

Evaluation of Bromelain Gel at Different Concentrations and Sodium Hypochlorite Gel in Chemo-mechanical caries removal: Analyzing of Flavor Acceptance: A Randomized Controlled Trial

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Abstract:

Background and Aim of the Study:

This study aimed to evaluate patient satisfaction and flavor acceptability of chemomechanical caries removal (CMCR) agents.

Materials and Methods:

Bromelain gels were prepared in three concentrations (10%, 15%, and 20%) using locally formulated bromelain powder and compared with a 2.4% sodium hypochlorite gel. A total of 44 children aged 6–10 years (22 males and 22 females; mean age 7.18 ± 1.32 years) participated in the study. Sixty Class V dentinal carious lesions in upper primary canines were treated using non-cutting hand excavators without local anesthesia. Flavor acceptability was assessed post-treatment.

Results:

Flavor acceptance varied significantly among the materials. Bromelain gels at 10% and 15% concentrations showed the highest acceptance rates (100%), while the 20% bromelain gel showed slightly lower acceptance (80%). Sodium hypochlorite gel had the lowest acceptance rate (60%). Statistical analysis revealed a significant difference in flavor acceptance between sodium hypochlorite and bromelain gels ($p = 0.004$). Pairwise comparisons indicated that sodium hypochlorite was significantly less acceptable than both the 10% and 15% bromelain gels ($p = 0.017$).

Conclusion:

Bromelain gels (10%, 15%, and 20%) demonstrated high patient acceptability during CMCR procedures, suggesting they are effective and patient-friendly alternatives to sodium hypochlorite gel. However, acceptability decreased slightly with higher bromelain concentrations, and sodium hypochlorite was the least favored.

Key Words: Chemo-Mechanical Caries Removal, Bromelain Gel, Sodium Hypochlorite.

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تقييم هلام البروميلين بتركيزات مختلفة وهلام هيبوكلوريت الصوديوم في إزالة النخر الكيميائية الميكانيكية : تحليل تقبل الطعم - دراسة سريرية مضبوطة معشاة

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الملخص:

خلفية البحث والهدف منه: هدفت هذه الدراسة إلى تقييم رضا المرضى وقبولهم طعم المواد المستخدمة في الإزالة الكيميائية الميكانيكية للنخر (CMCR).

المواد والطرائق: تم تحضير جل البروميلين بثلاث تراكيز (10%، 15%، و20%) باستخدام هلام البروميلين المحضّر محلياً، وتمت مقارنته مع هلام هيبوكلوريت الصوديوم بتركيز 2.4%. شارك في الدراسة 44 طفلاً تتراوح أعمارهم بين 6 و10 سنوات (22 ذكراً و22 أنثى؛ بمتوسط عمر 7.18 ± 1.32 سنة). تم علاج 60 آفة نخرية من الصنف الخامس حسب تصنيف بلاك في الأنثياب العلوية المؤقتة باستخدام مجارف عاج يدوية غير قاطعة، دون استخدام التخدير الموضعي. وتم تقييم تقبل النكهة بعد المعالجة.

النتائج: أظهرت النتائج تفاوتاً ملحوظاً في تقبل النكهة بين المواد المختلفة. حيث سجل هلام البروميلين بتركيزي 10% و15% أعلى نسب تقبل (100%)، بينما انخفض القبول قليلاً مع تركيز 20% (80%). في المقابل، سجل هلام هيبوكلوريت الصوديوم أدنى نسبة تقبل (60%). وأظهرت التحليلات الإحصائية وجود فرق معنوي في تقبل النكهة بين هلام هيبوكلوريت الصوديوم وهلام البروميلين ($p = 0.004$)، كما أوضحت المقارنات الثنائية أن هلام هيبوكلوريت الصوديوم كان أقل قبولاً بشكل ملحوظ مقارنةً بهلام البروميلين بتركيزي 10% و15% ($p = 0.017$).

