STUDY PROTOCOL

Official Study Title:
Clinical and Radiographic Evaluation of Three Premixed Bioceramic Materials for Pulpotomy in Immature Permanent Molars: A Randomized Controlled Trial

NCT Number:
"Pending"

Document Date:
9 January 2026

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Research protocol FMD-USJ
Master's Thesis
Department of Pediatric Dentistry- 2025
Presented by: Marilyn NOHRA

1. Title of the project:

A comparison of outcome of pulpotomy on immature permanent molars between different calcium silicate-based materials : a 12 months clinical study

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Statistical analysis and data curation

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- Department of Endodontics, Faculty of Dental Medicine, Strasbourg University, 67000 Strasbourg, France.

4. **Funding:**

This research will not receive any external funding, as the principal investigator is self-funding the project.

5. **Lab/division:**

(Faculty of Dental Medicine, Campus des Sciences Médicales, Saint Joseph University of Beirut, Beirut, Lebanon).

6. **Justification of the study:**

The emphasis on minimally invasive treatments aimed at preserving pulp vitality has become a key focus in Endodontics. (1) Vital pulp therapies (VPT) involve a range of techniques aimed at preserving all or part of the dental pulp, maintaining its developmental, defensive, and proprioceptive functions. (2)

According to the American Association of Endodontists (AAE), full pulpotomy is defined as "the removal of the coronal portion of a vital pulp as a mean of preserving the vitality of the remaining radicular portion". (3) It is considered a less challenging procedure compared to pulpectomy, particularly in younger patients. (3) Maintaining pulp vitality in immature permanent teeth with deep carious lesions is essential for continued root development and proper apical closure. (4) Additionally, clinical symptoms of symptomatic irreversible pulpitis do not always correlate with histopathologic findings, suggesting that pulpitis progresses gradually without a clear threshold for irreversibility. As a result, pulpectomy may not always be necessary, and conservative treatments could be considered. (5) Carious disease is reported to occur more frequently in pediatric patients, with various studies indicating that permanent molars are particularly vulnerable to early caries shortly after their eruption. (6) Molar-incisor hypomineralisation (MIH) in first permanent molars has been linked to a significantly increased risk—over six times higher—of developing dental caries, emphasizing the importance of early intervention. (7) This makes VPT especially relevant for young children, when these teeth are most vulnerable. (7)

Currently, there is no clear consensus on the best approach for managing deep carious lesions in immature vital permanent teeth. Immature teeth have a strong ability to repair and regenerate tissue, making them ideal candidates for conservative pulp therapies aimed at promoting root development. Arrested root development in immature permanent teeth results in thin dentinal walls, increasing the risk of fracture due to overloading. Achieving apical closure and root maturation is essential for long-term tooth integrity. (8)

Most available data focus primarily on pulp-related techniques or the longevity of materials in fully developed permanent teeth. (4) Pulpotomy is a reliable and consistent procedure, achieving success rates exceeding 90% in both immature and mature teeth, as long as proper case selection criteria are met. These criteria are determined by factors such as preoperative symptoms, clinical and radiographic evaluations—including the tooth's vitality, presence or absence of radiographic lesions—and intraoperative observations like the color and amount of bleeding, as well as the time needed to control hemostasis. (9) (10) (3)

There is emerging evidence about the ability of calcium silicate-based cements (CSC) to induce repair, in various endodontic procedures, including vital pulp treatments. (3) (11) (12) These materials are widely used in endodontics due to their favorable physicochemical and biological properties. (12) They exhibit an alkaline pH and release calcium ions, which contribute to their bioactivity and ability to stimulate biomineralization processes. (11) Mineral Trioxide Aggregate MTA has always been the gold standard for VPT. However, it presents some disadvantages; in particular, long setting time, difficult manipulation and tooth discoloration. (13) (14) Advancements in CSC formulations aim to address these limitations, enhancing their clinical efficacy. (12) With advances in nanotechnology, manufacturers have developed newer formulations of MTA and premixed bioceramics. These hydrophilic materials can be used in blood-contaminated environments, reducing technical sensitivity. Such examples include Neo PUTTY ® (Nusmile Inc, Houston, TX; USA), Total Fill® BC UNIVERSAL RRM ™ (FKG Dentaire, Switzerland) and Bio-C® Repair (BCR; Angelus, Londrina, Brazil).

