Clinical Trial Document Cover Page

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Introduction

Postoperative pain following root canal treatment is a critical factor affecting both clinical success and patient comfort. The choice of canal preparation system and root canal sealer may significantly influence the incidence and intensity of postoperative pain after instrumentation (1, 2).

Postoperative pain may arise from various factors, including microbial, chemical, and mechanical causes. Microbial factors include residual caries, inadequate chemo-mechanical preparation, poor coronal sealing, and the absence of intracanal medicaments between treatment sessions. Chemical factors involve the use of irrigation solutions, intracanal medicaments, and root canal filling materials. Mechanical factors may result in trauma to the periapical tissues and extrusion of debris, necrotic pulp tissue, irrigation solutions, and microorganisms into the periapical tissues (1, 2).

The selection of root canal sealer is another factor that may affect treatment outcomes. Extrusion of sealer during root canal obturation has been reported to exert cytotoxic effects on periapical tissues, leading to periapical inflammation, necrosis, and pain. The chemical composition of sealers also influences the degree of tissue reaction (3, 4). AH Plus sealer (Dentsply DeTrey, Konstanz, Germany) is an epoxy resin-based root canal sealer known for its excellent sealing ability, dimensional stability, and biocompatibility. It adheres well to both dentin and gutta-percha, thereby reducing the risk of microleakage and improving long-term treatment success.

In recent years, ProRoot Bio Sealer (Dentsply Tulsa Dental Specialties, Tulsa, OK, USA), with its calcium silicate-based formulation, has been reported to contain a higher proportion of bioactive cement compared to other bioceramic sealers. This property supports material setting, provides a high pH environment, and promotes hydroxyapatite formation. Interim clinical results have demonstrated high short-term healing rates and more stable radiographic visibility over time when compared with leading bioceramic sealers.

The innovative properties of ProRoot Bio Sealer are also reflected in its application system. The flexible and adaptable ProRoot Flex Tip design enables easy application in all canal anatomies and reduces material waste per tip by up to 49% (5).

These and similar properties make ProRoot Bio Sealer a preferred material in the bioceramic obturation approach (5):

- Appropriate flowability and syringe extrusion force
- Easy application into the root canal system
- Compatibility with all obturation techniques, including cold, warm, and carrier-based systems
- Easy retreatment
- Non-discoloring formula

- High pH value

BC Sealer ion+ (Brasseler, Savannah, GA, USA) is an Akermanite-based, patented, and innovative premixed bioceramic root canal sealer. Akermanite is a mineral widely used in the medical field because of its osteogenic and angiogenic properties. Unlike other bioceramics, BC Sealer ion+ releases both calcium and magnesium ions to maximize bioactivity (6).

Its main features include:

- Compatibility with cold and warm obturation techniques
- Improved handling properties
- Increased radiopacity
- Enhanced bioactivity
- Twofold greater tissue healing potential
- Support for stem cell differentiation
- Micronized particle structure
- Antibacterial effect

The structural differences between simple tetrahedral nesosilicates (e.g., C3S) and double tetrahedral sorosilicates (e.g., Akermanite) significantly affect ion release behavior and the resulting biological activities. While C3S provides an early effect through rapid Ca^{2+} release, Akermanite offers prolonged bioactivity, increased structural stability, and multifunctional biological advantages through the controlled release of both Ca^{2+} and Mg^{2+} ions (6).

The aim of this study was to comparatively evaluate the effects of three different root canal sealers—AH Plus, ProRoot Bio Sealer, and BC Sealer ion+—on postoperative pain in patients diagnosed with asymptomatic irreversible pulpitis undergoing root canal treatment. The null hypothesis of this study was that the different root canal sealers used would not produce a statistically significant difference in postoperative pain levels.

Materials and Methods

This study was designed as a prospective, randomized clinical trial including patients aged 18–60 years diagnosed with asymptomatic irreversible pulpitis. Following approval from the Ethics Committee of the European University of Lefke, a total of approximately 111 teeth, with 37 teeth allocated to each study group, will be included in the study.

Sample Size Calculation

The sample size was calculated using G*Power software. The primary outcome measure was determined as the postoperative pain score. Based on similar clinical studies reported in the literature, a medium effect size ($f = 0.30$) was assumed. With a significance level of $\alpha = 0.05$ and a statistical power of 80%, the minimum sample size required for three independent groups was calculated as 111. Considering a possible 20% dropout rate, the total sample size was increased to 135, and 45 patients were planned for inclusion in each group.

Patient Selection

Patients will be selected from individuals referred to the Dental Clinic for root canal treatment. Only mandibular first or second molars diagnosed with asymptomatic irreversible pulpitis will be included in the study. Asymptomatic irreversible pulpitis is defined as inflamed vital pulp tissue without clinical symptoms, usually caused by caries, caries excavation, or trauma (7).