الاستنتاجات: أظهر هلام البروميلين (10%، 15%، و20%) تقبلاً عالياً من قبل المرضى أثناء إجراءات الإزالة الكيميائية الميكانيكية للنخر، مما يشير إلى أنها بدائل فعالة ومحبة للأطفال مقارنةً بهلام هيبوكلوريت الصوديوم. ومع ذلك، لوحظ انخفاض طفيف في تقبل النكهة مع زيادة تركيز البروميلين، وكان هلام هيبوكلوريت الصوديوم الأقل قبولاً.

الكلمات المفتاحية: الإزالة الكيميائية الميكانيكية للنخر، هلام البروميلين، هيبوكلوريت الصوديوم.

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Introduction:

Dental caries constitutes one of the most widespread chronic infections within the oral cavity and is recognized as the second predominant etiological factor for tooth loss, subsequent only to periodontal disease (1). The conventional clinical management of dental caries has predominantly depended upon the utilization of high-speed handpieces and rotary instruments. While effective in removing decayed tissue, these conventional approaches often cause discomfort, anxiety, and result in the unnecessary removal of both caries-infected and caries-affected dentin, potentially compromising tooth structure (2).

In recent years, minimally invasive dentistry has gained prominence, emphasizing the selective removal of caries infected tissue while preserving caries affected dentin,. Among these innovations, chemo-mechanical caries removal (CMCR) has emerged as a promising technique (3).

The CMCR method employs chemical agents to soften decayed dentin, allowing its removal with hand instruments. This approach aims to minimize patient discomfort, reduce the need for anesthesia, and alleviate anxiety associated with conventional drilling methods (4-5). Since its appears in 1975, a variety of CMCR agents have been developed, and categorized into sodium hypochlorite (NaOCl)-based agents and enzyme-based agents (6).

NaOCl-based CMCR agents primarily function by chlorinating and breaking hydrogen bonds in partially degraded collagen, facilitating caries removal. On the other hand, enzyme-based agents, such as those containing papain (Papacarie®, Carie-Care™, and BRIX3000™), have demonstrated comparable efficacy to traditional methods (7).

Papain, a proteolytic enzyme Papain, a proteolytic enzyme, works through multiple mechanisms, including disrupting bacterial membrane permeability by breaking peptide bonds between amino acids. It exerts bactericidal and bacteriostatic effects (7).

Recently, bromelain, an enzyme extracted from pineapple, has emerged and get attention as a potential CMCR agent. Reddy et al compared the efficacy of bromelain and papain in caries removal, observing that bromelain resulted in less residual non-demineralized dentin while requiring a similar amount of time. (9). Further studies, such as Abinaya et al. (2020), also demonstrated bromelain's superior performance compared to traditional techniques, such as smart burs and atraumatic restorative treatment (ART)(10).

The present study aims to compare bromelain gel at three concentrations (10%, 15%, and 20%) with sodium hypochlorite gel (2.4%) through a randomized controlled trial to assess the acceptance of the materials' flavors among pediatric patients.

Materials and Methods:

Study Design

This research was conducted as a randomized controlled clinical trial. The required sample size was calculated to ensure an alpha level of 5% and a power of 95%, resulting in a total of sixty teeth.

Study Groups:

The study sample consisted of 60 primary upper anterior canines from children aged 6 to 11 years. Participants were divided into four groups based on the chemo-mechanical caries removal (CMCR) agent used:

- **Group A:** Treated with 10% bromelain enzyme-based gel
- **Group B:** Treated with 15% bromelain enzyme-based gel
- **Group C:** Treated with 20% bromelain enzyme-based gel
- **Group D:** Treated with 2.4% sodium hypochlorite gel (Clorox®)

Ethical Approval:

Ethical approval for this study was obtained from the Ethics Committee and the Board of Scientific Research at the Faculty of Dentistry, University of Damascus, as well as from the Ministry of Higher Education and Research. Parents or legal guardians of eligible participants were provided with comprehensive information about the study and signed an informed consent form prior to participation.

Randomization:

Each patient was assigned a coded number from 1 to 60 and randomly allocated to one of the four groups using a computer-generated randomization tool available at <http://www.random.org>.

