek tedaviler uvgulanmıştır. Sonuçlar: Bu yöntemlerin, derin çürük kavitesine sahip ve kök ucu kapanmamış kalıcı dişlerin tedavisinde geçici bir tedavi görevi görebileceği düşünülmektedir. Ayrıca, su soğutması içermeyen bu yöntemler çapraz enfeksiyon riskini anlamlı derecede azaltmaktadır. Anahtar Kelimeler: Dental artavmatik restoratif tedavi, Azı dişi, Ağrı, Papain, Polimer frez.

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