

Clinical Trial Document Cover Page

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Impact of TruNatomy and ProTaper Gold Ni-Ti Systems Using Resin-Based or Bioceramic Sealers on Postoperative Pain After Root Canal Treatment: A Randomized Clinical Trial

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Impact of Trunatomy and Protaper Gold Ni-Ti Systems Using Resin-Based or Bioceramic Sealers on Postoperative Pain After Root Canal Treatment: A Randomized Clinical Trial

Introduction

Postoperative pain following root canal treatment is a critical factor influencing both clinical success and patient comfort. Despite advances in endodontic techniques, pain after treatment remains a common concern and may negatively affect patient perception of care (1, 2).

Postoperative pain is multifactorial in origin and may result from microbial, chemical, and mechanical factors. Microbial causes include residual infection due to inadequate chemo-mechanical preparation or coronal leakage. Chemical factors involve the use of irrigants, intracanal medicaments, and obturation materials. Mechanical factors include apical extrusion of debris, irrigants, and microorganisms, as well as trauma to periapical tissues during instrumentation (1, 2).

Among these factors, the root canal preparation technique plays a crucial role in the development of postoperative pain. TruNatomy (Dentsply Maillefer, Ballaigues, Switzerland) is a recently introduced rotary system designed for minimally invasive canal shaping. Its slim design and regressive taper allow preservation of dentin and natural canal anatomy, which may reduce apical extrusion of debris and postoperative discomfort (1).

In contrast, ProTaper Gold (Dentsply Maillefer, Ballaigues, Switzerland) is a widely used rotary system characterized by a progressive taper and enhanced cutting efficiency. While effective in shaping complex canal anatomies, its more aggressive design may result in increased debris extrusion, potentially contributing to postoperative pain (3).

The type of root canal sealer is another important factor influencing treatment outcomes. Sealer extrusion into periapical tissues may induce inflammatory reactions depending on its chemical composition. The chemical composition of sealers also influences the degree of tissue response (4, 5). AH Plus (Dentsply DeTrey, Konstanz, Germany), an epoxy resin-based sealer, is known for its excellent sealing ability and dimensional stability. In contrast, TotalFill BC Sealer (FKG Dentaire SA, La Chaux-de-Fonds, Switzerland), a calcium silicate-based bioceramic sealer, demonstrates favorable biocompatibility and bioactivity through calcium ion release (6).

The aim of this study is to evaluate the effect of two rotary file systems (TruNatomy and ProTaper Gold) used in combination with two different sealers (AH Plus and TotalFill BC) on postoperative pain in patients with asymptomatic irreversible pulpitis.

The null hypothesis is that neither the instrumentation system nor the sealer type, nor their interaction, has a significant effect on postoperative pain.

Methods

This study is designed as a prospective, randomized clinical trial. Ethical approval was obtained from the European University of Lefke Ethics Committee (Protocol No: BAYEK057.03).

Sample Size Calculation

A total of 180 patients will be recruited and randomly allocated into four groups ($n = 45$ per group). Considering an anticipated dropout rate of approximately 20%, the final analyzable sample size is expected to be 144 patients (36 per group).

This sample size provides 80% power to detect a moderate effect size (Cohen's $d \approx 0.42$) and 90% power to detect a larger effect ($d \approx 0.48$) at a significance level of 5%. It also allows evaluation of potential interaction effects between the instrumentation system and sealer type.

Patient Selection

Patients will be recruited from individuals referred to the European University of Lefke Dental Clinic for root canal treatment. Only mandibular first and second premolars diagnosed with asymptomatic irreversible pulpitis will be included. This condition is defined as inflamed vital pulp tissue without clinical symptoms, caused by caries, caries removal, or trauma (7).

Written and verbal informed consent will be obtained from all participants prior to treatment (Appendix 1). An electronic questionnaire including the Numerical Rating Scale (NRS) and analgesic intake will be sent to patients (Appendix 2). Patients will be contacted by phone and asked to complete the questionnaire online. Submitted responses will not be editable. The primary outcome will be postoperative pain, while secondary outcomes will include analgesic consumption and flare-up incidence.

Inclusion Criteria

- Asymptomatic teeth with delayed positive response to thermal and electric pulp testing
- Vital teeth with signs of irreversible pulpitis
- Mature mandibular first or second premolars
- Periodontally healthy teeth

Exclusion Criteria

- Patients with systemic conditions (e.g., diabetes, immunocompromised status, pregnancy)
- Antibiotic use within the past month
- Use of analgesics within 7 days prior to treatment
- Known allergy to materials used
- Teeth with periapical lesions
- Non-vital or symptomatic teeth
- Teeth requiring post-core restorations
- Calcified canals, root resorption, or immature teeth

Randomization and Blinding

Participants will be randomly assigned to one of four groups using a computer-generated randomization sequence. Allocation concealment will be ensured using sealed opaque envelopes.

Patients and outcome assessors will be blinded to group allocation. Due to the nature of the intervention, the operator could not be blinded.

A total of 180 sealed envelopes containing combinations of TruNatomy or ProTaper Gold systems and AH Plus or TotalFill BC sealers will be prepared and mixed in an opaque container. Each patient will select one envelope, which determines the assigned group. To minimize bias, the operator will open the envelope only after gaining access to the root canal.

Treatment Protocol

All procedures will be performed by a single experienced clinician in a standardized clinical setting, using the same irrigation solutions and obturation techniques, and completed in a single visit.

