Postoperative Pain and Healing in Teeth Treated With GentleWave or EndoActivator

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Pain Assessment Protocol

This study protocol was approved by the Institutional Review Board of Saint Louis University, Saint Louis, MO (Protocol Number 31359). Patients were recruited for this study from the patients seen at the Center for Advanced Dental Education at Saint Louis University from September 2020 through March 2022. Informed consent was obtained from each patient for participation in this study. The following inclusion criteria were utilized for participation in the study: adults fully able to provide informed consent, with restorable, symptomatic molar teeth (reporting ≥20mm on the VAS during the previous 24 hours) seeking endodontic therapy. Patients where both Ibuprofen and Acetaminophen were contraindicated, patients with chronic pain issues for which they regularly need to consume analgesics, and patients having taken analgesics or antibiotics within the previous 6 hours were excluded from this study.

The first patient treated in the study was randomized by coin toss, followed by an alternating pattern thereafter for the 2 groups: GentleWave (GWS) (n=16) or EndoActivator (EA) (n=17). Prior to their clinical evaluation, the patients marked on: 1) a 100mm VAS instrument where they felt best represented their degree of pain experienced at that moment, and 2) a 2nd 100mm VAS instrument their maximum level of pain during the previous 24 hours. Clinical evaluation of the patient included percussion and palpation testing, periodontal probing measurements, thermal pulp sensibility testing using a cold source (Endo Ice), and an evaluation of tooth mobility. Radiographic examination (XDR Radiology, Los Angeles, CA) included bitewing, straight-on periapical, angled periapical, and 4X4 cm high-resolution limited field of view cone beam computed tomography (CBCT) (Carestream 9600-Carestream Dental, Atlanta, GA) imaging.

Following the administration of topical anesthetic (20% Benzocaine), the same high-level of anesthetic was administered to all patients, in order to standardize the number of injections received by the participants. If supplemental anesthesia was required, intrapulpal injections were performed for vital teeth and periodontal ligament injections were performed for necrotic teeth.

Rubber dam isolation and the surgical operating microscope were used throughout the treatment procedure. All deficient existing restorations and caries were removed. If inadequate isolation existed to perform the root canal treatment within an isolated environment, SoundSeal (Sonendo Inc., Laguna Hills, CA), a light-cured composite resin, was used to facilitate proper isolation[1].

Canal patency was achieved, and working length (WL) was determined using a #10 C-file and Root ZX II electronic apex locator (EAL) (J. Morita USA, Irvine, CA). WL was defined as being 1mm short of full tone on the EAL for patients in the GWS group (per the recommended Sonendo protocol)[2] and 0.5mm short of full tone on the EAL for the EA group. All canals were instrumented to a size #20/.06 Vortex Blue nickel titanium rotary file (DENTSPLY Tulsa Dental Specialties, Tulsa, OK). 5.25% sodium hypochlorite (NaOCl) was administered using a 30-gauge, side-vented needle (ProRinse Probes-DENTSPLY Tulsa Dental Specialties, Tulsa, OK) with each successive file placed into the canal.

For the GWS group, 70% isopropyl alcohol placed on a dry cotton pellet was used to clean and dry the tooth. After having created a suitable platform using SoundSeal, the choice of

GWS cycle was determined according to the clinical situation and the corresponding manufacturer-recommended protocol [3] (Fig 1).

Fig 1. GentleWave System Cycles

Case Type	3% NaOCl	Distilled Water	8% EDTA	Distilled Water
Necrotic	4 Minutes	30 Seconds	1.5 Minutes	15 Seconds
Vital	5 Minutes	30 Seconds	2 Minutes	15 Seconds
Extended	5 Minutes	30 Seconds	2 Minutes	15 Seconds
Low	**0.5% NaOCl**	**Distilled Water**	**8% EDTA**	**Distilled Water**
	8 Minutes	30 Seconds	2 Minutes	15 Seconds

Settings were chosen based off of the proximity of root apices to vital structures such as the inferior alveolar nerve or maxillary sinus: 'Extended'>2mm, 'Necrotic' or 'Vital' 1-2mm, 'Low'<1mm

After completion of the preprogrammed GWS cycle, the canals were flushed with saline. For obturation, gutta-percha cones were selected that would extend 0.5mm beyond the end point of mechanical instrumentation, in order to facilitate obturation 0.5mm short of full tone on the EAL. The canals were dried using sterile paper points. Hi Flo BC Sealer (Brasseler USA, Savannah, Georgia) was expressed directly into the canal. Cones were placed, and seared off at the opening of each canal orifice using a heated System B unit (SybronEndo, Glendora, CA). The chamber was cleaned of excess sealer using a cotton pellet moistened with water, then rinsed and air dried with an air/water syringe. A sterile sponge was placed on the chamber floor, and the access opening was temporized with Cavit (3M ESPE, Neuss, Germany). Straight-on and angled periapical radiographs were exposed postoperatively.

