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Original Article

Cleaning efficacy and apical pressure in sonically-activated irrigation systems: Impact of tip vertical stroke

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Abstract *Background/purpose:* A newly developed sonic device for root canal irrigation, the SmartLite Pro EndoActivator, features modified vibration frequencies and behaviors. This study aimed to examine the cleaning efficacy and periapical pressure generation of sonically-activated irrigation (SAI) with different number of vertical strokes.
Materials and methods: Seventy-two human anterior teeth were instrumented to a #25/0.07 taper. Experiment 1: 36 teeth were irrigated using: (1) EndoActivator (SAI-1), (2) SmartLitePro EndoActivator (SAI-2), and (3) syringe irrigation (SI) (n = 12, each). Experiment 2: 36 teeth were irrigated with SAI-2, varying the number of vertical strokes applied (0, 10, and 40 times; n = 12, each). Debris and smear layer scores were assessed using scanning electron microscopy. Experiment 3: Periapical pressures were measured during irrigation of plastic root canal models (#40/0.06 taper) with SAI-2 using 0, 10, or 40 strokes. Data were analyzed with the Kruskal Wallis and Mann—Whitney U tests ($P < 0.05$).
Results: In Experiment 1, the SAI-2 group showed significantly better smear layer scores than the SAI-1 and SI groups ($P < 0.05$). In Experiment 2, the 40-stroke group had significantly superior debris and smear layer scores than the 0-stroke group ($P < 0.05$), with similar scores to those of the 10-stroke group. In Experiment 3, the 40-stroke group generated significantly higher periapical pressure than the other groups ($P < 0.05$).
Conclusion: The SmartLite Pro EndoActivator outperformed EndoActivator and syringe irrigation regarding cleaning efficacy. Increasing the number of vertical strokes improved the cleaning efficacy but also resulted in higher apical pressures.

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Introduction

Irrigation is a critical component of successful root canal treatment.[1] Mechanical instrumentation produces debris as the instruments cut the canal walls, forming a smear layer that may include inorganic dentin debris and organic components such as microorganisms and necrotic pulp tissue.[2] The smear layer hinders intracanal medicament and irrigant penetration into the dentinal tubules, potentially diminishing disinfection efficacy.[3] Therefore, root canal irrigation is essential to remove debris, eliminate the smear layer, and disinfect the canal space and superficial dentin.[2]

Sodium hypochlorite (NaOCl) is the primary irrigant widely used in root canal treatments.[4] The use of NaOCl in combination with a chelator, as exemplified by ethylenediaminetetraacetic acid (EDTA), is recommended to enhance smear layer removal and improve canal cleanliness.[5] For optimal effectiveness, irrigants should directly contact the entire surface of the root canal wall.[6] As conventional syringe irrigation (SI) shows limited efficacy in achieving adequate distribution and agitation, irrigant activation methods, such as manual agitation, sonically-activated irrigation (SAI), ultrasonically-activated irrigation, and laser-activated irrigation[7–10] are increasingly used over SI alone[11] to facilitate more reliable cleaning.

SAI has demonstrated varying levels of effectiveness in endodontics.[5,7,12–14] SAI involves transmitting of acoustic energy to the irrigant, creating hydrodynamic effects that enhance cleaning efficacy.[15] The EndoActivator (Dentsply Sirona, Ballaigues, Switzerland) utilizes a non-cutting flexible polymer tip that reduces shear stresses and enhances the pumping action of the vibrating tip.[5] The recently introduced SmartLite Pro EndoActivator (Dentsply Sirona) applies similar principles to enhance irrigant agitation, while it operates at higher frequencies with an elliptical motion, ensuring more effective irrigant activation. Unlike first-generation circular tips, second-generation tips feature paddle-like, parallelogram cross-sections.

