

AIN SHAMS DENTAL JOURNAL

Official Publication of Ain Shams Dental School March2025 • Vol. 37

Post-operative pain after non-surgical root canal treatment with a single cone/ bio-ceramic sealer based obturation: A Randomized Clinical Trial

Mohamed Tarek Elemam¹, Shehabeldin Mohamed Saber¹, Mohamed Medhat Kataia²

Aim: compare the post- operative pain associated with sealer-based obturation technique (SBO) using bioceramic sealer and a (CWC) obturation technique with a resin-based sealer.

Materials and methods: two-arm randomized clinical trial with 2 parallel groups 20 patients each, after shaping the canals to a minimum dimension of 30/.04, except for a single middle mesial canal, which was shaped to 25/.04 patients randomly allocated into two groups based on the obturation material used. To ensure patient privacy, each name was replaced with a case number. Patients documented their pain on a 0-10 (VAS) at: 4 hours, one day, and two days after canal obturation. The pain score was recorded at its highest value three successive time points selected and then sorted. Data were presented as mean, standard deviation (SD), median, and interquartile range (IQR) values. They were analyzed by Mann-Whitney U and signed rank tests, respectively. The significance level was set at p<0.05 within all tests.

Results: The two groups showed no significant difference. With higher pain score for CWC group.

Conclusion: Within the restrictions of this study, both CWC with AH+ sealer with and sealer based obturation with Bio-C sealer showed no significant pain level.

Keywords: post-operative pain, single-cone, Ah plus, bioceramic Sealers.

1. Department of Endodontics, Faculty of Dentistry, The British University in Egypt, Cairo, Egypt.

2. Department of Endodontics, Faculty of Dentistry, University of Fujairah. UAE.

Corresponding author: Mohamed Tarek Elemam, email: Mohamed.Elemam@bue.edu.eg

Introduction

Despite the leap in endodontic materials and techniques, post-operative pain remains inadvertent.¹ The incidence of posttreatment pain ranges from 3%-58% amongst different studies.² Knowledge about the predisposing factors of such event is crucial to develop appropriate preventive measures. Number of visits, irrigation solution. instrumentation protocol, occlusal adjustment. the obturation technique. extrusion of filling material and/or sealer can potentially affect the degree of post-operative pain and healing of the periapical tissues.³⁻⁶

It is postulated that sealer extrusion outside the root canal system may distress the periodontal tissues and interfere with healing.⁷ The local inflammation associated with sealer extrusion can elicit postoperative pain. The degree of such inflammatory response is mainly affected by the chemical composition of the sealer and presence of apical periodontitis.8

Accordingly, it is important to select sealers with enhanced physicochemical properties that are well tolerated by the periapical tissues to avoid consequences of sealer and filling material extruded beyond root apex. Over years, resin-based sealers demonstrated accepted physical properties; however, concerns exist for the byproducts of their polymerization reaction.⁷ cytotoxic effects remain a concern, thus there is need for improved root-filling material. More recently, bioceramic materials were suggested as a more biocompatible as well as a bioactive option.9,10

Bioceramic sealers usually constitute calcium silicate, Bioactive glass, AL₂O₃, ZrO₂, hydroxyapatite, and soluble calcium phosphates. This chemical composition is the foundation for their biocompatibility and bioactivity.¹¹ There is an increase in number of clinicians that favors the use of the Single cone technique with the bioceramic sealers over warm vertical compaction due to its ease

of use. Yet, the evidence is scarce to prove a clear-cut advantage in terms of patientcentered outcomes such as post-operative pain. Thus, we aim in our study to compare the post- operative pain associated with a (SBO) and (CWC) techniques. The null hypothesis: no difference in the postoperative pain between either technique.

Materials and methods

Ethical consideration

The study was ethically approved by the research ethics committee BUE under approval number 22-015.

Design of the study

It is as a two-arm RCT with 2 parallel groups, superiority trial with 1:1 allocation ratio. Sample size calculated using G power (3.1.9.4) software, from data obtained from a previous study.¹² using (α) level of 0.05 and (β) level of 0.85. A total sample size (n) of 40 was predicted. The study flowchart is presented in Fig. 1.



