Evaluation of the Effect of Different Deproteinizing Agents on the Clinical Success of Fissure Sealants in Permanent Teeth: Splint Mouth Clinical Study

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RESEARCH PROTOCOL

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1. PURPOSE and HYPOTHESIS OF THE RESEARCH

Dental caries is a chronic infectious, preventable disease in which prolonged exposure to fermentable carbohydrate causes an ecological shift in the composition and activity of the bacterial biofilm, resulting in the physical and chemical destruction of dental hard tissues and disrupting the balance between demineralization and remineralization of tooth surfaces.[1] The teeth with the highest caries risk are permanent first and second molars, respectively. [2] The retantive areas formed by pits and fissures on the occlusal surfaces of molars are more favorable areas for caries initiation from the eruption of teeth.[3] Pit and fissure sealants are the most effective method used to prevent caries formation in these areas. Pit and fissure sealants are a non-invasive method that has been used for many years to prevent caries formation or to stop the progression of initial caries lesions limited to enamel on tooth surfaces considered to be at high risk of caries.[4] There are many clinical studies in the literature reporting that fissure sealants applied with non-invasive techniques are highly effective in preventing pit and fissure caries.[5,6] Various methods such as pumice prophylaxis and deproteinization have been recommended as surface preparation methods to increase the success of fissure sealants.[7,8] During the application of pit and fissure sealants, acid roughening of the enamel as a pre-application is an inevitable step.[9] Removal of organic materials from the enamel surface before acid roughening provides better acid roughening on the enamel, increases bond strength, improves adhesion and retention of the adhesive material. There are many studies in the literature showing that the use of 5.25% NaOCl as an enamel deproteinization agent is successful in positively affecting adhesion by removing the organic elements of the pellicle both in the enamel structure and on the enamel surface before acid application.[10-13] Hypochlorous acid is produced as a result of oxidative reactions by cells of the body immune system, neutrophilic polymorphonuclear leukocytes, to overcome pathogenic microorganisms and fight infection.[14,15] Recently, slightly acidic HOCl solutions developed by electrolyzing NaOCl have been widely used as disinfectants.[16] Hypochlorous acid has been shown to significantly reduce the lipopolysaccharide concentration of Porphyromonas gingivalis

compared to NaOCl and chlorhexidine, and is a well-tolerated agent by oral tissues.[17] Furthermore, HOCl used as a mouthwash has been reported to produce no systemic side effects.[18] In clinical dentistry, HOCl has been shown to be highly effective as a result of its antimicrobial and deproteinizing properties. With its low acidity, HOCl is an antiseptic irrigant with exceptional properties, exhibiting not only biocompatibility and low cytotoxicity, but also rapid and highly effective antimicrobial activity in physiological concentration ranges.[19] The aim of this study was to compare the effects of sodium hypochlorite and hypoclous acid, deproteinizing agents used to prepare the tooth surface for fissure sealant application in permanent teeth, on the clinical success of fissure sealants.

The null hypotheses of our study;

I. There is no significant difference in terms of retention loss and new caries formation between the fissure sealants in the group treated with sodium hypochlorite as deproteinizing agent and the fissure sealants in the group treated with hypoclurous acid.

II. There is no significant difference in edge integrity between the fissure sealants in the group treated with sodium hypochlorite as deproteinizing agent and the fissure sealants in the group treated with hypoclurous acid.

III. There is no significant difference in edge coloration between the fissure sealants in the group treated with sodium hypochlorite as deproteinizing agent and the fissure sealants in the group treated with hypoclurous acid.

IV. There is no significant difference in anatomical form between the fissure sealants in the group treated with sodium hypochlorite as deproteinizing agent and the fissure sealants in the group treated with hypoclurous acid.

Keywords: Deproteinization, Fissure sealant, Hypoclous acid, Sodium hypochlorite

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2. MATERIALS AND METHOD

Case Selection

This study will include patients between the ages of 6 and 9 years old who are admitted to Tokat Gaziosmanpaşa University, Faculty of Dentistry, Department of Pedodontics for routine check-ups, have no systemic problems, have a score of 3 and 4 according to the Frankl Behavior Scale 20 (Table 1), have no parafunctional habits such as clenching and/or grinding, have newly erupted caries-free permanent lower first molars, and have an indication for fissure sealant application. In our single-center, split mouth clinical study, sodium hypochlorite (Wizard, Turkey) will be applied to one of the lower first molars and hypochlorous acid (Superox, Anolit Hijyen ve Kimya Sanayi Anonim Şirketi, Ankara, Turkey) will be applied to the other as deproteinizing agent before non-invasive (without any abrasion on the tooth) fissure sealant application under rubber-dam isolation. Then 37% phosphoric acid (K-ETCHANT Syringe, Kuraray Noritake Dental Inc., Japan) will be applied. ClinproTM Sealant (3M ESPE, St. Paul, MN, United States of America), a resin-based sealant that polymerizes with light, changes color during polymerization, contains fluorine and has a low filler content, will be used as fissure sealant in both groups.

