Assessing Success of MTA and Pre-mixed Bioceramic in Mature Teeth With Irreversible Pulpitis With Full Pulpotomy. (GCP)

NCT05853185

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STUDY PROTOCOL

Operational Definition

Irreversible Pulpitis

Patients with a history of pain score of greater than 4 on visual analogue scale during clinical assessment with lingering of pain for more than 10 seconds on cold stimulus.

Apical Periodontitis

Patients with positive response to tenderness on palpation/percussion and presence of radiographic rarefaction will be diagnosed as positive for apical periodontitis.

Success

Modified Clinical and Radiographic Criteria[1]

- Clinical criteria of success
    - No history of spontaneous pain or discomfort except for the first 2 days after treatment
    - No tenderness to palpation or percussion and the tooth is functional.
    - Normal mobility with less than 1mm and probing pocket depth less than 4 mm.
    - Soft tissues around the tooth are normal with no swelling or sinus tract.
- Radiographic criteria of success
    - No pathosis evident on the radiograph such as root resorption, furcal pathosis or new periapical pathosis

Materials and Methods

Study Design

Randomized Controlled Trial (RCT)

Setting

This study will be carried out on patients visiting outpatient clinic of Department of Operative Dentistry, Institute of Dentistry, Department of Operative Dentistry, LUMHS, Jamshoro/Hyderabad

Duration of Study

9 months after approval of study from CPSP

Sampling Technique

Nonprobability convivence sampling

Sample Size

In this trial, based on the results of a previous studies showing a success of 73.8%[2] with Mineral Trioxide Aggregate and 98.4%[1] for other bioceramics for full pulpotomy procedures, the proportion in population 1 (P1; Mineral Trioxide Aggregate) and the proportion in population 2 (P2 Endosequence Bioceramic Root Repair Material) were determined to be total of 64 with 32 in each group based on Kelsey on Openepi with power of 80% with confidence level of 95.

Inclusion Criteria

- Patients with diagnosis of irreversible pulpitis without apical periodontitis
- Either gender
- Lower Age 10 Years – Upper Age 40 Years

Exclusion Criteria

- Teeth with signs of resorption
- Roots with open apices (Immature Teeth)
- Calcified or blocked canals
- Iatrogenic perforations
- Root fractures
- Non restorable teeth
- Negative response to cold testing and presence of sinus tract or swelling.
- No pulp exposure after caries excavation
- Bleeding could not be controlled after pulpotomy in 10 minutes.
- Insufficient bleeding after pulp exposure; the pulp is judged necrotic or partially necrotic.

Data Collection

After approval from CPSP and ethical approval from Liaquat University of Medical & Health Sciences. All patients visiting department of operative dentistry institute of dentistry Liaquat university of medical and health sciences, Jamshoro with diagnosis of irreversible pulpitis without apical periodontal pathosis will be recruited. After meeting with inclusion criteria, they will be informed of the details of procedure and their potential consequences and informed consent will be obtained. Demographic data including age, sex, as well as universal tooth number undergoing treatment will be registered. A history of the chief complaint and a clinical examination including visual inspection of the caries status, restorability of the tooth, palpation, percussion, probing pocket depth, mobility using dental mirror and probe and sensibility via cold testing will be performed. A clinical diagnosis consistent with irreversible pulpitis will be established in all cases based on a history of severe spontaneous lingering pain that could be reproduced by cold testing. Preoperative periapical radiographs will be taken using the parallel technique via a film holder. Pre- and intraoperative data including the electric pulp test (EPT, recorded by reading on electric pulp tester) and binary variables including the cold test, pulpal/periapical status will also be registered.

After anesthesia (lidocaine with 1/80,000 epinephrine), complete caries removal, isolation, and pulp exposure, the pulp chamber will be unroofed with a sterile bur, and the pulp from chamber will then be completely removed with a round-end sterile bur on high speed with very low pressure and copious irrigation. After irrigating the chamber with normal saline, a sterile cotton pellet soaked in 5.25% sodium hypochlorite will gently left over the orifices for 10 minutes to achieve hemostasis. After achieving hemostasis, each tooth will randomly be allocated to 1 of 2 parallel arms using a coin toss test performed by a dental assistant who will not be involved in the study. The pulpotomy agent MTA and EndoSequence Bioceramic Root Repair will then be prepared according to the manufacturer's instructions and placed over the orifices with a thickness of approximately 2–3 mm. The cement will then be covered by a layer of light-cured glass ionomer and the remaining cavity will then be restored with

resin-bonded composite. In case of unsuccessful after pulpotomy, teeth will be managed by other pulp therapy techniques.