Figure 1: Consort guidelines flowchart

Inclusion criteria

)en

Patients included in this study had an age range of 18-60 years old, who had restorable both posterior and anterior teeth diagnosed with asymptomatic chronic apical periodontitis or periapical lesion. Also, radiographically, included teeth had a periapical Index (PAI) ≥ 2 .

Exclusion criteria

Exclusion criteria included patients with compromised medical conditions that would alter the treatment. Teeth that would need more than one visit for treatment, as well as patients presenting with immature teeth. Patients already on antibiotics or analgesics.

Patients' Recruitment, allocation and randomization

joined from Patients were the outpatient the Endodontic clinic of Department British University in Egypt. Randomization done using computer software. patients allocated the were randomly into two equal groups. The generated sequential numbers were placed in an opaque envelope, and it was opened by an assistant just before the intervention in. the second visit. OF

Clinical procedures

A single endodontist performed all clinical procedures using 4% articaine (Septanest, Septodont) for anesthesia. An access cavity was opened under rubber dam. A sterile Kfile #15 (Mani Inc.) was used to determine the working length (WL) with the assistance of an apex locator (Morita Root ZX).

Rotary shaping instruments were utilized to shape using light pecking motions with a short vertical strokes of 2-3 mm. After every 3 pecking, the file was cleaned from debris, and canal was irrigated with 5 ml of 5.25% NaOCl using a 30-gauge side-vented needle.

A final rinse with 5 ml of 17% EDTA and 5 ml of 5.25% NaOCl for one minute per each canal. The total volume of NaOCl was standardized to 20 ml per canal. Passive ultrasonic irrigation activation was utilized to achieve better disinfection. All canals were shaped to a minimum dimension of 30/.04, except for a single middle mesial canal, which was shaped to 25/.04 as per literature recommendations.

After selecting the appropriate master gutta-percha cone, a periapical X-ray was taken. Then drying the canals using sterile paper points, and patients were randomly divided into two groups based on the obturation material used. To ensure patient privacy, each name was replaced with a case number.

- **Group 1:** Continuous Wave Condensation (CWC) technique with resin-based sealer (AH Plus, DENTSPLY).
- **Group 2:** Sealer-Based Obturation (SBO) with calcium silicate sealers (BIO-C® SEALER, Angelus).

For the SBO group, the Bio-C Sealer was injected into the middle third of the canal. Master-cone was inserted using an up-anddown motion for better sealer penetration inside the canal. Extra gutta-percha cones were added in wider canals for improved sealing. Gutta-percha cone was then cut at the orifice level.

In the CWC group, after coating guttapercha cones with AH Plus sealer it was placed in the prepared root canals. Mastercone was cut at 4-5 mm from working length using heated plugger (Fast Pack, Eighteeth Medical Technology, Changzhou, China. Using a thermoplastic injection technique with Fast Fill (Eighteeth Medical Technology, Changzhou, China) backfilling of the canal was achieved.

Finally, the access openings were sealed with bonding agent (All bond а universal, Bisco, USA) and composite resin (Tetric N, Ivoclar Vivadent, Schaan, Liechtenstein). Using operating microscope (OPMI PICO; Carl Zeiss, Göttingen, Germany) all endodontic procedures were conducted.

Postoperative Pain Assessment

Patients recorded their pain on scale of 0-10 visual analog scale (VAS), with 0 indicating no pain and 10 indicating the worst pain. Patients' pain level was obtained from them preoperatively, to strictly exclude anyone with a score other than VAS 0. Pain levels were also recorded at the following time points: 4 hours, one day, and two days after canal obturation. The pain score was recorded at its highest value three successive time points selected and then sorted into 4 categories: showed in Fig 2.

1. None (VAS 0): The treated tooth is asymptomatic, and the participant has no pain at all, 2. Mild (VAS 1-3): The tooth is slightly painful, but there is no need to take analgesics, 3. Moderate (VAS 4-7): The tooth causes discomfort and pain is somewhat tolerable but requires analgesics.

4. Severe (VAS 8-10): The pain is disturbing the normal activity or sleep, and analgesics would have little or no effect.

