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Comparative Study on Cleaning Efficacy of Two Single-File Systems in Oval Canals: Self-Adjusting File and Waveone Followed By Endoactivator

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Introduction

Endodontic instruments and irrigants generate debris and smear layer as a result of their action on root canal walls during pulp space preparation [1]. This debris can become compacted along the surface of canal walls, increasing the risk of bacterial 'contamination' or extrusion to periapical tissues in cases of infection [2].

Debris also reduces the adaptation of sealer and gutta-percha on the canal walls and inhibits the penetration of sealer into the dentinal tubules [3]. If tissue remnants and debris are not removed, the subsequent stage of root canal obturation can be jeopardized, leading to treatment failure [4].

Moreover, there is a high prevalence of oval and long oval canals, even in the apical root canal portion [5]. Uninstrumented recesses can be left in oval canals, irrespective of the instrumentation technique, leaving debris and unprepared root canal surfaces [4].

The Self-Adjusting File (SAF) (ReDedent-Nova, Ra'anana, Israel) is a hollow file that is designed as a compressible, thin-walled, lightly abrasive, pointed cylinder, of a 120-mm-thick nickel-titanium lattice [6]. When inserted into a root canal, it adapts itself to the canal's shape, and combined with the vibrating movement of the handpiece [7], removes dentin with a back-and-forth grinding motion [6]. It comes with a special irrigation device (VATEA; ReDent-Nova) that allows continuous irrigation throughout the procedure.

The WaveOne NiTi single-file system is used with a dedicated reciprocating motion motor.

This study examined the cleaning efficacy of two single-file systems, the WaveOne (primary file 25/08, 25 mm long) and SAF (1.5-mm diameter, 25 mm long) with regard to debris and smear layer removal in oval canals by optical microscopy.

Materials and Methods

Sample size calculation

The sample size was initially based on similar studies [7-9]. A formal, a priori sample size calculation was not possible, because there are no published results on this specific comparison.

However, we performed a detailed simulation-based post hoc power analysis to determine the minimum effect (odds ratio for WaveOne *vs.* SAF) that a study with the same design and sample size would be able to detect at an alpha level of 0.05 while retaining a power of 0.80. We assumed the distribution and differences in scores between examiners, magnification rates, and tertiles and the intra-class correlation of the results from the same sample to be the same as those in the current study.

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Tooth selection and specimen preparation

We selected 24 single-rooted, intact permanent human premolars with one main apical foramen and mature apices, extracted for orthodontic or prosthetic reasons from patients ranging in age from 25-34 years. We removed tissue remnants and external deposits from the teeth by placing them in 2.5% NaOCl solution for 5 minutes and removed the remains with curettes. We checked the specimens under a stereomicroscope to ensure the presence of one main apical foramen and mature apices. All teeth were examined for single-canal anatomy and the presence of a single oval canal (on digital radiographs in the mesial-distal and bucco-lingual directions) [5]. Only teeth with a curvature of less than 10° were used. We excluded teeth that did not meet all inclusion criteria and stored all selected specimens in physiological saline solution at 4 °C until use.

Group organization

We performed the first stratification of the specimens into groups by pair-matching individual teeth, based on the similarity of their physical appearance (total length, length of the root, bucco-lingual and mesio-distal dimensions at the cemento-enamel junction). Then, matches were verified by comparing the digital radiographs of both planes, detecting a single uncalcified, oval canal of the same size (excluding long, oval ones) to ensure the creation of homogeneous and standardized groups. We also considered the age of the teeth, because it affects the characteristics of dentin and the number of dentinal tubules.

Group A underwent preparation with the SAF system, whereas Group B was processed using the WaveOne system.