Operating the EndoActivator tip 2 mm short of the working length with short vertical strokes enhances irrigant exchange and cleaning,[15,16] but could cause tissue damage due to irrigant extrusion from the apical foramen.[17,18] Thus, irrigation in the apical root canal area should carefully balance efficacy and safety, with the appropriate number of vertical strokes being crucial. Previous studies have examined the efficacy of the SmartLite Pro EndoActivator in bacterial debridement[19] and compared SAI procedures for calcium hydroxide removal.[20] However, the effects of the number of vertical tip strokes on cleaning efficacy and irrigant extrusion remains unexplored.

Therefore, this study aimed to examine the efficacy of debris and smear layer removal and periapical pressure generation of SAI with different numbers of vertical tip movements. The null hypotheses were that (1) smear layer and debris do not differ between the tested groups and (2) the number of vertical tip movements does not influence cleaning efficacy or pressure generated outside the apical foramen.

Materials and methods

Specimen selection

This study was approved by the research ethics committee from the Ethics Committee, Tokyo Medical and Dental University (No. D2023-029). Based on previous research,[21] a minimum sample size of 12 teeth per group was calculated using G*Power 3.1.9 (Heinrich Heine University, Düsseldorf, Germany), with an effect size of 0.6, alpha error of 0.05, and beta power of 85 %.

Seventy-two extracted human permanent anterior teeth were selected for this research. Each tooth was radiographically evaluated to confirm adherence to the inclusion criteria: a single straight canal, complete apical formation, and no signs of caries, root fractures, cracks, or resorption. The samples further underwent micro-computed tomography scanning (inspeXio SMX-100CTPlus, Shimadzu, Kyoto, Japan; voxel size 0.03 mm), followed by three-dimensional reconstruction using imaging software (Amira 3D version 2023.2; Visage Imaging GmbH, Berlin, Germany). The samples were standardized according to canal volume, surface area, degree of curvature, and canal length to ensure anatomically matched experimental groups.[22] After confirming the morphological configurations, the teeth were randomly assigned to three test groups for Experiments 1 and 2, as described below. Analysis of the geometric characteristics of the experimental groups using Kruskal Wallis and Dunn's tests revealed no significant differences (Table 1).

Root canal preparation

After the access opening, a #10 K-file (Zipperer, Munich, Germany) was used to verify apical patency and establish a working length of 1 mm from the apical foramen. After creating a glide path with the WaveOne Gold Glider instrument (#15.06; Dentsply Sirona), all canals were instrumented to the working length using a reciprocating nickel-titanium instrument (WaveOne Gold Primary; #25.07; Dentsply Sirona) using an endodontic motor (X-Smart Plus, Dentsply Sirona). The root canals were irrigated with 6 % NaOCl (2 mL) using a 27 G needle (Dentsply Sirona) attached to a 3-mL syringe with gentle back-and-forth movements. Finally, the canals were irrigated with 17 % EDTA (3 mL), followed by distilled water (3 mL).

Table 1 Root canal morphometric values before instrumentation.

Parameter	Experiment 1			Experiment 2		
	SAI-1	SAI-2	SI	0-stroke	10-stroke	40-stroke
Volume (μm^3)	33255 (11465–93835)	37332 (10430–93835)	35896 (10430–82594)	33237 (8863–83215)	37332 (10430–82594)	37925 (6046–80407)
Surface area (μm^2)	14017.2 (5504.2–53017)	18766.5 (6518.7–52555)	14239 (5276.4–52316.4)	13017 (5504.3–53017.2)	15284.1 (5276.4–52316.4)	19261.2 (6518.7–52555)
Angle of curvature (degree)	5 (0–5)	5 (1–5)	5 (1–6)	2 (0–5)	5 (1–5)	5 (1–6)
Length (mm)	18.9 (16.5–20.3)	18.9 (16.6–20.8)	18.6 (16.1–20.5)	17.4 (16.6–20.9)	18 (16.5–20.6)	18.3 (16.3–20.4)

Values are median (minimum–maximum). Kruskal Wallis test indicated no significant differences among the test groups ($P > 0.05$). SAI-1, EndoActivator; SAI-2, SmartLite Pro EndoActivator; SI, syringe irrigation.

