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

18/12/2023

INFORMED CONSENT FORM

Researcher's & Physician's Statement

We are planning to conduct a scientific research to compare the effects of deproteinizing agents used to prepare the tooth surface for fissure sealant application in permanent teeth; sodium hypochlorite and hypoclous acid on the clinical success of fissure sealants. The name of the planned research is "Evaluation of the Effect of Different Deproteinizing Agents on the Clinical Success of Fissure Sealants in Permanent Teeth: Splint Mouth Clinical Study".

We invite you to participate in this study, which will be conducted on patients who have an indication for non-invasive fissure sealant application and/or who are admitted to our clinic for routine follow-up, as your medical condition meets these conditions. However, it should be noted that participation in the study is voluntary. You must make the decision to participate in this scientific study completely of your own free will. No one can suggest or pressure you while making this decision.

Before you make your decision, we would like to inform you about this scientific study and the procedures to be followed if you agree to participate in this study. After reading and understanding this information, please sign the form if you wish to participate in this scientific research.

Information about the scientific study

You are invited to participate in the study because you are an individual between the ages of 6-9 years, without any systemic disease, with newly erupted caries-free permanent lower first molars, and with an indication for non-invasive fissure sealant application. This study will be conducted at Tokat Gaziosmanpasa University, Faculty of Dentistry, Department of Pediatric Dentistry. The children included in the study will be followed up by two observers at 6, 12, 24 and 36 months.

Fissure sealants, which will be investigated in this study, are frequently used in pediatric dentistry clinics as a preventive treatment to prevent caries formation and it is a very important application to create a healthy society. Many surface preparation methods are used to increase the clinical success of fissure sealants, which are very successful in protecting newly erupted teeth. The use of deproteinization agents, one of these methods, has been proven to contribute positively to the success of fissure sealants.

The aim of this study was to compare the effect of two different deproteinizing agents, sodium hypochlorite and hypoclurous acid, on the clinical success of fissure sealants.

Thus, the success of these agents will be investigated and thus the success of fissure sealants will be increased.

Conditions to be known within the scope of the study and rules to be followed by researchers and volunteers

In case you participate in the research;

1. You will not be charged any fee.

2. You will not receive any additional payment for participating in the study.

3. The confidentiality of your information, which must remain between you and the physician, will be treated with the utmost care and respect.

4. Your personal information will be protected with the utmost sensitivity during the use of research results for educational and scientific purposes.

5. Researchers are responsible for any health and other problems that may occur during the study.

6. You can leave the study at any stage of the voluntary participation. However, it is important that you inform the researchers before you leave.

7. If you do not agree to participate in the study, there will be no change in your treatment and clinical follow-up, and the treatment of your disease will continue with the same care and attention as always.

8. Your child will be informed about this research in a way that he/she understands and his/her consent will be obtained for participation in the research.

Declaration of the Participant (Volunteer) / Patient

[redacted] informed me that a research would be conducted at Tokat Gaziosmanpasa University Faculty of Dentistry, Department of Pediatric Dentistry and provided me with the above information about this research. After this information, I was invited as a “participant” to such a research.

If I participate in this research, it has been clearly and explicitly stated that the confidentiality of my personal information, which should remain between me and the physician, will be treated with great care and respect during this research, and that my personal information will be carefully protected during the use of the research results for educational and scientific purposes.

I do not assume any financial responsibility for the expenses to be incurred for the research. It has been clearly and unequivocally stated that I will not be charged any fees and I will not be paid anything.

During the execution of the project, I was informed that I have the right to withdraw from the research without giving any reason. However, I am also aware that it would be appropriate to inform the researchers in advance that I will withdraw from the research in order not to leave them in a difficult situation. I may also be excluded from the research by the researcher provided that no harm is caused to my medical condition.

The responsibility for any health-related negativities that may arise during the research process, whether direct or indirect, belongs to the researchers and I will not be under any financial burden.

If I encounter a health problem related to the research during the research; I know that I can consult [redacted] at any time of the day by calling [redacted]

I do not have to participate in this research and I can choose not to participate. I have not been subjected to any coercive behavior in order to participate in the study. I understand that if I refuse to participate, this will not harm my medical care and my relationship with the physician.

I have understood all the explanations given to me in detail. After a period of reflection on my own, I have made the decision to take part in this research project as a “participant” (volunteer) of my own free will. I accept the invitation with great pleasure and willingness.

History:

Legal Representative of the Volunteer

Name Surname:

History:

Signature:

A Competent Researcher in the Research Team

Name Surname:

History:

Signature:

Physician Interviewing the Participant

Research Assistant [redacted]

Tokat Gaziosmanpasa University Faculty of Dentistry

Department of Pedodontics/ TOKAT

Tel: [redacted]

(A copy of this form with all pages signed will be given to the participant)

Tarih:

CHILD CONSENT FORM FOR RESEARCH STUDY

Dear Sibling,

Our names are [redacted] and [redacted]. We are pediatric dentists. We are conducting a research on protective fillings for children with newly erupted permanent teeth like you. The name of our research is "Evaluation of the Effect of Different Deproteinization Agents on the Clinical Success of Fissure Sealants in Permanent Teeth: Splint Mouth Clinical Study". We recommend you to participate in this research in which we aim to learn new information.

I[redacted], and my teacher, [redacted], are doing the research together. If you participate in this research, we will need to put a ring and a colorful cover on your tooth while filling your tooth with a protective filling. Thanks to this cover, you will not get any bad taste or water in your mouth, you will be able to breathe and swallow comfortably. After putting the cover on, we will clean your tooth with the tools we will show you, which look like a toothbrush. You will not feel any pain during this process. We will fill your tooth with blue and pink colored materials respectively. After hardening the protective filling with blue light and polishing it with tires, our process will be over. We may need to see you a few times afterwards to check your fillings.

We plan to provide this treatment to 60 friends like you and to fill their newly erupted teeth with protective fillings before decay develops. If the teeth are not filled and oral care is not adequate, tooth decay may occur, if the decay progresses, it may cause pain, abscesses may occur in the gums, and swelling may occur on the gums and face. In this case, we may need to apply treatments such as root canal treatment or extraction. For this reason, it is very important to perform preventive filling in the early period and to ensure oral hygiene habits.

The results of this research will provide new information for children who need protective fillings for their teeth. We will tell other doctors about the results of this research, we will report the results, but we will not mention your name.

Before you decide whether or not to take part in this study, you should talk to your parents and consult them. We will tell them about this research and get their approval. Even if your parents say yes, you may not agree. It is up to you to take part in this research and if you don't want to, you don't take part. No one will get angry or resent you for this. Even if you

agree to take part at first, you can refuse later, it is entirely up to you. Even if you do not agree, the doctors will treat you just as well during the examination and other procedures as before, and there will be no difference from before.

You can ask me any questions you have now or any questions you may have later. My phone number and address are on this sheet. If you agree to take part in this study, we ask you to sign your name and surname below.

The child,	**Legal representative of the child,**
Name-Surname:	Name-Surname:
Signature:	Telephone:
	Signature:

From the beginning of the consent process,

Name-Surname:

Telephone:

Signature:

Physician Interviewing the Participant

Research Assistant. [redacted]

Tokat Gaziosmanpasa University Faculty of Dentistry

Department of Pedodontics/ TOKAT

Tel: [redacted]