Treatment outcomes of full pulpotomy using two different calcium silicate-based materials in mature permanent teeth with irreversible pulpitis symptoms: A randomized clinical trial

NCT number: has not been created yet
Document Date;
Date of creation: 05.12.2023

Study Protocol

In this clinical study, patients will be blind; they will not know the material applied. The physicians performing the clinical and radiographic assessment will be blind; they will make the assessment without knowing which material it is. The person performing the statistical analysis will be blind to the groups. (Since the application procedures of the two materials to be applied are different, it is not possible to blind the physician performing the application.)

After the necessary clinical examination, the volunteers who meet the inclusion criteria for the study will be assigned to two separate groups by a physician outside the study according to the numbers created in the randomization table and recorded on the patient cards. The volunteers will be given standard oral hygiene training before the treatment. Two different calcium silicate-based materials (Biodentine or NeoPUTTY) will be applied as recommended by the manufacturers and specified in the user manual. All treatments will be performed by a single physician (endodontist) using dental magnification.

After the decay is cleaned and the exposed pulp is completely removed and calcium silicate cements of both groups will be placed on the remaining root pulp, all stages will be the same for both groups and stated below;

A periapical radiograph will be taken from the relevant tooth for diagnostic purposes before treatment. The radiograph will be taken with a parallel technique with the x-ray holder. The procedure will be performed by placing a small amount of silicone impression on the bite block

of the x-ray holder and taking an x-ray by biting the patient in order to ensure better quality of standardization. The same silicone impression will be disinfected and stored in the patient file under appropriate conditions and will be used in post-treatment and follow-up x-rays, and the radiographs to be taken will be at the same angle (after the filling is made, the filled part of the tooth will be abraded in the silicone for the silicone impression to fit). In addition, high-quality images will be taken from the relevant teeth with a camera before, during and after treatment. Deep local anesthesia will be provided in the tooth and surrounding tissues using lidocaine anesthesia with epinephrine. A rubber dam will be placed on the involved tooth and the oral environment will be isolated. After the tooth has been cleaned with chlorhexidine, initial caries removal will be performed circumferentially using a sterile high-speed diamond bur. Deeper layers of caries will be removed using a series of sterile low-speed burs of different diameters. Once the pulp tissue has been exposed by complete caries removal, initial total removal of the pulp tissue will be performed using a new sterile high-speed bur. After examination of the area for residual caries, the cavity will be irrigated with 5.25% NaOCl to remove carious dentine shavings and to initially disinfect the tissue and cavity. To control bleeding, a moist cotton pellet impregnated with NaOCl will be placed on the pulp wound surface for 2 minutes. If bleeding persists after removal of the cotton pellet, a new sterile cotton pellet soaked in 5.25% NaOCl solution will be placed on the pulp for a further 2 minutes. The bleeding will be checked every 2 minutes until the 10th minute, and pulp capping will be performed when the bleeding stops at any of these control intervals. If bleeding continues for more than 10 minutes, the case is deemed unsuitable and root canal treatment will be applied. After hemostasis is achieved, pulp capping material (Biodentine or NeoPUTTY) will be placed (Detailed explanations of these sections are provided below). Then, permanent composite material fillings will be made, filling photographs will be taken and periapical radiographs will be taken with silicone impressions. Routine post-treatment recommendations and post-operative pain information will be given to the patient and they will be asked to fill in the post-operative pain scale up to the 1st week after treatment and note the medications and doses if used. The patient will be checked at the 1st week (only for pain assessment) and at the 3rd, 6th and 12th months. During the controls, the necessary clinical examination (percussion, palpation, presence or absence of sinus tract) will be performed, vitalometric examination will be recorded, lamina dura will be radiated with silicone impression, lesion presence and canal obliteration will be evaluated and filling quality scoring will be performed. If conditions such as pain, swelling, sinus tract formation or lesion development are detected during the follow-up process, the patient will undergo root canal

treatment and will be evaluated as an unsuccessful case. Radiographic follow-up evaluations of the patients will be performed by two endodontic specialists independent of the study.

Biodentine group: After mixing the Biodentine material according to the instructions in the application guide, it will be placed on the pulp with hemostasis with the help of the carrier and condensed vertically so that no visible pulp tissue remains. After waiting for a setting period of 12 minutes, a self-etch bond will be applied around it, thinned with air and then cured. After the flowable composite is placed on the Biodentine material, it will be cured. Then, selective acidification will be applied to the enamel in the cavity, after it is removed with water and dried, self-etch bond will be applied to the cavity and irradiated and composite filling will be applied in layers. If possible, fillings will also be performed under rubber dam. If there is a problem in the matrix placement processes with rubber dam, Biodentine will be completely covered with flowable composite and after irradiation, the rubber dam will be removed and filling will be continued.

NeoPUTTY group: NeoPUTTY material will be placed on the pulp with hemostasis with the help of the carrier with a thickness of at least 1.5 mm so that no visible pulp tissue remains. Then, a self-etch bond will be applied around it and thinned with air and then cured. NeoPUTTY will be cured after the flowable composite is placed on it. The remaining procedures are the same as the Biodentine group.