Figure 2: VAS Scoring

Statistical analysis

Data were presented as mean, standard deviation (SD), median, and interquartile range (IQR) values. Analyzed by Mann-Whitney U and signed rank tests, respectively. p<0.05 was set as significant level within all tests. Statistical analysis was performed with R statistical analysis software version 4.4.1 for Windows (R Core Team (2024).

Results

65 participants were eligible for this clinical study and assigned randomly to the treatment groups. Patients who had taken analgesic are reported and excluded from the analysis. Table 1 demonstrates the demographic data and distribution of the participants.

Table 1: Intergroup comparisons and summary statistics for demographic data

Parameter		SPO	CWC	p-value
Gender [n (%)]	Male	14 (40.00%)	13 (43.33%)	0.806ns

Parameter		SPO	CWC	p-value
	Female	21 (60.00%)	17 (56.67%)	

ns not significant.

Table	2:	Intergrou	ір сот	parison	and	summary
statistics for postoperative pain score.						

Measurement	Postoperative	n-value	
Wieusurement	SPO	CWC	p value
Mean±SD	2.17±0.89	2.40±0.62	0.20(
Median (IQR)	2.00 (2.00)	2.00 (1.00)	0.3968

ns not significant.

Statistical analysis showed no significant difference between the two groups. With higher pain score for CWC group (fig 3)





Discussion

Several procedural steps involved in root canal treatment make it difficult to allocate pain occurrence to one of them exclusively.^{13,14} Therefore, in the designing the current study, care was taken to reduce probable confounding factors of postoperative pain. Presence of pre-operative pain is more likely to cause postoperative pain as showed by studies. Consequently, only patients with asymptomatic apical periodontitis were allowed to participate in this study.¹⁵ Also, there was no restriction on the tooth type included given the wide variety

Post-operative pain after non-surgical root canal treatment with a single cone/ bio-ceramic sealer based obturation: A Randomized Clinical Trial | Mohamed Tarek Elemam et al. MARCH2025.

of anatomical features presented by the Egyptian population.^{16,17} The traditional access cavity design was employed in molars even though the conservative design has been shown to provide a mechanical advantage.¹⁸ However, the primary concern in managing apical periodontitis is fulfilling the biological objectives of root canal preparation.¹⁹ Suboptimal cleaning of necrotic teeth would compromise the treatment outcome and flare-ups.⁴ predispose to However. in teeth with premolar one or more compromised marginal ridges, the caries driven access conservative access was adopted because it provided significant biomechanical advantage that did not compromise the disinfection process.²⁰⁻²² Treatments were concluded in single visits given that a Cochrane review has shown no significant differences between single and multiple visits in necrotic teeth.²³ The shaping procedures prioritized achieving efficient irrigation and obtaining white uninfected dentin, thus a minimum shaping dimension of 30/.04 was achieved in all canals.²⁴ An exception was the single middle mesial canal whose shaping was limited to only 25/.04 as recommended previously.¹⁹ exclude the effect of intracanal То medication on post operative pain any tooth that required intracanal medication or several sessions for patient-related reasons such as fatigue was excluded.

Pain intensity was measured using-VAS. It was selected because of its simplicity, ease of communication with patients, and established reliability in evaluating pain.²⁵

According to results, the null hypothesis is accepted. No significant differences were identified in the degree of post-operative pain after obturation with both techniques. This agrees Mittal et al. ¹ who suggested that as long as sealer extrusion was only 1-2mm, and distant from vital structures, this wouldn't elicit any post-operative complications. During this study, care was taken to create and validate a sound apical stop with strict adherence to the academic recommendations for either technique.

On the contrary, our results agree hyung et al.²⁶ who reported significant differences in post-operative pain using resin sealer and bioceramic sealers that was attributed to the byproducts of resin sealers like bisphenol A diglycidyl ether that might interact with periapical tissues and cause postoperative discomfort.²⁷

Limitations of this study include the subjectivity of pain intensity analysis that can vary from patient to another and may hinder the representation of entire population by the study sample. Future studies should address other patient-based outcomes like healing of apical periodontitis, or the quality of life after root canal obturation with recent techniques and materials.

