Assessment of apical extrusion of irrigation in mandibular molars during application of the novel Gentle Wave system in a simulated environment

by

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A thesis submitted in conformity with the requirements for the degree of Master of Sciences
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Abstract
This study assessed apical extrusion during treatment with GentleWaveTM (GW), conventional open-ended 30G needle (CN) or EndoVac® (EV) in root canals enlarged to different dimensions with and without apical constriction. No extrusion occurred with GW and EV, while frequency of extrusion with CN was 33%. Mean extruded water mass using CN ranged in mesial canals from 0.000±0.000 g (O1) to 0.047±0.098 g (M1) and in distal canals from 0.123±0.191 g (M1) to 0.505±0.490 g (O1). With TI and OI instrumentation, extruded mass in distal canals was significantly higher than in mesial canals (p<0.002) and than in distal canals with MI (p<0.020). Within this study's limitations, root canal treatment with GentleWaveTM and irrigation with EndoVac® was not associated with extrusion.
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**Introduction**

1. **Apical periodontitis**

1.1. **Apical periodontitis: a disease of biofilm origin**

Periapical tissues consist of cementum, periodontal ligament and alveolar bone. The response of the periapical tissues to various injuries is manifested as an immune-inflammatory reaction resulting in apical periodontitis (AP) (1). AP has been proven to be of bacterial origin and strongly associated with bacterial biofilms (2–4). AP is a tangible manifestation of the incapacity of the immune response to control the irritation caused by root canal’s microbes. Infected root canal counts of between 10^3 and 10^8 bacteria of different species often agglomerate into a biofilm. A biofilm is a well-organized micro-community of mono or multiple bacterial species embedded in a self-produced matrix of extracellular polymeric substance (EPS) and attached to a surface. Within the biofilm, microorganisms are more resistant to their eradication compared to their planktonic form (5). AP is the inflammation and destruction of the periapical tissues that is of pulpal origin. Radiographically it is manifest as periapical radiolucency. Although the microbial infection of the pulp is the primary cause of AP, the pathologic changes are not directly associated with the bacteria themselves but rather with their toxins, metabolic by-products and necrotic pulp remnants (1). The initiation of AP is mainly caused by bacterial lipopolysaccharides (LPS) and other microbial toxins released during bacterial cell growth and death entering into the periapex. Those irritants are capable of inducing an innate and
adaptive immune response. When entering the periapical tissues, pathogen-associated molecular patterns (PAMPs) found on pathogens such as LPS, a bacterial toxin, activate the innate immune system. PAMPs are recognized by different pattern recognition receptors (PRRs) or toll like receptors (TLRs) on host cells such as phagocytes, dendritic cells and B lymphocytes. Once activated, these local cells increase the permeability of the blood vessel, induce vasodilatation and activate cytokine production, including RANKL, IL-1, IL-6, TNF-α, and PGE2, and consequently promote osteoclastogenesis and bone loss (6).

Periapical inflammation is a direct result of interactions between the bacteria in an untreated infected root canal system and the host’s defense or immune system (7). It begins as an acute inflammatory response but it is a dynamic situation that can change spontaneously throughout the disease process. As there is no longer any blood supply to a necrotic pulp or into the root canal system in a pulpless tooth, the host’s defense cells can not reach the source of the irritation (i.e., the bacteria in the canal) and therefore the body is unable to eliminate the infection. Hence, a chronic inflammatory response develops in the periapical region and the intra-canal bacteria survive with nutrients being obtained from tissue fluid and inflammatory exudate that seep in to the root canal system through the apical foramen (8). Saliva and food substances may also penetrate through the original pathway of entry of the bacteria (i.e. caries, cracks or broken-down restoration margins) to help supply nutritional elements for the organisms. Once an infection is established within the root canal system, the bacterial numbers will gradually increase through normal cell reproduction and proliferation mechanisms (8). To eliminate the infection, proper debridement of the root canal system has to be performed.
1.2. Treatment of apical periodontitis

To eliminate bacteria and their toxic metabolites from the root canal system and to prevent their diffusion into the periapical tissues, which may cause bone destruction and AP, endodontic treatment is indicated. The primary goal of endodontic treatment is to prevent or to treat AP. The endodontic treatment of a tooth with irreversible pulp inflammation aims to prevent infection from developing in the periapical tissue, as the apical third is generally free of bacteria (9). In the presence of a necrotic infected pulp or a previously treated root canal with persistent or recurrent infection, AP has likely developed. Achieving adequate debridement of the necrotic pulp tissue and bacterial elimination are critical procedural goals when treating infected root canals. The reduction of the bacterial load to a number below the threshold necessary to sustain AP is correlated with a favourable outcome (9,10). Sjögren et al. (10) demonstrated that the bacteria remaining in the root canal will influence the endodontic outcome of teeth with AP. Periapical healing was observed five years after the completion of the treatment and healing occurred in 94% of teeth with no-growth cultures compared to 68% for teeth with positive cultures prior to root filling. Because culturing procedures have their limitations, a no-growth culture is not a confirmation of complete disinfection. It can be associated with improved prognosis relative to teeth with a positive culture (11). Therefore, bacterial reduction in the root canal system to the extent of achieving a no-growth culture should be a clinical goal to significantly improve the potential for healing of the periapical tissues. The biomechanical preparation of the root canal system is the primary manner used by clinicians in
attempting to eradicate bacteria, debris, vital and necrotic tissues from the root canal system (12).

1.3. Mechanical instrumentation

Endodontic mechanical instrumentation includes different endodontic hand files, rotary files, reamers and broaches that clinicians utilize according to their preference to achieve the following goals:

- Removal of vital and necrotic tissue from the main root canal(s).
- Creation of sufficient space for irrigation and medication.
- Preservation of the integrity and location of the apical canal anatomy.
- Avoidance of iatrogenic damage to the canal system and root structure.
- Facilitation of canal filling.
- Avoidance of further irritation and/or infection of the periapical tissues.
- Preservation of sound root dentine to allow long-term function of the tooth. (12)

Byström et al. (13), demonstrated that mechanical instrumentation alone is not sufficient to predictably reduce the level of bacteria, while mechanical instrumentation combined with antibacterial irrigation is. The disinfection improves when mechanical instrumentation is coupled with antibacterial irrigation. In addition, mechanical debridement leaves at least 35% of the canals walls untouched (14). Hence, cleaning of the canal in terms of soft tissue removal and elimination of bacteria relies heavily on the adjunctive action of chemically active irrigating solutions and is crucial in terms of reaching those untreated areas.
2. Irrigation

Mechanical instrumentation coupled with irrigation of the root canal with sodium hypochlorite (NaOCl) appreciably reduces the bacteria load in the root canal (13). A reduction has been reported in the proportion of positive bacterial cultures of between 11% and 53% and a bacterial count from an initial order of $10^3$ to $10^7$ to a level of $10^2$ to $10^6$ (15). The intricate nature of the root canal anatomy complicates the ability of endodontic instrumentation to substantially remove biofilms (16). Micro computed tomography (17,18) and tooth decalcification anatomic studies (19,20) reveal root canal systems that are complex with multiple isthmuses and an abundant number of lateral and accessory canals creating pathways to the periapical tissues. This complex root canal system is unreachable with mechanical instrumentation and requires irrigation to be properly disinfected. There are five well established aims of root canal irrigation (21):

1) To deliver irrigation throughout the entire length of the root canal so as to be in direct contact with debris and bacteria.

2) To provide lubrication for instrumentation.

3) To maintain a high concentration of the active component(s) by frequent refreshing.

4) To create wall shear stress in order to disrupt biofilm.

5) To prevent apical extrusion (irrigation should be restricted to within the root canal).

Irrigation is defined as the action of washing an organ or wound with the continuous flow of water or medication. In endodontics, it represents chemical debridement of the root canal
system. Several solutions are available to achieve this aim. The desired characteristics of an irrigation solution are as follows: effective germicide and fungicide, non-irritating to periapical tissues, stable in solution, prolonged antimicrobial effect, active in the presence of blood, serum and protein derivatives of tissue, low surface tension, non-detrimental to repair of periapical tissues, non-staining of tooth structure, possible to inactivate in a culture medium, non-inducing a cell-mediated immune response, able to completely remove the smear layer, able to disinfect the underlying dentin and its tubules, non-antigenic, non-toxic, and non-carcinogenic to tissue cells surrounding the tooth, no adverse effects on the physical properties of exposed dentin, no adverse effects on the sealing ability of filling materials, conveniently applied and relatively inexpensive (1).

2.1. Sodium hypochlorite

Currently, the irrigation solution of choice is sodium hypochlorite (NaOCl). It has excellent antibacterial properties and the capacity to dissolve organic tissue. However, it is very cytotoxic to the periapical tissues (22).

NaOCl was developed in France around 1789 and labelled as “Eau de Javel”. At first, it was used as a bleaching agent for cotton but eventually its antiseptic properties were recognized. Dakin recommended NaOCl as an antiseptic agent in hospitals and as a rinse to treat the wounds of the soldiers during the first world war (23).

The manufacture of NaOCl requires several steps. In the process, sodium hypochlorite
(NaOCl) and sodium chloride (NaCl) are formed when chlorine is passed into cold and dilute sodium hydroxide solution. It is prepared industrially by electrolysis with minimal separation between the anode and the cathode. The solution must be kept below 40 °C to prevent the undesired formation of sodium chlorate.

\[ \text{Cl}_2 + 2 \text{NaOH} \rightarrow \text{NaCl} + \text{NaOCl} + \text{H}_2\text{O} \]

Hence, chlorine is simultaneously reduced and oxidized; this process is known as disproportionation. Commercial solutions always contain significant amounts of sodium chloride (common salt) as the main by-product, as seen in the equation above. Sodium hypochlorite is a clear, slightly yellowish solution with a characteristic odour. It has a relative density of 1.1 g/cm\(^3\) (5.5% aqueous solution). As a bleaching agent for domestic use it usually contains \(\pm 5\%\) sodium hypochlorite with a pH of around 11.

\[ a. \quad \text{Mechanism of action of sodium hypochlorite} \]

Physico-chemical characteristics of NaOCl are important for the explanation of its mechanism of action. The antimicrobial process consists of saponification and enzymatic inactivation. Amino acid neutralization and chloramination reactions occur in the presence of microorganisms and organic tissue lead to the saponification. NaOCl also promotes irreversible inactivation by hydroxyl ions and a chloramination reaction related to bacterial essential enzymatic sites. The antimicrobial mechanism of NaOCl is also enhanced with the high pH of sodium hypochlorite that interferes with the cytoplasmic membrane integrity with an irreversible enzymatic inhibition, biosynthetic alterations in cellular metabolism and phospholipid degradation and lipidic peroxidation. The organic dissolution action can
be observed in the saponification reaction when sodium hypochlorite degrades lipids and fatty acids resulting in the formation soap and glycerol (24).

b. Concentration of sodium hypochlorite

In endodontics, NaOCl is used in concentrations of between 0.5% and 6%. There is considerable variation in the literature regarding the influence of the concentration on the antibacterial effect of NaOCl. Several clinical and laboratory studies have failed to demonstrate any significant difference in antibacterial effect between different NaOCl concentrations after root canal sampling (25). Other studies report considerably longer times for the killing of the same species when a lower concentration is utilized (26,27). Byström and Sundqvist studied the irrigation of root canals that were necrotic and contained a mixture of anaerobic bacteria. These investigators showed that using 0.5% or 5% NaOCl resulted in considerable reduction of bacterial counts in the canal when compared with irrigation with saline (13,28,29). Siqueira and colleagues (25) reported similar results using root canals infected with Enterococcus faecalis. The studies failed to show a significant difference in the antibacterial efficacy between the low and high concentrations of NaOCl (26).

