COMPARISON OF POST OPERATIVE PAIN IN RESIN-BASED AND BIOCERAMIC BASED ROOT CANAL SEALERS IN PATIENTS PRESENTING AT PESHAWAR DENTAL COLLEGE

DATE: 01/04/2024

INTRODUCTION:

The purpose of endodontic management after cleaning and shaping is three-dimensional filling and sealing of root canal system and to avert microorganisms and encourage peri radicular tissue repair [1]. The treatment of pain both during and after root canal therapy is one of the primary concerns of endodontic practice [2]. The International Association for the Study of Pain (I.A.S.P.) describes the sensation of pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" [3].

Pain is a frequent symptom that occurs after having root canal therapy, and it can begin anywhere from a few hours to many days following the procedure [4]. There have been reports of a high incidence rate, with estimates ranging from 3% to 58% [5]. Injuries to the periodontal tissues can be either mechanical, chemical, or microbiological, and any of them might exacerbate the patient's pain [5]. Postoperative discomfort after a single visit root canal treatment can be influenced by a number of different factors. These factors include the condition of the pulp, the level of pain experienced before to the procedure, the number of root canals present, the choice of instrumentation, the choice of root canal sealer, and the obturation technique [7].

Sealers that are placed in the root canal have the potential to interfere with periodontal tissues through the apical foramen and lateral canals, and they may also have an effect on the healing process that takes place in the periodontium [8]. It has been hypothesized that bio ceramic materials improve the treatment success by releasing physiologically active chemicals and fostering the differentiation of odontoblasts. In vitro testing has demonstrated that resin-based sealer (AH Plus) is more cytotoxic than the bio ceramic materials, which have been shown to be less toxic [9, 10]. A study reported that after 24 hours 100% patients in AH plus group experienced pain and in MTA Fillapex, 65% of patients in experienced pain. After 48 h in total 20 patients, **45%** of patients in AH plus (Resin-based sealer) group experienced pain and **25%** in MTA Fillapex (bio ceramic root canal sealer) group. After 24 hours, mean VAS score was significantly better for MTA fillapex than AH plus (P = 0.000166) [11].

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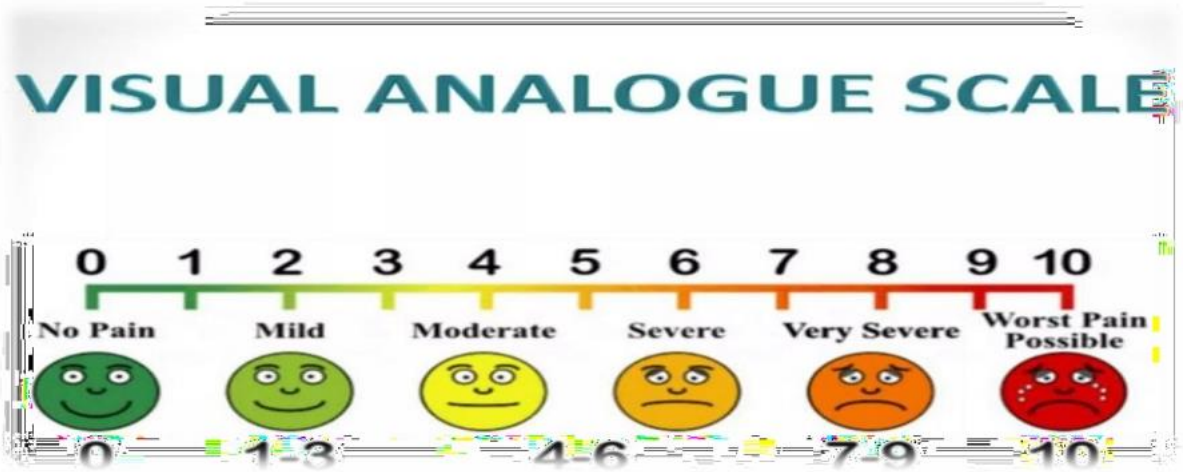
Post-operative pain is a common concern following endodontic procedures and can significantly impact patients' comfort and their perception of the treatment's success. Understanding how different types of root canal sealers affect post-operative pain is essential to improve patient experiences and clinical outcomes. However, limited comparative studies exist that specifically investigate their influence on post-operative pain, which shows the gap in available literature. Therefore, the goal of this study is to compare the post-operative pain in resin-based and bio ceramic based root canal sealers on after single visit endodontics.

OBJECTIVE: To compare the post-operative pain in resin-based and bio ceramic based root canal sealers in patients presenting at Peshawar dental college.

OPERATIONAL DEFINITIONS:

POST OPERATIVE PAIN: It will be defined on the basis of Visual Analog Score (VAS) after 24 hours in both treatment groups. VAS includes 0-10 numbers, where 0 indicates no pain, and 10 indicates the severe pain. Presence of pain will be validated, if Pain $\geq$ 3 on VAS.



HYPOTHESIS: There is a difference in the post-operative pain in resin-based and bio ceramic based root canal sealers in patients presenting at Peshawar dental college.

