Postoperative Pain after the Application of Two Different Irrigation Devices in a Prospective Randomized Clinical Trial

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Abstract

Introduction: The extrusion of irrigation solutions beyond the apical constriction may result in postoperative pain. Sodium hypochlorite can cause severe tissue irritation and necrosis outside the root canal system if extruded into the periodontal ligament (PDL) space. Different delivery techniques were discussed to reduce this potential risk. The aim of this study was to compare the postoperative level of pain after root canal therapy using either endodontic needle irrigation or a negative apical pressure device. **Material and Methods:** In a prospective randomized clinical trial, 110 asymptomatic single-rooted anterior and premolar teeth were treated endodontically with two different irrigation techniques. The teeth were randomly assigned to two groups. In the MP group (n = 55), procedures were performed using an endodontic irrigating syringe (Max-i-Probe; Dentsply Rinn, Elgin, IL). The EV group (n = 55) used an irrigation device based on negative apical pressure (EndoVac; Discus Dental, Culver City, CA). Postoperatively, the patients were prescribed ibuprofen 200 mg to take every 8 hours if required. Pain levels were assessed by an analog scale questionnaire after 4, 24, and 48 hours. The amount of ibuprofen taken was recorded at the same time intervals. **Results:** During the 0- to 4-, 4- to 24-, and 24- to 48-hour intervals after treatment, the pain experience with the negative apical pressure device was significantly lower than when using the needle irrigation ($p < 0.0001$ [4, 24, 48 hours]). Between 0 and 4 and 4 and 24 hours, the intake of analgesics was significantly lower in the group treated by the negative apical pressure device ($p < 0.0001$ [0-4 hours], $p = 0.001$ [4-24 hours]). The difference for the 24- to 48-hour period was not statistically different ($p = 0.08$). The Pearson correlation coefficient revealed a strongly positive and significant relationship for the MP group ($r = 0.851$, $p < 0.001$) and the EV group ($r = 0.596$, $p < 0.0001$) between pain intensity and the amount of analgesics. **Conclusion:** The outcome of this investigation indicates that the use of a negative apical pressure irrigation device can result in a significant reduction of postoperative pain levels in comparison to conventional needle irrigation. *(J Endod 2010;36:1295–1301)*

Key Words

EndoVac, irrigation, negative apical pressure, postoperative pain

Postoperative pain is an unwanted yet unfortunately common sensation after endodontic treatment. The incidence of postoperative pain was reported to range from 3% to 58% (1). Even severe pain may occur within 24 to 48 hours after therapy (2). After the treatment was finished, 12% of patients experienced severe pain within this time interval according to a visual analog scale (VAS) (2). The factors for postoperative pain are many-fold and can include microbial factors, the effects of chemical mediators, phenomena related to the immune system, cyclic nucleotide changes, psychological factors, and changes in the local adaptation and the periapical tissue pressure (3). Irritants to the periapical tissues that can evoke pain sensation include medications or irrigating solutions (3).

Antimicrobial debridement is a key step in root canal therapy. Bacteria play a primary role in the development of pulp necrosis, periapical pathosis, and posttreatment disease (4). Mechanical instrumentation alone is not enough to render canals free from microorganisms (5). Several studies have proven the effectiveness of sodium hypochlorite for bacterial reduction in addition to mechanical cleaning and shaping (6). Other irrigants with similar antimicrobial effects include chlorhexidine (7) and MTAD (8). Only sodium hypochlorite, however, has also proven highly effective in tissue dissolution (9) and the removal of bacterial biofilm (10). Because tissue dissolution is a prerequisite for antimicrobial action (11), sodium hypochlorite is considered the most important antimicrobial irrigant in root canal therapy (9). Sodium hypochlorite works because of its ability to hydrolyze and oxidize cell proteins, its release of free chlorine, and its pH of 11 to 12 (7).

Because of the strong cell toxicity, an associated risk with the use of sodium hypochlorite is the inadvertent injection into the periapical tissues through the apical constriction of the root canal, leading to severe, painful postoperative complications. Sodium hypochlorite accidents have been reported in the literature (12). Teeth with wide open foramina or with apical constrictions damaged by resorptive processes or by iatrogenic errors during instrumentation are at an elevated risk for the extrusion of sodium hypochlorite (13). Moreover, if excessive pressure is used during irrigation or the irrigation needle is bound within the root canal and prevents the safe coronal outflow of the solution, large quantities of sodium hypochlorite may be pushed out into the periapical tissues and subsequently lead to tissue necrosis and postoperative pain (13). This causes a dilemma because it is known that a high volume and frequency

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of irrigation (14) as well as the ability to reach the apical intraradicular tissues (15) are necessary for effective disinfection.

To prevent periapical tissue damage and lessen postoperative pain, a safe irrigation delivery system is desirable. Commonly, hypodermic or endodontic needles are used for irrigation. Recently, a new irrigation system, the EndoVac system (Discus Dental, Culver City, CA), was introduced to endodontics. Conventional irrigation works with positive pressure to flush the disinfecting solution into the root canal and force the irrigant out again coronally by displacement with new volumes of solution. The EndoVac system works with negative pressure. A detailed design and working mechanism have been described before (16). Briefly, an irrigation tip is attached to a conventional medical syringe containing the solution. Through this tip, irrigant is released into the pulp chamber. Overflow is prevented by a suction tip that is directly attached to the delivery tip and connects to the high-speed suction of the dental unit. A second tube, connected to the high-speed suction, is used for the attachment of cannulas of varying diameter for different levels of irrigation within the root canal. A stainless steel microcannula of size #32 with 12 small, lateral holes is used for the apical 0 to 3 mm. The tip is inserted to the working length and provides a constant flow of new irrigation solution to the apical third by sucking it apically from the fresh reservoir in the pulp chamber and disposing the used solution through the evacuation tube toward the high-speed suction of the dental unit.