These in vitro studies may not be applicable to the clinical reality where the root canal is partially filled with organic tissue. It has been demonstrated that the presence of organic tissue during the killing experiments has a negative effect on the antibacterial activity of NaOCl. Inflammatory exudate, tissue remnants and microbial biomass consume NaOCl and weaken its effect. NaOCl in higher concentrations have better tissue dissolving ability but
Haapasalo and colleagues (30) showed that the presence of dentin caused marked delay in the killing of *E. faecalis* by 1% NaOCl. To counteract the impact of an environment such as an infected tooth, continuous replenishment of NaOCl and adequate time exposure are recommended. An emphasis is placed on the importance of repeated exchanges of large volumes of irrigation to maintain adequate antibacterial effectiveness, which compensates for a lower concentration (25). Regarding the ability of NaOCl to dislodge biofilm; an in vitro biofilm study (31) demonstrated a significant difference in the effectiveness against biofilm bacteria with 3% and 6% NaOCl, the higher concentration being more effective. Nevertheless, the clinician must keep in mind that a higher concentration is more toxic to the periapical tissue.

c. *Sodium hypochlorite cytotoxicity and related accidents*

In light of the cytotoxicity of the NaOCl, its extrusion from the root canal will affect the periapical tissue and may cause the patient a series of complications of a variable clinical significance, including post-operative pain (32). Although devastating endodontic NaOCl accidents are rare (33), the cytotoxic effects of NaOCl on vital tissue are well established (34). The associated sequelae of NaOCl extrusion have been reported to include life-threatening airway obstructions (35), facial disfigurement requiring multiple corrective surgical procedures (36), permanent paraesthesia with loss of facial muscle control (37) and tooth loss (38).

Although the exact aetiology of a NaOCl accident is still uncertain, based on the evidence from actual accidents and the location of the associated tissue trauma, it would appear that
an intravenous injection might be the main cause. The patient shown in figure 1 (73) demonstrates a widespread area of tissue trauma that is in contrast to the characteristics of NaOCl accident reported by Pashley (34,39). This extensive trauma, particularly involving the pattern of ecchymosis around the eye, could only have occurred if the NaOCl had been introduced intravenously to a vein close to the root apex through which extrusion of the NaOCl occurred and the NaOCl then travelled to the venous complex. This would require positive pressure apically exceeding the venous pressure, for which the mean value is higher than 5.88 mmHg, the central venous pressure (22). In other words, NaOCl extrusion into the venous system is more likely to occur when the apical pressure of irrigation solution is greater than venous pressure or when there is a decrease in the apical resistance (22). Female bone density has a reduced resistance to apical extrusion (40). Moreover, the thickness of the cortical bone is thinner in women than in men (40). This could explain why NaOCl accidents are seen more often in women and maxillary teeth, more specifically the maxillary pre-molars (40). One in vitro study where a positive-pressure needle irrigation technique was used to mimic clinical conditions and techniques, demonstrated that the apical pressure generated easily exceeded the value of central venous pressure (41). The results of this study suggested that a combination of factors was necessary for a severe NaOCl accident to occur. The hypothesis that involves intravenous infusion of extruded NaOCl into the facial vein via non-collapsible venous sinusoids within the cancellous bone has been suggested (12).

This does not imply that NaOCl can or should be excluded as an endodontic solution; in fact, its use is essential to achieve adequate chemical debridement. Therefore it must be
delivered safely. With traditional root canal irrigation, clinicians must be careful when determining how far an irrigation needle is placed into the canal. Recommendations for avoiding NaOCl accidents include not binding the needle in the canal, adequate establishment of the working length, not placing the needle close to working length (WL) (i.e. 1 mm away from WL with a closed-ended needle and 3 mm away from WL with an open-ended needle), and using a gentle flow rate when delivering the solution with a positive pressure device (39).

**d. Sodium hypochlorite accident recognition and management**

When a surprising unfortunate accident happens, the clinician must be prepared to provide the best care to the patient. First, the clinician must be able to recognize that extrusion of sodium hypochlorite has occurred (23). Most of the time, a sharp pain despite the action of the local anaesthetic manifests it. The depolarization of the transient receptor potential vanilloid one (TRPV1) is suggested to cause the sudden painful sensation (42). TRPV1 is a non-selective cation channel that may be activated by a wide variety of exogenous and endogenous physical and chemical stimuli. The activation of TRPV1 leads to a painful, burning sensation. TRPV1 receptors are found mainly in the nociceptive neurons of the peripheral nervous system, but they have also been described in many other tissues, including the central nervous system (42). TRPV1 is involved in the transmission and modulation of pain (nociception). A profuse bleeding from the root canal follows the painful sensation felt by the patient (22). The clinician should reassure the patient, generously flush the root canal with saline and consider a local block with a long-acting local anaesthetic such as Bupivacaine HCl 0.5% with epinephrine 1:200,000. The patient should
be kept under observation for thirty minutes while removing the drainage (blood) with high volume to enhance further drainage. If the tooth drains after 30 min, the clinician should consider leaving it open for twenty-four hours. Amoxicillin 500 mg tid for 5 days is indicated in more severe cases. Other antibiotics can be prescribed if patient has an allergy to penicillin. In all cases, clinicians should prescribe analgesics and patients should be told to apply cold compresses for six hours (43). Some authors (43,44) mention that corticosteroids or anti-histamines would help minimizing the ensuing inflammatory process; therefore, they could be added to the list of prescribed drugs. The clinician should call the patient the night of the accident; the patient should be seen the day after and close follow-up should be maintained until complete resolution of the symptoms. If any kind of paresthesia persists for more than 10 weeks, the patient should be referred to a neurologist or an oral surgeon (43).

2.2. Convention Syringe and Needle for Irrigation

NaOCl is conventionally delivered via a positive-pressure syringe fitted with a needle, a variety of which are available (26). A 5 mL syringe has been recommended as a reasonable compromise between less frequent refilling and ease of use. This size of syringe allows the clinician to keep good control of the plunger and to not constantly having to refill the syringe. A smaller syringe could be responsible of a higher flow rate if the clinician applies the same force than when using a larger size of syringe. The irrigation flow rate is proportional to the pressure difference between the atmospheric pressure and the pressure built within the syringe by the force applied on the plunger. A larger syringe can be tiring as
the amount of force that needs to be applied to create the same flow rate is higher. A syringe of a small size is easier to press than one of a larger size. The needle size also influences the pressure of the delivered irrigation. For the same pressure difference, the flow through a smaller needle will be much less than through a larger needle. In other words, a larger difference is required to achieve the same flow rate through a smaller needle. Most of the time in endodontic treatment, irrigation is delivered with either a 30- or 27-G endodontic slot tipped needle placed into the canal until just short of the binding point. The difficulty with this technique is that the depth of needle penetration is dependent on the size and morphology of each canal.

With the current endodontic protocols, total elimination of the root canal bacteria is unpredictable. Nair et al. (45) looked at the microbial status of the apical root canal system of necrotic, mandibular first molars with apical periodontitis after single-visit endodontic therapy during which NaOCl was delivered using a conventional needle (CN) for irrigation. After removal of the apical root segment and evaluation using correlative light and transmission electron microscopy, they found that 14 of 16 teeth had residual intracanal bacteria (45). They noted that the microbes were located in inaccessible recesses, isthmuses and accessory canals. Even with the use of NaoCl, obtaining predictably root canal cleanliness and no-growth cultures remained unpredictable (46). Several studies (47–49) evaluated the root canal after initial root canal treatment and biofilms were located in areas inaccessible to root canal instrumentation. With bacteria frequently surviving the cleaning and shaping procedure and debris compromising cleanliness, adjuvant techniques
to conventional root canal treatment cleaning protocols may predicate better root canal cleaning and disinfection.

2.3. Vapour lock

In 1971, Senia was the first to describe vapor lock in root canal. Since roots are surrounded by the periodontium, unless the root canal foramen is open, the root canal behaves like a close-ended channel. This produces an apical vapour lock that resists displacement during instrumentation and final irrigation, thus preventing the flow of irrigation solution into the apical region and adequate debridement of the root-canal system (50,51). Apical vapour lock also results in gas entrapment in the apical one third (52). During irrigation, NaOCl reacts with organic tissue in the root-canal system, and the resulting hydrolysis liberates abundant quantities of ammonia and carbon dioxide (53). This gaseous mixture is trapped in the apical region and quickly forms a column of gas into which further fluid penetration is impossible. Extension of instruments into this vapour lock does not reduce or remove the gas bubble (54), just as it does not enable adequate flow of irrigation solution.

The phenomenon of apical vapour lock has been confirmed in studies in which roots were embedded in a polyvinylsiloxane impression material to restrict fluid flow through the apical foramen, simulating a close-ended channel (55). The results in these studies was found to be an incomplete debridement of the apical part of the canal walls with the use of a positive-pressure syringe delivery technique (55). Micro-CT scanning and histological tests conducted by Tay et al. (55) have also confirmed the presence of apical vapour lock. In fact,
studies conducted without ensuring a close-ended channel cannot be regarded as conclusive on the efficacy of irrigation solutions and the irrigation system (56–58). The apical vapour lock may also explain why in a number of studies investigators were unable to demonstrate a clean apical third in sealed root canals (59–61).

