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Evaluation of Extra-canal Apical Tissue Pressure Generated by the Gentle Wave System Compared to Three Traditional Irrigation Methods

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Evaluation of Extra-canal Apical Tissue Pressure Generated by the GentleWave System Compared to Three Traditional Irrigation Devices

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Abstract

Introduction: During endodontic procedures, excessive positive apical pressure could result in periradicular extrusion of irrigants. This study compared pressures created at the level of the apical foramen when using four irrigant delivery devices: Max-I Probe (side-vented needle), NaviTip (open-ended needle), EndoVac (microcannula) and the GentleWave System.

Methods: Twelve extracted anterior teeth were divided into four groups (n=3) according to apical prep size: groups 1 and 2 were instrumented to 25/.06 and 40/.04, respectively; groups 3 and 4 were instrumented to an open apical foramen size of 0.60mm and 1.00mm, respectively. To measure apical pressures created during irrigation, the roots of the teeth were placed into an air-tight custom fixture coupled to a piezoresistive pressure transducer. The Max-I Probe, NaviTip, and EndoVac were positioned 1mm short of working length or of first binding point. The GentleWave was used per manufacturer's instructions.

Results: The range of mean apical pressures (in mmHg) for each device tested across all groups were: Max-I Probe: 1.29 to 13.86; NaviTip: 0.443 to 28.71; EndoVac: -8.48 to -4.02; GentleWave: -23.39 to -19.81. GentleWave and EndoVac maintained significantly more negative apical pressure ($p < 0.003$) than the needle devices for all groups. GentleWave maintained significantly more negative pressure than all other devices for all groups except group 1, where EndoVac was statistically similar.

Conclusion: GentleWave had the most consistent and negative apical pressure of all the devices studied, irrespective of apical prep size. Used appropriately, the GentleWave and EndoVac systems provide a consistent and negative pressure method to irrigate root canal systems.

Introduction and Background

Irrigation is vitally important to successful root canal therapy [1]. To effectively debride the root canal system and remove necrotic tissue, irrigation is paramount [2]. Although instrumentation of canal walls is certainly important in the removal of necrotic tissue and bacteria from the root canal [3], studies have shown that currently used methods of root canal preparation alone do not effectively debride the entire root canal system. [4]. Therefore, irrigation plays a critical role in root canal preparation procedures [5]. Irrigating the canal system dissolves organic and inorganic tissue, facilitating its removal [6]. Not only is irrigation important for the removal of debris but it is a key element in the disinfection of the root canal system [6]. One of the major obstacles to effective irrigation is the size of the canal compared to the size of the irrigation needle. It can be challenging to place a delivery tip far enough into the canal to properly reach and disinfect all areas of the canal space [7]. Even if the canal space can be enlarged enough to get a delivery tip to the desired location, large areas of the main root canal still may remain untouched by instruments, especially in the apical part of the root canal [7]. Most current irrigation devices have the drawback of requiring a delivery or suction tip to be placed at or near working length to effectively deliver the solutions to the desired locations [8]. An ideal delivery system must have adequate flow and volume of irrigant as well as the ability to get that irrigant to working length to be effective in debriding the canal system and it must do this without forcing the solution beyond the apex and into periradicular tissues [9].

Negative pressure irrigation systems have been shown to deliver irrigant to the apical portions of the root canal in a safe and effective manner [10]. Devices that deliver a negative extra-canal pressure are presumably safer than positive-pressure devices and greatly minimize the risk of extrusion of irrigants such as sodium hypochlorite into periapical tissues [11]. Some studies have even found that negative pressure irrigation have other benefits such as a reduction in the postoperative pain a patient experiences [12] .One disadvantage of negative pressure devices, such as the Endovac, is that tin order to place the microcanula to the desired length, a minimum apical prep size of 0.35mm must be obtained. Sharp curves or constricted canals can make it impossible for a delivery tip to be placed to the desired depth [8].