Neo PUTTY ® (Nusmile Inc, Houston, TX; USA) is a premixed bioactive bioceramic composed of an inorganic powder containing tricalcium and dicalcium silicate in a water-free organic liquid. (15) This product is color-stable, non-staining, incorporating tantalum oxide for radiopacity instead of bismuth oxide, which is known to cause tooth discoloration. (15) (16) (17) Literature has shown that such products exhibit antimicrobial properties in-vitro, with physical and chemical properties comparable to MTA and better handeling properties. It has been demonstrated to set more quickly than conventional MTA materials, helping to shorten treatment duration and enhance patient comfort. (15) Neo PUTTY ® was approved by the U.S. Food and Drug Administration (FDA) in 2020 for root and pulp treatment. (17)

Total Fill® BC UNIVERSAL RRM™ (FKG Dentaire, Switzerland) is a premixed bioceramic material composed of calcium aluminosilicate paste designed for permanent root canal repair and surgical applications. (18) Its setting reaction is triggered by moisture present in the dentinal tubules, leading to the formation of hydroxyapatite, which enhances chemical adhesion between the dentin and the sealer. Studies have demonstrated that Total Fill® BC UNIVERSAL RRM™ exhibits higher calcium ion release compared to other sealers, contributing to its bioactivity and mineralization ability. (19)

Bio-C® Repair (BCR; Angelus, Londrina, Brazil) is a new ready-to-use bioceramic repair material. Bio-C has indications similar to MTA and is composed of calcium silicates [tricalcium silicate, dicalcium silicate], tricalcium aluminate, calcium oxide (for the release of calcium ions), and zirconium oxide as a radioopacifier. For pulpotomy, Bio-C® Repair promotes the formation

of a dentin barrier, which provides superior results than pure calcium hydroxide because the bioceramic is less soluble, has bactericidal action and hermetically seals the site due to its setting expansion. The average particle size of this material is significantly smaller than that of traditional MTA, measuring under 2 microns. This finer size enhances its reactivity, promoting a quicker release of calcium (Ca^{2+}) and hydroxyl (OH^-) ions. (20) (21)

The selection of pulpotomy agents can significantly influence clinical outcomes and should therefore be guided by both clinical and histological evidence, with a primary focus on maintaining pulpal vitality over time. (22) To the best of our knowledge, no study has yet compared these three biomaterials in the treatment of permanent molars with incomplete root development. Therefore, the aim of this study is to compare the clinical and radiographical outcomes of new bioactive materials (Neo PUTTY®, Total Fill® BC UNIVERSAL RRM™ and Bio-C® Repair) in pulpotomy on immature permanent teeth with irreversible pulpitis over a 12-months period.

Materials	Manufacturer	Composition
Neo PUTTY	Nusmile Inc, Houston, TX; USA.	Tricalcium Silicate (Ca3SIO4), Dicalcium Silicate (Ca2SiO4), Tantalum Oxide (Ta_2O_5), Calcium Hydroxide ($Ca(OH)_2$), Thickening Agents
TOTALFILL BC RRM Putty	FKG Dentaire, Switzerland.	Tricalcium Silicate (Ca3SIO4), Dicalcium Silicate (Ca2SiO4), Zirconium Oxide (ZrO2), Tantalum Pentoxide (Ta2O5), Calcium Sulfate (CaSO4).
BIO-C Repair	Angelus, Londrina, Brasil.	Calcium Silicate (Ca2SiO4), Calcium Oxide (CaO), Zirconium Oxide (ZrO2), Iron Oxide (Fe2O3), Silicon Dioxide (SiO2) and Dispersing Agent

7. Primary objective:

To compare the clinical and radiographic outcomes of three calcium-silicate-based materials (Neo PUTTY®, Total Fill® BC UNIVERSAL RRM™ and Bio-C® Repair) for pulpotomy in immature permanent molars with irreversible pulpitis after 12 months.

8. Research hypothesis:

-Null hypothesis (h0): There is no significant difference in clinical and radiographic outcomes between the three materials for pulpotomy performed on immature teeth with irreversible pulpitis.
-Alternative hypothesis (h1): There is a significant difference in clinical and radiographic outcomes between the three materials for pulpotomy performed on immature teeth with irreversible pulpitis.

9. Innovative character of the study:

This study's novelty lies it its design, as it is a randomized clinical trial, and in the materials tested. The study will compare new biomaterials (Neo PUTTY® , Total Fill® BC UNIVERSAL RRM™ and Bio-C® Repair) as pulpotomy agents in the treatment of immature permanent molars.

10. Clinical relevance:

Research on the impact of treatment on the continuation and completion of root development in immature permanent teeth with deep carious lesions is still limited and does not address the long-term survival of the teeth. Therefore, this study aims to assess the evidence on the effectiveness, clinical and radiographic success of new various biomaterials used for managing deep caries in immature permanent teeth with incompletely developed apices.