Final root canal irrigation protocols

After root canal preparation, each sample underwent final irrigation with SAI or SI in the following sequence:

1. 6 % NaOCl (3 mL) for 30 s
2. 17 % EDTA (3 mL) for 30 s
3. 6 % NaOCl (3 mL) for 30 s
4. distilled water (3 mL).

Experiment 1

The cleaning efficacy following the final irrigation was compared between SAI devices. Thirty-six teeth were randomly assigned into three groups (n = 12 per group) based on the irrigation system:

1. SAI-1: Each irrigant was activated using the EndoActivator with its dedicated tip (small, #15/02, 22 mm, Dentsply Sirona) at 10,000 cycles per min. According to manufacturer recommendations, the tip was positioned 2 mm from the working length, and short vertical strokes (2–3 mm) were applied 10 times (30 s each).
2. SAI-2: Each irrigant was activated using the SmartLite Pro EndoActivator with its dedicated tip (small, #15/02, 22 mm, Dentsply Sirona) at 18,000 cycles per min. The irrigant activation procedure followed the same method as that used in SAI-1.
3. SI: Each irrigant was delivered using a syringe pump (YSP-101, YMC, Kyoto, Japan; 6.0 mL/min) and a 27G flat-ended needle (Nipro, Osaka, Japan). The needle tip was placed 1 mm from its binding point, and irrigation was performed with 10 gentle up-and-down movements with 2–3 mm amplitude.

Experiment 2

The impact of the number of vertical strokes on the cleaning efficacy of the SmartLite Pro EndoActivator was evaluated. The irrigation protocol was identical to that used for SAI-2 in Experiment 1, except for the number of vertical strokes. Thirty-six teeth were randomly divided into three groups (n = 12 each) according to the number of vertical tip strokes, set at 0, 10, or 40.

Scanning electron microscopy evaluation of debris and smear layer

After the final irrigation, all teeth were split into halves after two parallel longitudinal grooves were created on the mesial and distal root surfaces using diamond burs. A matching gutta-percha cone was inserted into the canal to prevent accidental penetration and contamination by sharp debris. The specimens were examined under a scanning electron microscope (SEM; JSM-7900F, JEOL, Tokyo, Japan) at 15 kV. All samples were observed at 200 × and 1,000 × magnification for debris and smear layer assessments, respectively. Images were captured from the central region of the canal wall in the coronal, middle, and apical thirds. Two examiners who were not informed of the experimental methodology and blinded to the group assignments evaluated the specimens using the Hülsmann scoring system (Fig. 1).[23]

Measurement of periapical pressure (Experiment 3)

The periapical pressure produced by the SmartLite Pro EndoActivator was investigated based on the number of vertical strokes of the tip. A plastic pipette tip (10 μL long tip; Fukae Kasei, Hyogo, Japan) featuring an apical diameter of 0.40 mm, a 6 % taper, and a length of 20 mm was used as a simulated root canal. Distilled water was employed as the irrigant for all measurements. Irrigation was performed 10 times (30 s each) as in the SAI-2 group. The root canal models were assigned into three groups based on the number of vertical strokes: 0,10, or 40 times.

The apex of the root canal model was placed on a pressure sensor (AP-12S; Keyence, Osaka, Japan) via a vinyl tube filled with distilled water. The pressure sensor was linked to an amplifier (AP-81A; Keyence, Osaka, Japan) and connected to a recording device (high-speed microscope; VW-9000, Keyence) (Fig. 2). The pressure generated beyond the root apex during irrigation was measured 10 times for each group, and the mean maximum pressure was calculated.

