STUDY PROTOCOL

Treatment outcomes of partial pulpotomy using two different calcium silicate materials in cariously exposed mature permanent teeth: A randomized clinical trial

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In this clinical trial, patients will be blinded; they will not be aware of the material used. Both the clinicians conducting the clinical and radiographic evaluations and the statistician analyzing the data will be blinded to the materials used. Due to the different application procedures of the two materials used, it is not possible for the clinician administering the treatment to be blinded.

After the necessary clinical examination, volunteers meeting the inclusion criteria will be randomized into two groups (n=30 each) by an independent clinician using a randomization table, and this information will be documented in patient cards. All volunteers will receive standard oral hygiene training prior to treatment. The two different calcium silicate-based materials (Biodentine or TheraCal PT) will be applied according to the manufacturers' recommendations and as outlined in their usage instructions. All treatments will be performed by a single endodontist using dental magnification.

The treatment procedure for both groups after the removal of decay and partial removal of the exposed pulp is identical and outlined below:

Prior to treatment, a periapical radiograph of the relevant tooth will be taken for diagnostic purposes using a parallel technique facilitated by a radiograph holder. The process will involve the patient biting on a small amount of silicone placed in the bite block of the radiograph holder to ensure standardization and quality. This same silicone impression will be disinfected and stored under appropriate conditions in the patient's file to be used for subsequent radiographs to ensure consistency of the angles (the filled part of the tooth will be adjusted in the silicone to fit post-filling). Additionally, high-quality images of the relevant teeth will be taken before, during, and after the treatment using a camera. Deep local anesthesia will be achieved using lidocaine with 1/80,000 epinephrine. A rubber dam will be placed to isolate the tooth and eliminate contact with the oral environment. Initial decay removal will be conducted peripherally using a sterile, high-speed diamond bur. Deeper layers of decay will be removed using a series of sterile, low-speed burs of varying diameters. Once the decay is fully removed and the pulp tissue exposed, the initial partial removal of the pulp tissue will be performed using a new sterile high-speed bur. After examining the area for residual decay, a 5.25% NaOCl solution will be used to irrigate the cavity for the initial removal of carious dentin shavings and disinfection of the tissue and cavity. For hemorrhage control, a moist cotton pellet soaked in NaOCl will be placed on the pulp wound surface for 2 minutes. If bleeding continues, a new sterile cotton pellet soaked in 5.25% NaOCl solution will be placed for another 2 minutes. If bleeding persists

after the removal of the new cotton pellet, a second partial pulpotomy will be performed to reach non-inflamed pulp tissue, and the previous procedure will be repeated. Bleeding will be checked every 2 minutes up to 10 minutes; if it stops at any of these intervals, pulp capping will be performed. If bleeding continues for more than 10 minutes, the case will be deemed unsuitable for continuation with the current treatment, and total pulpotomy or root canal therapy will be considered. Once hemostasis is achieved, the pulp capping material (Biodentine or TheraCal PT) will be placed (detailed descriptions of these steps are provided below). Subsequently, the tooth will be restored with permanent composite material, and photographs of the filling will be taken along with a periapical radiograph using the silicone impression. Post-treatment routine advice and postoperative pain information will be provided to the patient, and they will be asked to fill out the postoperative pain scale for the first week after treatment and note any medications and dosages used if applicable. Follow-up visits at 1 week (for pain assessment only) and at 3, 6, and 12 months will be conducted. During these follow-ups, necessary clinical examinations (percussion, palpation, presence-absence of sinus tract) will be performed, vitalometric assessments recorded, radiographs taken using the silicone impression, and evaluations of lamina dura, presence of lesions, and canal obliteration conducted, along with scoring of filling quality. If issues such as pain, swelling, sinus tract formation, or lesion development are detected during follow-up, root canal treatment will be administered, and the case will be deemed a failure. Radiographic follow-up evaluations of the patients will be independently performed by two endodontists not involved in the study.

Biodentine Group: After mixing the Biodentine material according to the guidelines provided in the application manual, it will be placed vertically over the hemostatically treated pulp using a carrier to ensure no exposed pulp remains. After a setting time of 12 minutes, a self-etch bond will be applied around the material, thinned with air, and light-cured. Flowable composite will then be placed over the Biodentine material and light-cured. Next, selective etching of the enamel will be performed in the cavity, washed off with water, dried, then self-etch bond applied and light-cured, followed by layering of the composite filling. If possible, filling procedures will also be performed under the rubber dam. If issues arise with matrix placement under the rubber dam, the Biodentine surface will be completely covered with flowable composite and light-cured; subsequently, the rubber dam will be removed, and filling will continue.

TheraCal PT Group: TheraCal PT material will be placed over the hemostatically treated pulp using the injector tip found in its package to ensure no exposed pulp remains, and light-cured for 10 seconds. Subsequently, self-etch bond will be applied over and around the material, thinned with air, and light-cured. Flowable composite will then be placed over the TheraCal PT and light-cured. Remaining procedures are identical to those for the Biodentine group.