11. Introduction:

Pulpectomy has traditionally been seen as the preferred treatment for exposed pulp due to the unpredictable results of conservative approaches. Coronal pulpotomy was once limited to primary teeth or emergency treatment of irreversible pulpitis in permanent teeth. However, recent evidence suggests that vital pulp therapy (VPT) can now be a definitive option for irreversible pulpitis on permanent teeth. (2) By managing pulp infection and inflammation in permanent teeth, it is possible to allow the inflamed pulp to heal, supporting conservative treatment and ensuring root formation (apexogenesis). (3) (8) Recent American Association of Endodontists (AAE) statements have highlighted that a diagnosis of irreversible pulpitis no longer automatically warrants pulpectomy, marking a shift toward minimally invasive VPT. (3) (23)

The AAE defines full pulpotomy as the removal of the coronal portion of a vital pulp to maintain the vitality of the remaining root portion. (3) Failures in traditional endodontic treatments can occur due to improper root canal preparation or obturation, often due to the complex anatomy of the root canal system. (3) Additionally, such treatments can compromise the tooth's strength. These issues emphasize the need to preserve pulp vitality for long-term tooth health and the need for less invasive approaches, particularly for younger patients. In cases of symptomatic irreversible pulpitis, clinical symptoms do not always correlate with histopathologic findings, suggesting that pulpitis may progress gradually without a clear threshold for irreversibility. As a result, healing of the pulp could be achievable, especially with the use of new biomaterials. (3) (5)

Mineral Trioxide Aggregate MTA has always been the gold standard for VPT. However, it presents some disadvantage; in particular, long setting time, difficult manipulation and tooth discoloration. (13) (14) Other biomaterials were developed to overcome the disadvantages of MTA. Advancements in calcium silicate-based cements (CSC) formulations aim to address these limitations, enhancing their clinical efficacy. (12) The ideal pulpotomy material should be antibacterial, biocompatible, promote healing of the root pulp, without causing excessive calcification of the remaining pulp tissue that would impede a later reintervention, and should minimize tooth discoloration. (22) Several manufacturers have developed newer formulations of MTA and premixed bioceramics, such as Neo PUTTY® (Nusmile Inc, Houston, TX; USA), Total Fill® BC UNIVERSAL RRM™ (FKG Dentaire, Switzerland) and and Bio-C® Repair (BCR; Angelus, Londrina, Brazil) for endodontic applications. These bioactive materials exhibit antimicrobial properties, set in the presence of moisture, and promote hydroxyapatite formation, ensuring strong chemical adhesion to dentin. These characteristics contribute to their effectiveness in pulp treatments, making them valuable choices in modern endodontics. The difference in

composition among these three commercially available premixed bioceramic materials plays a crucial role in their clinical behavior and performance. Variations in key components can affect their setting reaction, biocompatibility, and bioactivity. (15) (16) (17) (18) (19) (20) Premixed materials have been shown to overcome several limitations of traditional powder–liquid systems. They exhibit superior handling, consistency, and physical properties, along with a reduced risk of preparation errors, leading to more reliable and reproducible results compared to traditional materials. (24)

The use of VPT in young patients is supported by the fact that their pulps have greater blood supply and cellularity, which is believed to lead to more predictable pulp healing. Teeth with an open apex show significantly good outcomes when a strict protocol is followed. (1,25) Immature teeth have a strong ability to repair and regenerate tissue, making them ideal candidates for conservative pulp therapies aimed at promoting root development. Arrested root development in immature permanent teeth results in thin dentinal walls, increasing the risk of fracture due to overloading. Thus, achieving apical closure and root maturation is vital for long-term tooth integrity. (8) Pulpotomy in immature permanent teeth shows high success rates, generally ranging from 86.7% to 95% across various studies and materials. (26) (27)

The success of VPT depends on the pre-treatment pulpal condition. (4) During radiographic analysis of immature teeth, radiolucent areas at the apices may be mistaken for non-vital pulp or pathology, when they are actually normal structures of the developing apical papilla. (3) Radiographic evaluations should be combined with clinical examination to ensure accurate pulpal diagnosis. To assess pulp vitality, sensibility tests such as the cold stimulus are used, where a heightened and prolonged response indicates severe pulpal inflammation, driven by C-fiber sensitization and inflammation-induced hypersensitivity. (3) To improve diagnostic accuracy, working with magnification enhances visualization of the operating field. This can aid in identifying canal entrances and increase the success rate of any endodontic procedure. (28) (29) A healthy pulp typically appears bright red, and spontaneous hemostasis should be achieved within 5–10 minutes; excessive bleeding may indicate advanced pulpal disease. (3) The European Society of Endodontology (ESE) and the AAE advise that pulpal disinfection be accomplished using cotton pellets, soaked in sodium hypochlorite.