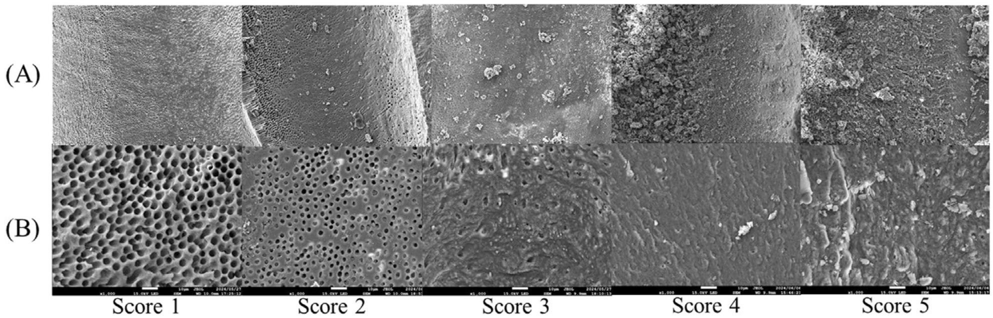

Figure 1 Representative scanning electron microscopy images showing (A) residual debris and (B) smear layer scores according to Hülsmann et al.[23] Debris scores: 1, clean root canal wall with only a few small debris particles; 2, small clusters of debris; 3, multiple debris clusters covering <50 % of the root canal wall; 4, debris covering >50 % of the root canal wall; and 5, debris covering entire or nearly entire root canal wall. Smear layer score: 1, no smear layer with open dentinal tubules; 2, minimal smear layer, some open dentinal tubules; 3, uniform smear layer covering the root canal wall with a few open dentinal tubules; 4, root canal wall fully covered by a uniform smear layer, no open dentinal tubules; and 5, heavy, irregular smear layer completely covering the root canal wall. Scale bars = 0.1 mm (A) and 0.01 mm (B).

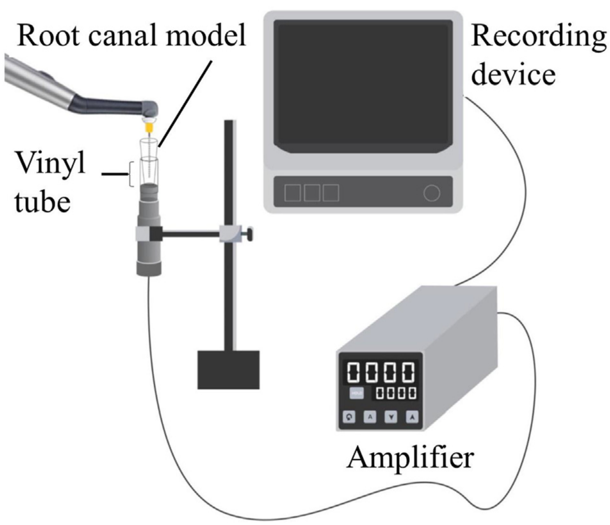

Figure 2 Schematic diagram of the experimental setup in Experiment 3. The pressure caused by the irrigation was measured by a pressure sensor connected to the root canal model using a vinyl tube filled with distilled water.

Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics (version 26.0; IBM, Armonk, NY, USA) at $\alpha = 0.05$. Data were initially assessed for normality with the Shapiro–Wilk test and for homogeneity of variance using the Levene test. The cleaning efficiency scores and apical pressures were analyzed using Kruskal Wallis test and Mann–Whitney U test with Bonferroni correction. The Cohen's kappa test was employed to assess the inter-examiner reliability.

Results

The kappa values in Experiments 1 and 2 were 0.79 and 0.81, respectively.

Experiment 1

The debris score was highest in the SI group across all root regions ($P < 0.05$). The SAI-1 and SAI-2 groups presented similar debris scores with no significant differences ($P > 0.05$). The smear layer scores were significantly lower for SAI-2 compared with the other groups across all root regions ($P < 0.05$). In the apical and middle thirds, the SAI-1 group had significantly lower smear layer scores than the SI group ($P < 0.05$) (Figs. 3 and 4).

Experiment 2

The debris scores revealed comparable effectiveness in debris removal between the 10- and 40-stroke groups ($P > 0.05$), which were significantly better compared to the 0-stroke group in all root regions ($P < 0.05$). The smear layer scores did not differ significantly between the 10- and 40-stroke groups in all regions ($P > 0.05$). At the apical third, the 10-stroke group removed more smear layers than the 0-stroke group ($P < 0.05$). At the coronal level, the 40-stroke group showed significantly greater removal of smear layers than did the 0-stroke group ($P < 0.05$). No significant differences were observed among all groups at the middle level ($P > 0.05$) (Figs. 5 and 6).

