Effect of Resin-based and Bioceramic Root Canal Sealers on Postoperative Pain: A Split-mouth Randomized Controlled Trial

Indre Graunaite, MD, Neringa Skucaite, PhD, Greta Lodiene, PhD, Indre Agentiene, MD, and Vita Machiulskiene, PhD

Abstract

Introduction: The aim of this study was to compare the effect of resin-based and bioceramic root canal sealers on the occurrence and intensity of postoperative pain in patients with asymptomatic apical periodontitis (AAP). **Methods:** Patients presenting with AAP in previously endodontically treated teeth were included in this split-mouth blinded randomized controlled trial. For each patient, 2 single-rooted teeth were retreated and obturated using the warm vertical condensation technique and different obturation materials (ie, a gutta-percha point with resin-based sealer and a bioceramic-coated gutta-percha point with bioceramic sealer). Treatment of 1 root canal was performed in a single visit. Postoperative pain was recorded by a visual analog scale (VAS) at 24 hours, 48 hours, 72 hours, and 7 days after obturation. **Results:** Of the 61 included patients, 57 individuals presenting 114 teeth completed the study. There was no statistically significant difference between the tested root canal sealers regarding postoperative pain at any time points assessed ($P > .05$). In total, 20 (35%) patients perceived pain. Only 1 patient reported severe pain. VAS scores of 80 and 70 were reported in the AH Plus (Dentsply Maillefer, Ballaigues, Switzerland) and Total Fill (FKG Dentaire SA, La Chaux-de-Fonds, Switzerland) groups, respectively. Pain intensity decreased about 2-fold in both groups at 48 hours after treatment. There were no reports of pain since 72 hours after obturation. The odds ratio for pain occurrence in the lower premolars was 7.2 (95% confidence interval, 1.708–30.352) compared with the upper front teeth. **Conclusions:** AH Plus and Total Fill perform similarly in terms of the occurrence and intensity of postoperative pain in teeth with AAP with no material extrusion beyond the apex. *(J Endod 2018;■:1–5)*

Key Words

Calcium silicate–based sealer, epoxy resin–based sealer, postoperative pain, root canal obturation

Significance

This randomized controlled trial investigated the incidence of postoperative pain after root canal obturation with resin-based and bioceramic root canal sealers in patients with asymptomatic apical periodontitis. The results indicate that both sealers perform similarly in terms of postoperative pain.

Reports about postoperative pain in endodontics range from 3%–58% in different studies (1). Pain can be provoked by mechanical, chemical, or microbiological injuries to periodontal tissues (2). A number of treatment-related parameters have been shown to be associated with the presence of postoperative pain, including working length (WL) estimation with an apex locator connected to every file (3), the number of visits (4), the choice of instrumentation (5), and the choice of root canal sealer (6). Sealers placed in the root canals interfere with periodontal tissues through the apical foramina, lateral canals, or leaching and can potentially affect the healing process in the periodontium. Thus, the local inflammation caused by root canal obturation materials may result in postoperative pain. The intensity of inflammatory reactions depends on a number of different factors, including the composition of the sealer (7).

It has been suggested that bioceramic materials improve the outcome of endodontic treatment by promoting the differentiation of odontoblasts (8) and by releasing biologically active substances (9). The bioceramic materials have been shown to be less cytotoxic compared with resin-based AH Plus (Dentsply Maillefer, Ballaigues, Switzerland) *in vitro* (10). However, AH Plus (FKG Dentaire SA, La Chaux-de-Fonds, Switzerland) exhibited stronger bonding capacity (11) and higher radiopacity (9) compared with bioceramic sealers. The clinical significance of these characteristics is still unclear. Data on the clinical behavior of bioceramic sealers are scarce and of great interest.

The aim of this randomized clinical trial was to compare the potential effects of resin-based and bioceramic sealers on the occurrence and intensity of postoperative pain in patients with asymptomatic apical periodontitis (AAP).

Materials and Methods

The protocol of the trial was approved by the local research ethics committee (no. BE-2-23).

From the Faculty of Odontology, Clinic of Dental and Oral Pathology, Lithuanian University of Health Sciences, Kaunas, Lithuania.

Address requests for reprints to Indre Graunaite, Faculty of Odontology, Clinic of Dental and Oral Pathology, Lithuanian University of Health Sciences, Eiveniu g 2, LT-50009, Kaunas, Lithuania. E-mail address: indre.graunaite@lsmuni.lt

0099-2399/$ - see front matter

https://doi.org/10.1016/j.joen.2018.02.010

Patient Selection

The study was performed using a split-mouth design. Patients requiring root canal retreatment of at least 2 single-rooted teeth diagnosed with AAP because of radiographically detected periapical lesions were included. Diagnosis was confirmed based on the clinical examination and periapical x-rays. Only teeth presenting with no clinical symptoms and with a periapical score from 2 to 4 according to Orstavik et al (12) were included. Cases with a widened periapical periodontal space and inadequate root canal filling corresponded to a score of 2. Teeth with large periapical lesions (score 5) were excluded to minimize the chances of exacerbation of the local inflammatory process.