In a paper published in 1983, Chow determined that traditional positive-pressure irrigation had virtually no effect apical to the orifice of the irrigation needle in a closed root-canal system (62). Fluid exchange and debris displacement were minimal. Equally important to his primary findings, Chow set forth an infallible paradigm for endodontic irrigation: “For the solution to be mechanically effective in removing all the particles, it has to: (a) reach the apex; (b) create a current (force); and (c) carry the particles away.”(62) The apical vapour lock and consideration for the patient’s safety have always prevented the thorough cleaning of the apical 3 mm. It is critically important to determine which irrigation system will effectively irrigate the apical third, as well as isthmuses and lateral canals (63), and do it in a safe manner that prevents the extrusion of irrigation solution.

2.4. Additional Cleaning Techniques

Several adjuvant techniques to the conventional chemico-mechanical regiment have been suggested. For instance, increasing apical enlargement to ISO size 60 achieves 93% of no-growth cultures [10]; however, it also produces higher risk of canal transportation (12). Some postulate that inter-appointment medication such as calcium hydroxide has the ability to decrease the percentage of positive cultures [11]. The drawback of this approach
is that it requires a second treatment session (64). Moreover, two randomized control trials (65,66) found no significant difference between the percentage of no-growth cultures after instrumentation and calcium hydroxide application inside the root canal.

In recent years several systems have been developed to activate and to deliver NaOCl into the root canal. Optimizing delivery of NaOCl throughout the root canal by continuous replenishment while avoiding periapical extrusion has been a subject of research and development in recent years (67–71).

**a. Manual and Machine-assisted Irrigation Techniques**

Root-canal irrigation systems can be divided into two categories: manual irrigation techniques and machine-assisted irrigation techniques (52). Manual irrigation techniques include the positive-pressure syringe fitted with a variety of needle designs and the manual dynamic agitation using a gutta-percha point. Machine-assisted irrigation techniques include sonics and ultrasonics, as well as newer systems such as the EndoVac (SybronEndo) designed to generate apical negative pressure, the GentleWave (Sonendo) based on multisonic pressure wave formation, the plastic rotary F File (Plastic Endo), the Vibringe sonically agitated syringe (Vibringe), the Rinsendo (Air Techniques) and the EndoActivator (Dentsply Tulsa Dental Specialties). Two important factors that should be considered during the process of irrigation are whether the irrigation systems can deliver irrigation to the apical terminus, and whether irrigation is capable of debriding areas that could not be reached with mechanical instrumentation, such as lateral/accessory canals, isthmuses and
b. Continuous and Intermittent Flushing Techniques

Two flushing methods are currently employed to irrigate root canal systems: intermittent and continuous (52). With the intermittent flushing technique, irrigation is injected in the root canal space with a syringe and the solution can then be activated; the canal is filled several times after each activation cycle. Inversely, the continuous flush techniques provide an uninterrupted supply of fresh irrigation solution into the root canal. This technique can provide more effective results and reduce the time required for final irrigation when compared with intermittent irrigation devices. Taking into consideration that chloride (responsible for dissolving the organic tissues and NaOCl’s antibacterial property) is unstable and quickly consumed, a continuous flow of irrigation would make intuitive sense (52).

2.5. Apical Negative Pressure

Pressure is defined as a force per area. During root canal treatment, pressure is exerted onto the root canal wall when the irrigation is delivered into the root canal space. Negative pressure refers to a situation in which an enclosed volume has lower pressure than its surroundings.
2.6. The EndoVac System

The EndoVac system was developed to safely and predictably deliver irrigation to the apical terminus thereby allowing a better penetration of the irrigation solution into the intricate anatomy and morphology of the root canal system such as isthmuses, inter-canal and intracanal communications, curvatures and oval shaped canals (63). Apical negative pressure systems for irrigation have the ability to suction, thereby drawing and delivering the irrigation solution passively to the apex (52). The EndoVac system delivers the chosen irrigation solution passively to the apex (63,72) and positively addresses the problem of irrigation penetration past the apex into the periapical tissue which may result in treatment complications (73,74).

The EndoVac apical negative-pressure irrigation system has three active component parts (figure 2): the Master Delivery Tip (MDT), the macro cannula and the micro cannula. The MDT accommodates a syringe of irrigation solution, which is expressed through a 20-gauge needle. There is also a plastic suction hood attached around the 20 gauge needle which is connected to clear plastic tubing which inserts into a multiport adaptor which in turn is inserted into the high volume suction (54). As such the MDT can simultaneously deliver and evacuate any excess irrigation solution that may flow over from the pulp chamber. The macro cannula is used to draw irrigation solution by way of suction from the chamber to the coronal and middle segments of the canal while irrigation solution is simultaneously delivered to the pulp chamber directed towards an axial wall and never towards a canal orifice. The macro cannula or micro cannula is connected via clear plastic tubing to the high-speed suction of the dental unit via the multiport adaptor. The plastic macro cannula
has an external diameter of 0.55 mm and an internal diameter of 0.35 mm. It is made of blue translucent plastic, has a 0.02 taper and is meant for single use only. It is attached snug to an autoclavable aluminium handpiece and is used in an up and down pecking motion while the irrigation solution is simultaneously delivered passively into the pulp chamber in the manner mentioned above. It is used to remove the gross debris and tissue left behind during instrumentation. The stainless-steel micro cannula has an external diameter of 0.32 mm and zero taper. It has four sets of three laser-cut, laterally positioned offset holes adjacent to its closed end, each 100 µ in diameter and spaced 100 µ apart (71). While the micro cannula acts to evacuate debris at full working length, these micro holes act as filters to prevent the clogging of the internal lumen of the micro cannula which is 0.20 mm in diameter. The micro cannula is attached to an autoclavable aluminum finger piece and is used for irrigation of the apical part of the canal when it is positioned at working length. The micro cannula has a closed end and should be taken to the full working length to aspirate irrigation solution and debris. Because of the dimensions of the micro cannula, canals need to be enlarged to ISO size 35 with 0.04 taper or larger. Alternatively, the manufacturer recommends an enlargement of the root canal to ISO size 40/0.02.

During irrigation, the MDT delivers irrigation solution to the pulp chamber and siphons off the excess irrigation solution to prevent overflow. Both the macro cannula and micro cannula exert negative pressure that pulls fresh irrigation solution from the chamber, down the canal to the tip of the cannula, into the cannula, and out through the suction hose. Thus, a constant flow of fresh irrigation solution is delivered by negative pressure to working length, allowing the reaction of hydrolysis to continually occur. Figure 3 present the final
irrigation protocol using EndoVac system.

\[ a. \text{ Debris Removal} \]

Several studies were carried out to evaluate the EndoVac system’s ability to remove debris within the root canal system after instrumentation with rotary files (70,75–79). Debridement is a principal objective of root canal treatment and remains a challenge especially in the apical portion of the canal and within the isthmuses and lateral and accessory canals. Debridement is the elimination of organic and inorganic substances as well as microorganisms from the root canal by mechanical and/or chemical means (80). When compared to traditional syringe and side-vented needle irrigation, the EndoVac system has demonstrated better control to reach the last millimetre of the root canal.

Some \textit{in vitro} and \textit{in vivo} studies have demonstrated greater removal of debris from the apical walls and a statistically cleaner result using negative apical pressure irrigation in closed root-canal systems with sealed apices. In an \textit{in vivo} study of 22 teeth by Siu and Baumgartner (81), less debris remained at 1 mm from the working length using negative apical pressure compared to the use of traditional needle irrigation. Shin et al. (78) found in an \textit{in vitro} study of 69 teeth comparing traditional needle irrigation with negative apical pressure that these methods both resulted in clean root canals, but that apical negative pressure resulted in less debris remaining at 1.5 and 3.5 mm from working length (70,78,81). When comparing root-canal debridement using manual-dynamic agitation (using a well fitted gutta-percha cone in an up and down motion in the canal) or the EndoVac system for final agitation in a closed system and an open system, it was found that
the presence of a sealed apical foramen adversely affected debridement efficacy when manual-dynamic agitation was used, but did not adversely affect results when the EndoVac system was used. Apical negative-pressure irrigation is an effective method to overcome the fluid-dynamic challenges inherent in closed root-canal systems (55,82). The ability of the EndoVac system to significantly clean more debris from the mechanically inaccessible recess of the in vitro root canal model may be caused by bubble formation during irrigation delivery, creating higher wall shear stresses by a two-phase air-liquid flow phenomenon that is well known in other industrial debridement systems (83). To enhance cleanliness of the root canal system, EndoVac system has the ability to safely deliver irrigation solution to working length (70) by pulling the irrigation solution into the canal and removing it by negative pressure (70). This vacuum action enhances the volume of solution and the circulation of the irrigation solution in the apical end of the root canal. Moreover, the negative pressure avoids air entrapment in the apical third (79) and promotes a regular replenishment of the irrigation solution apically (79). A recent study demonstrated that the volume of irrigation solution delivered apically was significantly higher than the volume delivered by conventional syringe needle irrigation within the same period (70), and resulted in significantly more debris removal at 1 mm from working length than did needle irrigation.

One study is not in agreement with those positive outcomes discussed above (76). Jiang et al. (76) evaluated the EndoVac system’s ability to remove dentin debris from artificially made grooves in standardized root canals. The model was made of a single tooth root in which an apical groove comparable to an ovoid apical canal was created and packed with
dentine debris. They compared several devices to activate the irrigation solution. Once the irrigation regimen was completed, they viewed the grooves through a stereomicroscope to evaluate the residual dentine debris. A score between 0 and 3 was given to each specimen, 0 = the groove is empty, 1 = less than half of the groove is filled with debris. 2 = More than half of the groove is filled with debris. 3 = the complete groove is filled with debris. The specimens irrigated with the EndoVac System had their groove completely filled with debris (score 3) 65% of the time while 35% had less than half filled with debris (76). It is important to note that Jiang et al. (76) failed to follow the manufacturer’s instructions by failing to use the critical macro cannula, an error that could easily cause the micro cannula to clog and become ineffective. A weaker capacity of the EndoVac system to remove apical debris could be attributed to the minimal turbulence intensity produced within the canal by the micro cannula (84). This evidence of low wall shear stress values causes a minimum physical interaction between the irrigation solution and the root canal walls (84). This absence of interaction may explain the difficulty of the irrigation solution to reach the root canal’s lateral canals and anastomoses(72).

