



May 30, 2025

Version 1

The Effect of Final Irrigation with 9% Etidronate or 17% Ethylenediamine tetra-acetic acid on the Push-out Bond Strength and Marginal Adaptation of Premixed Calcium Silicate-based Material in Furcal Perforation Repair: A comparative in-vitro study V.1

DOI

<https://dx.doi.org/10.17504/protocols.io.ewov1m6zyvr2/v1>

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Protocol Citation: Dina Hazem Elsayed, Prof. Dr. Hany Samy Sadek, Dr. Radwa Sameeh Emara, Dina Hazem Elsayed Ahmed 2025. The Effect of Final Irrigation with 9% Etidronate or 17% Ethylenediamine tetra-acetic acid on the Push-out Bond Strength and Marginal Adaptation of Premixed Calcium Silicate-based Material in Furcal Perforation Repair: A comparative in-vitro study. protocols.io <https://dx.doi.org/10.17504/protocols.io.ewov1m6zyvr2/v1>Version created by **Dina Hazem Elsayed Ahmed**

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Protocol status: In development

We are still developing and optimizing this protocol

Created: May 29, 2025

Last Modified: May 30, 2025

Protocol Integer ID: 219182

Keywords: marginal adaptation of premixed calcium silicate, bond strength of premixed bioceramic, successful root canal treatment, best clinical outcome for successful root canal treatment, premixed calcium silicate, effect of final irrigation, final irrigation, material in furcal perforation repair, bond strength, irrigation with these agent, furcal perforation repair, premixed bioceramic, irrigation, comparative in vitro study

Abstract

This study evaluates the effect of final irrigation with 9% Etidronate or 17% Ethylenediamine tetra-acetic acid (EDTA) on the push-out bond strength and marginal adaptation of premixed calcium silicate-based material in furcal perforation repair. The research question addresses whether the final irrigation with 9% Etidronate differs from 17% EDTA in terms of push-out bond strength and marginal adaptation. The study aims to determine the best clinical outcome for successful root canal treatment by evaluating the push-out bond strength of premixed bioceramics (Endocem MTA) after irrigation with these agents.

Guidelines

The protocol will be registered in: <https://www.nature.com>. The proposed study is self-funded. Investigator: Dina Hazem Elsayed, a Master's degree student at the Department of Endodontics, Faculty of Dentistry, Cairo University, is the main researcher responsible for collecting and entering baseline data, collecting appropriate teeth, performing methods, and writing the research. Chief Supervisor: Prof. Dr. Hany Samy Sadek, Professor at the Department of Endodontics, Faculty of Dentistry, Cairo University, is the main supervisor responsible for monitoring and editing data and the whole process of the study. Assistant Supervisor: Dr. Radwa Sameeh Emara, Lecturer at the Department of Endodontics, Faculty of Dentistry, Cairo University, is the co-supervisor responsible for generating a random sequence of samples, undergoing proper allocation concealment, implementation, and accessing the final data.



Materials

Twenty-two mandibular permanent first and second molars with completely formed roots, healthy furcation areas, and normal anatomy will be used. Teeth will be cleaned from calculus and any soft tissues using an ultrasonic scaler, disinfected in 5% sodium hypochlorite solution for 30 min, then rinsed with water and preserved in saline at room temperature.

Introduction

- 1 Research question: Will the final irrigation with 9% Etidronate differ from 17% Ethylenediamine tetra-acetic acid on the push-out bond strength and marginal adaptation of premixed calcium silicate-based material in furcal perforation repair?
- 2 Statement of the problem: A perforation refers to a mechanical or pathologic connection between the external surface of a tooth and the root canal system, which can result from pathological causes like cavities or resorption, as well as iatrogenic factors. Furcal perforations are a frequent issue in endodontic procedures and can negatively affect treatment outcomes by causing periodontitis and irreversible loss of attachment. Several factors influence the prognosis in these cases, such as the perforation's location, size, and timing. Determining the overall treatment prognosis also heavily depends on how well the perforation is sealed using the right materials.
- 3 Rationale: Etidronate is defined as 1-hydroxyethylidene-1, 1-bisphosphonate (HEBP). These bisphosphonates are highly applied systemically biocompatible chelators in the treatment of bone diseases. 9% HEBP, a biocompatible chelating agent, has proteolytic and antimicrobial properties, does not cause a reaction when used with NaOCl, and does not affect the antimicrobial properties of NaOCl. HEBP effectively removes the smear layer and causes less erosion on the dentin than EDTA.
- 4 Review of literature: Various studies have been conducted to evaluate the push-out bond strength and marginal adaptation of different materials used in furcal perforation repair. These studies highlight the importance of selecting appropriate materials and irrigation protocols to achieve optimal clinical outcomes.

Methods

- 5 Calculated sample size: A power analysis was designed to have adequate power to apply a statistical test of the null hypothesis that there is no difference between different groups regarding push-out bond strength. By adopting an alpha (α) level of 0.05 (5%), a beta (β) level of 0.2 (i.e., power=80%), and an effect size (f) of (1.425) calculated based on the results of a previous study, the predicted sample size (n) was a total of (27) teeth (i.e. 9 teeth per group). Sample size was increased by (20%) to compensate for anticipated missing data to be a total of (33) teeth (i.e. 11 teeth per group). Sample size calculation was performed using G*Power version 3.1.9.7.
- 6 Description of study sample: Sample selection: Twenty-two mandibular permanent first and second molars with completely formed roots, healthy furcation areas, and normal anatomy will be used. All the teeth will be examined to exclude teeth free of cracks, fractures, root caries, root resorption, previous root canal treatment, and restoration. Collected teeth will be cleaned from calculus and any soft tissues by using an ultrasonic

scaler, disinfected in 5% sodium hypochlorite solution for 30 min, then rinsed with water and preserved in saline at room temperature.

- 7 Intervention for each group: Grouping of samples: Teeth will be randomly divided into three groups (n=11) according to the type of final irrigant used: Intervention I1: 9% Etidronate (HEBP), Intervention I2: 17% Ethylenediaminetetraacetic acid (EDTA), Control: Saline.
- 8 Outcomes: Primary outcome: Push-out bond strength, Secondary outcome: Marginal adaptation.
- 9 Assignment to Intervention: Sequence generation: Random allocation and sequence generation will be performed using a computer random sequence generator program. Allocation concealment mechanism: To prevent selection bias in the interventions, the allocated sequence will be protected and concealed until assignment using sequentially numbered opaque sealed envelopes in which the teeth will be placed.
- 10 Blinding: The outcome assessor and statistician will be blinded.
- 11 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.