For the EA group, instrumentation was performed as described above, but to 0.5mm short of full tone on the EAL, and the canals and chambers were flooded with 5.25% NaOCl. The

small EA tip (ISO 15/.02) was placed 2mm short of WL and activated vertically, in 2-3mm strokes for 30 seconds within each canal, as per the manufacturer's directions [4]. The canals were subsequently flushed with fresh 5.25% NaOCl and then the irrigant was reactivated with the EndoActivator for an additional 30 seconds within each canal. Fresh sodium hypochlorite was again applied, and then removed by retracting the plunger on the syringe. A total of five milliliters of 5.25% NaOCl was used to irrigate each tooth during each procedure for patients within the EA Group. All canals were then irrigated with 3 milliliters of 17% EDTA using a 30-gauge, side-vented needle for a total of 1 minute. Canals and chamber were once again evacuated by retracting the plunger on the syringe and then a final flush with 3mL of saline was delivered using a 30-gauge side-vented needle. Canals were then dried with sterile paper points. The same single-cone obturation technique was used as for the GWS group.

Prior to leaving the clinic, the patient was provided an 8.5X11 inch, pre-stamped envelope containing 4 blank VAS forms to be filled out by the patient at 24 hours, 48 hours, 72 hours, and 96 hours postoperatively, as well as 4-days' worth of Ibuprofen (600mg Ibuprofen X 16 tablets) (Ascend Laboratories, LLC, Parsippany, NJ) and Acetaminophen (650mg Acetaminophen X 16 tablets) (Perrigo, Allegan, MI). The printed patient instructions were to take 1 tablet of Ibuprofen every 6 hours as needed for pain. If the Ibuprofen did not provide adequate pain relief, then the patient was instructed to also take 1 tablet of Acetaminophen every 6 hours as needed for pain. If the patient maximized the Ibuprofen and Acetaminophen intake and still required additional pain relief, then patient was instructed to call the clinic and a prescription would be provided for Tramadol 50mg X 12 tabs, to be taken every 6 hours as needed for pain. The patients were provided with a Pain Pill Log to record what analgesics were

taken at what times. After ninety-six hours postoperatively, patients were instructed to mail, or physically return, back to the clinic the large envelope with the 4 completed VAS forms, the Pain Pill Log, as well as any unused analgesics. Patients who properly returned all of the requested paperwork were compensated with a $75 Visa gift card.

Pain Assessment Statistical Analysis

Data was compiled and analyzed by a biostatistician at two different time periods. Therefore, participants that were seen between 09/2020-06/2021 were analyzed separately from those seen between 07/2021-03/2022. Data points for pain assessment and analgesic intake were plotted for visualization. A Shapiro-Wilk test of normality indicated a non-normal distribution of the pain data. Due to the skewness observed, a non-parametric analysis was utilized.

The level of pain recorded from each postoperative VAS was compared to the patient's preoperative VAS score to determine if their pain level had increased or decreased. A two-sided Fischer's Exact Test for Count Data was then used to determine whether postoperative pain decreased relative to preoperative pain scores more often in one group as compared to the other group.

Results were considered significant if the $p \leq .05$.

CBCT Healing Assessment and statistical analysis

Patients (GWS=12, EA=14), were recalled at 12 months postoperative, and the same imaging and clinical endodontic testing was done as had been performed preoperatively. A 3-D volumetric analysis using ITK Snap software (ITK SNAP, Philadelphia, PA) was completed

to measure the volume of pre-and-post-operative periapical findings in mm^3. Each individual root was then assigned a 3Droot classification of either healed (normal PDL around the root at recall), healing (reduced size of finding), or diseased (same or larger size finding). Pearson's Chi squared test was used to evaluate if there was any difference in 3Droot healing outcomes between the GWS and EA groups. Results were considered significant if the $p \leq .05$.

Clinical tooth healing classification based on clinical examination and patient report (Ctooth)

Teeth were classified as being clinically successful if the patient had no symptoms other than mild tenderness to percussion. Teeth were not considered as failures due to mild percussion sensitivity alone, as long as the patient reported no pain when chewing.

Pearson's Chi squared test was used to evaluate if there was any difference in Ctooth healing outcomes between the GWS and EA groups. Results were considered significant if the $p \leq .05$.

References

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2. Inc. S. The GentleWave System Training Manual. 2020.

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