Table 1. Frankl Behavior Scale

1	-	Definitely negative	Refusal of treatment, crying forcefully, fearful or any other overt evidence of extreme negativism.
2	--	Negative	Reluctant to accept treatment; uncooperative, some evidence of negative attitude but not

			pronounced, i.e. /sullen, withdrawn.
3	+	Positive	Acceptance of treatment; at times cautious, willingness to comply with the dentist, at times with reservation but patient follows the dentist's directions cooperatively.
4	++	Definitely positive	Good rapport with the dentist, interested in the dental procedures, laughing and enjoying the situation.

Power Analysis of the Study

As a result of the power analysis of the study with 95% confidence (1-α), 95% test power (1-β) and Chi-square test with an effect size of w=0.576, the number of samples to be included in the study was found to be 47. When the dropout rate was taken as 20%, the study was planned to be conducted with 60 samples.[21]

Clinical Assessments

The patients included in the study will be followed up by two observers at 6, 12, 24 and 36 months. At the control sessions, loss of retention and new caries formation (Table 2) according to the Modified Simonsen Criteria (1991) (22), edge integrity (Table 3) and edge coloration (Table 4) according to the criteria of Feigal et al. (2000) and anatomical form (Table 5) will be evaluated.

Table 2. Modified Simonsen Criteria

Score 0 Fissure sealant completely in the mouth and no new caries formation.

Score 1 Partial loss of fissure sealant, no new caries formation.

Score 2 Partial loss of fissure sealant and new caries formation.

Score 3 Complete loss of fissure sealant, no new caries formation.

Score 4 Complete loss of fissure sealant and new caries formation.

Table 3. Edge Integrity Evaluation Criteria

0 Fissure sealant and tooth surface are intact and indistinguishable with the probe.

1 The edge of the fissure sealant can be distinguished with a probe.

2 There is spacing along the edge of the fissure seal and deep cracks reaching the central fossa.

Table 4. Edge Coloration Evaluation Criteria

0 No discoloration between fissure sealant and tooth

1 Discoloration in only one area

2 Discoloration in many areas

3 Severe discoloration indicating the presence of leakage

Table 5. Anatomical Form Evaluation Criteria

0 Consistent and continuous and structure in harmony with occlusal form

1 Change in anatomical form but all pits and fissures covered

2a Partial loss of one or two pits or fissures, but no need to repair or replace fissure sealant

2b Partial loss of pits and fissures, replacement or repair of fissure sealant required

3 Loss in all pits and fissures

7 Partial loss due to occlusion

9 Bubble not connected to margins

Statistical Analysis

All statistical analyses will be analyzed using IBM SPSS V23. Chi-square test will be used to compare categorical data by groups.

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PLACE(S) OF IMPLEMENTATION OF THE RESEARCH

☒ Single Center

☐ Multicenter

	Name of the center	Name of the principal investigator	phone
Center 1	Tokat Gaziosmanpasa University, Faculty of Dentistry	[redacted]	[redacted]

INFORMATION ABOUT RESEARCHERS

Name-Surname	**Title**	**Mission**	**phone**
[redacted]	Research assistant	Obtaining and evaluating data, writing the research	[redacted]
[redacted]	Assistant professor	Planning the research, Evaluation of the data	[redacted]

INFORMATION ABOUT VOLUNTEERS

Qualification of volunteers	Patients aged 6-9 years with no systemic problems, a score of 3 or 4 on the Frankl Behavior Scale, no habit of clenching and/or grinding, newly erupted caries-free permanent lower first molars, and indication for fissure sealant application
Working group	60
Number of control groups	60
Inclusion criteria	He has no systemic problems and scores 3 and 4 on the Frankl Behavior Scale, No habit of clenching and/or grinding teeth, He has newly erupted permanent lower first molars without decay, Patients aged 6-9 years with an indication for fissure sealant application.
Exclusion criteria	Teeth with fissure sealant applied, Teeth with developmental defects such as hypoplasia, Teeth with aproximal or initial carious lesions on one or both lower permanent first molars, Children who are not systemically healthy, Non-cooperative children with scores of 1 and 2 on the Frankl Behavior Scale, Children and parents who refuse to attend follow-up appointments, Children with parafunctional habits such as teeth clenching.

I will comply with the World Medical Association (WMA) HELSINKI Declaration (and/or World Psychiatric Association HAWAI Declaration), Good Clinical Practices and Good Laboratory Practices Rules during this research, and I will immediately notify the Clinical Research Ethics Committee in case of any unexpected adverse effect or event, I promise to notify the committee in writing in case of any changes in the study protocol during the research,

to submit a report on the progress of the research to the Clinical Research Ethics Committee every 6 months according to the duration of the research, and to notify the Clinical Research Ethics Committee immediately if the research is stopped.

RESEARCH RESPONSIBLE COORDINATOR

[redacted]