Experiment 3

The maximum pressure generated beyond the apical foramen increased with higher numbers of vertical strokes. Although the apical pressures did not differ significantly between the 0- and 10-stroke groups, the pressure was significantly higher in the 40-stroke groups than in the other groups ($P < 0.05$) (Fig. 7).

Discussion

The findings of this study revealed differences in the effectiveness of debris and smear layer removal between two generations of sonic devices. Furthermore, increasing

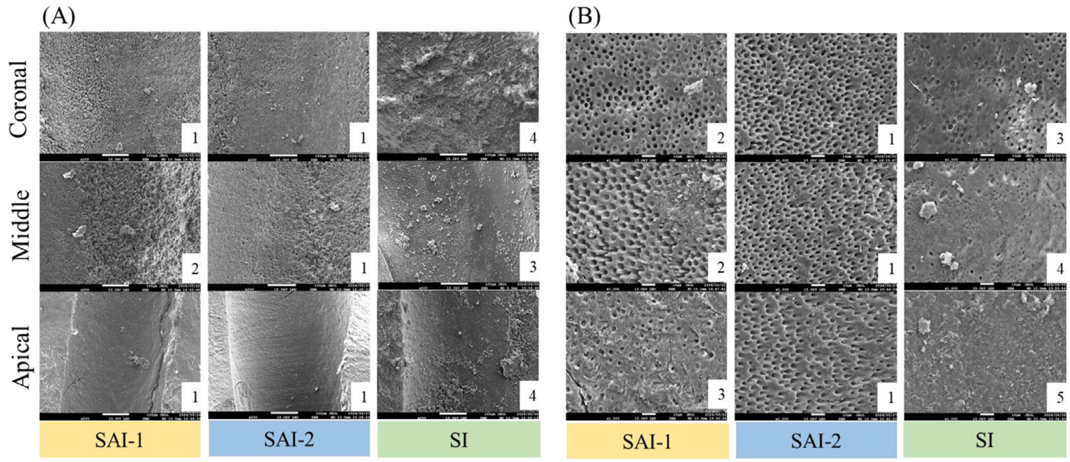

Figure 3 Representative scanning electron microscopy images showing (A) residual debris and (B) smear layer in Experiment 1. Root canals were irrigated using different irrigation protocols. The scoring criteria are detailed in the legend of Fig. 1, with the score displayed in the lower-right corner of each panel. SAI-1, Endoactivator; SAI-2, SmartLite Pro EndoActivator; SI, syringe irrigation. Scale bars = 0.1 mm (A) and 0.01 mm (B).