Inclusion Criteria

Participants included healthy children without systemic conditions such as diabetes, congenital heart disease, or autoimmune disorders. Selection was based on their cooperation level, classified as fourth or fifth degree on the Salviov-Tinawi scale (Tinawi, 1989)(11). Eligible participants were aged between 6 and 11 years and presented with Class V carious lesions affecting the dentin on the vestibular surfaces of upper primary canines, without pulp involvement. All teeth were vital, exhibited no clinical signs of pulpal pathology, and showed no malformations or developmental anomalies.

Exclusion Criteria

Exclusion criteria included children with known allergies to any of the materials used, systemic conditions.

Procedure:

After verifying the inclusion criteria, eligible participants were enrolled in the study, the procedure was explained to participants using the Tell-Show-Do technique to ensure comfort and cooperation.

1. Preparation:

- Prophylaxis was performed to remove dental biofilm and improve visibility.
- The tooth was isolated with cotton rolls and a mouth retractor, and suction was used for moisture control.

2. Caries Removal:

- Specific gels were applied to the cavity and left for 60 seconds. Once the gel appeared cloudy, it was removed using a spoon excavator without applying pressure.
- Fresh gel was reapplied, and the softened dentin was removed gently. This process was repeated until the gel remained clear, indicating the absence of caries.
- The cavity was then cleaned with a damp cotton pellet. Two blinded researchers independently assessed the cavity visually and tactilely.

- A caries detector dye was used for a final confirmation of caries removal. If caries remained, the gel was reapplied, and the process was repeated until the cavity was entirely caries-free.

- Restorations were completed with glass ionomer cement (GC Fuji IX GP, GC Corporation, Tokyo, Japan).

3. Gel Preparation:

Bromelain gels were formulated in three concentrations (10%, 15%, and 20%). The preparation method included:

- Pineapple powder dissolved in 100 mL of distilled water.
- Sodium benzoate as a preservative.
- Glycerin for consistency.
- Carbopol as a thickening agent.
- Trimethylamine (TMA) as a neutralizing agent.
- Alpha-D-tocopherol as an antioxidant.
- Green apple flavor drops to improve acceptance.

An in-vitro pilot test was conducted on ten extracted primary teeth with caries to determine the gel's effectiveness and ideal application time. The results indicated that 60 seconds was optimal for each application.

The flavor acceptance of the materials was assessed using a two-point Likert scale, with participants indicating either "accepted" or "not accepted."

Results:

Three concentrations of bromelain (10%, 15%, 20%) were compared with a single concentration of sodium hypochlorite (2.4%)

Flavor Acceptance:

The flavor acceptance of the tested materials varied across the study groups. Table 1 summarizes the acceptance rates, where groups A (10% bromelain) and B (15% bromelain) showed the highest flavor acceptance, with all participants (100%) reporting the flavor as acceptable. In group C (20% bromelain), flavor acceptance decreased slightly, with 80% reporting acceptance, while 20% found the flavor unacceptable. Group D (2.4% sodium hypochlorite) showed the lowest acceptance, with 60% reporting acceptance and 40% indicating they did not accept the flavor.

Statistical Analysis

A Chi-square test was conducted to assess differences in flavor acceptance between the groups. The test revealed a statistically significant difference ($p = 0.004$) in flavor acceptance among the four groups (Table 2).

Pairwise Comparisons

Further pairwise Chi-square tests indicated significant differences in flavor acceptance between group D and groups A and B ($p = 0.017$). However, no statistically significant differences

were observed between the other groups, including comparisons involving group C ($p > 0.05$).

These findings suggest that bromelain gels (10%, 15%, and 20%) were generally better tolerated in terms of flavor compared to sodium hypochlorite gel. Notably, the higher concentration of bromelain (20%) showed a slight decline in flavor acceptance, while sodium hypochlorite gel had the lowest overall acceptance rate. Table 1:

Table 1. Frequency and Percentage of Flavor Acceptance (Acceptable , Unacceptable) Across All Study Groups:

STUDY GROUP	NUMBER OF TEETH	FLAVOR ACCEPTED (N)	FLAVOR NOT ACCEPTED (N)	ACCEPTANCE (%)	NON-ACCEPTANCE (%)
A (10% BROMELAIN)	15	15	0	100	0
B (15% BROMELAIN)	15	15	0	100	0
C (20% BROMELAIN)	15	12	3	80	20
D (2.4% SODIUM HYPOCHLORITE)	15	9	6	60	40

N: number of children

Table 2, Chi-Square Test Results for Pairwise Differences in Flavor Acceptance Between Study Groups.

