İZMİR KATİP ÇELEBİ UNIVERSITY
INTERVENTIONAL CLINICAL STUDIES INSTITUTIONAL REVIEW BOARD

To: Asst. Prof. Ebru KÜÇÜKYILMAZ, PhD

From: Assoc. Prof. Barış KARADAŞ, MD,Chair

Date: 22.05.2025

IRB#:59

Study Title: **A Comparative Clinical Evaluation of Two Resin-Based Fissure Sealants Applied with Different Isolation Techniques: An 18-Month Follow –Up Study**

At its board meeting on 22.05.2025 your submission for the above referenced research study has received review and approval from İzmir Katip Çelebi Interventional Clinical Studies Institutional Review Board.

Assoc. Prof. Barış KARADAŞ
Chair

(İzmir Kâtip Çelebi Üniversitesi, Atatürk Eğitim ve Araştırma Hastanesi, Poliklinik Kat -2, Kapı No: F 2058, 35363 Karabağlar / İZMİR) 0 232 245 04 38 / 0 232 244 44 44 / 1234 Faks: 0 232 245 04 38 e-posta: ikcetik@gmail.com

Study Protocol with Statistical Analysis Plan, Informed Consent Forms, Ethical Approval

Materials and Method

Study Design

The randomized, controlled, single-blind study was approved by the Medical Ethics Committee of Izmir Katip Celebi University (approval number: 2025/059). Prior to the initiation of treatment, written informed consent was obtained from the parents of the children participating in the study. The study was conducted in accordance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines to ensure transparent and comprehensive reporting of the clinical trial methodology and findings.

Sample Size

The estimation of sample size was conducted utilizing G*Power 3.1.9.7 software (Germany). According to the statistical parameters reported in a reference study,[22] the effect size was set at 0.56, the alpha error at 0.05, and the power of the study at 0.81. It was determined that, in consideration of the established parameters, the minimum requisite sample size was to be calculated as 43 teeth per group. However, to account for an estimated loss of 20 of participants, which is a common occurrence in pediatric clinical studies due to factors such as non-compliance, anxiety, or missed follow-up appointments, the target sample size was adjusted to 50 teeth per group. Consequently, a total of 200 teeth (100 teeth per material and 50 teeth for four subgroups) was established to ensure sufficient statistical power and maintain the validity of the study despite potential participant loss.

Sample Inclusion and Exclusion Criteria

The study comprised 100 healthy children aged between 6 and 12 years, with a mean age of 7.9 years, ASA class I (American Society of Anesthesiologists), who were determined to exhibit cooperative behavior with a score of 3 or 4 on the Frankl Behavior Rating Scale. All participants had fully erupted lower first permanent molars on both sides (200 teeth), which

required the application of pit and fissure sealants. The inclusion criteria were based on the International Caries Detection and Assessment System II (ICDAS II) criteria, including deep and retained pits and fissures, no restorations, and no evidence of caries lesions. Participants with special needs or systemic disease (ASA classification II or higher), requiring emergency dental care, suffering from a severe gag reflex or an allergy to latex, exhibiting uncooperative behavior (Frankl Score 1 or 2), exhibiting molars with anomalies of the enamel/dentin, or unable to attend follow-up appointments were excluded from the study.

Screening Participants

The clinical phase of the study was conducted by two researchers. One was responsible for examination and treatment procedures, while the other (who was blinded) was responsible for follow-up procedures. The training process was repeated at 20 randomly selected sites until examiners demonstrated substantial correlation, as measured by Cohen's Kappa ($k \geq 0.7$). After the training of the examiners, the study was initiated. The first operator, who had undergone training and performed the evaluation of the presence of caries using visual examination methods following ICDAS criteria, screened 178 children to determine their eligibility. The health history and demographics of each participant were obtained, and a clinical examination was carried out. The latter was performed with the aid of a blunt instrument and a mouth mirror, the first mandibular molars selected for inclusion in this study were examined using radiography, with the objective of ruling out the presence of any signs of dental caries. This examination involved the analysis of bitewing radiographs, which were taken from both the right and left sides of each patient. In addition, a caries risk assessment was performed on the patients to be included in the study using the Cariogram programme (CarEng, version 3.0, Malmö University, Sweden). The following factors were taken into consideration during the evaluation process: caries experience (DMFT/DMFS values, new caries in the last year, number of fillings and missing teeth); systemic diseases; dietary content (especially sugar

consumption); number of daily meals and snacks; Silness-Löe Plaque Index scores; Streptococcus mutans level in saliva (by strip test); fluoride exposure information; salivary flow rate (by stimulated saliva test); and salivary buffer capacity (by Saliva-Check Buffer or strip tests). All data were entered into the Cariogram programme, which created a caries risk profile for each patient. Patients with moderate caries risk were included in the study. Participants who met the inclusion criteria were enrolled in the study after obtaining consent from their parents or legal guardians and assent from the participants themselves.