**b. Microbial control**

The effective removal of organic and inorganic tissues would allow better access and elimination of endodontic pathogens, responsible for apical periodontitis, localized in the root canal system. Hockett et al. (85) tested the ability of apical negative pressure irrigation to remove a thick biofilm of *E. faecalis* in mesial roots of mandibular molars, finding that these specimens rendered no-growth cultures after 48 hours of incubation, while some of those irrigated using traditional positive-pressure irrigation were positive at 48 hours (85).
One *in vivo* dog study found that negative apical pressure irrigation with 2.5% NaOCl resulted in similar bacterial reduction than the use of apical positive pressure irrigation combined with seven days of intracanal medication with the triple-antibiotic paste (86). The triple-antibiotic Trimix (metronidazole, ciprofloxacin, and minocycline) has been utilised for pulpal regeneration/revascularisation in teeth with incompletely formed apices (87). The antibiotic medication is applied in regeneration cases to safely kill bacteria. Since the triple-antibiotic versus the use of EndoVac with NaOCl were statistically equivalent for mineralised tissue formation and the repair process (86); the study (86) suggests that EndoVac may overcome the need for intracanal medication. Further research is required to evaluate this potential. Using apical negative pressure with NaOCl also decreases the risk of drug resistance, tooth discoloration, and allergic reactions often seen with the administration of antibiotics (88,89). A recent randomized controlled clinical trial (90) compared the antimicrobial effectiveness of EndoVac system and the traditional positive pressure syringe and needle for irrigation. From the sixteen mandibular molars treated with the conventional method, no-growth culture was found in 67% compared to 100% among the apical negative pressure irrigation group. A second clinical study (91) demonstrated a higher frequency of obtaining no-growth cultures with the EndoVac system compared to a syringe with regular needle. Unlike Cohenca et al. (90), Pawar et al. (91) did not report a significant difference between the two clinical groups. However, Pawar et al. (91) added an overriding codicil in their discussion: “The original EndoVac protocol recommends using a concentration of 5.25% NaOCl. Almost all studies investigating the efficacy of EndoVac have used NaOCl at concentrations ranging from 2.5%-6%. The use of 0.5% NaOCl [a 1,000 % dilution from the manufacturer’s instructions] in this study could be
considered responsible for the lack of significant differences in antimicrobial efficacy between EndoVac irrigation and standard irrigation” (35).

c. Smear Layer removal

The smear layer is created when the dentinal walls of the root canal system interact with endodontic instruments (92). The smear layer is comprised of inorganic and organic material such as dentin filings and pulp tissue remnants (93). This deposit can be penetrated by bacteria and may offer protection to biofilms adhering to the root canal walls (94). Furthermore, the smear layer interferes with the tight adaptation of currently used root canal sealers to dentin walls and may therefore promote micro-leakage (95). Torabinejad et al. (96) suggested that removal of the smear layer would decrease bacteria and improve adaptation of root filling materials to the canal walls. Another study (97) showed that the smear layer produced during root canal preparation promoted adhesion and colonization of P. nigrescens to the dentin matrix and might increase the likelihood of canal reinfection. Removing the smear layer reduces the potential for microleakage (77,98) and improves sealer penetration in dentinal tubules (99). When the manufacturer’s recommendations are followed, the EndoVac system delivers a sufficient volume of irrigation to enable removal of the smear layer (77,100,101).

Compared to passive ultrasonic irrigation, negative apical pressure irrigation and manual dynamic irrigation are more efficient in removing the smear layer in the apical one third (101). A possible explanation for this is that both techniques reach full working length of instrumented canals, eliminate the apical vapour lock at the apex and hence allow adequate
solution replacement (100,101). When evaluating irrigation of the apical one third, the phenomenon of apical vapour lock should be considered (55,102,103).

d. Calcium hydroxide removal

As stated previously, the debridement of the root canal system consists of elimination of organic, inorganic and microbial components, thus accomplished by mechanical instrumentation supported by various irrigation regimens and placement of intracanal medication. Calcium hydroxide \( \text{(Ca(OH)}_2) \) is a commonly used intracanal medication (104) that has antimicrobial activity proven to contribute to bacterial endotoxin neutralization (105) and to periapical repair (106). However, to provide a maximum interface between the root canal walls and the filling material, \( \text{Ca(OH)}_2 \) has to be removed (107) otherwise the bond strength (108) of the sealer and its penetration into the dentine tubules could be reduced (109). Conventional irrigation methods have demonstrated limited capacity to remove \( \text{Ca(OH)}_2 \) from the apical third of the root canal (110). A scanning electron microscopic evaluation of longitudinally sectioned canines demonstrated that EndoVac system performs better than the traditional syringe irrigation in removing \( \text{Ca(OH)}_2 \) from the apical one third of root canals (111). The results were similar to another study (112) where EndoVac system was compared to the traditional syringe irrigation and the ProUltra® Piezoflow™ ultrasonic irrigation needle (Dentsply Tulsa, Tulsa, OK, USA). The EndoVac system left significantly less calcium hydroxide compared to the traditional syringe irrigation and were found to be as efficient as the PiezoFlow™ in removing \( \text{Ca(OH)}_2 \) (112). Although the EndoVac system improves the removal of \( \text{Ca(OH)}_2 \), the apical portion of the canal was not completely free of intracanal medication. Therefore, the use of the master
apical file in combination with the EndoVac system may result in better removal of Ca(OH)$_2$ (112).

**e. Safety**

As stated previously, with traditional root canal irrigation, clinicians must be careful when determining how far an irrigation needle is placed into the canal. Recommendations for avoiding NaOCl accidents include not binding the needle in the canal, not placing the needle close to working length, and using a gentle flow rate when using positive pressure irrigation (39). In contrast, the EndoVac system pulls irrigation solution into the canal to working length and the solution and debris are removed by negative pressure. Negative apical pressure has been shown to enable irrigation solutions to safely reach the apical one third and help overcome apical vapour lock (70,78).

Apart from being able to avoid air entrapment, the EndoVac system is also advantageous in its ability to deliver irrigation solution safely to working length without causing their undue extrusion into the periapex (70,71), thereby avoiding NaOCl accidents. It is important to note that it is possible to create positive pressure in the pulp canal if the MDT is misused, which would create the risk of a NaOCl accident. The manufacturer’s instructions must be followed for correct use of the MTD by never directing towards the orifice of a canal.

In order to compare the safety of six current intra-canal irrigation delivery devices, an *in vitro* test was conducted using the worst-case scenario of apical extrusion, with neutral atmospheric pressure and an open apex (71). The study concluded that the EndoVac system
did not extrude irrigation solution even after deep intra-canal delivery and suctioning of the solution from the chamber to full working length, whereas other devices did. The EndoActivator extruded only a very small volume of solution, the clinical significance of which is not known.

Mitchell and Baumgartner (73) tested NaOCl extrusion from a root canal sealed with a permeable agarose gel. Significantly less extrusion occurred using the EndoVac system compared with positive-pressure needle irrigation. A well-controlled study by Gondim et al. (32) found that patients experienced less post-operative pain, measured objectively and subjectively, when apical negative-pressure irrigation was performed (EndoVac system) than with apical positive-pressure irrigation (32). Furthermore, PiezoFlow™ shows a greater potential to cause apical extrusion compared with EndoVac system’s safety. When positioned within the last five millimetres of the root canal, the ultrasonic activated needle could cause apical extrusion of irrigation solution (67).

3. GentleWave System

Recently, a novel system to clean the root canal was developed. The GentleWave™ system (Sonendo, Laguna Hills, CA) is composed of a console and a handpiece (Figure 4). The console includes several electrical circuits, three irrigation solution containers, one waste canister, a degassing system and a pressure generator. GentleWave™ continuously delivers energized treatment solution throughout the root canal system via a handpiece positioned on an accessed occlusal tooth surface (113,114). A built-in impingement plate disrupts the
irrigation stream redirecting the resulting mist to flow across the pulp chamber and over canal orifices. When the liquid interacts with the stationary liquid inside the pulp chamber it generates a shear stress strong enough to induce acoustic streaming and cavitation. The sound waves then reverberate against the dentinal wall and the energy is propagated apically. The GentleWave™ handpiece collects excess of fluid from the canals via its three-point vented suction and removes the outflowing fluid creating negative pressure within the root canal system. The fluid motion induced also generates fluid motion such as vortices and swirls.

Three different irrigation solutions can be charged in the system. The manufacturer suggests the combination sodium hypochlorite and ethylenediaminetetraacetic acid (EDTA) with a rinse of distilled water between each of them to avoid potential damaging chemical reaction. Each irrigation solution is degassed before being delivered by the hand piece. The degassing process eliminated air in the liquid, therefore potentially decreases the occurrence of a phenomenon called vapour lock.

a. GentleWave characteristics

GentleWave™'s manufacturer suggests that their novel technology avoids the creation of vapour lock and promotes a constant exchange of solution of the entire length of the root canal. According to their previous in house experimentations, canals need not be enlarged beyond ISO size 15 for the GentleWave™ system to work effectively.


**b. Tissue dissolution**

One study reported the superiority of GentleWave in dissolving vital tissue when compared to passive ultrasonic activation, EndoVac or a positive-pressure conventional needle coupled to a syringe for irrigation (113). This study has several limitations and the conclusion should be interpreted with caution.

**c. Calcium hydroxide removal**

According to Ma et al. (114), the GentleWave system has the capacity to remove calcium hydroxide along the entire canal length and inside root canal complexities. Mesial and distal canals of 30 mandibular molars were prepared with the WaveOne Primary (25/.08) and WaveOne Large (40/.08) instruments (Dentsply Tulsa Dental Specialties, Tulsa, OK), respectively. All canals were then filled with Ca(OH)$_2$. The teeth were divided into the following 3 irrigation protocols: (1) needle irrigation, (2) passive ultrasonic activation, and (3) GentleWave system. The irrigation time in each group was 7.5 minutes. To further test the efficiency of the GentleWave system, shorter times of 90 seconds were used. Reconstructed micro-computed tomographic scans measured the volume of the canals and Ca(OH)$_2$ after instrumentation, after filling of Ca(OH)$_2$, and after its removal. The percentage of Ca(OH)$_2$ remaining in the canals was calculated. None of the 10 teeth in the conventional irrigation and passive ultrasonic activation groups were completely cleaned of Ca(OH)$_2$ and the GentleWave system removed significantly more Ca(OH)$_2$ with 100% and 98.78% in the mesial and distal canals, respectively. Additional experiments in 10 teeth revealed that the GentleWave system removed 99.85% and 99.97% of Ca(OH)$_2$ within 90 seconds in the mesial and distal canals, respectively.


