Post-operative Pain Following Treatment Using the Gentlewave System
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Research Design

This study was a single-blind, randomized, controlled clinical trial comparing the incidence and severity of postoperative pain and mechanical allodynia following root canal treatment. Based on a similar previous study (81), a sample size of 38 patients (19 per group) was necessary to achieve a power of 80%. Following a standard endodontic cleaning and shaping protocol, the independent variables are (1) conventional side-vented needles for irrigant delivery combined with ultrasonic activation and (2) irrigation using the Gentlewave system. Five 2nd year residents in the Graduate Endodontics division at the University of Minnesota School of Dentistry performed all treatments. The target population of the study included patients of the Graduate Endodontics clinic requiring root canal treatment.

Inclusion criteria were:

(i) Patients who are 18 years of age or older

(ii) Patients with premolar or molar with a pulpal diagnosis of necrotic pulp, symptomatic irreversible pulpitis, asymptomatic irreversible pulpitis and a periapical diagnosis designated as symptomatic including symptomatic apical periodontitis, chronic apical abscess, acute apical abscess requiring root canal therapy.

(iii) teeth with fully formed apices

(iv) teeth without internal or external resorption.

Exclusion criteria were:

(i) patients under the age of 18 or those incapable of giving informed consent

(ii) Patient with premolar or molar with a pulpal diagnosis of normal pulp, previously treated, previously initiated and a periapical diagnosis of asymptomatic apical periodontitis or normal apical tissue requiring root canal therapy.

(iii) teeth with immature apices

(iv) teeth with apices in the maxillary sinus or those teeth where the apical lesion has eroded the bone of the maxillary sinus floor.

(v) teeth with internal or external resorption,

(vi) teeth with carious lesions or deficient crowns that cannot be repaired before accessing the pulp chamber.

Prior to treatment, a diagnostic exam and sensibilty testing were performed. Pain data was collected at the time of presentation by having patients indicate their peak pain or discomfort level at the six-hour mark prior to root canal treatment and symptomatic apical periodontitis was confirmed by using percussion testing and a modified occlusal force meter (Occlusal Force-Meter, GM10, Nagaro Keiki, Tokyo, Japan), as demonstrated by Khan (75). The occlusal force meter numerical reading was recorded at maximal bite force prior to feeling pain on the symptomatic tooth and maximal bite force on the contralateral tooth. Pain measurements were made using a 0-100 NRS. The '0' mark represented 'no pain' and the '100' mark represented 'the worst pain imaginable'. There were 39 additional numeric markings between the '0' and '100' marks that patients could choose, and patients were instructed to write in their pain rating if it was not sufficiently represented on the scale. Along with the numeric scale, the surveys included Wong-Baker FACES as well as verbal markers indicating low, mild, moderate, high, and very high pain. For this study, scores in the very high range were considered severe pain. Scores 0-19 represented low pain, 20-39 was mild pain, 40-59 was moderate pain, 60-79 was high pain, and 80-100 was very high or severe pain.

Patients were divided into one of two treatment groups. Each treatment was scheduled for two appointments regardless of experimental group. For both groups, following confirmation of profound anesthesia, a rubber dam was placed in order to isolate the tooth in treatment. Prior to

accessing the pulp chamber, all caries, defective restorations, and deficient crowns were removed. A pre-endodontic build-up was placed if necessary, to maintain isolation. Straight-line access to the pulp orifices was then achieved. Hand files and an electric apex locator were used to determine the working length which was then verified with a periapical radiograph.

For the control (standard endodontic treatment) group, during the initial appointment the following were accomplished: Clinical exam, pre-endodontic build-up (if necessary), working length determination, all canals were instrumented using hand and rotary files to a minimum size and taper of at least 25/04 to within ½ to 1 mm short of the apical terminus. Between each file, 5.25% NaOCl was used to disinfect the canals and flush debris. Following instrumentation, NaOCl was ultrasonically activated for 30 seconds in each canal. Canals were then dried; UltraCal XS (Ultradent Products, Inc., South Jordan, UT) was placed into each canal measured 2mm short of working length. A spacer of either sterile cotton pellet or sterile sponge were placed followed by an interim restoration of either Cavit or Glass ionomer to a minimum thickness of 3.5mm.

In the experimental group during the initial appointment the following were accomplished: Clinical exam, pre-endodontic build-up (if necessary), working length determination, all canals were instrumented using hand and rotary files to a maximum size and taper of 20/07 to 1 mm short of the apical terminus. Between each file, 5.25% NaOCl was used to disinfect the canals and flush debris. Following instrumentation of the canals, Kool-dam heatless liquid dam was used to build an occlusal platform that functioned to support the GWS handpiece and seal the access opening during treatment. For molars, included gauges were used to determine the proper handpiece attachment. The GWS handpiece was positioned on the tooth for the entirety of the GWS treatment, which varied in length of time depending on the pulpal diagnosis of the tooth. The canals were then dried using paper points and UltraCal XS (Ultradent Products, Inc., South

Jordan, UT) was placed into each canal measured 2mm short of working length. A spacer of either sterile cotton pellet or sterile sponge were placed followed by an interim restoration of either Cavit or Glass ionomer to a minimum thickness of 3.5mm. Once the temporary restoration was completed, patients were given the same 0-100 NRS pain assessment to take home and were asked to record their level of pain at 6, 24, 72, and 168 hours post-treatment. In order to control any pain that may have been unbearable, patients were educated on the ibuprofen and acetaminophen regimen introduced by Menhinick et al 2004 (92) and instructed to record how much was taken.

Patients then returned for a second appointment 2-4 weeks after the initial visit. Pain data was collected at the time of presentation by having patients indicate their peak pain or discomfort level at the six-hour mark prior to the appointment. The occlusal force meter numerical reading was recorded at maximal bite force prior to feeling pain on the symptomatic tooth and maximal bite force on the contralateral tooth. Pain measurements were made using a 0-100 NRS-41. Patients were anesthetized, teeth isolated with rubber dam, access was re-established by removing the interim restorative material and intracanal medicament. The appropriate final canal size was determined by the treating clinician and between each file, 5.25% NaOCl was used to continue to disinfect the canals and flush debris. Following instrumentation, NaOCl was ultrasonically activated for 30 seconds in each canal, each canal was then flushed with 17% EDTA for 1 minute followed by a rinse of 5.25% NaOCl. A final rinse of 95% ethanol was used for all sealers except for those made of bioceramic materials. Canals were then dried and filled with gutta-percha and the clinician's sealer of choice. In order to control any pain that may have been unbearable, patients were educated on the ibuprofen and acetaminophen regimen introduced by Menhinick et al 2004 and instructed to record how much was taken.

Statistical Method

NRS pain scores were compared between treatment groups at each post-operation time point (6, 24, 72, 168 hours) using linear mixed-effects models with fixed effects for treatment, time, treatment-by-time interaction, and pre-operation NRS pain score, and a random effect for participant to account for within-participant correlation of longitudinal measurements. Categorical NRS pain scores were compared using mixed-effects logistic regression models with fixed effects for treatment, time, treatment-by-time interaction, and pre-operation NRS pain score category, and a random effect for participant. Mechanical allodynia bite force was compared between treatment groups using the two sample t-test. Mechanical allodynia bite force was compared between treated and control teeth within each treatment group, and between visit 1 and visit 2 in treated teeth within each treatment group, using the paired t-test. Age category, sex, pulpal diagnosis, tooth type, and visit 2 NRS pain category were compared between groups using the chi-square test for association. Continuous measures are summarized using means with 95% confidence intervals. Categorical measures are summarized using rates. Analyses were conducted using R version 4.0.3.