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Evaluation of the Effect of a Hydroxyapatite-Forming Desensitizing Agent on Postoperative Sensitivity in Composite Restorations

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PROJECT SUMMARY

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INTRODUCTION AND GENERAL INFORMATION

Nowadays, both esthetic concerns and ecological awareness have led to the preference of composite resin instead of amalgam in most restorations. However, the acidic adhesive monomers used during the application of composite resins can cause pain following restoration. This type of pain, defined as postoperative sensitivity, generally occurs independently of restoration failure and is reported by patients at different levels and intensities. Typically, this pain lasts for a period of several days to one month after the restoration and then subsides. In rare cases where severe pain occurs, endodontic treatment may become necessary (1).

Postoperative sensitivity may arise due to several factors, including the remaining dentin thickness, the diameter and patency of dentin tubules after acid etching, the general condition of the pulp, and clinician-related factors (2). To reduce postoperative sensitivity, several approaches have been suggested, such as avoiding excessive drying during cavity preparation (3), applying desensitizers and liners to the cavity (2), and using self-etch adhesives (4). However, current evidence shows that the type of adhesive itself is not a determining factor for postoperative sensitivity (5). It has also been reported that desensitizers applied to the cavity may influence bond strength. Therefore, careful selection of the material to be applied is important for the success of the restoration.

Teethmate Desensitizer (Kuraray Noritake), a desensitizing agent containing tetracalcium phosphate and dicalcium phosphate anhydrous, forms hydroxyapatite through a dissolution–precipitation reaction. An in vitro study demonstrated that this material does not adversely affect bond strength (6). Another in vitro study (7) reported that while Teethmate Desensitizer reduced adhesive bond strength, it also decreased microleakage. For this reason, it was suggested that in multimode adhesives used in self-etch mode, Teethmate Desensitizer could be applied to the cavity before adhesive application in order to reduce postoperative sensitivity.

Although the effectiveness of Teethmate Desensitizer in occluding dentin tubules and reducing sensitivity has been reported in clinical studies (8–10), no study investigating its effect on postoperative sensitivity following composite resin restorations has been identified.

Based on literature review, the aim of this phase IV study is to evaluate the effects of Teethmate Desensitizer, when applied under composite restorations, on postoperative sensitivity compared with a control group.

MATERIALS AND METHODS

This study will be conducted in three phases. In the first phase, sample size calculation was performed using statistical methods.

Statistical Pre-analysis:
The sample size was calculated using the online calculator at www.sealedenvelope.com. Assuming a power of 90% and an error margin of 5%, the required number for each group (experimental and control teeth) was found to be 43. Since a split-mouth design will be used, in which each patient will have both experimental and control groups, the required number of participants was also determined to be at least 43. Considering possible dropouts during the study, the final sample size was set at 50 participants. Randomization will be achieved using a blocked randomization technique at www.sealedenvelope.com. For blocked randomization, the seed number will be set as 12345 and block size as 2.

In the second phase, volunteer participants will be selected among patients who apply to the Faculty of Dentistry, Başkent University, and are referred to the Department of Restorative Dentistry for treatment after clinical and radiological examination revealed carious lesions. The inclusion criteria will be as follows:
- Voluntary acceptance of participation in the study
- Age between 18–65 years
- Presence of at least 12 teeth in occlusion
- The teeth to be included must have natural antagonists and adjacent teeth (normal occlusion)
- Anterior or posterior teeth with primary or secondary carious lesions in which the cavity preparation is expected to approach the pulp closely but without pulpal exposure
- Each participant must have two teeth, one on the right and one on the left, fulfilling the above criteria
- Absence of any other factor causing sensitivity or pain that might interfere with evaluation