The novel GentleWave system (Sonendo® Inc., Laguna Hills, CA) using "Multisonic Ultracleaning" technology delivers irrigants to the root canal system without the use of a canula. The GentleWave system uses self-contained distilled water, EDTA and sodium hypochlorite that it delivers to the root canal system using a handpiece that is placed on a custom built platform surrounding the access made in the tooth. This handpiece forms a seal with the platform which is paramount to the proper function of the system. Once the GentleWave system determines there is a positive seal, it delivers the irrigants to the root canal system using a broad-spectrum acoustic streaming technology under high pressure. The hand piece has small suction holes that continuously removes the irrigants as it delivers them. Some studies have shown very promising results using the GentleWave system to clean root canals [13-16]. Due to the high pressures generated in the pulp chamber and the high volumes of irrigants delivered during operation the risk of extrusion of the irrigants needs to be considered [13].

Materials and methods

Twelve extracted human anterior teeth were collected. Exclusion criteria included teeth with apparent fractures, deep caries or caries below the cemento-enamel junction, more than one apical foramen, teeth with previous root canal therapy, and internal or external resorption. The teeth were viewed under a microscope at 12x magnification to verify the teeth met the inclusion criteria. Clinical and proximal view radiographs were made to verify only one canal was present in all of the samples. The teeth were stored in 0.1% Thymol throughout the study. Teeth were accessed with and were randomly assigned to four groups (n=3).

For all teeth, patency was established and verified with a #10 K-file. Working length was determined by visualizing the tip of the #10 file at the apical foramen and subtracting 1mm from that length. The teeth were prepared as follows:

Group 1: The canal was shaped progressively to a 25/.06 Vortex Blue file; a Lightspeed LSX file was used manually without cutting to verify that the apical foramen maximum diameter did not exceed 0.30mm.

Group 2: The canal was shaped progressively to a 40/.04 Vortex Blue file; a Lightspeed LSX file was used to verify that the apical foramen maximum diameter did not exceed 0.45 mm.

Group 3: The canal was shaped progressively to a Lightspeed LSX file size #60 file through the apical foramen, to simulate an open apex with a size of 0.6mm. A Lightspeed LSX #70 file was used without cutting to verify the apical prep size did not exceed 0.6mm.

Group 4: The canal was shaped progressively to a Lightspeed LSX file size #100 file through the apical foramen. This simulated an open apex with a size of 1.00mm. A Lightspeed LSX #110 file was used without cutting to verify it did not pass through the apical foramen, to confirm apical prep size.

Testing fixture

The apical pressure testing setup was completed as follows: A 10ml syringe was filled with distilled water and connected to the needle devices via tubing with a Luer-lock connection. A peristaltic pump was calibrated by measuring a known volume of fluid and transferring it at a set rate for a set amount of time to verify the flow rate of the pump. The pump was set to deliver irrigant at a constant 4ml/min. This flow rate was used for all needle devices. Tooth samples were secured in an acrylic cap with glue. The acrylic cap was screwed into the acrylic testing block to form an airtight chamber. The chamber was filled with distilled water and all bubbles were removed. A platform was constructed on top of the tooth per GentleWave's instructions to allow an airtight seal with the GentleWave anterior handpiece. This platform was kept in place while testing all devices. The acrylic block had a threaded port to which a pressure transducer (PXM409-350; Omega, Stanford CT, USA) was attached to allow for pressure readings. The pressure transducer was connected to a computer via USB connection and used LabVIEW (National instruments, Austin, TX, USA) software to record all pressure readings during testing at a rate of 200 readings per second.

Irrigation devices

Device 1: An open-ended 30-gauge irrigation needle (Nav-I-tip, Ultradent Products Inc., St. Louis, MO USA).

Device 2: A side-vented 30-gauge irrigation needle (Max-I-probe, Dentsply, Elgin, IL USA).

Device 3: The EndoVac system utilizing the MicroCannula (Kerr Detroit, MI, USA).

Device 4: The anterior handpiece of the GentleWave system (Sonendo Inc., Laguna Hills, Ca, USA).