In three recent *in vitro* studies, the EndoVac system showed significantly better apical debridement (17) and an equal performance in antimicrobial disinfection (18, 19) in single straight canals when compared with other irrigation techniques. Yet, no literature exists claiming whether the irrigation with a negative apical pressure device provides more or less favorable results in terms of postoperative pain when compared with positive-pressure irrigation protocols. The purpose of this study was to evaluate and compare the postoperative pain after the use of two different irrigation protocols.

Materials and Methods

In this prospective randomized clinical trial, single-visit root canal treatments were performed. A questionnaire was given to the participants to note the amount of analgesics taken postoperatively as well as the intensity of pain. A pain scale frequently used for medical studies, the CR10 Borg list (20), was implemented to quantify the participants' individual pain experience.

Patient Selection

Eighty volunteer patients with 110 teeth fitting the inclusion criteria described later were included in this study. All patients were treated by a single operator in a private practice specializing in endodontics over a period of 25 months. Only single-rooted teeth with one canal were selected for this investigation. Diagnoses were either asymptomatic irreversible pulpitis caused by carious exposures or normal pulp if the patient had been referred for intentional endodontic therapy for prosthetic reasons. The individual diagnosis was confirmed by obtaining the dental history, periradicular radiographs, periodontal evaluation, percussion, and cold test (EndoIce; Coltène/Whaledent Inc, Cuyahoga Falls, OH). The diagnostic findings were verified by comparing them with adjacent sound teeth with vital pulps. Only patients who had a noncontributory medical history and did not take analgesic medication at the initiation of the root canal treatment were asked to participate in the study. The treatment and the study design were explained to the qualifying patients. Patients were informed that participation was voluntary and did not affect the treatment. All patients who agreed to participate in this study signed an informed consent. Although the patients were informed which irrigation devices were used in general, there was no information for the participant which system was used for the particular treatment.

Randomized Selection of Irrigation Device

The goal of the study was 100 patients, with at least 50 procedures in each group. In order to compensate for a possible dropout rate of 10%, the prospective sample size for each group was set at 55. To ensure randomization of the process, 55 red and 55 green chips were placed in a bag at the beginning of the investigation. Before each treatment, a dental assistant of the operator randomly determined the irrigation device by taking out one of the colored chips without replacement until all 110 procedures had been performed. The assistant could not see the color of the chip before it was removed from the bag. Group MP (red) was assigned for treatment with a conventional endodontic needle syringe (Max-i-Probe 30G; Dentsply Rinn, Elgin, IL). Group EV (green) received treatment with the negative-pressure device (EndoVac).

Endodontic Protocol

All patients received a topical anesthetic (Benzotop; DFL, Rio de Janeiro, Brazil) before infiltration. Local anesthesia was achieved by local infiltration with 3.6 mL of lidocaine with 1:100,000 epinephrine (Alphacaine, DFL). After anesthesia, a rubber dam was placed and disinfected with 3% hydrogen peroxide, and the tooth was accessed using sterile carbide burs under a dental operating microscope. In cases with deep carious lesions, the main decay was excavated before accessing the pulp to prevent the introduction of microorganisms into the root canal system. A glide path was established with stainless steel hand instruments up to a size #15. The canal was instrumented with Gates Glidden burs #4, #3, and #2 (Dentsply Maillefer, Ballaigues, Switzerland) followed by nickel-titanium rotary instruments (ProTaper; Dentsply Tulsa, Johnson City, TN). Patency was established and verified with #10 files. The working length to the apical constriction was confirmed by an electronic apex locator (Root ZX; Morita, Irvine, CA) and periapical radiographs. The established working length was checked repeatedly throughout the procedure. Depending on the individual tooth, the final instrumentation size was determined as three sizes larger than the first file binding at the working length. Final preparation ended either with ProTaper F3, F4, F5, or F5 plus additional apical enlargement with nickel-titanium hand instruments to size #60. A smaller taper #35 ISO nickel-titanium hand instrument was used for the F3 preparations in group EV to verify free access to the full working length for the microcannula. All teeth were obturated in the same session using gutta-percha with warm vertical compaction in the continuous wave technique (System B; Sybron Endo, Orange, CA) and a gutta-percha backfill (Obtura II; Obtura Spartan, Earth City, MO). Depending on whether a post placement was planned by the referring dentist, the tooth was either temporized using a sterile cotton pellet and Cavit (3M, St Paul, MN) or a direct adhesive buildup with a composite resin material (P60 Singlebond, 3M). After the treatment, all patients received postoperative instructions and eight tablets of ibuprofen 200 mg with the instructions to take only one tablet if it was needed within the 0- to 4-hour time interval after the treatment and then one every 8 hours in the event of pain.

Irrigation Protocols

All teeth received the same volume of irrigants. Altogether, 130 mL 2.5% sodium hypochlorite (Formula & Acao, Sao Paulo, Brazil) and 10 mL EDTA 17% (Formula & Acaol) were used. For both groups, the sodium hypochlorite was held in and dispensed from a mechanical syringe pump (Aladdin Pump; World Precision Instruments, Sarasota, FL) providing a constant flow. Twenty milliliters of sodium hypochlorite