Exclusion criteria:
- Refusal to participate in the study
- Age under 18 or over 65 years
- Presence of dental or orofacial pain
- Presence of bruxism
- Presence of advanced periodontal disease
- Presence of systemic diseases that may hinder treatment procedures or follow-up visits
- Teeth with excessive loss of tooth structure requiring full crown restoration, or with severe attrition, cracks, or non-vital teeth
- Pulpal exposure during cavity preparation
- Presence of gingival recession
- Use of analgesics, anti-inflammatory, or psychotropic drugs within the last 15 days or currently using them
- Pregnancy or lactation
- Known allergy to the materials to be used

Eligible individuals will be invited to participate in the study after verbal explanation

of the purpose and methodology. Participation will be voluntary, and those who accept will sign an Informed Consent Form. If deemed necessary, participants will receive oral hygiene motivation, and interventions will begin once oral hygiene has reached a satisfactory level.

In the third phase, before starting treatment of the teeth diagnosed with caries through clinical and radiological examination, vitality tests will be performed. After cavity preparation of two teeth per participant, the cavities will be isolated. At the point closest to the pulp, a calcium hydroxide-based pulp capping agent (Dycal, Dentsply Sirona, York, USA) will be applied in paste form. Subsequently, Teethmate Desensitizer will be applied according to the manufacturer's instructions to one cavity randomly, while the other will receive no desensitizer. To ensure randomization, pre-prepared allocation lists from www.sealedenvelope.com will be placed in opaque envelopes, which will be opened only at the time of intervention.

When necessary depending on cavity type, a matrix system (Mylar strip, sectional matrix, or Tofflemire) will be applied before restoration. All cavities will be treated with a one-step self-etch adhesive (Clearfil SE Bond, Kuraray Noritake, Tokyo, Japan) according to manufacturer's instructions and light-cured with an LED unit (LedMax Cordless 550, Benlioğlu Dental, Ankara, Turkey) at a constant intensity >1,500 mW/cm^2 for 10 seconds. Restorations will be completed using a universal composite resin (Filtek Z250, 3M Espe, St. Paul, MN, USA) with the oblique incremental technique. Each increment of composite will be polymerized for 20 seconds with the same LED device. Finishing and polishing will be performed using diamond finishing burs, polishing rubbers, and disks (Soflex, 3M Espe, St. Paul, MN, USA). All restorations will be performed by a single operator.

After restoration, participants will be given two forms (one for each tooth) to record their daily pain levels for one week. Instructions for filling out the forms will be provided. The forms will include the Numerical Rating Scale (NRS, 0–4) and the Visual Analog Scale (VAS, 0–100 mm). One week later, patients will return for follow-up, and the completed forms will be collected. Six weeks after the restorations, patients will return for another follow-up. At both the one-week and six-week follow-up visits, restorations will be evaluated by another dentist to ensure double blinding.

At the one-month control visit, tooth vitality will first be assessed. If the tooth is vital, postoperative sensitivity will be evaluated using VAS scores and by applying a cold spray (Ice Spray, Picdare S.p.A, Casnate con Bernate, Italy) with a cotton pellet to the mid-buccal surface of the teeth for 5 seconds.

Study Start Date: May 3, 2021
Study Completion Date: May 3, 2022

STATISTICAL ANALYSIS

Measurements will be obtained from two paired teeth of the same patient. The VAS and NRS values of these paired groups will be compared. For this purpose, chi-square test will be used for NRS values, and independent two-sample t-test will be used for VAS values. The significance level will be set at $p = 0.05$.

EXPECTED OUTCOMES AND SCIENTIFIC CONTRIBUTIONS

The aim of this study is to evaluate the effect of applying a hydroxyapatite-forming desensitizing material (Teethmate Desensitizer) to the cavity prior to restoration, compared with a control. Teethmate Desensitizer is a biocompatible material. Therefore, it may be effective in reducing postoperative sensitivity in cavities and increasing patient comfort.

As a result of this original study, it is expected that data on the effect of using Teethmate Desensitizer beneath restorative materials on postoperative sensitivity will contribute both to national and international literature.

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