COVERING LETTER FOR RCT REGISTRATION

Submission date: 05th December, 2025

To
The Registration Officer
ClinicalTrials.gov

SUBJECT: SUBMISSION OF RCT FOR REGISTRATION

Dear Sir/Madam,

STUDY TITLE: "A COMPARATIVE EVALUATION OF POSTOBTURATION PAIN AFTER ROOT CANAL TREATMENT USING TRICALCIUM SILICATE V/S RESIN BASED SEALERS IN CASES WITH SYMPTOMATIC IRREVERSIBLE PULPITIS"

This study is an interventional, two-arm randomized controlled trial evaluating postoperative pain management after single-visit root canal therapy. All required documents have been uploaded to the PRS system, and the study is ready for review.

Please process the registration at your earliest convenience. I will provide any additional Information if needed.

Date of submission of research proposal: **05th December, 2025**

NCT Number: **"Not Issued yet"**

Unique Protocol ID: **POSTOBTURATION PAIN e SEALAR**

Ethical Committee Approval Number: **918/trg**

RTMC No: **DSG-2023-115-4776**

Department: **Department of Operative Dentistry & Endodontics AFID, Rawalpindi, Pakistan**

Yours Sincerely,

Dr. Pooja Kumari

T.M.O Operative Dentistry & Endodontics

AFID, Rawalpindi, Pakistan

A COMPARATIVE EVALUATION OF POSTOBTURATION PAIN AFTER ROOT CANAL TREATMENT USING TRICALCIUM SILICATE V/S RESIN BASED SEALERS IN CASES WITH SYMPTOMATIC IRREVERSIBLE PULPITIS

DR POOJA KUMARI

FCPS II TRAINEE OPERATIVE DENTISTRY

ARMED FORCES INSTITUTE OF DENTISTRY

CORRESPONDENCE:DHOMEJAPOOJA@GMAIL.COM

SUPERVISOR:

MAJ GEN NADEEM AHMAD RANA

BDS (PB), MCPS, FCPS

CLASSIFIED SPECIALIST IN OPERATIVE DENTISTRY

DEPARTMENT OF OPERATIVE DENTISTRY

ARMED FORCES INSTITUTE OF DENTISTRY

DEPARTMENT OF OPERATIVE DENTISTRY & ENDODONTICS
ARMED FORCES INSTITUTE OF DENTISTRY (AFID)
RAWALPINDI

NON-DUPLICATION CERTIFICATE

It is to certify that **DR. POOJA KUMARI, RTMC No. DSG-2023-115-4776** TMO in Operative Dentistry & Endodontics. She is working on the synopsis **"A COMPARATIVE EVALUATION OF POSTOBTURATION PAIN AFTER ROOT CANAL TREATMENT USING TRICALCIUM SILICATE V/S RESIN BASED SEALERS IN CASES WITH SYMPTOMATIC IRREVERSIBLE PULPITIS"**. No one other than her worked on the same topic for the last five years in our unit.

Trainee signature

Maj Gen
CMD AFID
(Nadeem Ahmad Rana)
Supervisor Signature

INTRODUCTION:

Pain involves both physiological and psychological components, rendering pain perception subjective and susceptible to numerous influencing factors. The Visual Analog Scale (VAS) represents a straightforward, effective, and sensitive method for patients to assess pain intensity from their own perspective. **(1)**

Postoperative pain following endodontic treatment often arises from an exacerbation of the inflammatory process in the periapical region. It is related to mechanical, chemical and microbial injury to periradicular tissues. The intensity of this inflammatory reaction depends on various factors, one of which includes the composition of the sealer used (2)

Root canal sealers are typically intended to remain within the root canal system, but they may come into contact with periapical tissues through lateral canals, the apical foramen, or by leaching. As a result, root canal sealers can potentially trigger an inflammatory response and cause postoperative pain. (3)

A proper seal is essential to prevent reinfection by isolating the root tip (apex), surrounding periodontal space, and the entire canal. An ideal root canal sealant should be biocompatible, inert, and adhere strongly to the canal walls after setting. Moreover, it should offer superior sealing properties once hardened. (4)