Selecting appropriate pulpotomy agents is essential for achieving favorable clinical outcomes and should have a primary focus on maintaining pulpal vitality over time. (30) However, to date, no studies have compared the use of these new biomaterials (Neo PUTTY®, Total Fill® BC UNIVERSAL RRM™ and Bio-C® Repair) in pulpotomies for immature permanent teeth.

Therefore, the aim of this study is to compare the clinical and radiographical outcomes of three bioactive materials (Neo PUTTY® , Total Fill® BC UNIVERSAL RRM™ and Bio-C® Repair) for pulpotomy in immature permanent teeth with irreversible pulpitis over a 12-months period.

The null hypothesis is there is no significant difference in clinical and radiographic outcomes between the three materials for pulpotomy performed on immature permanent teeth with irreversible pulpitis.

Keywords: Bio-C Repair, Calcium silicate, Endodontics, Neo PUTTY, Pulpotomy, Total Fill

12. Materials and Methods:

Study design

This randomized clinical trial will be written according to Preffered Reporting Items for Randomized Trials in Endodontics (PRIRATE) 2020 guidelines and the CONSORT guidelines to ensure the quality and transparency of this study. (31) (32)

The research will be conducted in the Department of Pediatric Dentistry of Saint Joseph University of Beirut, in affiliation with the Department of Endodontics of the same university, between September 2025 and February 2026.

A consent form will be distributed and signed by all the patients enrolled in accordance with the principles of the Helsinki Declaration.

Strict eligibility criteria will be applied according to which patients and relevant teeth will be recruited.

The data collected for this study will be securely stored in a password-protected Excel sheet on a private, access-restricted computer. To ensure confidentiality, patients will be anonymized and identified only by numerical codes. All data will be handled in accordance with local data protection guidelines and ethical research standards.

11.1 Inclusion criteria:

-Healthy patients (according to ASA classification) with noncontributory medical history. (33)

-Patients aged between 7 and 11 years of age, with at least one immature permanent molar with deep caries, needing full pulpotomy.

-Cooperative pediatric patients (Frankl's behavioral rating scale). (34)

-Restorable immature permanent molar with deep caries: caries involving the pulpal roof or where complete caries removal would likely result in pulpal exposure.

-Physiological mobility.

-Vital pulp (detected by clinical signs/symptoms) presenting symptoms classically indicative of irreversible pulpitis according to AAE diagnostic criteria : positive but heightened response to cold sensibility testing, presence of spontaneous pain. (3)

-No clinical signs of pulp necrosis; absence of a sinus tract or swelling.

-Patients who agree to return for periodic examination (follow-up).

-Patients who are willing to sign the consent form (written informed consent).

11.2 Exclusion criteria:

-Medically compromised patients.

-Patients older than 11 years or younger than 7 years of age.

-Mature permanent molar.

-No signs and symptoms of irreversible pulpitis.

-No pulp exposure even after complete caries excavation.

-Clinical signs of pulp necrosis on the tooth to be treated, such as insufficient bleeding or no bleeding after pulp exposure.

-Uncontrollable pulp hemorrhage (more than 10 minutes of hemostasis).

-Teeth previously endodontically treated.
-Teeth with pathological root resorption.
-Impossibility to place a rubber dam.

11.3 Sample size calculation: (22)
A priori sample size calculation was performed using G*Power (version 3.1, Heinrich Heine University, Düsseldorf, Germany). Assuming a large effect size (Cohen's w = 0.5), a significance level (α) of 0.05, and a power of 80% (1 - β = 0.80), a total sample size of 39 subjects was estimated to be sufficient for detecting statistically significant differences among the three groups using a chi-square test with 2 degrees of freedom (df=2) . To account for potential loss to follow-up over the 12-month period, an additional 20% was added, resulting in a final required sample size of 48 participants (16 per group).

11.4 Randomization/allocation concealment/blinding:
[This part will be further developed once we consult with the statistician].
A single clinician will be responsible for examining all patients, and only those who meet the inclusion criteria will be randomly assigned to one of three groups. To reduce potential variations due to interpersonal differences, a single operator will perform all treatments using a standard protocol and aseptic precautions. Patients will be blinded to the type of material used for the treatment of their teeth. The operator cannot be blinded during the study due to the nature of the intervention. Two examiners (experienced endodontists) blinded to all the experimental groups will independently assess the teeth clinically and the follow-up radiographs. Patients will be randomly assigned to one of three groups: Group 1 (**G1**) will consist of n_1 teeth treated with Neo PUTTY®, Group 2 (**G2**) will consist of n_2 teeth treated with Total Fill® UNIVERSAL RRM™, Group 3 **(G3)** will consist of n_3 teeth treated with and Bio-C® Repair.