For devices 1, 2 and 3 tests were conducted as described; this study does not follow manufacturer's instructions on these devices as this study is only interested in the apical pressure changes that occur with the device in use in the apical segment and not the efficacy of the device. Device 4 was used per manufacturer's instructions however only with a 30 second cycle. Distilled water was used with all devices as other irrigants are harmful to the pressure transducer. Pressures were recorded at a rate of 200 times per second using the Labview software.

Each tooth was tested with each device three times; apical pressures were recorded while the device was in use (for a period of 30 seconds during use of all four devices). Values for each sample were recorded and analyzed. The first and last 5 seconds were not used in the statistical analysis, however the data were still reviewed to verify that both the EndoVac and GentleWave system never produced a positive pressure value.

Statistical analysis

Statistical analysis was performed using JMP 13 (SAS Institute) software. The mean and standard deviation were calculated for the devices tested and each sample group. A Oneway ANOVA with post-hoc Tukey-Kramer HSD (honestly statistical difference) analysis was completed and evaluated for each group and device. The level of significance was set at $p = 0.05$. An analysis of variances was also completed.

Results

The EndoVac and the GentleWave systems consistently generated negative pressures throughout the study. At no time did either device generate a positive pressure. The EndoVac maintained a negative pressure regardless of apical dimensions with mean values ranging from -4.02 to -8.48mmHg. The GentleWave maintained a negative pressure regardless of apical dimensions with mean values ranging from -19.81 to -23.39mmHg. The positive pressure needle devices were less consistent than the negative pressure devices and showed a significant increase in pressure in the smaller prepared groups than the open apex groups. The side-vented needle mean pressure range was (1.29 to 13.86mmHg). The side-vented needle had higher-pressure levels in the smallest apical prepared group at 13.86mmHg while the 0.6mm and 1.0mm groups were 4.51mmHg and 1.29mmHg respectively. The open-ended needle mean pressure range was 0.44 to 28.71 mmHg. The open-ended needle had significantly higher-pressure levels in the smallest apical prepared group at 28.71mmHg while the 0.6mm and 1.0mm groups were 3.57mmHg and 0.44mmHg respectively.

Discussion

The Endovac and the GentleWave irrigation system consistently created a negative pressure throughout this study, while the needle delivery devices maintained positive apical pressures. The needle delivery devices and EndoVac pressures generated were less consistent between groups than the GentleWave which delivered a very consistent apical pressure regardless of apical preparation size. While this in vitro study was a simplified version of what actually happens when a tooth is irrigated during root canal therapy in vivo, some conclusions can be drawn from this study. Within the confines of this study it can be said that the EndoVac and GentleWave systems, if used appropriately, are safer than needle delivery devices. Pressures increased dramatically in the needle devices as the apical preparation sizes decreased. In teeth that require minimal instrumentation to achieve a successful outcome such as dramatically curved roots, a device such as the GentleWave, which advocates for minimal preparation, could be beneficial and safer.

In group 1 (25/.06) two of the teeth had all of the needle devices bind approximately 2mm from working length or about 1mm from the desired testing depth and were backed up an additional 1mm during testing. In all other groups, the needle devices were tested 1mm from working length. This depth was chosen primarily for consistency among the needle devices, but also as a clinically relevant depth, shown to effectively remove debris. According to Chow T.W. “The apical extent of effectiveness of irrigation is a function of the depth of insertion of the needle” (9).

All devices were tested for 30 seconds in each tooth in each group. This was done three times for a total of 90 seconds of testing for every device in every tooth. For each 30 second session the working length of the needle devices was verified prior to starting the next cycle. This was done to maintain the most consistent data possible; in the smaller apical preparation groups even a small change in the depth of placement for the needle devices could have a dramatic difference in pressure readings. In the open apex groups this process was repeated, however it was noted that the depth of needle placement was far less critical.

The GentleWave had a more consistent, more negative pressure than the EndoVac throughout this study. The EndoVac and GentleWave system both appear to be a safe device for delivery of irrigants during root canal therapy when used within the confines of this study.

Conclusion

GentleWave had the most consistent and negative apical pressure of all the devices studied, irrespective of apical prep size. Used appropriately, the GentleWave and EndoVac systems provide a consistent and negative pressure method to irrigate root canal systems.

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Conflict of interest

None

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