Blinding and randomization

A split-mouth study design was employed, whereby two different fissure sealant materials were applied using two different isolation techniques. Each patient received both sealants, with one applied under rubber dam isolation and the other under cotton roll isolation. The allocation of materials and isolation methods to specific teeth was randomized to minimize bias. A computer-generated randomized list *Research Randomizer (Ver;4.0)* was employed to determine the sequence of application of fissure sealant materials, as well as the side (right or left mandibular molar) on which each material would be applied. In accordance with the sealant material and isolation protocol, this randomized process resulted in the formation of four different study groups.

(a) a highly filled fluoride-containing fissure sealant with rubber dam isolation,

(b) a highly filled fluoride-containing fissure sealant with cotton roll isolation,

(c) an unfilled fluoride-containing fissure sealant with rubber dam isolation,

(d) an unfilled fluoride-containing fissure sealant with cotton roll isolation.

The chemical composition, manufacturer, and application procedures of the tested fissure sealant materials are shown in Table 1.

Clinical Procedure

The plaque and debris were removed from the occlusal surfaces using a rotating brush and non-fluoride prophylactic paste. In accordance with the results of the randomization process and following the determination of the materials and isolation methods to be employed on each side of the patient, each tooth was isolated using a rubber dam, an arch and metal clasps, or cotton rolls with a high-volume suction, to avoid contamination from saliva. The application was carried out under proper illumination in accordance with the manufacturers' recommendations, as outlined in Table 1. Following the successful application of the designated sealant to the first tooth, the contralateral homologous tooth was sealed using an alternative material. The polymerisation of all materials was conducted using an LED light-curing unit (Valo, Ultradent Products Inc., South Jordan, Utah, USA), in accordance with the manufacturer's instructions. After each application, the sealant was subjected to testing for the absence of air bubbles, marginal adaptation, retention, and complete polymerisation. If a deficiency was identified, the tooth was re-treated. The occlusion was then subjected to evaluation, with any potential premature contacts being eliminated. All children were provided with oral hygiene instructions and any other necessary dental treatment.

Follow-up

The evaluation of pit-and-fissure sealants was conducted to record the presence of caries lesions and sealant retention at 6-, 12-, and 18-month follow-up visits. The evaluation was performed by one calibrated pediatric dentist, who was unaware of which sealant had been used and the teeth were air-dried and observed under appropriate illumination following toothbrush prophylaxis. The International Caries Detection and Assessment System (ICDAS) II criteria were employed to record caries lesions and following classification system was employed for the retention evaluation of the sealants: 1 = complete retention; 2 = partial loss; or 3 = complete loss. The pit-and-fissure sealants that were noted to have undergone complete loss during the

follow-up appointments were subjected to re-treatment, exclusion from the study, and documentation as complete loss until the conclusion of the follow-up period.

Statistical Analysis

The analysis of the retention rates of the fissure sealant materials was conducted utilizing the IBM SPSS Statistics 30.0 statistical software package (SPSS, Chicago, Illinois, USA). Chi-square tests were used to determine whether there were statistically significant differences in retention rates between sealant materials and isolation techniques at different time points at the five percent significance level. The Kaplan-Meier survival analysis was applied to assess the cumulative retention rates of the sealants over time. The Log-Rank test was utilized to compare the survival distributions between different groups. The median and mean survival times for each fissure sealant and isolation technique were calculated, along with their 95% confidence intervals (CI).

A Comparative Clinical Evaluation of Two Resin-Based Fissure Sealants Applied with Different Isolation Techniques: An 18-Month Follow-Up Study

Version number 1 Date: 10.04.2025

INFORMED CONSENT FORM (FORM 15)

PLEASE READ CAREFULLY !!!

You have been invited to participate in this study. Before you agree to take part in this study, you need to understand the purpose of the study and make your decision freely after this information. Please read this information prepared especially for you carefully and ask for clear answers to your questions.

WHAT IS THE PURPOSE OF THE STUDY?

To prevent the development and progression of dental caries on the chewing surfaces of your child's permanent first molars, which are known as caries-prone surfaces.

