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 The Effect of Final Irrigation with Glycolic Acid or Ethylene diamine tetra-acetic acid on the Push-out Bond Strength and Marginal Adaptation of Premixed Calcium Silicate-based Material in Furcal Perforation Repair: (A Comparative InVitro Study)

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We are still developing and optimizing this protocol

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Abstract

The aim of the present study is to evaluate the effect of final irrigation with glycolic acid or EDTA on the push-out bond strength and marginal adaptation of premixed calcium silicate-based material in furcal perforation repair.

Materials

1. Premixed calcium silicate based furcal perforation repair material.
2. Glycolic acid 17% chelating agent
3. EDTA 17% chelating agent

Samples, interventions and outcomes

1 Calculated sample size

- 1.1 power analysis was designed to have adequate power to apply a statistical test of the null hypothesis that there is no difference between different tested groups regarding push-out bond strength. By adopting an alpha (α) level of (0.05), a beta (β) level of (0.2) (i.e. power=80%) and an effect size (d) of (1.425) calculated based on the results of a previous study (Gade et al, 2021); the predicted sample size (n) was a total of (18) teeth (i.e. 9 teeth per group). Sample size was increased by (20%) to compensate for anticipated missing data to be a total of (22) teeth (i.e. 11 teeth per group). Sample size calculation was performed using G*Power version 3.1.9.7 (Heinrich Heine University, Dusseldorf, Germany).

2 Samples description

- 2.1 Sample selection:
Mandibular molars teeth extracted for periodontal diseases will be collected. All the teeth will be examined to exclude those with previous root canal treatment, root caries, root resorption and root fracture or cracks. Collected teeth will be cleaned from calculus and any soft tissues by using ultrasonic scaler, then disinfected with 5% sodium hypochlorite at 37 °C for 1 hour and after that immediately immersed and stored in distilled water until the start of the study.
- 2.2 Eligibility Criteria:
Inclusion criteria:
Teeth free of cracks, fractures, root caries, root resorption, previous root canal treatment and restoration.
Completely formed apices
Non-fused diverging roots
Exclusion criteria:
Teeth with cracks, fractures, root caries, root resorption, previous root canal treatment and restoration.

3 Sample Preparation

- 3.1 Preparation of the Perforations:
The tooth trunk length will be measured using a caliper to ascertain a furcation location relative to cemento-enamel junction of 3 mm buccally and 4 mm lingually (Greenstein et

al., 2014). The access cavities will be made with a size 12 diamond ball bur (Dentsply Sirona, Ballaigues, Switzerland) under running water. The endo Z bur (Dentsply Sirona) will be used to deroof entirely the pulp chamber and create divergent walls, then the teeth will be then rinsed with water and air-dried (Dayyoub et al., 2024).

The samples will be marked 4 mm above the pulpal floor and 4 mm below the furcation area with the help of a periodontal probe and a black marker. The samples will be decoronated 4 mm above the pulpal floor, and the roots amputated 4 mm below the furcation using a water-cooled diamond disk (Komet Dental, USA) attached to the mandrel (Nagas et al., 2017).

A perforation will be made in the center of the furcation area from the external surface using a size 3 round diamond bur (DentsplySirona). The defects will be instrumented with Gates Glidden burs (Dentsply Sirona) #2 to #5 to unify the width and reach a standardized diameter of 1.3 mm. The height of the defects will be adjusted to 2.5 mm using wheel-shaped diamond bur (Dentsply Sirona) and controlled with probe to 2.5 mm under an operating microscope (Kassab et al., 2021).

Subsequently, the teeth will be embedded in acrylic molds leaving 4-mm at the furcal area out of the acrylic resin to provide sufficient space for the placement of a gelatin Sponge (Gelatang Roeko, Coltene Whaledent, Switzerland) that would act as a matrix to pack repair materials against and to simulate the periodontal environment (Dayyoub et al., 2024).

3.2 Perforations repair:

The repair material will be applied according to the manufacturer's recommendations and will be incrementally placed into the perforation site under an operating microscope $\times 16$ (Zeiss Extaro 300, Oberkochen, Germany). Excess material will be trimmed from the surface of the samples with a scalpel. Specimens will be wrapped in a piece of wet gauze and placed in an incubator at 37°C and 100% relative humidity for 72 hours to ensure the hardening of the tested materials.

4 Interventions

4.1 Samples grouping:

The teeth will be randomly divided into two experimental groups according to the final irrigant used to remove the smear layer.

- Group 1: 17% GA
- Group 2: 17% EDTA

4.2 Irrigation:

Firstly, a 3ml of 5.25% NaOCl will be applied in all tested groups for 1 min. Then Irrigants will be applied gently with a 27G needle 3ml for 1 min. (Sybron Endo, Orange, CA, USA). Afterward, the irrigants

will be withdrawn and washed with 3ml saline for 1 min to control the working time and prevent the prolonged effect of the irrigant solution on the perforation repair material

4.3 Push-out bond strength test:

The pushout bond strength will be measured using a universal testing machine (Instron, Norwood, MA, USA). The laboratory operator will be blinded to which material will be used in each group. The compressive load will be applied by exerting a download pressure on the surface of the test material in each sample with the probe moving at a constant speed of 1 mm/min. The maximum force applied to materials at the time of dislodgement will be recorded in Newton. The pushout bond strength will be calculated in Megapascals using the following formula:

Push-out bond strength (MPa) = Force necessary for dislodgment (N) / Bonded surface area (mm²)

5 Marginal adaptation test:

Marginal adaptation will be tested by examination of the samples under 1500X magnification to measure the gap distance between pulpal floor and repair material in micrometers. For the sake of accuracy, readings will be taken along the whole gap length and mean gap distance will be calculated.

Assignment of intervention

6 Randomization

Randomization will be generated using (www.randomization.com).

7 Allocation concealment mechanism

A checklist will be designed to identify each material specimen. A series of sequentially numbered opaque envelopes will be used for each group.

8 Implementation

A participant who has the checklist and the envelopes will allocate the randomly selected specimens into the envelopes to prevent bias.

9 Blinding

The allocation group will be blinded from those assessing the outcome by handling specimens in tightly sealed, sequentially coded opaque containers. The data analysts will be blinded by labelling the groups' results with non-identifying terms.

10 Statistical methods

Statistical methods Data will be coded and entered using the statistical package SPSS version 22. Comparisons between the groups will be done using P value less than 0.05 will be considered statistically significant. Tests will be two tailed. The Data will be tested for normality using Shapiro Wilk test and presented as mean and standard deviation or median and range. ANOVA test and Tukey post hoc test will be used for analyzing

normally distributed data, while Kruskal Wallis test was for analyzing non-normally distributed data followed by Mann-Whitney U test for pairwise comparison.

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