11.5 Data collection/ preoperative clinical and radiographic examination:

a) Demographic data

i. Age
ii. Sex
iii. Tooth
iv. Medical history
v. Dental history
   1. Chief complaint
   2. The severity of pain including the spontaneity or the lingering of pain after temperature stimulation and if there was any sleep disturbance

b) Clinical examination

i. Visual inspection of the caries lesion
ii. Evaluation of the restorability of the tooth
iii. Cold test (Endo Ice (Coltene/Whaledent, Inc, Cuyahoga Falls, OH)

iv. Percussion test
v. Palpation test

c) Radiographic examination

Preoperative periapical radiograph with the parallel cone technique using dental X-ray films (Eastman, Kodak Co., Rochester, NY) with a 70 kVp machine (Runyes; Unicorn Denmart, New Delhi, India) and a Rinn film holder (Dentsply, Tulsa, OK)

The patients that meet the inclusion criteria will be informed in detail about the aims and scope of the study including advantages, disadvantages, and risks of complications associated with the intervention. Subsequently, a written informed consent will be obtained from each patient willing to participate in a study. Then, they will be enrolled with a unique identification number, following randomization.
All patients will receive permanent restorations (Stainless-Steel Crown SSC) on their treated teeth during the same session, as per the AAE recommendations.

11.6 Study intervention:

a- Caries excavation and access cavity preparation

Local anesthesia of the tooth and the surrounding tissues will be administered by using 4% Articaine with 1:100 000 Epinephrine (Septodont). For lower teeth, a block anesthesia will be administered. If pain persists, an additionnal intraligamentary injection will be administered to achieve adequate anesthesia. Patients and their caregivers will be given the proper post-operative recommendations to avoid any lip/ soft tissue injury following the anesthesia. A rubber dam will be placed to ensure proper isolation. Liquid dam will be applied to any gap between the tooth and the rubber dam and light cured to completely isolate the tooth from the oral environment. To enhance success rates, the treatment will be conducted under magnification using dental loupes (x2.5).To minimize bacterial contamination in the pulp, all decayed tissues will be removed, starting from the peripheral edges of the cavity and progressing towards the roof of the pulp chamber, using sterile high-speed round tapered diamond burs (Dentsply Maillefer, Ballaigues, Switzerland) with water coolant *(fig1)* . The deeper layers of caries will be removed using a series of different diameters sterile low speed round burs. After complete caries removal and pulp tissue exposure, the cavity with be disinfected with 3% sodium hypochlorite NaOCl to reduce bacterial presence and prevent the accumulation of dentinal debris in the pulpal tissue.

b- Pulp amputation and hemostasis

A sterile 016-diameter round bur (Dentsply Maillefer, Ballaigues, Switzerland) will be used to remove the roof of the pulp chamber *(fig2)* . The access cavity will be prepared using sterile tapered diamond burs and Endo-Z bur (Dentsply Maillefer, Ballaigues, Switzerland) in a high-speed handpiece with water cooling to maintain constant irrigation *(fig3).* Following full pulp exposure, pulp vitality will be assessed through direct visualization with magnification using dental loupes (x2.5) to provide a more accurate diagnostic information about the degree of pulp inflammation and to identify any potentially necrotic tissue. To achieve hemostasis and disinfect the resected pulp tissue, a sterile cotton pellet soaked in 3% NaOCl will be placed over the amputated pulp for

5 minutes (AAE guidelines) with repetition if required, up to maximum 10 minutes. (3) Lower concentrations of NaOCl have been found to be as effective as higher concentrations for disinfection, with better outcomes in terms of pulp vitality and reduced postoperative pain, especially for regenerative endodontic procedures. (35) If bleeding persists for more than 10 minutes despite attempts to stop it, root canal treatment will be considered as the most appropriate treatment, and the patient will be excluded from the study. (3) (36).

Fig 1 : 016-diameter diamond round bur (Dentsply Maillefer, Ballaigues, Switzerland)

Fig 2 : 016-diameter stainless-steel round bur (Dentsply Maillefer, Ballaigues, Switzerland)

Fig 3: Endo-Z bur (Dentsply Maillefer, Ballaigues, Switzerland)

c- Material placement

After achieving hemostasis, premixed putties will be applied according to the manufactures instructions using an MTA carrier (MAP system, Produits Dentaires SA, Switzerland) *(fig4)* and then gently packed over the pulp stumps in a uniform thickness of 2-3mm with a moist gauze or micro brush. All materials will be applied following the manufacturers' instructions. The desired amount of each material must be dispensed onto a clean glass slab with a sterile instrument, and placed with an MTA carrier to the treatment site then gently spread with a moist gauze.