Aslan and Donmez Ozkan reported that both calcium silicate–based and epoxy resin–based root canal sealers were associated with comparable levels of postoperative pain. Shashirekha et al found that pain levels in the AH Plus group were higher compared to the Sealapex group, although the difference was not statistically significant (5)

According to the meta-analyses performed by (Seron, M.et al) for quantitative data, the group of bio ceramics sealers had a lower incidence of postoperative pain compared to the control group (Resin based sealer) **(6)**

Drummond JPSC et al. found that the mean postoperative pain at 24 hours was 0.15 (0.4) with a resin-based sealer and 0.54 (1.3) with a bio ceramic sealer. After 7 days, the pain levels for both materials approached 0, with significant differences observed over time within the groups. The study concluded that calcium silicate-based root canal sealers cause similar, low-intensity postoperative pain compared to resin-based sealers. (1)

The quality of root canal filling plays a crucial role in the success rate of nonsurgical root canal treatments. Various types of endodontic sealers have been recommended to achieve satisfactory root fillings, with epoxy resin-based sealers traditionally regarded as the gold standard up to the present time.**(7)**

Biocompatibility and bioactivity are critical properties of root canal sealers, given their close proximity to tissues and their impact on tissue repair. However, Kim et al. reported that resin-based sealers lack bioactive properties and osteogenic potential compared to calcium silicate-based sealers (CSBSs).[8]

Recently, tricalcium silicate (TCS)-based sealers have garnered attention due to their superior biocompatibility and bioactive properties, which promote tissue healing and regeneration [9]

In addition, bioceramic-based sealer demonstrated less cytotoxic and genotoxic effect in comparison with epoxy resin-based sealers [10]

However, despite these advantages, the effect of TCS-based sealers on postoperative pain has not been thoroughly investigated. And the literature shows the contrasting results. So the rationale of this study is to evaluate whether a TCS (Tricalcium silicate) based sealer, specifically Bio ceramics, effectively reduces or eliminates postoperative pain compared to commonly used resin-based sealers. This comparison is crucial as postoperative pain management is a significant concern in endodontic procedures, and the choice of sealer could potentially impact patient outcomes and comfort.

OBJECTIVE:

To compare the mean & standard deviation of postobturation pain using two different sealer tricalcium silicate based sealer (CERASEAL) and resin based sealer (ENDOPLUS) in patients with symptomatic irreversible pulpitis

OPERATIONAL DEFINITIONS:

- **Post –Operative Pain:** will be defined as unpleasant sensory or emotional physical sensation, assessed by visual analogue scale VAS at time interval of 24hrs, 72hrs and 7 days, after obturation with two different sealers
  (VAS is given in ANNEX C)
- **Symptomatic Irreversible Pulpitis:** A clinical diagnosis of symptomatic irreversible pulpitis is based on subjective and objective findings, such as severe, lingering thermal pain that may be spontaneous, referred, or nocturnal. This diagnosis is confirmed through patient history, clinical examination, and an exaggerated response to pulp vitality tests.
- **Root-canal sealer:** is radiopaque luting agent used, usually in combination with solid or semisolid core material, to fill voids and to seal root canals during obturation.
- **Resin based sealer:** is a sealer containing epoxy-resin and is available with the name ENDOPLUS manufactured by PRESIDENT DENTAL Gmbh. It is available as 2 paste formulation (composition ANNEX –D)

- **Tricalcium silicate based sealer:** Bioceramic sealers are advanced materials used in endodontic procedures. Available as premixed sealer with name CERA SEAL manufactured by META BIOMED.CO (composition ANNEX –D)

HYPOTHESIS:

Null hypothesis: There is no difference in post-obturation pain using tricalcium silicate based sealer (bio ceramics) and resin based sealer

Alternative hypothesis: There is a difference in post-obturation pain using tricalcium silicate based sealer (bio ceramics) and resin based sealer

MATERIAL AND METHOD:

Study design: Randomized controlled clinical trial
Sample size calculation: A sample size of 118 (59 patients in each group) was calculated using the WHO calculator, with a significance level of 5% and a test power of 80%. The mean pain values on the VAS were extracted from a study by Drummond JPSC et al. (1). The ratio between the two groups was calculated at 24 hours, with an average standard deviation of 0.85.

