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Postoperative pain after root canal filling using two different bio-ceramic sealers

Submission date
28/06/2026

Recruitment status
No longer recruiting

Registration date
30/06/2026

Overall study status
Completed

Last Edited
30/06/2026

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Postoperative pain is a common complication after root canal therapy. Bioceramic root canal sealers are widely used due to their excellent biological properties, but clinical data comparing specific brands remains limited. This study aims to evaluate and compare the incidence and intensity of postoperative pain following root canal treatment using two different bioceramic sealers: Bio-C Sealer and TotalFill BC Sealer.

Who can participate?
Medically healthy patients aged 18 years and older requiring non-surgical root canal treatment on a restorable tooth with a normal periapical appearance or a small periapical lesion (<2 mm)

What does the study involve?
Participants are randomly assigned to one of two groups to receive root canal filling using either Bio-C Sealer or TotalFill BC Sealer. Patients and clinicians are blinded to the sealer type used. Following the procedure, patients record their pain levels at 24 hours, 48 hours, 72 hours, and 7 days after treatment.

What are the possible benefits and risks of participating?
Participants benefit from receiving high-standard endodontic treatment with advanced bioactive materials. The primary risk is mild-to-severe postoperative pain, which is a standard complication of root canal therapy and can be managed with standard over-the-counter pain relievers.

Where is the study run from?
Al-Baha University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
March 2025 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Mohammed S. Alzahrani, m.sarhan@bu.edu.sa

Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Postoperative pain after root canal filling with different bio-ceramic endodontic sealers: a double-blind randomised clinical trial

Study objectives
To evaluate the effect of two different bioceramic sealers on post-obturation pain. Specifically, the incidence of postoperative pain will be compared following the use of randomly assigned TotalFill® BC Sealer or Bio-C Sealer over a 7-day period after endodontic treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/03/2025, Research Ethics Committee of Al-Baha University (BASA7438, 7438 Al-Baha University 3, 4577, Al Jamiah Dist., AL AQIQ, Bahah, Albaha, 65779, Saudi Arabia; +966 (0) 17 7257700; contact@bu.edu.sa), ref: 2025/46113615

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Post root canal treatment pain

Interventions
Non-surgical root canal treatment with two different types of tricalcium silicate sealers (TotalFill® BC Sealer or Bio-C)

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Postoperative pain measured using visual pain analogue scale at 7 days

Key secondary outcome(s)

Completion date
15/12/2025

Eligibility

Key inclusion criteria
1. Willing to participate and provide informed con-sent
2. Required root canal treatment
3. Medically healthy (American Society of Anesthesiologists [ASA] Class I or II)
4. Aged 18 years or older
5. Normal periapical radiographic appearance or a periapical lesion <2 mm
6. Restorable tooth
7. Periodontally healthy tooth

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit

18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Under 18 years of age
2. Pregnant
3. Declined participation
4. Previously endodontically treated tooth
5. Tooth with an open apex
6. Presence of a deep isolated periodontal pocket
7. Tooth fracture
8. Root resorption
9. Endo-perio lesion
10. Non-restorable tooth
11. Tooth with mishaps

Date of first enrolment
15/03/2025

Date of final enrolment
15/06/2025

Locations

Countries of recruitment
Saudi Arabia

Sponsor information

Organisation
Al Baha University

ROR
https://ror.org/0403jak37

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available