Inferior alveolar nerve block anesthesia will be administered using 2% articaine hydrochloride with 1:80,000 epinephrine (Jetokain; Adeka). After rubber dam isolation, caries and old restorations will be removed, and standard access cavities will be prepared.

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

Root Canal Shaping

- **TruNatomy Groups (Groups 1–2):**
Preparation will be performed at 500 rpm and 1.5 Ncm torque using TruNatomy Glider (17/0.02) followed by Prime file (26/0.04).
- **ProTaper Gold Groups (Groups 3–4):**
Preparation will be performed at 300 rpm and 2 Ncm torque using ProGlider followed by SX, S1, S2, F1, and F2 files.

Irrigation with 2.5% NaOCl will be performed using a 30-gauge side-vented needle. Final irrigation will include activated NaOCl (EndoActivator), EDTA, distilled water, and 2% chlorhexidine.

Obturation

Modified single-cone technique will be used:

- Group 1: TruNatomy + AH Plus
- Group 2: TruNatomy + TotalFill BC
- Group 3: ProTaper Gold + AH Plus
- Group 4: ProTaper Gold + TotalFill BC

Excess gutta-percha will be removed and compacted below CEJ, followed by composite restoration (Filtek Z250; 3M ESPE).

Postoperative Pain Assessment

Primary Outcome

Postoperative pain will be evaluated at different time points—6, 12, 24, 48, and 72 hours, as well as on the 7th day—using the Numerical Rating Scale (NRS). The NRS is a numerical version of the Visual Analog Scale (VAS), ranging from 0 (no pain) to 10 (unbearable pain) (8, 9). It will be explained to participants as follows:

- No pain (0)
- Mild pain (1–3): Low-level pain that does not require analgesics
- Moderate pain (4–6): Tolerable pain that can be controlled with analgesics\
- Severe pain (7–10): Unbearable pain that is not adequately controlled by analgesics and often requires rest

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

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

Statistical Analysis

Data will be analyzed using appropriate statistical software. Statistical significance will be set at $p < 0.05$.

References

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Appendix 1. Patient Informed Consent Form

Study Title: Impact of Trunatomy and Protaper Gold Ni-Ti Systems Using Resin-Based or Bioceramic Sealers on Postoperative Pain After Root Canal Treatment: A Randomized Clinical Trial

Principal Investigator: Dt. Kaan Nurhan

Faculty of Dentistry, European University of Lefke

1. Purpose of the Study

You are invited to participate in a research study. The aim is to compare two different systems for cleaning root canals and two different root canal sealers used to fill the canals after cleaning. All systems and sealers are commonly used in dental practice and considered safe. We want to see if there is any difference in the level of pain patients feel after treatment depending on the file system and sealer used.

2. Procedures

- If you agree, root canal treatment will be performed on the tooth that has been indicated as irreversible pulpitis, and during this procedure, one of the file systems and one of the sealers included in the study will be used.
- You will be randomly assigned to one of the study groups (instrument system + sealer).
- The treatment will follow standard clinical procedures: local anesthesia, cleaning and shaping of the root canals, irrigation, and obturation (filling) using one of the two tested sealers.
- After treatment, you will be asked to record your level of pain on a 0–10 scale at several times (6h, 12h, 24h, 48h, 72h and 7 days).
- You may also receive a follow-up phone call to confirm your pain scores.
- You will be given pain-relief medication to use if needed and asked to record your use.

3. Risks and Discomforts

- Root canal treatment may cause temporary discomfort or pain after the procedure.
- There are no additional risks from participating in this study compared with routine root canal treatment.
- All file systems and sealers used are approved and commonly applied in dental practice.
- If you feel severe pain or swelling, you can contact your dentist immediately.

4. Benefits

- You will receive necessary root canal treatment for your tooth.
- The information collected may help improve treatment protocols and patient comfort in the future.

5. Voluntary Participation

- Your participation is voluntary. You may refuse to join or withdraw at any time without affecting your dental treatment.
- If you decide not to participate, you will still receive appropriate treatment.

6. Confidentiality

- Your personal data will be kept strictly confidential.
- Only coded study numbers will be used in the research data.
- Results may be published in scientific journals, but your identity will never be revealed.

7. Costs and Compensation

- You will not have to pay any additional costs for participation.
- You will not receive financial compensation for participation.

8. Questions

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

Dt. Kaan Nurhan,

Faculty of Dentistry European University of Lefke

Phone Number: 00905338406054

Email: knurhan@eul.edu.tr

9. Consent Statement

I have read and understood the information provided above. I have had the opportunity to ask questions and they have been answered to my satisfaction. I voluntarily agree to participate in this study.

Participant's Name: _____

Signature of Participant: _____ Date: _____

Researcher's Name: _____

Signature of Researcher: _____ Date: _____

Appendix 2. Patient Pain Diary Form

Study Title: Impact of Trunatomy and Protaper Gold Ni-Ti Systems Using Resin-Based or Bioceramic Sealers on Postoperative Pain After Root Canal Treatment: A Randomized Clinical Trial

Participant ID: _____

Date of Treatment: _____

Tooth Number: _____

Instructions to the Patient

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

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

Numerical Rating Scale (NRS): 0 1 2 3 4 5 6 7 8 9 10
(0 = No Pain 10 = Worst Possible Pain)

Pain Record Table

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

Analgesic Use (if any):

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

Patient Signature: _____ Date: _____

Investigator Signature: _____ Date: _____