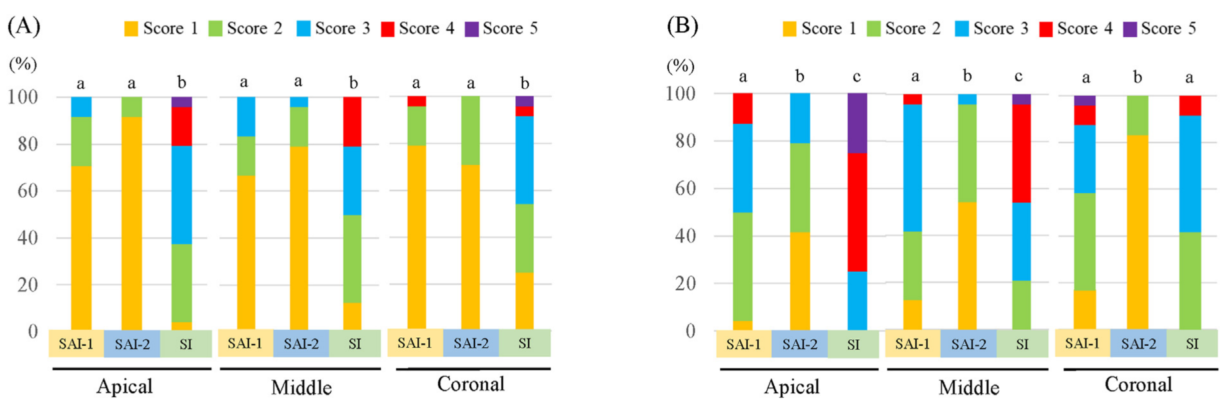

Figure 4 Percent distributions of (A) residual debris and (B) smear layer scores in Experiment 1. Root canals were irrigated using different irrigation protocols. Different lowercase letters in each root level in a panel indicate a significant difference between groups ($P < 0.05$). SAI-1, Endoactivator; SAI-2, SmartLite Pro Endoactivator; SI, syringe irrigation.

the number of tip vertical strokes resulted in enhanced cleaning efficacy, along with an increase in apical pressure. Consequently, the null hypotheses were rejected.

Previous studies have indicated that the SmartLite Pro EndoActivator achieved better, though statistically insignificant, results regarding bacterial debridement and calcium hydroxide removal compared to the first-generation EndoActivator.[19,20] In the present study, the SmartLite Pro EndoActivator removed significantly more smear layers across all canal thirds than the EndoActivator. This could be due to the paddle-like, parallelogram-shaped polymer tips of the SmartLite Pro EndoActivator, which operate in a novel, multi-directional elliptical motion that impacts more internal canal walls than the linear motion of the first-generation tip. Additionally, at a speed of 18,000 cycles per min, the SmartLite Pro EndoActivator delivers greater energy, synergistically enhancing the cleaning efficiency compared to the EndoActivator at 10,000 cycles per min.

Despite the lower sonic activation frequency, pumping motion may promote the hydrodynamic phenomenon.[5] However, there is no consensus on the ideal number of vertical strokes. This study is the first to investigate the cleaning efficacy of the SmartLite Pro EndoActivator for debris and smear layer removal with a defined number of vertical strokes.

The present results revealed significantly better smear layer removal in the 40-stroke group compared with the 0-stroke group in the coronal third, likely owing to the larger space in this region, which facilitated better circulation and a greater displacement amplitude to effectively activate irrigants. In contrast, a narrower apical portion resulted in increased wall contact, which limited free oscillations and attenuated irrigant streaming. This aligns with previous reports of excellent cleaning efficacy in the coronal part among different methodologies.[10,24—26]

The 0-stroke group in the present study showed significantly less debris removal than did the 10- and 40-stroke groups in all regions. This could be because the additional vertical strokes served as manual agitation and enhanced irrigant penetration or renewal in the canal.[11,27,28] The comparable smear layer and debris removal between the 10- and 40-stroke groups suggests that 10 vertical strokes