Conclusion

Within the restrictions of this study, both CWC with AH+ sealer with and sealer based obturation with Bio-C sealer showed no significant pain level. Additional research is necessary to evaluate different sealers with each obturation technique on patient-based outcomes like healing of apical periodontitis, or the quality of life after root canal obturation.

nfunding ournal

Self-supported study.

Competing interests

There is no conflict of interest.

Ethics approval and consent to participate:

This trial was conducted with the approval of the ethics committee at the Faculty of Dentistry, British university, Cairo, Egypt (FDBUE-REC-22-015). Patient asked to follow general instructions and signed a printed informed consent explaining the aim of study, brief of the study methodology, benefits and complications of the procedure and requesting that they allow clinician to follow up after performing the treatment.

References

1. Mittal N, Thangamuthu T, Gupta S, Gupta S, Aggarwal H, Kharat S. Comparative evaluation of resin-based sealers and bioceramic sealers for postoperative pain after endodontic treatment: A systematic review. Dent Med Probl. 2024 Apr 30;61(2):293–300.

2. Graunaite I, Skucaite N, Lodiene G, Agentiene I, Machiulskiene V. Effect of Resin-based and Bioceramic Root Canal Sealers on Postoperative Pain: A Split-mouth Randomized Controlled Trial. J Endod. 2018 May;44(5):689–93.

3. Bugea C, Cerutti F, Ongaro F, Sforza F, Scarano A, Rampino M, et al. Postoperative pain and one year follow up success rate of warm vertical compaction, single cone, coneless and bioconeless obturation methods. J Osseointegration. 2022 Dec 6;14(4):209–16.

4. Fahim MM, Saber SEM, Elkhatib WF, Nagy MM, Schafer E. The antibacterial effect and the incidence of post-operative pain after the application of nanobased intracanal medications during endodontic retreatment: a randomized controlled clinical trial. Clinical Oral Investigations. 2022 Feb 1;26(2):2155– 63.

5. Saber SM, Alfadag AMA, Nawar NN, Plotino G, Hassanien EES. Instrumentation kinematics does not affect bacterial reduction, post-operative pain, and flare-ups: A randomized clinical trial. Int Endod J. 2024 Oct 20;55(5):405–15.

6. Eldeeb IM, Nawar NN, Saber SM, Hassanein EES, Schäfer E. Smear layer removal and sealer penetration with different tapers after using photoninitiated photoacoustic streaming technique. Clinical Oral Investigations. 2024 Oct 21;25(8):5025–32.

7. Saber S, Raafat S, Elashiry M, El-Banna A, Schäfer E. Effect of Different Sealers on the Cytocompatibility and Osteogenic Potential of Human Periodontal Ligament Stem Cells: An In Vitro Study. J Clin Med. 2023 Mar 17;12(6):2344.

8. Saber S, Galal MM, Ismail AG, Hamdy TM. Thermal, chemical and physical analysis of VDW.1Seal, Fill Root ST, and ADseal root canal sealers. Scientific Reports. 2023 Sep 13;14829(2023:1–9.

9. Saber S M, Gomaa SM, Elashiry M M, El-Banna A, Schafer E. Comparative biological properties of resin-free and resin-based calcium silicate-based

endodontic repair materials on human periodontal ligament stem cells. Clin Oral Investig. 2023 Nov;27(11):6757-6768.

10. Shalabi M, Saber S, Elsewify T. Influence of blood contamination on the bond strength and biointeractivity of Biodentine used as root-end filling. Saudi Dent J. 2020 Dec 1;32(8):373–81.

11. Hamdy TM, Galal MM, Ismail AG, Saber S. Physicochemical properties of AH plus bioceramic sealer, Bio-C Sealer, and ADseal root canal sealer. Head Face Medicine. 2024 Jan 3;20(1):2.

12. Kim J hyung, Cho SY, Choi Y, Kim D hyun, Shin SJ, Jung IY. Clinical Efficacy of Sealer-based Obturation Using Calcium Silicate Sealers: A Randomized Clinical Trial. J Endod. 2022 Feb;48(2):144–51.