Data Analysis

Primary outcome for clinical success will be clinical parameters which will be described in binary units, including post-operative pain which will be performed by asking the patient if there is pain either continuous or intermittent, swelling through visual examination, sinus, or fistula through visual examination of the gingiva and tooth mobility by back of mirror to detect mobility in any direction. This assessment will be performed throughout the study at baseline, 6 days, and 6 months. Secondary outcome will be radiographic assessment to detect presence of radiolucency described in binary at baseline, 6 days, and 6 months through periapical radiograph.

All data will be collected and analyzed in SPSS Version 27. Qualitative data will be presented as frequencies and percentages. Quantitative data will be presented as mean and standard deviation. Chi-square test and Fisher's Exact test will be used for comparisons clinical parameters in two groups. Student's t-test will be used to compare between mean age values in the two groups. Friedman's test will be used to study the changes by time within each group. Kaplan-Meier survival curve will be constructed to calculate the mean survival estimates of the two groups. Comparison between survival times will be performed using Log rank test. The significance level will be set at $P \leq 0.05$.

Consent Form

I UNDERSTAND that dental treatment requiring PULPOTOMY THERAPY PROCEDURES, which I desire to have performed, include certain risks and possible unsuccessful results or procedural failure. Even though care and diligence will be exercised in this treatment, there are no guarantees of desired or anticipated results, or of the longevity of the treatment. I AGREE to assume the risks, possible unsuccessful results or procedural failure associated with the treatment, including but not limited to the following:

- I understand that a pulpotomy is an interim treatment done with the intention of temporarily preserving a vital permanent tooth without removing all the pulpal or nerve tissue. It is also a procedure which helps to maintain a baby, or primary tooth that is infected, thus preventing premature loss.
- Even though it is anticipated that this treatment may extend the time in which a tooth will remain vital until further necessary procedures may be successfully performed at a more appropriate time, it will be necessary to perform complete root canal therapy as soon as practical. Care should be taken not to unduly delay completion of the root canal process. Referral to an endodontic specialist may be necessary as determined by the attending dentist.
- There is always the possibility of injury to the nerves of the face or tissues of the oral cavity during the administration of anesthetics, or during the treatment procedures which may cause a numbness of the lips, tongue, tissue of the mouth, and/or facial tissues. This numbness is usually temporary but may be permanent.
- In as much as the crown portion of the tooth may have been weakened due to the extensive nature of the procedure and/ or that the tooth injury or disease which necessitated this procedure, the tooth may be more susceptible to fracture or breakage. Removal of vital tissue within the tooth causes it to dehydrate, and that can lead to fracture.
- Should the tooth structure, which is remaining appear to be excessively compromised, it may be necessary to place a temporary crown on the tooth to preserve it.
- Should the tooth not heal properly, experience an extensive fracture, or become unable to have complete root canal therapy performed, extraction of the tooth may be the only alternative.
- In most cases, once the pulpal tissue has been removed, and the initial pain has subsided, the tooth usually becomes pain free. However, in some cases, severe pain or extreme sensitivity will persist. If so, it is the patient's responsibility to notify the dentist immediately.
- It is my responsibility to contact the dentist and seek attention should any abnormal postoperative circumstances occur.
- I will diligently follow any preoperative and postoperative instructions given me.

As indicated my signature below, the doctor and dental team have given me the opportunity to read this document in its entirety and have allowed me to ask all questions pertaining to the procedure(s) above, their nature and purpose. They have also explained to me alternative forms of treatment and the risks of nontreatment. They have answered all my questions and concerns to my satisfaction with language I could understand. I voluntarily assume all possible risk, including risk of substantial harm, if any, which may be associated with any phase of this, or any unforeseen additional, dental treatment in hopes of obtaining the desired results for me, or for my minor child or ward. I also voluntarily assume the risk that the desired result may not be achieved. I have also been given the option to seek treatment from a specialist. No guarantees or warranties have been made to me concerning the results. Moreover, the fee(s) associated with these services have been explained to me, and I accept the financial responsibilities.

By signing this form, I am willingly, under no duress, giving my consent to allow and authorize the doctor, dental team members, and their associates, to render any treatment they believe necessary, appropriate, and/or beneficial to me, or my minor child or ward, including the administration and prescribing of any/all anesthetics and/or medications.

Patient's Name	Signature
Doctor's Name	Signature