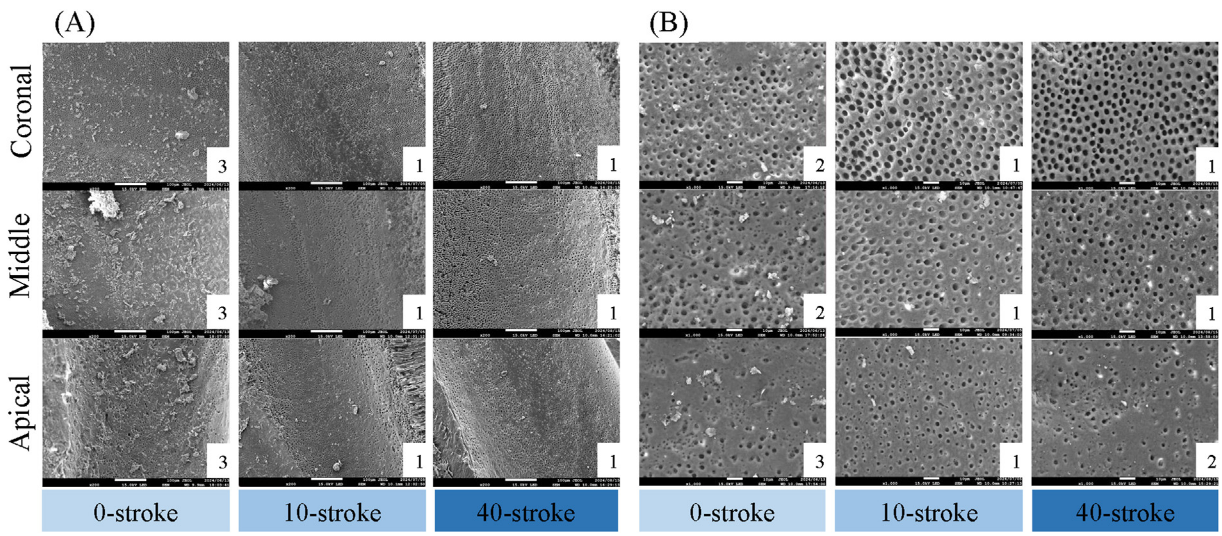

Figure 5 Representative scanning electron microscopy images showing (A) residual debris and (B) smear layer in Experiment 2. Root canals were irrigated using the SmartLite Pro EndoActivator with different numbers of vertical strokes (0, 10, or 40). The scoring criteria are detailed in the legend of Fig. 1, with the score displayed in the lower-right corner of each panel. Scale bars = 0.1 mm (A) and 0.01 mm (B).

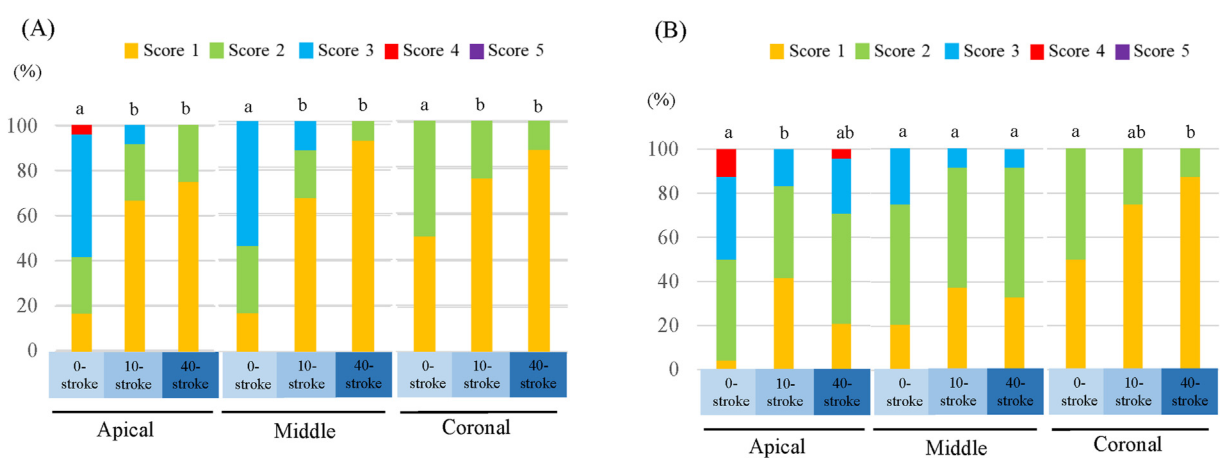

Figure 6 Percent distributions of (A) residual debris scores and (B) smear layer scores in Experiment 2. Root canals were irrigated using the SmartLite Pro EndoActivator with different numbers of vertical strokes (0, 10, or 40). Different lowercase letters in each root level in a panel indicate a significant difference between groups ($P < 0.05$).

are sufficient to achieve adequate intracanal fluid movement.

Combining deep tip insertion with vertical strokes may lead to significant irrigant extrusion through the apical foramen, increasing the risk of periapical tissue damage.[29,30] The mean apical pressure generated in the 40-stroke group was significantly higher than that in the 0- and 10-stroke groups. Therefore, while increased mechanical agitation may enhance cleaning effectiveness, it also raises safety concerns. Other studies have also demonstrated that a higher irrigant flow rate may increase apical pressure and extrusion risk.[29,31–33] Human central venous pressure (0.76 kPa) can be employed as a safety threshold, as it represents the lowest reference value associated with apical extrusion and reflects the natural pressure in the periapical tissue.[34,35] Under the present test conditions, the pressure generated in the 40-stroke groups slightly surpassed the level stated above, suggesting that an increased number of vertical strokes raises the risk of irrigant extrusion.