Fig 4 : MTA carrier (MAP system, Produits Dentaires SA, Switzerland)

Group 1 (G1) will be treated with NeoPUTTY *(fig5)* . Working time at room temperature is >1 hr. Setting begins in the presence of moisture from the dentinal tubules or pulp tissue. (15)
Group 2 (G2) will be treated withTotal Fill BC Universal RRM *(fig6).* Working time is more than 30 minutes, initiating setting upon contact with moisture. (18)
Group 3 (G3) will be treated with Bio-C® Repair *(fig7)* . Setting time is approximately 120 minutes under moist conditions. (20)
A glass ionomer base is recommended to support the restoration.

Fig 5 : Neo PUTTY ® (Nusmile Inc, Houston, TX; USA)

Fig 6 : Total Fill® BC UNIVERSAL RRM™ (FKG Dentaire, Switzerland)

Fig 7 : Bio-C® Repair (BCR; Angelus, Londrina, Brazil)

A thin layer of RMGIC (Fuji IX, GC, Japan) will be placed immediately over all the materials and cured for 20 seconds *(fig8).* The RMGIC build up will be followed by the placement of a Stainless Steel crown (SSC) as a definitive restoration in the same session, cemented with GIC (Fuji I, GC, Japan) *(fig9)* .To minimize the risk of restorative failure, the coronal seal, in form of a Stainless Steel crown (3M, Minnesota, United States) will be applied in the same session. This technique helps prevent coronal leakage, which could be a potential cause of failure, originating from either the endodontic or restorative procedure. (37) An immediate post-operative intraoral periapical radiograph will be taken following the paralleling technique.

Fig 8 : RMGIC (Fuji IX, GC, Japan)

Fig 9 : GIC (Fuji I, GC, Japan)

11.7 Study follow-up and evaluation:

The patient will be evaluated clinically at 1 week, and radiographically at 3, 6 and 12 months after the intervention by two examiners blinded to all the experimental groups.

When different evaluations will be attributed by the two examiners, a reevaluation of the case will be made with a third examiner to reach a consensus. Cases will be considered as successful only when they met the criteria for both clinical and radiographic success.

Clinical success will be determined by the absence of any symptoms (postoperative pain or tenderness on percussion and palpation, no abcess or fistulation, no sinus tract, no swelling, no pathological tooth mobility).

Radiographic success will be considered when there are no evidence of root resorption (internal/external), no periapical lesions and no periodontal ligament widening at each recall visit. There should be continued root development and ongoing proper apical closure.

Participants will be advised to report earlier if any issues arose in relation to the treated tooth. In case of severe pain persisting after the intervention, the patient will be scheduled for root canal treatment and the case will be recorded as an immediate clinical failure and the date of failure will be recorded.

Postoperative Evaluation Criteria:

Clinical evaluation:

Clinical success will be defined as:

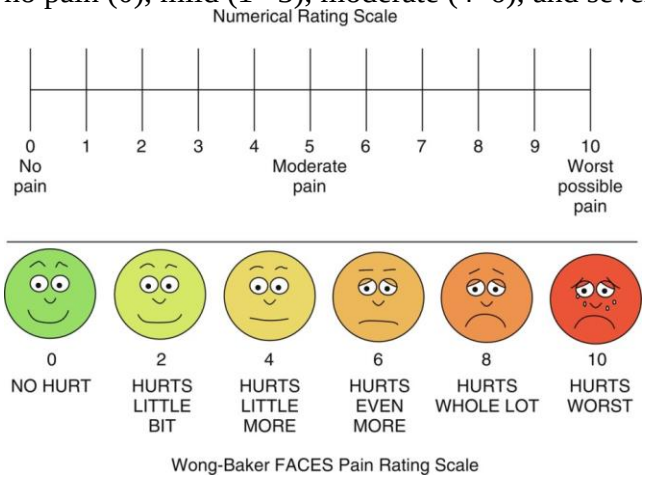
- no discomfort or spontaneous pain associated with the treated tooth, except during the initial post-intervention period; in case of severe, spontaneous and persistent pain for more than 1 week, the patient will be scheduled for root canal treatment
- no tenderness on percussion or palpation
- no signs of infections such as soft tissue swelling, presence of a sinus tract or abscess
- no complaint of increased sensitivity to cold or hot stimuli
- normal functionality of the tooth
- no pathological mobility
- continued root development and proper apical closure

Pain assessment:

Pain intensity before and after treatment will be evaluated using the Numerical Rating Scale (NRS) (0 to 10). Additionally, the Wong-Baker FACES Scale (WBS), which has been validated in various pediatric settings, will be used in association to support and complement the numerical scale in assessing pain. (38)

Assessment will first be done preoperatively then post-operative at 1 week, 3 months, 6 and 12 months.

no pain (0), mild (1– 3), moderate (4–6), and severe (7–10).