Before treatment, written and verbal informed consent will be obtained from all participants (Appendix 1). An online questionnaire including the Numeric Rating Scale (NRS) and the number of analgesics taken will be electronically sent to the participants (Appendix 2). Patients will subsequently be contacted by telephone and asked to complete the questionnaire online. Submitted responses will not be modifiable after completion. The primary outcome will be postoperative pain, while secondary outcomes will include analgesic consumption and flare-up incidence.

Inclusion Criteria

- Asymptomatic teeth showing delayed positive responses to thermal testing (EndoIce; Coltene/Whaledent Inc.) and electric pulp testing (Parkell)
- Teeth with extensive pulp exposure during caries excavation
- Inflamed pulp tissue in which bleeding cannot be controlled within 5 minutes
- Periodontally healthy, mature mandibular first or second molars

Exclusion Criteria

Patients presenting with the following conditions will be excluded from the study:

- Diabetes mellitus, immunocompromised conditions, or pregnancy
- Use of antibiotics within the last month or requirement for antibiotic prophylaxis
- Use of analgesics within 7 days prior to treatment
- Allergy to any material used during root canal treatment
- Teeth suitable for vital pulp therapy in which bleeding can be controlled within 5 minutes
- Non-vital or symptomatic teeth
- Presence of radiographically detectable periapical lesions
- Teeth requiring post-core restorations or prosthetic support
- Calcified root canals, root resorption, or immature teeth

Randomization and Blinding

Patients will be randomly allocated into three groups using a computer-generated randomization program (http://random.org). Both the patients and the outcome assessor will be blinded to the group allocation.

Patients will be assigned to the groups using a computer-assisted randomization method. Allocation concealment will be ensured through the use of opaque, sealed envelopes.

- **Group 1:** AH Plus sealer (Dentsply DeTrey, Germany)
- **Group 2:** ProRoot® Bio Sealer (Dentsply Tulsa Dental Specialties, USA)

- **Group 3:** BC Sealer ion+ (Brasseler, USA)

Patients and the outcome assessor will remain unaware of the group distribution (single-blind study).

Treatment Protocol

To ensure standardization, all treatments will be performed by a single experienced clinician in the same clinical setting, using identical irrigation solutions and obturation techniques, with treatment completed in a single visit.

All patients will receive inferior alveolar nerve block anesthesia using 2% articaine hydrochloride with 1:80,000 epinephrine (Jetokain; Adeka). Following rubber dam isolation, caries and old restorations will be removed, and standard access cavities will be prepared using high-speed diamond burs. Pulp vitality will be confirmed by observation of bleeding.

Working length will be determined using an electronic apex locator (Raypex 6; VDW) and confirmed radiographically. Initial glide path preparation will be established using size 8–10 K-files, and apical patency will be verified with a size 10 K-file.

Root Canal Shaping

The ProTaper Universal Ni-Ti rotary system (Dentsply Maillefer) will be used at 300 rpm and 2 Ncm torque. Glide path preparation will first be performed using the ProGlider file, followed by canal shaping with SX, S1, and S2 files according to the manufacturer's recommendations, and finalized with F1–F2 files. During instrumentation, canals will be irrigated with 2.5% NaOCl using a 30-gauge side-vented needle, while apical patency will be maintained with a size 15 K-file.

Irrigation activation will be performed with 2.5% NaOCl using the EndoActivator system (Dentsply Tulsa Dental, USA) for a total of 60 seconds in three cycles. To remove the smear layer, irrigation with 5 mL of 17% EDTA (Merck, Germany) will be performed for 1 minute. Subsequently, the root canals will be rinsed with 2 mL sterile distilled water and dried using paper points (Dentsply Maillefer, Switzerland). Finally, 2 mL of 2% chlorhexidine (Klorhex; Drogsan, Türkiye) will be left in the canal for 2 minutes, and the canals will then be dried again.

Root Canal Obturation

Obturation will be performed using a modified single-cone technique with gutta-percha cones (Dentsply Maillefer) corresponding to each system's master file and the respective root canal sealers:

- **Group 1:** AH Plus sealer (Dentsply DeTrey, Germany)
- **Group 2:** ProRoot® Bio Sealer (Dentsply Tulsa Dental Specialties, USA)
- **Group 3:** BC Sealer ion+ (Brasseler, USA)

If lateral voids remain within the canal, accessory gutta-percha cones will be added. A spreader will be gently used to identify lateral spaces without applying pressure. After radiographic confirmation of obturation quality, excess gutta-percha will be removed and compacted below the cemento-enamel junction (CEJ). Permanent composite resin restoration (Filtek Z250; 3M ESPE) will be placed during the same appointment.

Postoperative Pain Assessment

Postoperative pain will be evaluated at 6, 12, 24, 48, and 72 hours, as well as on day 7, using the Numeric Rating Scale (NRS). The NRS is the numerical version of the Visual Analog Scale (VAS), ranging from 0 (no pain) to 10 (unbearable pain) (8, 9). Participants will be instructed as follows:

- **0:** No pain
- **Mild pain (1–3):** Low-intensity pain not requiring analgesics
- **Moderate pain (4–6):** Tolerable pain controllable with analgesics
- **Severe pain (7–10):** Unbearable pain not adequately controlled by analgesics and generally requiring rest

Postoperative Analgesic Protocol

All patients will be prescribed 400 mg ibuprofen and advised to use it only in cases of severe pain. Analgesic consumption will be recorded.