WHAT ARE THE CONDITIONS OF PARTICIPATION?

To be included in this study, your child must be between the ages of 6 and 12, have deep grooves on the chewing surfaces of both lower permanent first molars, have no systemic disease, and be sufficiently compliant to allow clinical procedures.

WHAT KIND OF APPLICATION WILL BE MADE?

In our study, we will evaluate the retention time of protective filling materials applied under a cotton roll and rubber blanket and compare the effectiveness of the materials with each other. Which material will be applied will be determined completely randomly by a computer-aided method (randomization via random.org website). Patients will be called for clinical control at 6-month intervals to check the applications made and to check whether their attachment to the teeth continues. If deemed necessary, the application will be repeated.

WHAT ARE MY RESPONSIBILITIES?

During the study, it is your responsibility to comply with the investigator's recommendations regarding oral hygiene and to regularly attend routine clinical controls. If you do not comply with these conditions, the investigator has the authority to exclude you from the study.

HOW MANY PARTICIPANTS?

The number of volunteers to take part in the study is 100.

HOW LONG WILL MY PARTICIPATION LAST?

The timeframe for taking part in this research is 24 months.

WHAT IS THE POTENTIAL BENEFIT EXPECTED FROM PARTICIPATING IN THE STUDY?

In this study, the surfaces of your child's teeth that are more prone to decay will be treated with protective filling materials. In addition, the retention time of the protective filling materials to the tooth will be clinically evaluated and the clinical effectiveness of these

materials will be contributed to the literature. The results of the study will contribute to determining the most comfortable method for the future treatment of both other children and your child. The positive findings obtained may help to shape treatment plans with a preventive medicine approach by raising awareness among dentists. In addition, considering the health expenditures for caries treatments, it is aimed to provide added value to the country's health system by guiding the development of longer-lasting and effective preventive practices.

WHAT ARE THE POTENTIAL RISKS ASSOCIATED WITH PARTICIPATING IN THE STUDY?

Within the scope of this research, protective filling will be applied to the chewing surfaces of your child's permanent teeth in deep grooves under a rubber blanket and cotton roll insulation. The procedures and treatments to be performed during the research described above are not expected to cause any risks or side effects.

PREGNANCY

Since the age range of the patients to be included in our study is 6-12 years, it is not thought that pregnancy will be encountered in children of this age. However, it should be noted that pregnant and breastfeeding women cannot participate in this study.

WHAT MEDICINES/FOODS ARE KNOWN TO BE DANGEROUS TO USE TOGETHER DURING THE RESEARCH PROCESS?

There are no medicines or foods that are contraindicated during the study.

UNDER WHAT CIRCUMSTANCES CAN I BE EXCLUDED FROM THE STUDY?

If you do not comply with the requirements of the treatment regimen, if you miss your check-ups, if you disrupt the work schedule or if you do not cooperate during treatment, your doctor may remove you from the study without your permission.

WHAT ARE OTHER TREATMENTS?

Fluoride application, caries promoting agents and filling applications are other methods used as alternatives to fissure sealants to prevent caries formation on the masticatory surfaces or to reduce the risk of caries.

WHO IS LIABLE/RESPONSIBLE IN CASE OF ANY DAMAGE AND WHAT TO DO?

No harmful effects are expected to occur in relation to the study. However, in case of a research-related harm, the responsibility will be borne by Prof. Dr. Ebru KÜÇÜKYILMAZ, Dr. Assist. Prof. Dr. Ebru KÜÇÜKYILMAZ, Dr. Selçuk SAVAŞ, Dt. Tuğba ÖZDEMİR and Dt. Merve Nur ÇELİK. Any damage or costs that may develop due to the procedure applied will be covered by the responsible researchers.

WHO SHOULD I CALL FOR PROBLEMS THAT MAY ARISE DURING THE RESEARCH?

For additional information about the study during the implementation period or for any problems, unwanted effects or other discomforts related to the study, you can contact Dt.

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Tuğba ÖZDEMİR at 05069391139, Dt. Merve Nur ÇELİK at 05337621302, Dr. Lecturer Selçuk SAVAŞ at 05337621302 and Prof. Dr. Ebru KÜÇÜKYILMAZ at 05323612156.

WILL THE COSTS OF THE STUDY BE COVERED?

The costs of any examinations, physical examinations and other investigations will not be charged to you or to any public or private institution or organization under your guarantee.

IS THERE AN ORGANIZATION SUPPORTING THE STUDY?