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MATERIAL AND METHOD:

STUDY DESIGN: Randomized Controlled Trial

STUDY SETTING: Operative Dentistry and Endodontics, Peshawar Dental College Peshawar

DURATION OF STUDY: Minimum six months, after the synopsis approval

STARTING DATE: 30/11/2025

PRIMERY COMPLETION DATE: 02/04/2026

STUDY COMPLETION: 02/04/2026

SAMPLE SIZE: The WHO sample size is used for sample size calculation with following assumptions:

- Frequency of post-operative pain **(45%)** in AH plus (Resin-based) root canal sealer on after single visit endodontics [11].
- Frequency of post-operative pain **(25%)** in MTA Fillapex (bio ceramic based) root canal sealers on after single visit endodontics [11].
- Power 80%
- Confidence level 95%
- The calculated sample size is **180** (**90** in each group)

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SAMPLING TECHNIQUE: Non-Probability Consecutive Sampling

SAMPLE SELECTION:

Inclusion Criteria:

- Gender Both (Male & Female)
- Age Group (18-70) Years
- Patients with Mandibular or Maxillary single-rooted teeth identified with symptomatic irreversible pulpitis either with symptomatic apical periodontitis or normal apical tissues

Exclusion Criteria:

- Patients with immature apices
- Patients with root resorption
- Patients medically compromised,
- Pregnant/lactating females,
- Patients on medications i.e. analgesic or anti-inflammatory drugs,
- Patients come with flare-up (pain or swelling)
- Patients who refused to participate in this study.

DATA COLLECTION PROCEDURE:

The study will be carried on, once the approval is taken from the hospital's ethical committee board and the College of Physicians and Surgeons of Pakistan (CPSP) research department. In this research work, a total of 180 with single-rooted tooth requiring endodontic therapy will be enrolled Only participants who satisfy the inclusion criteria will be included in the research work from the OPD of the hospital. Patients will be briefed with information related to the goals, risks, and

benefits of the study, and written informed consent form will be taken from all participating patients. To make sure the inclusion criteria are strictly enforced, medical history will be taken. Demographic information like to age, gender, and address will be recorded on a designated proforma. Maxillary or mandibular single-rooted teeth confirmed with symptomatic irreversible pulpitis i.e. normal apical tissues/symptomatic apical periodontitis will be included. Patients will be randomly divided into two groups Resin-based sealer (AH Plus)-Group A (90) and mineral trioxide aggregate (MTA) fillapex-Group B (90) by lottery method. Before treatment the patients will be educated that how to complete a visual analogue scale (VAS) to evaluate their pain score. The VAS included a 10 cm straight horizontal line numbered at each centimetre with the following criteria. Local anaesthetic with 2% lignocaine containing 1:80000 epinephrine will be administered to each patient. A rubber dam will be applied. The endodontic access cavities will be formed with endo access burs. Working length will be established with #10 K file and the root canal will be instrumented with one shape rotary system up to #25.6% under copious irrigation with 3% sodium hypochlorite. Before obturation root canals will be final rinse with 5 ml of 17% EDTA solution. In both treatment groups, the root canal will be dried with paper points and obdurate with cold lateral compaction technique with the help of gutta-percha cones and AH plus /MTA fillapex. Coronal access cavities will be restored with direct composite restorations with the help of dentinal adhesives and universal composite resin. The continuous-wave approach will be used in the AH Plus group, and the single-cone approach will be used in the MTA fillapex. Postoperative VAS scores will be recorded after the 24 hours and 48 hours of the treatment for the determination of post-operative pain. All assessment will be recorded on a pre-designed proforma.

DATA ANALYSIS PROCEDURE:

SPSS 23 will be used to for performing data analysis. Shapiro Wilko test will be used to assess the normality of the data. Mean $\pm$ SD or Median (IQR) for non-normal data will be measured for numerical data i.e. age. Frequencies and percentages will be measured for categorical data i.e. gender, post-operative pain, swelling, teeth involved (Maxillary/Mandibular), diabetes, hypertension, and smoking status. Post-operative pain will be compared in each group by using the chi-square test keeping p-value $\leq$ 0.05 as significant. Effect modifiers i.e. age, gender, teeth involved, diabetes, hypertension, and smoking status will be controlled through stratification. Post stratification chi-square/fisher exact test will be performed by keeping the p-value $\leq$ 0.05 considered as significant.

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Proforma

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Date: 01/04/2025

Group A (Resin-Based) ☐ **Group B (Bio ceramic Based)** ☐

Case#._____ MR#._____

Age. _____Years Gender._Male/Female

Address._____

Diabetes:

Yes ☐ No ☐

Hypertension:

Yes ☐ No ☐

Smoking status:

Smoker ☐ Non-Smoker ☐

Teeth involved:

Maxillary ☐ Mandibular ☐

POST OPERATIVE PAIN:

Yes ☐ No ☐

Inform consent form

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Date: 01/04/2024

Patient Name: _____

Father/ Husband Name: ____

I hereby, authorize concern doctor to include me in this study. The doctor has explained to me the procedure of collection of data in detail and I fully understand that being part of this study sample does not make me prone to any complications/ hazards. I have no binding or compulsion to be part of this study and I have freedom to refuse from being part of this sample.

I have read this form and I am satisfied.

Name and signature of patient: _____