The current experiment had strengths and limitations that warrant careful consideration. One strength is the creation of well-balanced test groups using micro-computed tomography to measure root canal morphology in Experiments 1 and 2. The setup of the apical pressure measurement in Experiment 3 was designed similarly to those used in previous studies,[18,36] enabling standardized real-time monitoring of the force of extruded irrigant by measuring the pressure beyond the apical foramen. However, this study was limited by the age variability among the tooth samples, which may cause differences in sclerotic dentin. Additionally, this study focused solely on straight

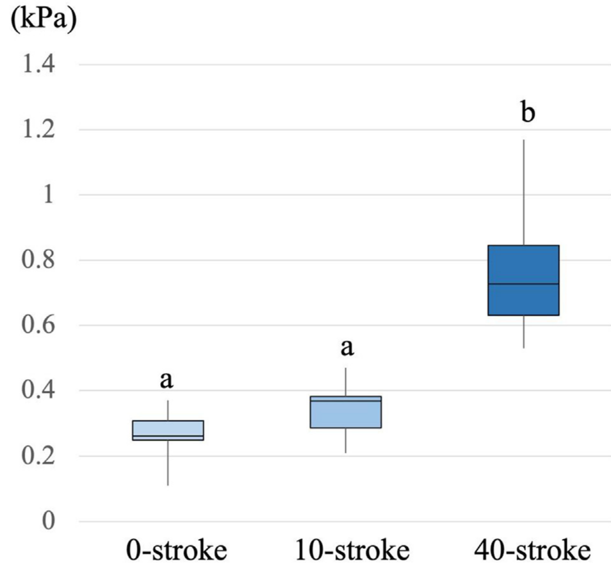

Figure 7 Maximum, 75th percentile, median, 25th percentile, and minimum values of the maximum pressures generated outside the apical foramen. Root canals were irrigated using the SmartLite Pro EndoActivator with different numbers of vertical strokes (0, 10, or 40). Different lowercase letters indicate a significant difference between groups ($P < 0.05$).

root canals with simple curvatures. Another limitation was the use of scanning electron microscopy, which does not allow for longitudinal observations. In Experiment 3, distilled water was employed as the irrigant instead of NaOCl to prevent equipment malfunctions, similar to procedures used in previous studies[18,36] Furthermore, the artificial design of the plastic model may differ from the actual root canal wall, potentially affecting the irrigant dynamics.[37,38] Although the viscosities of NaOCl and distilled water are reported to be similar,[39] future research will aim to employ a corrosion-resistant experimental model specifically designed for NaOCl.

Our results suggest that the SmartLite Pro EndoActivator provides sufficient cleaning efficacy without requiring many vertical strokes, and that the pressure outside the root canal increases in proportion to the number of vertical strokes. Given the risk of irrigant extrusion outside the root canal, clinicians should avoid excessive vertical strokes. Further studies are needed to investigate the fluid dynamics underlying the activation process, particularly through visualizing the oscillatory amplitude, to better understand and confirm the effects of multiple vertical strokes. Moreover, the impact of root canal curvature on the cleaning efficacy and safety of new-generation sonic devices should be explored.

In conclusion, the SmartLite Pro EndoActivator showed a significantly higher cleaning efficacy than the EndoActivator and the syringe irrigation. Increasing the number of vertical strokes enhanced debris and smear layer removal using the SmartLite Pro EndoActivator. Although performing 40 strokes exhibited superior cleaning efficiency, the apical pressure was significantly higher than that generated when performing 10 strokes, which demonstrated comparable cleaning efficiency.

Declarations of competing interest

The authors declare no conflict of interest relevant to this study.

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