There is no institution supporting the study.

WILL ANY PAYMENT BE MADE FOR MY PARTICIPATION IN THE STUDY?

You will not receive any payment for taking part in this research.

WHAT SHOULD I DO IF I DO NOT AGREE TO PARTICIPATE IN THE STUDY OR IF I LEAVE THE STUDY?

Taking part in this study is entirely voluntary on your part. You may refuse to take part in the study or withdraw from the study at any stage; even if you refuse or withdraw, your aftercare will be guaranteed. The investigator may exclude you from the study against your will but with your knowledge for reasons such as not fulfilling the requirements of the treatment scheme, disrupting the study program or increasing the effectiveness of the treatment. In this case, your aftercare will be guaranteed.

The results of the study will be used for scientific purposes; if you withdraw from the study or are removed by the investigator, medical data about you may also be used for scientific purposes if necessary.

WILL CONFIDENTIALITY BE ENSURED WITH REGARD TO INFORMATION ABOUT NON-PARTICIPATION?

All medical and identifying information about you will be kept confidential and your identity will not be disclosed even if the study is published, but study monitors, surveyors, ethics committees and authorities may access your medical information if necessary. You can also access your own medical information at any time.

Consent to Participate in the Study:

I have read and orally listened to the 4-page text above, which shows the information that should be given to the volunteer before the study begins. I have asked the investigator all the questions that come to my mind, and I have understood in detail all the explanations given to me in writing and orally. I have been given enough time to decide whether I want to participate in the study. Under these conditions, I authorize the researcher to review, transfer and process my medical information and I accept the invitation to participate in this study voluntarily and without any coercion or pressure. I understand that by signing this form I will not lose any rights granted to me by local law.

I was given a signed and dated copy of this form.

A Comparative Clinical Evaluation of Two Resin-Based Fissure Sealants Applied with Different Isolation Techniques: An 18-Month Follow-Up Study

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VOLUNTEER'S		SIGNATURE
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A COMPETENT RESEARCHER IN THE RESEARCH TEAM		SIGNATURE
NAME and SURNAME		
DATE		

WITNESS IN NECESSARY CASES		SIGNATURE
NAME and SURNAME		
JOB		
DATE		

A Comparative Clinical Evaluation of Two Resin-Based Fissure Sealants Applied with Different Isolation Techniques: An 18-Month Follow-Up Study

Version number: 1 Date: 10.04.2025

INFORMED CONSENT FORM FOR CHILDREN (AGED 0-6)

PLEASE READ CAREFULLY !!!

You have been invited to participate in this study. Before you agree to take part in this study, you need to understand the purpose of the study and make your decision freely after this information. Please read this information prepared especially for you carefully and ask for clear answers to your questions.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to determine whether treatments using different filling creams are effective in protecting teeth that are prone to decay.

WHY WAS I CHOSEN?

Because we need to protect your teeth from decay.

DO I HAVE TO PARTICIPATE?

You do not have to participate in the study, and you can withdraw from it if you wish. No one will be upset with you or hold it against you. This will not change our approach to you or any other treatments you may receive.

WHAT WILL HAPPEN IF I PARTICIPATE?

First, I will clean any food debris from your teeth that are prone to decay using a brush. I need to apply a special protective filling cream to your teeth to prevent decay. It is very important that saliva does not come into contact with your teeth while applying this cream. For this reason, I will place a rubber cover or cotton roll on your tooth before applying the cream. I will then carefully apply this protective cream to your teeth and harden it with a special blue light. After this procedure, I will remove the rubber dam or cotton rolls, and we will be done. I will call you back for check-ups at 6months, 1 year, 1.5 years, and 2 years to check if the protective cream I applied to your teeth is still there and if your teeth are healthy.

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Version number: 1 Date: 10.04.2025

WHAT DO I NEED TO DO?

During the treatment, you must brush your teeth thoroughly and arrive on time for your appointment**s.**

WHAT MEDICATION IS BEING TESTED?

We are not testing a medication. We are simply looking at whether certain protective filling materials used to protect teeth that are prone to decay are effective.

WHAT ARE THE DIAGNOSIS OR TREATMENT ALTERNATIVES?

Sensitivity-reducing gels, mouthwashes, and toothpastes are other methods used to reduce tooth sensitivity and pain.

WHAT ARE THE POSSIBLE HARMS OR RISKS OF PARTICIPATING?

There are no additional harms or risks to you from participating in this study.

WHAT SIDE EFFECTS WILL THE TREATMENTS HAVE ON PARTICIPANTS?