**Rationale**

Because the GentleWave™ system delivers energized irrigation solution, including NaOCl, the risk of periapical extrusion must be considered and assessed as a measure of safety in clinical usage.

**Aim**

This study assessed apical extrusion during treatment with GentleWave™ (GW), conventional open-ended 30G needle (CN) or EndoVac® (EV) in root canals enlarged to different dimensions with and without apical constriction.

**Hypothesis**

The null hypothesis was that incidence and mass of extrusion would not differ significantly between groups GW and CN for all instrumentation subgroups.
Assessment of Apical Extrusion during Root Canal Irrigation with the Novel GentleWave System in a Simulated Apical Environment

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Abstract

Introduction: This study assessed apical extrusion during treatment with GentleWave (GW; Sonendo, Laguna Hills, CA), a conventional open-ended 30-G needle (CN), or Endovac (EV; SybronEndo, Orange, CA) in root canals enlarged to different dimensions with and without apical constriction. Methods: Sixteen mandibular molars were mounted in an in vitro apparatus. Roots were immersed in a pressure-regulated chamber containing distilled water with pressure kept at 5.88 ± 0.15 mm Hg to simulate periapical back pressure. Mesiodistal (curved ≤ 30°) and distal (straight) canals were instrumented to the working length (WL) as follows: minimal instrumentation (MI, #15/.04), traditional instrumentation (#35/.06), or overinstrumentation (OI, #35/.06, to the WL + 1 mm). Canals were tested 5 times each with distilled water using GW, CN (at WL-3 mm), or EV and the mass (g) of extruded water recorded. Extrusion frequency and mean extruded mass were compared for each canal, irrigation group, and canal instrumentation mode (Wilcoxon t test, P < .05). Results: No extrusion occurred with GW and EV, whereas the frequency of extrusion with CN was 33%. Mean extruded water mass using CN ranged in mesial canals from 0.000 ± 0.000 g (OI) to 0.047 ± 0.098 g (MI) and in distal canals from 0.123 ± 0.191 g (MI) to 0.505 ± 0.490 g (OI). With traditional instrumentation and OI instrumentation, extruded mass in distal canals was significantly higher than in mesial canals (P < .002) and distal canals with MI (P < .020). Conclusions: Within this study’s limitations, root canal treatment with GW and irrigation with EV was not associated with extrusion. Extruded irrigation mass using the open-ended 30-G needle depended on the canal type and enlargement. These results have to be interpreted with caution, and further investigations are warranted to evaluate the possibility of extrusion using GW in different tooth types and clinical situations. (J Endod 2015;1–6)

Key Words
Apical extrusion, apical foramen, Endovac, GentleWave, hypochlorite accidents, needle irrigation
including NaOCl, the risk of periapical extrusion must be considered and assessed as a measure of safety in clinical usage. Therefore, this study evaluated the extrusion of solution during use of the GW system in root canals enlarged to different dimensions with and without preservation of the apical constriction.

## Materials and Methods

### Specimens

The University of Toronto Research Ethics Board approved the study protocol (929320). To estimate the sample size, the mass of extruded solution using an open-ended needle was determined in a pilot study (not reported) with a setup similar to that described later. The difference between the extruded irrigation mass and 0 (assumed for GW) suggested that 12 canals/group would support analysis with 80% power and alpha of 5%. To accommodate variation of data, a repeated measures design was used, and the sample was increased to 16 canals/group, which was consistent with that reported in previous studies on apical extrusion (21, 22).

Extracted human mandibular molars with fully developed roots; a pulp chamber height of ≥2 mm; and no root caries, cracks, fractures, or internal and external resorption were stored in 4°C phosphate-buffered saline until use (23). Micro-computed tomographic imaging was performed to standardize the samples and identify 16 molars with 2 independent and moderately curved (23–36) mesial canals and a single relatively straight (<20°) distal canal (24). The pulp chamber was accessed conventionally, and the mesiobuccal and distal canals were located. The WL for each canal was established 1 mm short of the emergence of a size 10 K-type file (Dentsply Maillefer, Ballaigues, Switzerland) through the major foramen. A glide path was prepared with size 15 PathFile instruments (Dentsply Maillefer), and the canals were enlarged with Vortex instruments (Dentsply Tulsa Dental Specialties, Tulsa, OK) and irrigated with distilled water with a 30-G open needle in 5 successive steps:

1. Minimal instrumentation (MI); size 15/.04 Vortex instruments were used to the WL and apical patency was confirmed 1 mm longer with size 10 K-type files.
2. Traditional instrumentation (TI); Vortex instruments were used sequentially to size 35/.06 at the WL, and apical patency was confirmed 1 mm longer with size 10 K-type files.
3. Overinstrumentation (OI); Vortex instruments were used to size 35/.06 to 1 mm beyond the WL. In addition to simulating inadvertent OI, this step also simulated canals with large apical foramina.

### Apical Extrusion Apparatus and Measurement

After each canal instrumentation step (MI, TI, and OI), 1 tooth specimen at a time was mounted in an airtight chamber filled with distilled water (Fig. 1A and B). To enable independent extrusion measurements for each canal, all other apical foramina were sealed with hot glue. The tooth crown remained exposed to apply different devices, whereas the roots were submerged in the water-filled chamber.

The airtight chamber was connected to a custom pressure vessel by a 12 VDC precision solenoid valve (01540-01; Cole-Palmer, Vernon Hills, IL). Pressure within the vessel was maintained at 5.88 ± 0.15 mm Hg, the solenoid valve opened allowing extrusion of solution through the apical foramen, causing water displacement from the chamber into the pressure vessel. A load cell (FSH025S6; Futek, Irvine, CA) mounted within the pressure vessel weighed the displaced water (g). Displaced water mass data were recorded by a linked computer equipped with a Data-Acquisition DAQ Board (USB6008; National Instruments Corp, Austin, TX) and LabVIEW software (National Instruments Corp).

Pressure readings obtained from the experimental apparatus were calibrated with the hydrostatic pressures determined for 5 different water columns in a 10-mL pipette attached to a water-filled chamber. The coefficient of determination (R²) between the theoretic apical pressure and the measured apical pressure was 0.9997.

### Groups

To avoid NaOCl damage to the experimental apparatus, canals were irrigated with distilled water. A pilot study (not reported) confirmed that extruded masses were similar for water and NaOCl. Teeth (N = 16) were randomly assigned to different pre-established sequences of the following 3 groups and positive control:

1. GW: the delivery tip was positioned in the center of the access cavity 1–2 mm coronal to the pulp floor, strictly avoiding placement at canal orifices and contact with cavity walls. Treatment fluid was dispensed for 30 seconds at 45 mL/min.
2. Conventional needle (CN): a 30-G conventional open-ended needle (Nastip, Ultradent, South Jordan, UT) connected to a peristaltic pump (New Era Pump, Farmingdale, NY) was inserted 3 mm short of the WL or slightly coronal to that point if it bound in the canal. Irrigation was dispensed for 30 seconds at 5 mL/min. The CN group was used to ascertain the ability to record extrusion with the needle kept within the root canal as previously reported (5, 9, 10, 21, 23).
3. EV: the micrcannula was inserted to the WL. The master delivery tip was connected to the peristaltic pump and irrigation dispensed for 30 seconds at 5 mL/min while moving the cannula from the crown to apex at a low amplitude every 6 seconds (23). The EV group was considered as the negative control based on previous reports of no extrusion during its use (8, 9). It could not be used in canals with MI.

### Positive control (n = 9); a 30-G open-ended needle attached to the peristaltic pump set at a flow rate of 5 mL/min was inserted 2 mm beyond the apical foramen, and the access cavity was sealed with vinyl polysiloxane impression material. Apical extrusion was determined for a period of 30 seconds.

### Validation Experiment

Because the manufacturer of GW recommends continuous application of NaOCl for 5 minutes, an experiment was performed to ensure that irrigation extrusion over a 30-second period did not underestimate the risk of extrusion during irrigation for 5 minutes. Canals of 8 teeth with OI were irrigated with GW for 5 minutes. The data were compared with that of the GW group.

### Analysis

To compensate for the systematic error of the experimental setup (+0.2 g), all negative extrusion values were replaced with 0, and 0.2 g was subtracted from all positive values. Data were analyzed with GraphPad Prism (GraphPad Software Inc, La Jolla, CA). Extrusion occurrence and mean mass calculated for each canal and group. Groups were compared with the Wilcoxon t test (P < .05). Because the

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**References:**

1. Charara et al.
2. F1
3. FLA 5.2.0 DTD
4. JDE3131_proof
5. JOEN3131_proof
6. 2 May 2015
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8. ce BT
9. 34
extrusion mass data were nonparametric, a correlation of extrusion and canal size was explored with Spearman rho coefficients (\( P > .4 \) represents a strong correlation). The null hypothesis was that incidence and mass of extrusion would not differ significantly between the GW and CN groups for MI, TI, and OI.

**Results**

Extrusion occurred in all 9 positive controls (100%) and did not occur in any of the canals in the EV group (negative control), validating the experimental model. In the GW group, no extrusion occurred throughout the experiments (0%). In the CN group (Table 1), extrusion incidence varied among MI, TI, and OI groups and between mesial and distal canals. Overall, extrusion incidence was higher in distal canals (27/48, 47%) than in mesial canals (5/48, 10%). In distal canals, the highest extrusion incidence was recorded for TI and OI (10/16, 63%), and in mesial canals, the highest extrusion incidence was recorded for MI (4/16, 15%).

In the CN group, the mass of extruded solution across all specimens ranged from 0.000–1.373 g. In mesial canals, the mean water mass ranged from 0.000 g (OI) to 0.047 g (MI), and it did not differ significantly with the GW and EV groups (\( P > .125 \)). In distal canals, the mean extruded water mass ranged from 0.123 g (MI) to 0.505 g (OI) and was significantly higher than in the GW and EV groups in MI, TI, and OI (\( P < .015 \)). Comparing the 3 instrumentation modes, the mean extruded water mass in distal canals was significantly higher in TI and OI than in MI (\( P < .018 \)). In TI and OI, the extruded water mass was significantly higher in distal canals than in mesial canals (\( P < .002 \)).

The application of GW for 5 minutes yielded 0 apical extrusion, validating the results obtained during the 30-second activation. All the measurements made were within the error limits of the experimental setup (data not reported).