Mean pain score in Group 1 (resin based): 0.15 (0.4)

Mean pain score in Group 2 (calcium silicate based):0.54 (1.3)

Place of study: Operative dentistry and endodontics department, Armed Forces Institute of Dentistry, Rawalpindi.
Duration of study: 6 months after the approval of synopsis.
Sampling technique: Non probability consecutive sampling technique.

Selection criteria:

***Inclusion criteria*:**

- Patients of age group 18 to 60 years
- Healthy patients with ASA class 1 and 2
- Patients of both genders
- Teeth diagnosed as symptomatic irreversible pulpitis
- Single as well as multirooted teeth

Exclusion Criteria:

- Teeth with calcified or previously treated canals
- Immunocompromised or mentally handicapped patients

- Pregnant or lactating mothers
- Teeth with periodontal probing depths of 5 mm or more
- Cracked or un restorable teeth
- Teeth where root canal instrumentation could not reach within 2 mm of the radiographic apex

DATA COLLECTION PROCEDURE:

Study will be conducted after the approval of Institutional Ethics Review Committee of Armed Forces Institute of Dentistry. (Annex-A)

Clinical trial will be registered through clinical trial.gov. An informed written consent of the patients will be obtained. (Annex-B) and whole procedure will be explained to the patient and attendant in simple language. Demographic details (including name, age, gender, contact) will be obtained on data collection forms. (Annex-C). Pulpal and periodontal diagnosis will be made after history taking and thorough clinical examination and preoperative pain status will be recorded. Patients will be selected based on inclusion criteria & exclusion criteria.

Sample size will be randomly divided into 2 groups with the help of computer generated randomized patient code concealed in opaque envelope, that will be revealed just before obturation. One group will receive ENDOPLUS sealer and other will receive CERA SEAL bio ceramic sealer.

Root Canal procedure will be similar for all patients ie Access Cavity preparation after administering local anesthesia (2% Lignocaine 1:100000 epinephrine) and rubber dam isolation. Working length will be determined using apex locator (Denta port ZX) and periapical radiograph with 8k and 10 k files (dentsply sirona), chemo-mechanical preparation of the root canal system will be done using hybrid technique and copious irrigation with 2.5% NaOCL (Vista dental products) and 17% EDTA (Techno dent edetect gel) solution with hand files (dentsply sirona) and nickle titanium rotary file (dentsply Sirona) cleaning and shaping will be done up to F2 protaper (dentsply Sirona), recapitulation will be done before each increasing file to maintain the patency. Now canals will be dried with sterile paper point (sure endo) and nonsetting caoh dressing will be done, temporary filling cavit (provis) will be placed and patient will be recalled after one week for obturation and permanent filling.

Obturation will be done in next visit when patient will be asymptomatic. Now patients will be randomly assigned to two groups based on computer generated patient's code, one group will receive ENDOPLUS resin based sealer and will be obturated using single cone gutta percha point (Bio GP points-sure endo, sure dent cooperation) and heated plugger (system B). Other group will receive Tricalcium silicate based sealer(CERASEAL) and will be obturated using matched bioceramic points (FKG Dentaire SA) heated plugger (system B). For both the groups additional accessory cones will be used in case of wide or irregular

canals. Permanent restoration with composite (Coltene) will be done for both the groups and occlusion will be adjusted.

Now patient will be provided VAS pain diary recalled for follow-up at 24 hours, 72 hours and 7 days.