Mobility evaluation:
Miller classification will be used for tooth mobility assessment.
Class 1: < or = 1 mm (Horizontal mobility)
Class 2: > 1 mm (Horizontal mobility)
Class 3: > 1 mm (Horizontal and vertical mobility)
Mobility will be checked at 3 months, 6 and 12 months.

Radiographic evaluation:
Periapical X-ray will be taken preoperative, and postoperative at 3 months, 6 and 12 months. The X-rays will be compared to check for any periapical changes.
Radiographic examinations will include the assessment of:

- The periapical status. Cases with a Periapical Index (PAI) score ≤2, with no evidence of furcal radiolucency or signs of internal/external tooth resorption, were deemed radiographically successful.
- The possible presence of internal resorption or root canal obliteration.
- Continued root development and proper apical closure.

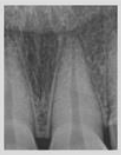
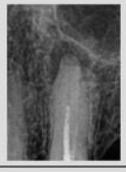
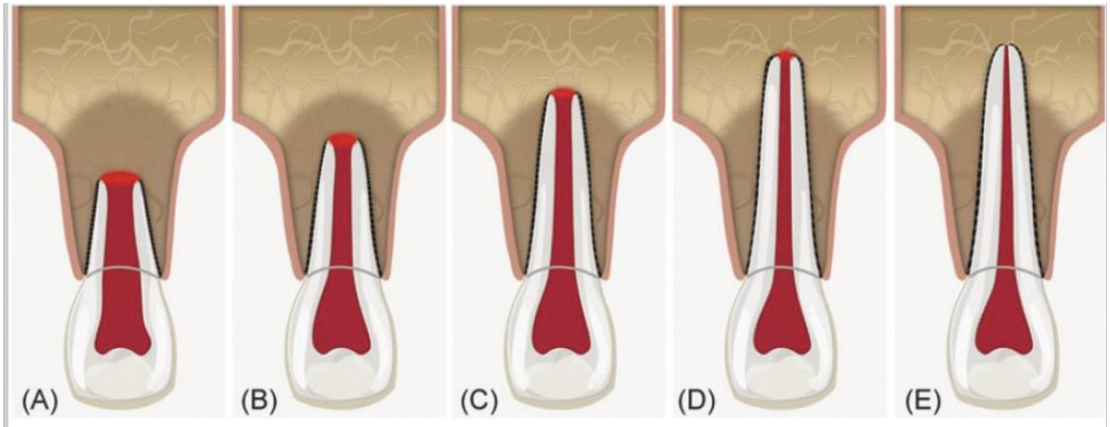
1	**Ligament:** Narrow and uniform width of the ligament space **Lamina dura:** Radiopaque border uniform and regular.		
2	**Ligament:** Slight increase of the width of the ligament space in and at foramen **Lamina dura:** Border almost continuous.		
3	**Ligament:** Slightly larger more irregular widening of the ligament space at foramen and/or around excess canal filling related to the demineralization process. **Lamina dura:** Loss of continuity of the bone border and disappearance at the foramen		
4	**Ligament:** Well defined balloon-like radiolucency around apex and/or excess canal filling. **Lamina dura:** Complete disappearance of the bone border.		
5	**Ligament:** Shell like configuration around the radiolucency with extensions toward the radiolucent area around apex and/or excess canal filling.. **Lamina dura:** Complete disappearance of the bone border.		

Figure of the Practical guide for scoring PeriApical Index (PAI). (39)

The Ørstavik periapical index will be used to assess the presence or absence of a periapical lesion (40). Success scores are 1 and 2. Scores 3, 4, and 5 or any progression from scores 1 and 2 are considered as failures. (39)



Schematic of Cvek's stages of root development. (41)

Cvek's stages of root development provide a radiographical classification for studying continued root development, particularly in cases involving regenerative procedures. It categorizes teeth based on apical foramen size and root length, making it relevant for tracking root maturation and closure. (41)
Cvek's classification describes the five stages of root development: I (A) = < 1/2 root length, II (B) = 1/2 root length, III (C) = 2/3 root length, IV (D) = wide open apical foramen and nearly complete root length and, V (E) = closed apical foramen and completed root development. (41)
Continued root development and proper apical closure will be signs of success.

Outcome Classification and Evaluation Criteria

The outcomes will be categorized into two main groups: success and failure.
Success will be defined as the simultaneous fulfillment of both clinical and radiographic criteria. Clinical success includes the absence of spontaneous pain, sensitivity to percussion or palpation, swelling, sinus tract, or pathological mobility. Radiographic success will require no signs of internal or external root resorption, periapical pathology (PAI score ≤ 2), or periodontal ligament widening, along with evidence of continued root development and apical closure as per Cvek's classification. Any deviation from these criteria in either the clinical or radiographic assessment will be considered as treatment failure.