Group	Comparison Groups	Chi-Square Value (χ^2)	Degrees of Freedom	p-Value
A	B	-	-	-
	C	7.8	1	0.224
	D	7.5	1	0.017
B	C	7.8	1	0.224
	D	7.5	1	0.017
D	C	1.4	1	0.427

Discussion:

Flavor Acceptance

The findings of this study demonstrated significant differences in children's acceptance of the flavor among the four materials tested, particularly with sodium hypochlorite compared to the bromelain-based materials. Sodium hypochlorite was found to be the least accepted by the children, likely due to its strong, sharp chemical taste, which can be unpleasant and cause discomfort. In contrast, the bromelain gels,

formulated with added flavoring agents, were generally well-tolerated, with no significant differences in flavor acceptance among the various bromelain concentrations.

These results suggest that the natural composition of bromelain, combined with the addition of flavoring agents, contributed to its milder and more acceptable taste. Conversely, sodium hypochlorite, being a chemically agent, which can influence children's low acceptance during dental procedures.

The results align with previous studies that highlighted the sensory challenges of chemical-mechanical caries removal agents. For example Maragakis et al. (2001) noted that Carisolv™ was less favorable due to its chlorine-like smell and taste, which negatively impacted patient acceptance, despite its clinical effectiveness.

The results of the current investigation revealed that the child participants faced difficulties in accepting the taste of sodium hypochlorite, which was utilized as a component of the chemical-mechanical caries removal procedure. These findings corroborate those documented by Maragakis et al., who identified that the aversive taste and chlorine-like scent of substances such as Carisolv constituted detrimental factors influencing patient acceptance of these agents. Additionally, their research indicated that children subjected to treatment with Carisolv exhibited a less favorable disposition toward this modality in comparison to traditional rotary instruments, predominantly due to the impact of taste and olfactory sensations on their treatment experiences (12).

Although chemical-mechanical agents like Carisolv aim to provide a less invasive and more comfortable treatment experience compared to traditional drilling, sensory properties such as taste and odor remain critical factors influencing patient preferences and satisfaction with treatment. This observation is consistent with the current study's findings, where the unpleasant taste of sodium hypochlorite negatively impacted the children's experience, emphasizing the importance of improving the sensory characteristics of such materials to enhance patient acceptance of chemical-mechanical caries removal methods.

Moreover, none of the participants in the study conducted by Nalawade et al. reported any signs of discomfort related to taste or odor when using the Carie-Care chemical-mechanical agent. Patients did not report any unpleasant taste or bad smell, which aligns with our study results, showing high acceptance among children for enzyme-based chemical-mechanical agents, such as bromelain and papain(13).

Similarly, the study by Venkataraghavan et al. reported that none of the participants exhibited signs of taste or odor intolerance, whether using the Carie-Care chemical-mechanical method or the conventional approach. Their findings confirmed that using agents like Carie-Care does not cause undesirable side effects such as unpleasant taste or bad smell. This contributes to improving the patient experience and enhances acceptance of this treatment modality, making it a promising option for minimally invasive caries removal techniques (14).

While chemical-mechanical caries removal methods aim to offer a gentler and more patient-friendly alternative to traditional drilling, this study highlights the importance of sensory factors, such as taste, in determining patient comfort and acceptance. The significantly lower acceptance of sodium hypochlorite in this study underscores the need for future improvements in the sensory properties of such agents to enhance their overall patient acceptance and usability, particularly in pediatric populations.

Conclusions:

This study demonstrates the advantages of chemical-mechanical caries removal (CMCR) techniques in pediatric dentistry. Flavor acceptance varied significantly, with bromelain gels being well-tolerated due to added flavoring, while sodium hypochlorite was less acceptable due to its sharp taste.

CMCR techniques offer a minimally invasive, comfortable alternative to traditional methods, making them particularly suitable for children. Further research is recommended to enhance both efficacy and patient acceptance.

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