We do not expect any side effects. If you feel anything that bothers you, you must tell someone close to you. They can also consult with your doctor about this issue. We will explain what you need to pay attention to after the procedure.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

By applying these creams to your teeth, we can prevent tooth decay. Additionally, each time you visit, I will examine you and explain how to maintain good oral and dental health, so your teeth will become healthier over time.

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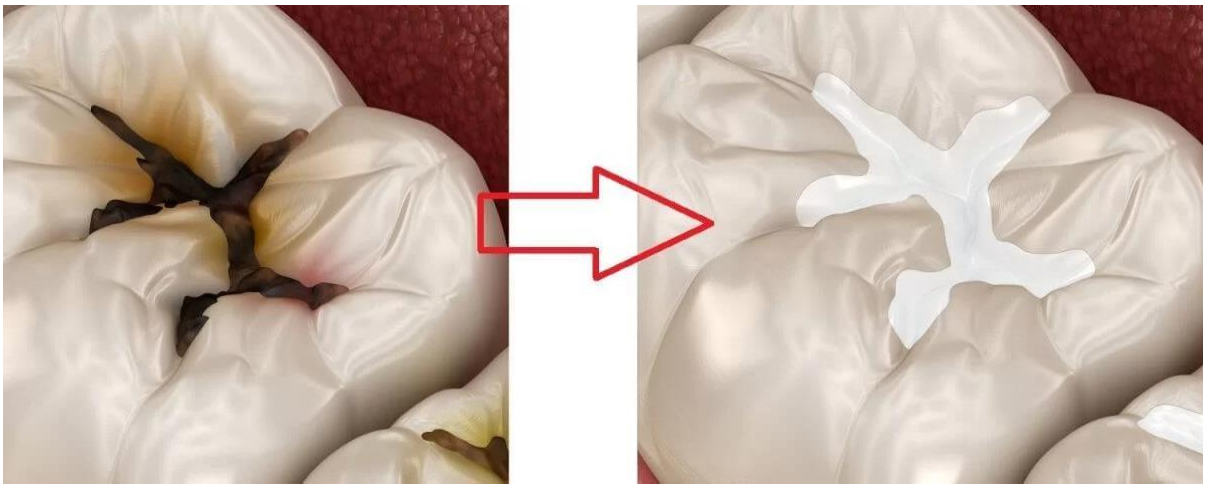

WHAT HAPPENS IF THE RESEARCH IS STOPPED?
Even if the research is stopped, all necessary treatments will be completed.

WHAT HAPPENS IF I DON'T WANT TO CONTINUE THE RESEARCH?
Participation in this study is voluntary. If you do not want to continue, you can withdraw from the study at any stage. If you do not participate in the study or withdraw from it, your treatments will be administered by physicians outside of the study.

Consent to Participate in the Study:
I have read and listened to the 3-page document above, which contains the information that must be provided to volunteers before the study begins. I asked the researcher all the questions that came to mind and fully understood all the explanations given to me in writing and verbally. I was given sufficient time to decide whether or not I wanted to participate in the study. I accept the invitation to participate in this study without any coercion or pressure.
A signed and dated copy of this form was given to me.

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INFORMED CONSENT FORM FOR CHILDREN (AGES 7-12)

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The purpose of this study is to determine whether treatments using different filling creams are effective in protecting teeth that are prone to decay.

WHY WAS I CHOSEN?

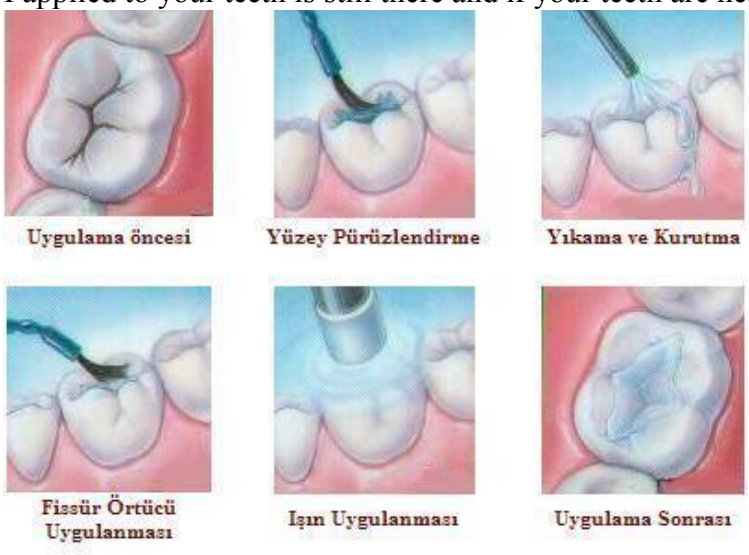
Because we need to protect your teeth from decay.