**Figure 1.** (A and B) The apical extrusion measurement apparatus. (A) The tooth is mounted on a customized cap and secured into an airtight chamber filled with incompressible fluid (D). If the periapical pressure, detected by pressure transducer (C), is greater than the simulated periapical back pressure, fluid passes through the extrusion line (D), which consists of a 12 VDC precision solenoid valve. Extruded fluid is then collected onto a glass dish (E) positioned on a load cell. The load cell is placed inside a pressure vessel (F). The pressure vessel is pressurized via a pressure generator (G) that simulates the periapical back pressure. The pressure within the vessel is measured by another pressure transducer (H) and is regulated by a pressure valve (I).
TABLE 1. Mean Extruded Irrigation Mass (g) in Each of 16 Specimens Tested, Having Canals Instrumented Consecutively with 3 modes (MI, TI, and OI) and Irrigated with an Open-ended 30-G Needle Inserted 3 mm Short of the Working Length

<table>
<thead>
<tr>
<th>Tooth no.</th>
<th>Minimal instrumentation (MI)</th>
<th>Traditional instrumentation (TI)</th>
<th>Over-instrumentation (OI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mesial canal</td>
<td>Distal canal</td>
<td>Mesial canal</td>
</tr>
<tr>
<td>1</td>
<td>0.139</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>2</td>
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<tr>
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<td>0.000</td>
<td>0.537</td>
<td>0.000</td>
</tr>
<tr>
<td>6</td>
<td>0.045</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>7</td>
<td>0.255</td>
<td>0.124</td>
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<td>0.022</td>
<td>0.000</td>
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<tr>
<td>13</td>
<td>0.000</td>
<td>0.100</td>
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<tr>
<td>14</td>
<td></td>
<td>0.130</td>
<td>0.000</td>
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<td>0.000</td>
<td>0.000</td>
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<tr>
<td>16</td>
<td>0.000</td>
<td>0.468</td>
<td>0.000</td>
</tr>
<tr>
<td>Mean mass (±SD)</td>
<td>0.047 (0.098)</td>
<td>0.123 (0.191)</td>
<td>0.021 (0.084)</td>
</tr>
</tbody>
</table>

SD, standard deviation. Each canal was tested 5 times.

Discussion

Serious NaOCl accidents during endodontic treatment have been rare and mostly occurred during syringe-delivered irrigation using open-ended needles (16, 28). Over the years, needle designs have been modified and negative pressure delivery systems introduced to enhance irrigation delivery throughout the canal volume while preventing inadvertent extrusion (10, 22, 29, 30). GW is a novel root canal cleaning system shown to deliver treatment fluid to the canal terminus, as shown by its ability to remove calcium hydroxide throughout the length of molar canals instrumented to size 25/08 and 40/08 (20). Considering that the GW system uses NaOCl for treatment, it was deemed necessary to assess the risk of periapical extrusion during its use in a variety of simulated clinical conditions.

The experimental apparatus was developed to mimic the resistance to extrusion afforded by periapical tissue. Because the exact apical pressure that might result in a NaOCl accident is not known (31), the safety limit in this study was set to not exceed the central venous pressure of 5.88 mm Hg (25), suggested to prevent the occurrence of intravascular accidents (25). In maxillary molars and incisors, reduced apical resistance may be affected by bone porosity, fenestrations, anatomic variations such as drainage of a tooth by the facial vein (12), or location of root apices within the maxillary sinus without bone or Schneiderian membrane cover (32). In these situations, there may be an increased risk of NaOCl accidents (12). Because of this concern, the manufacturer of the GW system considers its use contraindicated in maxillary teeth contacting the sinus.

Keeping the roots in pressurized medium provided a quantitative assessment of extrusion, which could occur only when irrigation pressure at the apical foramen exceeded the set back pressure (10, 22). This model offered a lower risk of overestimating the amount of apical extrusion than previously reported when an air-filled vial was used (10, 22, 30). The same airtight chamber and pressure transducer were previously used to measure the apical pressure generated in canals of mandibular molars by different needle designs (31).

Molars were used for the study primarily because the GW system had only a molar handpiece available at the time of the study. The selection of mandibular molars afforded 3 canals per tooth, including the moderately curved molar canals and relatively straight distal canals. The same 16 teeth were used in random sequence for the 3 irrigation groups to avoid impacts of varying canal anatomy on extrusion, as previously reported (22). To simulate different clinical situations, 3 modes of instrumentation were tested, representing minimally invasive preparation (MI), conventional preparation (TI), and the absence of apical constriction (OI) as might occur in overinstrumented canals and externally resorbed and immature roots.

For the negative control, it was deemed appropriate to use the negative-pressure EV system because it has been shown to not cause extrusion during use (5, 8, 9, 23). Irrigation with a needle extending beyond the apex was the positive control. Consistent extrusion in the positive control and none with EV validated the experimental model. In addition, irrigation with an open-ended needle positioned 3 mm short of the WL, shown to cause minimal extrusion (10), was also tested to ascertain that the experimental apparatus was adequately sensitive to detect such minimal amounts of extrusion.

The absence of extrusion with the use of GW and EV systems suggested that both devices generated apical pressures during use that did not exceed 5.88 ± 0.15 mm Hg. However, syringe irrigation with an open-ended needle did cause significant extrusion of irrigation solution in distal canals, partially rejecting the null hypothesis. The amount of extruded irrigation solution in distal canals was positively correlated with the extent of canal instrumentation, corroborating suggestions in previous studies (20–22).

The GW system is composed of a console and a sterile disposable handpiece. It delivers a stream of treatment solution from the tip of the handpiece into the pulp chamber while excess fluid is simultaneously removed from the chamber by the built-in vented suction through the handpiece into a waste canister inside the console. According to the manufacturer, upon initiation of flow through the treatment tip of the handpiece, the stream of the treatment fluid interacts with the stationary fluid inside the pulp chamber creating a shear force, which causes hydrodynamic forces to enhance irrigation delivery throughout the canal volume while also preventing inadvertent extrusion.
cavitation in the form of a cavitation cloud. The continuous formation and implosion of thousands of microbubbles inside the cavitation cloud generate an acoustic field with broadband frequency spectrum that travels through the fluid into the entire root canal system. Throughout the treatment, the fluid starts with 3% NaOCl and changes to 5% EDTA with a water rinse in between. The treatment tip of the handpiece is designed to deflect the stream of treatment fluid in such a way to generate a flow over the orifices of the root canals. This flow induces gentle vortical flow as well as a slight negative pressure within the root canal system. The energy and the vortical flow dissipate as they travel apically into the root canal system.

One reason to explain the energy dissipation would be the lack of hard tissue in the periapical space that is needed for the reflection of the sound waves. Furthermore, the positive pressure created by the peritubular tissue when encountered by the negative pressure inside the root canal system would prevent apical ejection. Independent studies to show the mechanism of action and the flow dynamics of the GW system are warranted.

EV simultaneously delivers irrigation solution and draws it out of the canal close to the apical level, preventing it from expressing to the apical tissue. Exudation had been tested in a variety of in vitro conditions with consistently negative results (5, 8, 9, 21, 23), as also shown herein.

Syringe irrigation with a 30-G open-ended needle occasionally results in irrigation extrusion characterized by a broad range of volumes and large standard deviation values (30). Similar inconsistency observed herein could be attributed to variations in irrigation flow dynamics caused by differences in root canal anatomy and needle position, impacting apical pressure and resulting extrusion (10, 33). Moreover, involuntary operator movement leading to changes in needle position and angulation might also have contributed to extrusion (10, 51).

This study was designed to answer a very specific research question, and its results should not be extrapolated to clinical application or different conditions than those tested herein. Extrusion of irrigation with the GW system was assessed as 1 measure of usage safety specifically in intact molars. As the GW system is further adapted for use in other tooth types, further akin assessments are warranted. Further- more, the results of this study may not apply to teeth presenting with reduced apical resistance, proximity of the mental foramen, undiagnosed vertical root fracture, perforating resorptive defects, and cartilaginous lesions communicating with the pulp chamber. These conditions require specific evaluation before the assessment of GW safety can be considered complete.

Conclusion

Within the limitations of this in vitro study, GW and EV did not cause treatment fluid extrusion in the apparatus with an apical pressure threshold of 5.88 ± 0.15 mm Hg. Occasional extrusion during irrigation with a 30-G conventional open-ended needle was noted and associated with canal size. These results have to be interpreted with caution, and the safety of GW needs to be investigated further.

Acknowledgments

The authors thank Dr Calvin Torneck for his insights into this article.

This study was supported by grants from the American Association of Endodontists Foundation, the Canadian Academy of Endodontics Endowment Fund, and Sonendo Inc.


Statistics

The purpose of the following section is to describe the various statistical analyses of the data acquired for this study.

1.1. Amount of Extrusion and Canal Size

The mean mass of extruded irrigation in relation to canal size is summarized in Figures 7 and 8 for mesial and distal canals, respectively. Percent mass extruded is represented in Figures 9 and 10.

In order to test the null hypothesis regarding differences between CN and GW in the mean mass of extruded irrigation, a Wilcoxon t-test was used as the data was paired (a result from the repeated measures study design) but normality could not be assumed. Different Wilcoxon t-tests were performed to compare the mesial and distal canals at different canal sizes. Results are summarized in Table 1. EV was not compared to GW because these devices both demonstrated zero extrusion.

In the mesial canals tested, there was no significant difference in mean mass of extrusion for CN and GW for any canal size. In the distal canals tested, there was a significant difference in the mean mass of extrusion between CN and GW for all canal sizes.

1.2. Correlation of Extrusion Masses and Canal Size

In order to determine the correlation between mass of extruded irrigation and canal size, Spearman’s rho coefficients were calculated to measure the degree of dependence between
two variables. A Spearman's test (non-parametric) was used instead of a Pearson's test (parametric) because normality tests of the data (D'Agostino & Pearson omnibus normality test, Shapiro Wilk normality test, and KS normality test) concluded that the extrusion mass was non-parametric.

The larger the absolute value of the rho coefficient represents a stronger relationship. The sign of the rho coefficient indicates the direction of the relationship. Table 2 summarizes the coefficients for various comparisons and whether or not these rho coefficients were significant.

In distal canals, CN showed a positive correlation between mass of extrusion and canal size. Thus, it was extrapolated that as canal size increased, the amount of extrusion increased as well.

GW and EV were not associated with any extrusion of irrigation regardless of canal size.