FOLLOW UP AND OUTCOME EVALUATION:

Patients will be recalled after 1 week of obturation, and permanent filling and asked to record their response in terms of post-op pain through a self-reported questionnaire using a visual analogue scale (VAS). Patient will be taught how to fill this questionnaire and a pain killer medicine (ibuprofen) will be prescribed in case of unbearable pain and will be guided to record the dose and frequency of taken medicine. Two independent blinded endodontist will check the treatment radiograph for technical error or sealer extrusion.

DATA ANALYSIS PROCEDURE:

Data will be analysed using SPSS version 2023. Independent sample t-test will be used to compare post-operative endodontic pain for group A and group B at 24 hours, 72 hours and 7 days after completion of the treatment. Descriptive statistics will be presented for both qualitative and quantitative variables. For quantitative variables like age, pain score Mean $\pm$ S.D will be reported. For qualitative variables like gender frequencies and percentage will be reported. Effect modifiers like age, gender, tooth location in the arch and consumption of any analgesics will be controlled by stratification .post stratification independent t test will be applied. P value less than 0.05 will be taken as statistically significant.

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1) Drumond JPSC, Maeda W, Nascimento WM, Campos DL, Prado MC, de-Jesus-Soares A, et al. Comparison of postobturation pain experience after apical extrusion of calcium silicate– and resin–based root canal sealers. J Endod. 2021;47(8):1278-1284.
2) Sponchiado Junior EC, Vieira WDA, Normando AGC, Pereira JV, Ferraz CCR, Almeida JFA, et al. Calcium silicate-based sealers do not reduce the risk and intensity of postoperative pain after root canal treatment when compared with epoxy resin-based sealers: A systematic review and meta-analysis. Eur J Dent. 2021;15(2):347-359.
3) Ferreira N de S, Gollo EKF, Boscato N, Arias A, da Silva E JNL. Postoperative pain after root canal filling with different endodontic sealers: A randomized clinical trial. Braz Oral Res. 2020;34:e0069.
4) Memon J, Iqbal K, Mallick MR, Dehraj MA, Ali A, Kumar K. Evaluation of mean apical sealing ability of bio ceramic and AH Plus (Dentsply Sirona) sealer in single rooted teeth: An in vitro study. Pak J Health Sci. 2024;5(5):110-115.
5) Büker M, Sümbüllü M, Ali A, Ünal O, Arslan H. The effects of calcium silicate- and calcium hydroxide–based root canal sealers on postoperative pain: A randomized clinical trial. J Endod. 2023;49(12):1588-1594.
6) Seron MA, Nunes GP, Ferrisse TM, Strazzi-Sahyon HB, Victorino FR, dos Santos PH, et al. Postoperative pain after root canal filling with bioceramic sealers: A systematic review and meta-analysis of randomized clinical trials. Odontology. 2023;111(4):793-812.
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8) Chopra V, Davis G, Baysan A. Clinical and radiographic outcome of non-surgical endodontic treatment using calcium silicate-based versus resin-based sealers—A systematic review and meta-analysis of clinical studies. J Funct Biomater. 2022;13(2):38.
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10) Coronas VS, Villa N, Nascimento AL do, Duarte PHM, da Rosa RA, Só MVR. Dentinal tubule penetration of a calcium silicate-based root canal sealer using a specific calcium fluorophore. Braz Dent J. 2020;31(2):109-115.

ANNEX - A

TOPIC: "A COMPARATIVE EVALUATION OF POSTOBTURATION PAIN AFTER ROOT CANAL TREATMENT USING TRICALCIUM SILICATE V/S RESIN BASED SEALERS IN CASES WITH SYMPTOMATIC IRREVERSIBLE PULPITIS"

Members Ethics Committee:

1. Brig Shafi Ullah Khan (HoD OMFS), AFID Rwp — Approved ☑ Not Approved ☐
2. Brig Mubashir Sharif (HoD Prostho), AFID Rwp — Approved ☑ Not Approved ☐
3. Brig Abdullah Jan (HoD Orthodontics), AFID Rwp — Approved ☑ Not Approved ☐
4. Col Syed Muzammil Hussain (HoD Operative), AFID — Approved ☑ Not Approved ☐
5. Lt Col Muhammad Farooq (Social Member), G-I Adm AFID — Approved ☑ Not Approved ☐
6. Maj Muhammad Sharjeel Ashraf (HoD Periodontics), AFID Rwp — Approved ☑ Not Approved ☐
7. Assoc Prof Dr. Erum Amin (NUMS Faculty), AFID Rwp — Approved ☑ Not Approved ☐
8. Demo Dr. Madeeha Nazar Tiwana Medical Educationist, NUMS — Approved ☑ Not Approved ☐
9. N/Khateeb Khalid Mehmood Religious Member, AFID — Approved ☑ Not Approved ☐

President Ethics Committee:

Brig Ali Akhtar Khan
(CI Spec in Oral & Maxillofacial Surgery), AFID Rwp — Approved ☑ Not Approved ☐

Final Decision:-

Approved ☑ Not Approved ☐ Resubmit ☐

Date: 29 Aug 2024

Maj Gen
Comdt
(Nadeem Ahmad Rana)

(ANNEX-B)

DEPARTMENT OF OPERATIVE DENTISTRY ARMED FORCES INSTITUTE OF DENTISTRY RAWALPINDI

CONSENT FORM

I, [**Patient's Name]** hereby authorize **DR POOJA KUMARI**, department of operative dentistry, Armed Forces Institute of Dentistry to perform Root canal therapy using digital radiography and ultrasonic apex locator.

I have been fully informed about the complete procedure and its chances of success and failure.

I acknowledge that the information provided to me was in simple language and was fully understood along with being sufficient for me to consent for the procedure. I was given opportunity to ask questions and they were answered to my satisfaction.

I have been fully informed about benefits of the study.

All treatment will be performed free of cost for me.

I am willing to undergo for the treatment.

Signature of patient, **Doctor's Signature:**

Date:

(ANNEX-C)

DEPARTMENT OF OPERATIVE DENTISTRY ARMED FORCES INSTITUTE OF DENTISTRY RAWALPINDI

(Data collection form)

S.No. _____ Hospital Registration no. _____ Name _____

Contact number: _____

Group: _____

Effect modifiers

Age: ____ Gender: M/F _____ Tooth no _____

Location in arch ☐ Maxillary ☐ Mandibular

Consumption of any analgesic after treatment (if any):
☐ Name ☐ Frequency ☐ None

Groups	Pain after 24 hours using VAS	Pain after 72 hours using VAS	Pain after 7 days Using VAS
A			
B			

VISUAL ANALOGUE SCALE (VAS)

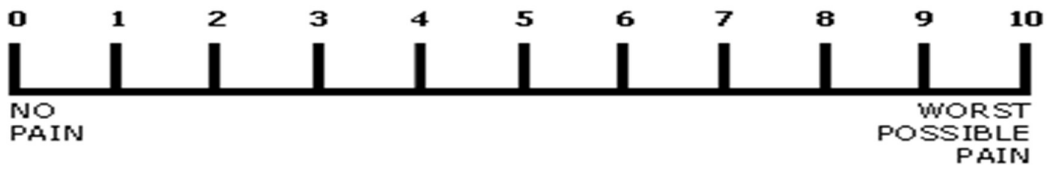
0 – No pain

1-3 – Mild Pain

4-6 – Moderate pain

7-9 – Severe pain

10—worst pain



(ANNEX-D)

Composition of (ENDOPLUS) resin based sealer

It is available as 13.5g dual syringe EndoPlus (Base 9g, catalyst 4.5g) manufactured by PRESIDENT DENTAL Gmbh

Base	**Catalyst**
Epoxy oligomer resin	Poly amino benzoate
Ethylene glycol salicylate	Triethanolamine
Calcium phosphate	Calcium phosphate
Bismuth sub carbonate	Bismuth sub carbonate
Zirconium oxide	Zirconium oxide
	Calcium oxide

Composition of (BIO CERAMIC) sealer

It is available as single paste premixed system containing

Tricalcium silicates
Dicalcium silicates
Calcium aluminates
Zirconium oxides
Thickening agents