13. Choice of the type of the study: For each section, check one or more answers

Descriptive / Comparative

☐ Descriptive study (describing a health status in a population)
☑ Comparative study (comparing interventions, groups, etc.)
☐ Validation study (validating diagnostic tools, measurements, etc.)

Observational / Interventional

☐ Observational study (non-interventional)
☑ Experimental study (interventional)

Clinical / Preclinical

☑ Clinical study (dental or medical practice)
☐ Preclinical in vivo study (animals, cells, etc.)
☐ Preclinical in vitro study (specimens, blocks, teeth, etc.)
☐ Field study (patient recruitment from hospitals, institutions, clinics, schools, etc.)
☐ Pilot study
☐ Phase I study (toxicity of a product in humans)
☐ Phase II study (efficacy of a product in humans)
☑ Phase III study (randomized controlled clinical trial)
☐ Phase IV study (post-marketing trial)

Retrospective / Prospective / Cross-sectional

☐ Retrospective study (past data)

☑ Prospective study (follow-up)
☑ Cross-sectional study (no follow-up)

Meta-analysis

☐ Systematic review (exhaustive data collection, critical evaluation, and synthesis of existing knowledge)
☐ Meta-analysis (statistical approach of a systematic review)

Other

☐ Other (specify):

14. Ethical approval :

This study was approved by the Ethics Committee of the Saint Joseph University of Beirut (USJ-CER-2025-289) on 09.09.2025.

15. Studied factors :

-Postoperative pain.
-Percussion and/or palpation pain.
-Presence of mobility.
-Presence of periapical lesion.
-Root formation and apical closure.

16. Description of variables:

-Postoperative pain.
-Percussion and/or palpation pain.
-Presence of mobility
-Presence of periapical lesion.
-Root formation and apical closure.

17. Statistical analysis: (22)

[Statistical analyses will be carried out.]
Descriptive statistics will be performed for all variables. Categorical variables (e.g. sex, clinical/radiographic success rates) will be presented as frequencies and percentages. Continuous variables (e.g. age, pain scores) will be expressed as mean and standard deviation (SD) or median and interquartile range (IQR), depending on the normality of data.
Clinical and radiographic outcomes will be defined as binary variables. Each case will be classified as a ‘success’ (coded as 1) or ‘failure’ (coded as 0). Chi-square test (or Fisher’s exact test where appropriate) will be used to analyze associations between the type of pulpotomy material and binary outcomes (clinical and radiographic success).

To assess changes in pain scores over time between the three groups, a repeated measures ANOVA with a within-between design will be used. A p-value < 0.05 will be considered statistically significant.

18. Date of beginning and ending of the project: brief description of the different stages that will be followed for the accomplishment of the thesis, including a calendar with the expected dates of achievements.

Date	Expected time window	Stage of the project
March-May 2025	2 months	Literature review + detailed writing of the protocol + validation
May 2025	1 month	Preparation of the required materials and participants recruitment
September 2025- February 2027	1 year	Execution of the protocol
March 2027	1 month	Statistical analysis
April 2027	2 months	Writing of the manuscript
May 2027	1 month	Finalization of the manuscript and writing of the article

19. Informed consent

I am Doctor Marilyn Nohra, a pediatric dentistry resident at Saint-Joseph University Faculty of Dental Medicine. Under the supervision of Doctor Marlene Khoury and the research team, we are conducting a research to assess the success rate of calcium silicate material in the treatment of symptomatic irreversible pulpitis. By participating in this study, you will be asked to complete your endodontic treatment under our supervision. You will also be asked to register the level of pain on a visual analog scale at different stages. You will need to visit the center after 1 week, 3, 6 and 12 months to complete follow up. Your participation in this research is entirely voluntary. No extra fees will be applicable.

It is your choice whether to participate or not. By signing this consent form, I confirm that:

-I have received the necessary information on the indications, contraindications, therapeutic alternatives, benefits and prognosis concerning the treatment protocol that I will follow in this study, which is carried out at the dental center of the faculty of Dentistry of Saint Joseph University. χ Yes χ No

-I am fully aware of the risks and side effects of the treatment that have been explained by the researcher himself. χ Yes χ No

-I have obtained clear explanations allowing me to guide my choice. χ Yes χ No

-I am committed to respecting and following all the explained instructions and coming back for follow-ups. χ Yes χ No

I give my full consent to participate in this study:

Participant's first and Last Name:

……

Participant's signature: …….

Date: ……

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