The patients were selected from those referred to the Hospital of Lithuanian University of Health Sciences, Kaunas, Lithuania, for endodontic therapy over a 9-month period extending from January to September 2017. All patients who met the inclusion criteria were invited to participate in the study. The inclusion/exclusion criteria are listed in Table 1. All patients received oral and written information about the study and signed an informed consent form.

A pilot study with 13 patients was performed in order to determine the sample size. The protocol of the pilot study was the same as that of the main study. The sample size was calculated based on a type I error of 0.05 and a power of 80%. The least mean difference between the groups was considered 1. The standard deviation obtained from the pilot study was 2.5. Thus, the calculated sample size was 50 patients. Assuming possible loss to follow-up, 61 patients were included in the study.

Treatment Protocol

The treatment was performed at the Clinic of Dental and Oral Pathology, Hospital of Lithuanian University of Health Sciences by 2 experienced endodontists. Each root canal was retreated in 1 visit in order to minimize the number of procedures and the potential effect of intracanal medication. Treatment of the second root canal was scheduled no earlier than 1 week after the first treatment session. No local anesthesia was applied during the treatment. The entire procedure was performed under an operating microscope (OPMI Pico; Carl Zeiss, Gottingen, Germany) and rubber dam (Hygenic, Akron, OH) isolation. An old root canal filling material was removed with ProTaper Universal retreatment files (Dentsply Maillefer) and/or using Sonofile K-file tips #25 (Satelec Acteon, Merignac Cedex, France) mounted in a P5 Booster ultrasonic scaler (Satelec Acteon) device. No chemical solvent was used. The WL was established by #10 or larger K-files (Dentsply Maillefer) and a Root ZX II apex locator (J Morita, Kyoto, Japan) and confirmed on the x-ray. A glide path was created using Pathfiles (Dentsply Maillefer). The root canals were shaped using the ProTaper Gold system (Dentsply Maillefer). All rotary files were driven by an X-Smart endodontic motor (Dentsply Maillefer). The WL was verified by the apex locator after each instrument to avoid overinstrumentation. The canals were irrigated with 2 mL 2% sodium hypochlorite (NaOCl) (Cerkamed, Stalowa Wola, Poland) using Appli-Vac 27-G tips (Inter-Med, Racine, WI) after each file. The size of the master apical file varied from F2 to F5 according to the size of the apical foramen. Final irrigation was performed with ultrasonic activation for 30 seconds with each solution (ie, 2.0 mL NaOCl, 2.0 mL 17% EDTA [Cerkamed], and 2.0 mL NaOCl per canal).

Root Canal Obturation

For every patient, the root canal of 1 tooth was obturated with an epoxy resin–based sealer (AH Plus) and a gutta-percha point (Dentsply Maillefer). The root canal of another tooth was obturated with bioceramic Total Fill sealer and a Total Fill BC point (FKG Dentaire SA). The choice of the material was randomly made by the dental assistant using a coin toss. The patient was blinded to treatment allocation. Blinding of the operator was impossible because of the different appearances of the obturation materials.

The root canal sealer was prepared according to the manufacturer's instructions. After drying with paper points, a small amount of the sealer was introduced into the canal with a paper point. A gutta-percha point was adapted, and the canal was obturated by a warm vertical condensation technique using the Calamus Dual System (Dentsply Maillefer) in both groups. The depth of the plugger was minus 5 mm from the WL. The temperature of the heated plugger was 180°C and 150°C for the AH Plus and Total Fill groups, respectively, as recommended by the manufacturers. The coronal cavity was sealed with Intermediate Restorative Material (Dentsply Maillefer).

Assessment of Postoperative Pain

The primary study outcome was postoperative pain. Every patient received a visual analog scale (VAS) to record pain intensity at 24 hours, 48 hours, 72 hours, and 7 days after treatment. The VAS consisted of a 100-mm-long line divided into 10 equal intervals from 0 (no pain) to 100 (very severe pain). Every patient was asked to mark his or her perceived postoperative pain level on the line. The distance between "no pain" and the mark defined the subject's pain (13). The patients were contacted at 4 consecutive time points, and the recorded pain scores were collected. VAS was not applied for preoperative pain assessment, assuming that the absence of any clinical symptoms before endodontic retreatment would correspond to a score of 0. The patients were asked to report whether they had taken analgesic medication after treatment.

TABLE 1. Inclusion/Exclusion Criteria of the Study Participants

Inclusion criteria	Exclusion criteria
Patients requiring root canal retreatment of at least 2 teeth	Medically compromised patients (with immunosuppressive/systemic diseases, patients on medications)
Both teeth are single rooted with a single (type I according to Weine) canal	Patients who refuse to participate
Both teeth are diagnosed with asymptomatic apical periodontitis	Symptomatic teeth
The periapical index score is from 2 to 4 according to Orstavik et al (12)	Inability to reach the full working length
Teeth are asymptomatic	Periodontologically compromised teeth (probing depth >4 mm)
	Complications during treatment (separation of a file, ledging, and so on)
	Overfilling (filling beyond the radiographic apex) or short filling (>2 mm from the radiographic apex)