13. Ng Y -L., Glennon JP, Setchell DJ, Gulabivala K. Prevalence of and factors affecting post-obturation pain in patients undergoing root canal treatment. Int Endod J. 2004 Jun;37(6):381–91.

14. Saber S.M., Hashem A.A., Khalil D.M., Pirani C., Ordinola-Zapata R. Efficacy of four local anaesthesia protocols for mandibular first molars with symptomatic irreversible pulpitis: A randomized clinical trial. International Endodontic Journal. 2022 Mar;55(3):219-230.

15. Alonso-Ezpeleta Lo, Gasco-Garcia C, Castellanos-Cosano L, Martin-Gonzalez J, Lopez-Frias Fj, Segura-Egea Jj. Postoperative pain after one-visit root-canal treatment on teeth with vital pulps: Comparison of three different obturation techniques. Med Oral Patol Oral Cirugia Bucal. 2012 Jul 1;17(4):e721-7.

16. Saber S M, Elashiry M M, Sadat S, Nawar N N. A microcomputed tomographic analysis of the morphological variabilities and incidence of extra canals in mandibular first molar teeth in an Egyptian subpopulation. Sci Rep. 2023 Jun;13:8985.

17. Saber S, Ek Sadat S, Taha A, Nawar N, Azim A. Anatomical Analysis of Mandibular Posterior Teeth using CBCT: An Endo-Surgical Perspective. European Endodontic Journal. 021 Dec;6(3):264-270.

18. Saber S, Hayaty D, Nawar N, Kim HC. The Effect of Access Cavity Designs and Sizes of Root Canal Preparations on the Biomechanical Behavior of an Endodontically Treated Mandibular First Molar: A Finite Element Analysis. (2020) Journal of Endodontics. 2020,46 (11):1675-168.

19. Nawar NN, Elkholy MMA, Ha WN, Saber SM, Kim HC. Optimum Shaping Parameters of the Middle Mesial Canal in Mandibular First Molars: A Finite Element Analysis Study. J Endod. 2023 May;49(5):567–74.

20. Elsewify T.M., Saber S.M., Plotino G. Cyclic fatigue resistance of three heat-Treated nickel-

Post-operative pain after non-surgical root canal treatment with a single cone/ bio-ceramic sealer based obturation: A Randomized Clinical Trial | Mohamed Tarek Elemam et al. MARCH2025. Titanium instruments at simulated body temperature. Saudi Endodontic Journal, 2020 Sep;10(2):131-136. 21. Nawar NN, Abdelfattah RA, Kataia M, Saber SM, Kataia EM, Kim HC. Effect of Proximal Cariesdriven Access on the Biomechanical Behavior of Endodontically Treated Maxillary Premolars. J Endod. 2023 Oct;49(10):1337–43.

22. Abdelfattah RA, Nawar NN, Kataia EM, Saber SM. How loss of tooth structure impacts the biomechanical behavior of a single-rooted maxillary premolar: FEA. Odontology. 2024 Jan;112(1):279–86.

23. Mergoni G, Ganim M, Lodi G, Figini L, Gagliani M, Manfredi M. Single versus multiple visits for endodontic treatment of permanent teeth. Cochrane Oral Health Group, editor. Cochrane Database Syst Rev. 2024 Nov;3:2023.

24. Boutsioukis C, Arias-Moliz MT. Present status and future directions – irrigants and irrigation methods. Int Endod J. 2022 May;55(S3):588–612.

25. Shashirekha G, Jena A, Pattanaik S, Rath J. Assessment of pain and dissolution of apically extruded sealers and their effect on the periradicular tissues. J Conserv Dent. 018 Sep-Oct;21(5):546-550 26. Kim J hyung, Cho SY, Choi Y, Kim D hyun, Shin SJ, Jung IY. Clinical Efficacy of Sealer-based Obturation Using Calcium Silicate Sealers: A Randomized Clinical Trial. J Endod. 2022 Feb;48(2):144–51.

27. Lodienė G, Kopperud HM, Ørstavik D, Bruzell EM. Detection of leachables and cytotoxicity after exposure to methacrylate- and epoxy-based root canal sealers in vitro. Eur J Oral Sci. 2013 Oct;121(5):488–96.

ASDJ

Ain Shams Dental Journal