1.3. CNI Extrusion masses for Mesial vs. Distal Canals

Because CN was the only device that resulted in extrusion of irrigation from the apex, a test was done to see if there was a significant difference between type of canal and extrusion mass (Figure 11 a, b, c). A Wilcoxon test was performed due to the nonparametric and paired nature of the data set.
Use of CN resulted in greater extrusion in distal canals than in mesial canals. There was a significant difference in the amount of extruded irrigation by CN in mesial canals compared to distal canals for traditional instrumentation (TI) and over instrumentation (OI) (Figure 9b, c).


Discussion

Serious NaOCl accidents during endodontic treatment have been rare and most occurred during syringe-delivered irrigation using open-ended needles (33). Over the years, needle designs have been modified and negative pressure delivery systems have been introduced to enhance irrigation delivery throughout the canal volume while also preventing inadvertent extrusion (63,72,73,81,115). GentleWave™ is a novel irrigating system shown in preliminary experiments using dye in transparent teeth to deliver irrigation to the level of the apical foramen (113). In a previous study aiming to access the ability of GentleWave™ to remove calcium hydroxide throughout the length of molar canals instrumented to size 25/.08 and 40/.08, it was demonstrated that the treatment fluid reaches to the canal terminus, as all the calcium hydroxide was removed (114). Considering that GentleWave™ utilizes NaOCl for irrigation, it was deemed necessary to assess the risk of periapical extrusion during its use in a variety of simulated clinical conditions.

1. Methodology

1.1. Experimental set-up

Although different, the design of the experimental apparatus was inspired by Psimma et al. (116). Keeping the roots in pressurized medium provided a quantitative assessment of extrusion that could occur only when irrigation pressure at the apical foramen exceeded the predetermined back-pressure (116). Psimma et al. (116) had a set-up able to measure apical extrusion in a real-time manner. The teeth were placed into a chamber filled with
distilled water and extrusion was measured as the amount of electrolytes diffused in the water. Using a conductivity probe of high sensitivity has been proven to be accurate. With their system, an open valve allowed the quantification of apical extrusion in a compliant system, which aimed to mimic a clinical situation where a sinus tract is present. Keeping the valve closed decreased the compliance of the experimental set-up and significantly less extrusion was seen when compared the open valve measurements.

Psimma et al. (116) did not control the periapical backpressure. Disregarding the backpressure produced by the periapical tissue by evaluating extrusion into vials filled with air possibly overestimates the extruded amount of irrigation (71,116). It also creates an obvious discrepancy with in vivo conditions because periapical tissues act as a barrier against irrigation extrusion.

Another method suggested to quantify apical extrusion of irrigation is to embed teeth in an agarose gel which changes color when NaOCl contacts the gel (73,74). This method has a clear advantage over the previous one described; however, the quantification of extruded irrigation is difficult and the system is affected by chemical diffusion.

In the present study, the experimental apparatus was developed to mimic the resistance to extrusion afforded by periapical tissues. The backpressure was constantly applied and controlled. Moreover, the quantification of extruded irrigation was not influenced by chemical diffusion.
1.2. Back pressure

Because the exact apical pressure that might result in a NaOCl accident is not known (117), the safety limit in this study was set to not exceed the central venous pressure of 5.88 mmHg (83), suggested to prevent occurrence of intravenous accidents (83). The pressure detected in dogs’ periapical lesions also supports this threshold (118). In maxillary molars and incisors, reduced apical resistance may be effected by bone porosity, fenestrations, anatomic variations such as drainage of a tooth by the facial vein (22) or location of root apices within the maxillary sinus without covering bone or Schneiderian membrane (119). In these situations, there may be an increased risk of NaOCl accidents (22). Because of this concern, the manufacturer of the GentleWave™ system considers its use contraindicated in maxillary teeth contacting the sinus.

Keeping the roots in pressurized medium provided a quantitative assessment of extrusion, which could occur only when irrigation pressure at the apical foramen exceeded the set back-pressure (116,120). This model offered a lower risk of overestimating the amount of apical extrusion than previously reported when an air-filled vial was used (116,120,121). The same air-tight chamber and pressure transducer were previously used to measure the apical pressure generated in canals of mandibular molars by different needle designs (117).

1.3. Tooth selection

Molars were used for the study primarily because the GentleWave™ system had only a molar handpiece available at the time of the study. The selection of mandibular molars
afforded three canals per tooth, including the moderately curved mesial canals and relatively straight distal canals. The same 16 teeth were used in random sequence for the three irrigation groups to avoid impact of changes in root canal anatomy on extrusion, as previously reported (116).

1.4. Instrumentation levels

Furthermore, to simulate different clinical situations, three modes of instrumentation were tested: MI represented a minimally-invasive preparation (MAF: #15/.02), TI represented conventional preparation (MAF: #35/.04) and OI represented absence of apical constriction as might occur in over-instrumented, externally resorbed and immature roots (MAF: #35/.04 WL +1mm).

1.5. Validation and control groups

In addition, to test extrusion with the GentleWave™ system, it was deemed appropriate to use the negative-pressure EndoVac® system as a negative control as it is reported to not cause extrusion during use (67,70,71,73,74). Irrigation with a needle extending beyond the apex was the positive control. Consistent extrusion in the positive control and none with EndoVac® validated the experimental model. In addition, irrigation with an open-ended needle positioned 3 mm short of working length and shown to cause minimal extrusion (120), was also tested to ascertain that the experimental model was adequately sensitive to detect such minimal amounts of extrusion.

The absence of extrusion with the use of GentleWave™ and EndoVac® systems suggested
that both devices generated apical pressures during use that did not exceed 5.88 ± 0.15 mmHg.

1.6. Solution choice

Distilled water was used for irrigation to avoid corrosion of the experimental apparatus by NaOCl. A pilot study confirmed that NaOCl and distilled water resulted in similar extrusion values (figure 6).

2. Results

Syringe irrigation with an open-ended needle did cause significant extrusion of irrigation in distal canals, partially rejecting the null hypothesis.

2.1. Needle

The amount of extruded irrigation in distal canals was positively correlated with the extent of canal instrumentation, in agreement with previous studies (20–22). Syringe irrigation with the 30 G open-ended needle has occasionally resulted in irrigation extrusion characterized by a broad range of volume and a large standard deviation (121). Such inconsistency was also seen in this study and could be attributed to variations in irrigation flow dynamics caused by differences in root canal anatomy and needle position, impacting on apical pressure and the risk of extrusion (120–122). Moreover, involuntary operator movement leading to changes in needle position and angulation, has also been reported as a
possible contributor to extrusion of irrigation (120).

2.2. GentleWave

The GentleWave™ system is composed of a console and a sterile disposable handpiece. It delivers a stream of treatment solution from the tip of the handpiece into the pulp chamber while excess fluid is simultaneously removed from the chamber by the built-in vented suction through the handpiece into a waste canister inside the console. According to the manufacturer, upon initiation of flow through the treatment tip of the handpiece, the stream of the treatment fluid interacts with the stationary fluid inside the pulp chamber creating a strong shear force that causes hydrodynamic cavitation in the form of a cavitation cloud. The continuous formation and implosion of thousands of microbubbles inside the cavitation cloud generates an acoustic field with broadband frequency spectrum that travels through the fluid into the entire root canal system. Throughout the treatment, the fluid starts with 3% Sodium Hypochlorite and changes to 8% EDTA following a water rinse in between. The treatment tip of the handpiece is designed to deflect the stream of treatment fluid in such a way to generate a flow over the orifices of the root canals. This flow induces gentle vortical flow as well as a slight negative pressure within the root canal system. The energy and the vortical flow dissipate as they travel apically into the root canal system.

One explanation for the energy dissipation would be the lack of hard tissue in the periapical space which is needed for the reflection of the sound waves. Further, the positive pressure
created by the periapical tissue when encountered by the negative pressure inside the root canal system would prevent apical extrusion. Independent studies to demonstrate the mechanism of action and the flow dynamics of the GentleWave™ system are warranted.

2.3. EndoVac

EndoVac® has been proven to be safe because it simultaneously delivers irrigation and draws it away from the canal and apical tissue. EndoVac® has been tested under a multitude of in-vitro conditions and the results have consistently shown that no extrusion of irrigation occurred (67,70,71,73,74). Apart from being able to avoid air entrapment, the EndoVac system is also advantageous in its ability to deliver irrigation safely to working length without causing undue extrusion into the periapex (70,71), thereby avoiding NaOCl accidents. It is important to note that it is possible to create positive pressure in the pulp canal if the Master Delivery Tip is misused, which would create the risk of a NaOCl accident. The manufacturer’s instructions must be followed for correct use of the Master Delivery Tip by never directing it towards the orifice of a canal. In order to compare the safety of six current intra-canal irrigation delivery devices, an in vitro test was conducted using the worst-case scenario of apical extrusion, with neutral atmospheric pressure and an open apex (71). The study (50) concluded that the EndoVac system did not extrude irrigation even after deep intra-canal delivery and suctioning of the irrigation from the chamber to full working length, whereas other tested devices did. The EndoActivator extruded only a very small volume of irrigation, the clinical significance of which cannot be speculated on. Mitchell and Baumgartner (73) tested irrigation (NaOCl) extrusion from a root canal sealed
with a permeable agarose gel. Significantly less extrusion occurred using the EndoVac system compared with positive-pressure needle irrigation (54). A well-controlled study by Gondim et al. (32) found that patients experienced less post-operative pain, measured objectively and subjectively, when apical negative-pressure irrigation was performed (EndoVac system) than with apical positive-pressure irrigation. Furthermore, PiezoFlow™ showed a greater potential to cause apical extrusion compared with EndoVac system’s safety (112). When positioned within the last five millimetres of the root canal, the ultrasonic activated needle could cause apical extrusion of irrigation solution (67).