DO I HAVE TO PARTICIPATE?

You do not have to participate in the study, and you can withdraw from it if you wish. No one will be upset with you or hold it against you. This will not change our approach to you or any other treatments you may receive.

WHAT WILL HAPPEN IF I PARTICIPATE?

First, I will clean any food debris from your teeth that are prone to decay using a brush. I need to apply a special protective filling cream to your teeth to prevent decay. It is very important that saliva does not come into contact with your teeth while applying this cream. Therefore, I will place a rubber cover or cotton roll on your tooth before applying the cream. I will then carefully apply this protective cream to your teeth and harden it with a special blue light. After this procedure, I will remove the rubber dam or cotton rolls, and we will be done. I will call you back for check-ups at 6 months, 1 year, 1.5 years, and 2 years to check if the protective cream I applied to your teeth is still there and if your teeth are healthy.



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WHAT DO I NEED TO DO?
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WHAT MEDICATION IS BEING TESTED?
We are not testing a medication. We are simply looking at whether certain protective filling materials used to protect teeth that are prone to decay are effective.

WHAT ARE THE DIAGNOSIS OR TREATMENT ALTERNATIVES?
Sensitivity-reducing gels, mouthwashes, and toothpastes are other methods used to reduce tooth sensitivity and pain.

WHAT ARE THE POSSIBLE HARMS OR RISKS OF PARTICIPATING?
There are no additional harms or risks to you from participating in this study.

WHAT ARE THE SIDE EFFECTS OF THE TREATMENTS ON PARTICIPANTS?
We do not expect any side effects. If you feel anything that bothers you, you should definitely tell someone close to you. They can also consult with your doctor about this issue. We will explain what you need to pay attention to after the procedure.

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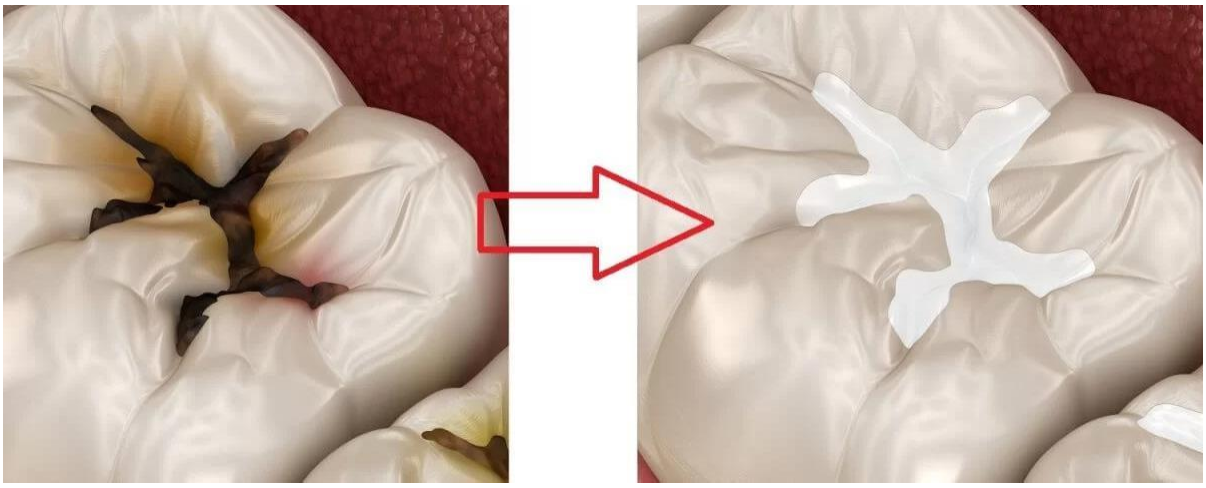

WHAT HAPPENS IF THE RESEARCH IS STOPPED?

Even if the research is stopped, all necessary treatments will be completed.

WHAT HAPPENS IF I DON'T WANT TO CONTINUE THE RESEARCH?

Participation in this study is voluntary. If you do not want to continue, you can withdraw from the study at any stage. If you do not participate in the study or withdraw, your treatments will be administered by physicians outside of the study**.**

Consent to Participate in the Study:

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