Follow-up Visits

Follow-up visits will be scheduled on the 7th day to clinically verify patient-reported outcomes.

Statistical Analysis

Data will be analyzed using statistical software. Appropriate statistical tests will be selected according to whether the data demonstrate parametric distribution. A value of $P < 0.05$ will be considered statistically significant.

References:

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9. Jensen MP, Karoly P, Braver S. The measurement of clinical pain intensity: a comparison of six methods. Pain. 1986;27(1):117–26.

Appendix 1. Patient Informed Consent Form

Study Title

Comparison of Postoperative Pain Following Root Canal Treatment Using AH Plus, ProRoot Bio Sealer, and BC Sealer ion+: A Randomized Clinical Trial

1. Purpose of the Study

You are being invited to participate in this research study. The purpose of this study is to compare the effects of different root canal sealers (AH Plus, ProRoot Bio Sealer, and BC Sealer ion+) used during root canal treatment on postoperative pain.

These materials are safe and approved products that are routinely used in modern dentistry. The aim of the research is to evaluate whether different root canal sealers create differences in the level of pain experienced by patients after treatment.

2. Study Procedures

- If you agree to participate, root canal treatment will be performed on your tooth diagnosed with irreversible pulpitis.
- The same treatment protocol will be applied to all patients in the study; only the root canal sealer used will differ.
- You will be randomly assigned (by chance) to one of the three study groups, which will determine the root canal sealer to be used.
- The treatment will include the following standard clinical procedures:
    - Administration of local anesthesia
    - Cleaning and shaping of the root canals
    - Irrigation (washing procedure)
    - Filling of the canal using the selected root canal sealer
- After treatment, you will be asked to record your pain level using a scale ranging from 0–10 at the following time intervals:
    - 6 hours
    - 12 hours
    - 24 hours
    - 48 hours
    - 72 hours
    - 7 days
- If necessary, you may be contacted by telephone to confirm your pain scores.
- Pain medication will be provided for use if needed, and you will be asked to record the amount used.

3. Possible Risks and Discomforts

- Mild to moderate temporary pain may occur following root canal treatment.
- Participation in this study does not involve any additional or different risks compared to routine root canal treatment.
- All materials used are widely accepted and considered safe in clinical practice.

- In case of severe pain, swelling, or any unexpected condition, you should contact your dentist immediately.

4. Potential Benefits

- The necessary root canal treatment for your tooth will be provided.
- The data obtained from this study may contribute to the improvement of future treatment approaches and enhancement of patient comfort.

5. Voluntary Participation

- Participation in this study is entirely voluntary.
- You may refuse to participate or withdraw from the study at any time.
- Withdrawal from the study will not affect your treatment process in any way.
- Even if you choose not to participate, your required dental treatment will still be provided.

6. Confidentiality

- All of your personal information will be kept confidential.
- A code number will be used instead of your identity in the research records.
- The collected data will only be used for scientific purposes, and your identity will not be disclosed even if the results are published.

7. Costs and Compensation

- You will not be required to pay any additional fee to participate in this study.
- No financial compensation will be provided for participation.

8. Questions

If you have any questions regarding the study, you may contact:

Mohamad Abduljalil
Faculty of Dentistry, European University of Lefke
Phone: +90 539 121 3636
Email: Mohamad_abduljalil@hotmail.com

9. Consent Statement

I have read and understood the information provided above. I have had the opportunity to ask questions, and satisfactory answers were given to me. I voluntarily agree to participate in this study.

Participant’s Full Name: _____

Participant’s Signature: _____ Date: _____

Researcher’s Full Name: _____

Researcher’s Signature: _____ Date: _____

Appendix 2. Patient Pain Diary Form

Study Title

Comparison of Postoperative Pain Following Root Canal Treatment Using AH Plus, ProRoot Bio Sealer, and BC Sealer ion+: A Randomized Clinical Trial

Participant No: _____

Treatment Date: _____

Tooth Number: _____

Instructions for the Patient

After your root canal treatment, please record the level of pain you experience at the specified time intervals. Use the following Numeric Rating Scale (NRS) to indicate the severity of your pain:

Pain Score	Description
0	No pain
1–3	Mild pain
4–6	Moderate pain
7–10	Severe pain

Numeric Rating Scale (NRS)

0 1 2 3 4 5 6 7 8 9 10

(0 = No pain 10 = Unbearable pain)

Pain Recording Table

Time After Treatment	Date / Time	Pain Score (0–10)	Notes (e.g., type of pain, analgesic use, other symptoms)
6 hours			
12 hours			
24 hours			
48 hours			
72 hours			
Day 7			

Analgesic Use (If Any)

Medication Name Dose Time Taken Reason (if other than pain)

Patient Signature: _____ Date: _____

Researcher Signature: _____ Date: _____