This study was designed to answer a very specific research question and its results should not be extrapolated to clinical application or different conditions than those tested herein. Extrusion of irrigation with the GentleWave™ system was assessed as one measure of usage safety specifically in intact molars. As the GentleWave™ system is further adapted for use in other tooth types, further akin assessments are warranted. Furthermore, this study results might not apply to teeth presenting with reduced apical resistance, proximity of the mental foramen, undiagnosed vertical root fracture, perforating resorption defects and carious lesions communicating with the pulp chamber. These conditions require specific evaluation for safety of use of GentleWave™. Furthermore, because clinical application of irrigation systems may be influenced by additional factors other than those that can be assessed in vitro, more comprehensive assessment of the safety of GentleWave™ in clinical use is warranted.
**Conclusion**

Within the limitations of this *in vitro* study, GentleWave™ and EndoVac® did not cause extrusion of irrigation in the apparatus with apical pressure threshold of 5.88 ± 0.15 mmHg. Occasional extrusion during irrigation with a 30G conventional open-ended needle was noted and associated with canal size. These results have to be interpreted with caution and the safety of GentleWave™ to be further investigated.
References


86. Cohenca N, Heilborn C, Johnson JD, Flores DSH, Ito IY, da Silva LAB. Apical negative pressure irrigation versus conventional irrigation plus triantibiotic intracanal


Figures

Figure 1

Clinical aspect of emphysema related to extravasation of sodium hypochlorite solution associated with endodontic treatment, with ecchymosis and severe swelling of the right side of the face. These symptoms appeared after a root canal treatment of the upper right canine (Reproduced with permission from Elsevier).
Figure 2
The components of the EndoVac system: the Master Delivery Tip (MDT) accommodates different sizes of syringes, the macrocannula is attached to the autoclavable aluminium handpiece and the microcannula is attached to an autoclavable aluminium fingerpiece. The macrocannula, the microcannula and the MDT are connected via clear plastic tubing. The tubes are connected to the high-volume suction of the dental chair via the multiport adaptor (Courtesy John Schoeffel).
Final irrigation protocol using EndoVac system

### Macro Cycle
The macro cannula is inserted into the root canal and constantly moved up and down in short pecking motions as close as possible to working length while a continuous irrigation of NaOCl is delivered with the MDT for 30 seconds into the pulp chamber directed against a chamber wall.

### First Micro Cycle
1. Place the micro cannula to WL
2. Deliver NaOCl for 10 sec
3. Stop irritant flow for a brief moment to purge out the gas bubbles
4. Deliver NaOCl for 10 sec
5. Stop irritant flow for a brief moment to purge out the gas bubbles
6. Deliver NaOCl for 10 sec
7. Remove the micro cannula as the pulp chamber is filled with NaOCl
8. Leave it charged for 60 sec

### Second Micro Cycle
1. Place the micro cannula to WL
2. Deliver EDTA for 10 sec
3. Remove the micro cannula as the pulp chamber is filled with EDTA
4. Leave it charged for 60 sec

### Third Micro Cycle
1. Place the micro cannula to WL
2. Deliver NaOCl for 10 sec
3. Stop irritant flow for a brief moment to purge out the gas bubbles
4. Deliver NaOCl for 10 sec
5. Stop irritant flow for a brief moment to purge out the gas bubbles
6. Deliver NaOCl for 10 sec
7. Remove the micro cannula as the pulp chamber is filled with NaOCl
8. Leave it charged for 60 sec
9. Place the micro cannula to WL for a moment to dry the canal

### Debris Removal
Several studies were carried out to evaluate the EndoVac system's ability to remove debris within the root canal system after instrumentation with rotary files [16–21]. Debridement is a principal objective of root canal treatment and remains a challenge especially in the apical portion of the canal and within the isthmuses and lateral and accessory canals. Debridement is the elimination of organic and inorganic substances as well as microorganisms from the root canal by mechanical and/or chemical means [22]. When compared to traditional syringe and side-vented needle irrigation, the EndoVac system has demonstrated better control to reach the last millimetre of the root canal. Some in vitro and in vivo studies have demonstrated greater removal of debris from the apical walls and a statistically cleaner result using apical negative-pressure irrigation in closed root canal systems with sealed apices. In an in vivo study of 22 teeth by Siu and Baumgartner, less debris remained at 1 mm from working length using apical negative pressure compared to the use of traditional needle irrigation, while Shin...
Figure 4

GentleWave™ system (Sonendo, Laguna Hills, CA)
Figure 5A and 5B

Experimental apparatus

A) The tooth is mounted on a customized cap and secured into an air-tight chamber filled with incompressible fluid (B). If the periapical pressure, detected by pressure transducer (C), is greater than the simulated periapical back pressure, fluid passes through the extrusion line (D), which consists of a 12 VDC precision solenoid valve. Extruded fluid is then collected onto a plexi glass dish (E) positioned on a load cell. The load cell is placed inside a pressure vessel (F). The pressure vessel is pressurized via a pressure generator (G) that simulates periapical back pressure. The pressure within the vessel is measured by another pressure transducer (H) and regulated by a pressure valve (I).
Figure 6

Pilot study comparing the apical extrusion of 0.5% NaOCl and water.
Figure 7

Mass of extruded irrigation (mean +/- SD, N=16) during 30 seconds measurement in mesial canals for different devices and canal size.

![Graph showing extruded mass in mesial canals for different instrumentation levels](image-url)
Figure 8

Mass of extruded irrigation (mean +/- SD, N=16) during 30 seconds measurement in distal canals for different devices and canal size.
Percent of extruded mass during 30 seconds measurements in mesial canals for different devices and canal sizes.

**Figure 9**

Percent of extruded mass during 30 seconds measurements in mesial canals for different devices and canal sizes.
Figure 10

Percent of extruded mass during 30 seconds measurements in distal canals for different devices and canal sizes.

![Percent of Mass Extruded in Distal Canals](image)

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Canal Size</th>
<th>GW (Minimal)</th>
<th>CN (Minimal)</th>
<th>EV (Minimal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNI vs. MU (Mesials)</td>
<td>Minimal</td>
<td>&gt;0.9999</td>
<td>No</td>
<td>EV</td>
</tr>
<tr>
<td>CNI vs. MU (Distals)</td>
<td>Minimal</td>
<td>&gt;0.9999</td>
<td>No</td>
<td>EV</td>
</tr>
<tr>
<td>CNI vs. MU (Mesials)</td>
<td>Traditional</td>
<td>&gt;0.9999</td>
<td>No</td>
<td>EV</td>
</tr>
<tr>
<td>CNI vs. MU (Distals)</td>
<td>Traditional</td>
<td>&gt;0.9999</td>
<td>No</td>
<td>EV</td>
</tr>
</tbody>
</table>

Table 1: Summary of Wilcoxon t-test comparing CNI and MU for each root and canal size.

Concluding Remarks

In the mesial canals tested, there was no significant difference in average amount of extrusion for CNI and MU for any canal size. Distal canals resulted in a significant difference in the average amount of extrusion between CNI and MU for all canal sizes.
Figure 11

Mass (mean +/- SD, N=16) of extruded irrigation during 30 s Conventional Needle Irrigation for Mesial and Distal canals in a) minimally shaped canals, b) traditionally shaped canals, and c) over-instrumented canals. Differences in the average amount of extrusion were considered statistically significant if the p-value was less than 0.05.

Mass Extruded During Conventional Needle Irrigation

(a) Minimal instrumentation
(b) Traditional instrumentation
(c) Over instrumentation

Minimal instrumentation

Traditional instrumentation

Over instrumentation
Tables

Table 1

Summary of Wilcoxon t-test comparing CN and GW for each canal size.

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Canal Size</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CN vs. GW (Mesials)</td>
<td>MI</td>
<td>0.1250</td>
</tr>
<tr>
<td>CN vs. GW (Distals)</td>
<td>MI</td>
<td>0.0156*</td>
</tr>
<tr>
<td>CN vs. GW (Mesials)</td>
<td>TI</td>
<td>&gt;0.9999</td>
</tr>
<tr>
<td>CN vs. GW (Distals)</td>
<td>TI</td>
<td>0.0020*</td>
</tr>
<tr>
<td>CN vs. GW (Mesials)</td>
<td>OI</td>
<td>&gt;0.9999</td>
</tr>
<tr>
<td>CN vs. GW (Distals)</td>
<td>OI</td>
<td>0.0020*</td>
</tr>
</tbody>
</table>

*Significant values
Table 2

Summary of the Correlation Analysis using Pearson’s r coefficient. Comparisons were made for each device type and canal size for both mesial and distal canals. No data is shown for GW and EV because the extrusion mass for these devices is 0 g. All cells marked with a “-” had no correlation coefficient to report as all extrusion values were 0 g.

<table>
<thead>
<tr>
<th>Device</th>
<th>Comparison</th>
<th>Canal</th>
<th>Sperman’s rho coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>CN</td>
<td>MI vs. TI</td>
<td>Mesials</td>
<td>0.55</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Distals</td>
<td>0.69*</td>
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<tr>
<td></td>
<td>TI vs. OI</td>
<td>Mesials</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Distals</td>
<td>0.05</td>
</tr>
</tbody>
</table>

*Significant values*
Table 3

Summary of the chance of extrusion for each endodontic treatment device for all canals and all canal sizes.

<table>
<thead>
<tr>
<th>Device</th>
<th>Frequency of Extrusion</th>
<th>Chance of Extrusion</th>
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</thead>
<tbody>
<tr>
<td>MU</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>CN</td>
<td>32</td>
<td>33%</td>
</tr>
<tr>
<td>EV</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>
Table 4

Mean extruded irrigation mass (gram) in each of 16 specimens tested, having canals instrumented consecutively with three modes (MI, TI, OI) and irrigated with an open-ended 30G needle inserted 3 mm short of the working length. Each canal was tested 5 times.

<table>
<thead>
<tr>
<th>Tooth number</th>
<th>Minimal Instrumentation (MI)</th>
<th>Traditional Instrumentation (TI)</th>
<th>Over-instrumentation (OI)</th>
</tr>
</thead>
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<tr>
<td></td>
<td>Mesial Canal</td>
<td>Distal Canal</td>
<td>Mesial Canal</td>
</tr>
<tr>
<td>1</td>
<td>0.139</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>2</td>
<td>0.000</td>
<td>0.573</td>
<td>0.000</td>
</tr>
<tr>
<td>3</td>
<td>0.000</td>
<td>0.225</td>
<td>0.000</td>
</tr>
<tr>
<td>4</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>5</td>
<td>0.000</td>
<td>0.537</td>
<td>0.000</td>
</tr>
<tr>
<td>6</td>
<td>0.045</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>7</td>
<td>0.255</td>
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<td>0.000</td>
</tr>
<tr>
<td>8</td>
<td>0.000</td>
<td>0.360</td>
<td>0.000</td>
</tr>
<tr>
<td>9</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
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<td>10</td>
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<tr>
<td>11</td>
<td>0.305</td>
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<tr>
<td>Mean mass (±SD)</td>
<td>0.047 (0.098)</td>
<td>0.123 (0.191)</td>
<td>0.021 (0.084)</td>
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