UNIVERSITY OF PENNSYLVANIA

RESEARCH PROTOCOL

Protocol Title:	Postoperative pain after one-visit root canal treatment on teeth with vital pulps: Comparison of two different root filling techniques
Protocol ID:	825494
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Protocol

Objectives

To investigate and compare postoperative pain after one-visit root canal treatment (RCT) on teeth with vital pulps using two different obturation techniques.

Background

In the past, different obturation techniques have been compared. The study listed below compared 2 different techniques with significant findings. The most current technique used, single cone with bioceramic sealer, has not been compared. Our project will compare the postoperative pain of this technique to another common technique used in our clinic. Postoperative pain after one-visit root-canal treatment on teeth with vital pulps: Comparison of three different obturation techniques Med Oral Patol Oral Cir Bucal. 2012 Jul 1;17 (4):e721-7. Luis-O. Alonso-Ezpeleta, Carmen Gasco-Garcia, Lizett Castellanos-Cosano, Jenifer Martín-González, Francsico-J. López-Frías, Juan-J. Segura-Egea

Study Design and Ethics

This prospective clinical trial was reviewed and approved by the institutional review board (Protocol ID: 827968). Our study will be a non-randomized clinical trial. Patients will sign a dental consent for prior to treatment. Patients participation in the study is voluntary. We will perform our normal diagnostic tests to determine the need for root canal treatment and the vitality of the tooth. Only vital teeth will be included in this study. Once we have determined need for root canal therapy, we will determine if it can be done in one visit. One month we will use the warm vertical/AH+ sealer, the next month will use single cone/ bioceramic sealer to obturate these teeth. Patients will be asked to complete a pain scale questionnaire before treatment and at 4, 24, and 48 hours after completion of treatment. Patient's names, insurance, and medical information will not appear on the forms, only a chart number. The patients will receive a pre-stamped, pre-addressed envelope to return the surveys. The sample size was calculated based on a type I error of 0.05 and the power of 80%. The minimum sample size was determined to be 50 patients in each group. We will increase the number to compensate the possibility of losing follw-up (Graunaite et al., 2018).

Study duration

The subjects were recruited for the study from November 2016 to May 2018 during the planned eighteen-month period at the Department of Endodontics.

Subject enrollment and inclusion/exclusion criteria

The study was performed on teeth with vital pulps in patients at least 18 years old. Consecutive patients presenting to the Department of Endodontics for routine root canal treatment were recruited for the study.

Inclusion criteria:

Diagnosis of asymptomatic or symptomatic irreversible pulpitis according to AAE consensus. The diagnosis was based on clinical examinations and confirmed upon accessing the teeth.
Non-contributory medical history (ASA Class I & II)
Consenting adults age 18 years and older
Included patients were given oral and written information agreed for participation and signed the informed consent
Record of detailed clinical examinations, including but not limited to percussion/palpation testing and periodontal probing.

Exclusion criteria:
Non-consenting patients and patients below 18 years of age
Medical history with ASA Class III & IV
Non-restorable teeth
Teeth with a non-vital pulp
Periapical radiolucency showed on the radiographs
Periodontal probing depths were more than 4mm
Pre-medication with antibiotics and/or analgesics 24 hours before the treatment
Patients taking analgesics routinely for non-dental reasons

Treatment Protocol

Patients will present to the endodontic clinic as needed. If a patient is determined to have a diagnosis of irreversible pulpitis, then they will be asked if they would like to participate in the study. If a patient chooses not to participate, they will proceed with their root canal treatment as needed. If a patient agrees to participate, they will be asked to sign a consent form for participation. Patients will be given a questionnaire to complete regarding pain before the procedure. At that point, an endodontic resident will perform the root canal treatment and fill the root canal with one of the two techniques scheduled that month. At the end of treatment, the patient will be given a survey to fill out asked to fill out the survey at 4, 24, and 48 hours after the completion on treatment. The survey will be a pain questionnaire on a Visual Analog scale (see attached) concerning their level of pain following root canal treatment. Patients are typically given a 6 month follow up after root canal treatment, however, there will be no follow up concerning our study.

Statistical Analysis

We compared the VAS scores between the root canal filling techniques using chi-square or two-way ANOVA to explore the differences between the groups. Changes in outcome variables over time were compared by generalised estimating equation (GEE) analysis, which allows for correlation within repeated observations per individual (Liang and Zeger, 1986). Statistical analysis of the data was performed with IBM SPSS Statistics Version 23 (IBM Corp, Armonk, NY). Statistical significance was set at 0.05 level.