Root canal preparation in each group was performed as described by Farmakis et al. [10]. In summary, preparation in each group was

performed by following each manufacturer's instructions and any modifications reported in detail. Flow rate was set at 4 ml/min for SAF. The design of the study ensured that equal volumes of each irrigant were used for both groups: a total of 22 mL 2.4% NaOCl (2 mL during glide path preparation, 10 ml during instrumentation, 10 mL final flushing) and 10mL 17% EDTA solution.

In both groups, we performed recapitulation with #10 K-file 0.5 mm beyond the WL to ensure patency [11], avoid apical plugging [12], and prevent the vapor lock effect at the apical third [13]. A single, previously trained operator conducted all procedures.

Assessment of preparation

We cut 2 shallow longitudinal grooves into each root in a buccolingual direction, with care taken not to penetrate the canal. The sample was then immersed in liquid nitrogen and split longitudinally with a mallet and chisel, resulting in mesial and distal halves of the root canal. For each specimen, the half with the more intact canal and visible apex was conserved. During this process, we discarded two specimens from each group, because the roots were split inconveniently.

Specimens were then coded and examined blindly by one examiner under an optical microscope (Nikon, Eclipse ME600 - camera Nikon FDX-35).

We took serial photo-micrographs of the canal walls at x200 and x500 magnification at the cervical, middle, and apical levels (9,6, and 3 mm from the apex, respectively). These serial photographs were then placed adjacent to each other, forming a continuous horizontal examination strip for each level of observation.

Helicon Focus (Helicon Soft Ltd) is a program for focus stacking; a post-processing technique that can extend the depth of field beyond what is available in a single shot. Thus, for each specimen and each specific area of assessment, we took several shots. For each shot, we adjusted the microscope lens to focus on a slightly different part of the canal wall, with slight linear movement from the nearest to the farthest section of the area. Then, the software merged all shots into a single sharp image by blending all of the sharp areas. Thus, more "focused" images were produced by stacking 10 to 70 or more photos, depending on the characteristics (depth of field, curvature) of each specimen.

Three examiners evaluated the resulting pictures for the presence of debris (x200) and smear layers (x500).

Presence of debris was defined as the existence of particles or chips of any structure on the surface of the root canal [4].

Smear layer was defined as a surface film of debris that was retained on dentine after instrumentation with rotary instruments or endodontic files, consisting of dentine particles, remnants of vital or necrotic pulp tissue, bacterial components, and retained irrigant [14].

We graded the amounts of debris at 200x magnification and the amounts of smear layer at 500x magnification, using a 5-step scale, from 1 (best) to 5 (worst), as proposed by Peters and Barbakow [15].

To ensure intra examiner consistency, the first eight specimens were evaluated twice by each examiner.

The recordings of the two groups were analyzed statistically to examine the differences between groups, examiners, root tertiles, and magnification rates.

Statistical methods

We performed all analyses with Stata 11 (Stata Corp., TX USA); p-values less than 0.05 were considered to be statistically significant.

Results

No completely clean root canals were found after instrumentation with any system at any magnification (x200, x500).

All scores ranged between 1 and 3 (for groups and magnifications), indicating that in general, root canals had relatively minimal amounts of remaining debris and smear layer in both groups (Figures 1 and 2).

Analysis of kappa coefficient of agreement values demonstrated an inter-examiner agreement of 88% between examiners 1 and 2, 67% between examiners 1 and 3, and 68% between examiners 2 and 3. However, the percentage of agreement between examiners was higher than 93.64% in all cases.

According to (Table 1), the odds ratio of 3.88 for WaveOne *vs* SAF indicates that higher scores were nearly 4 times more likely in the WaveOne group. The difference between groups by magnification and root third (tertile) was statistically significant (p=0.005), with the SAF group exhibiting better cleaning efficacy.

Overall, we observed higher scores for the smear layer (higher magnification, x500) than for debris (smaller magnification, x200) in both groups (p< 0.001).

The scores were higher at the middle third of the root, but the difference was not statistically significant.

Post hoc power analysis

Results from a post hoc power analysis showed that a study with the same design; similar distribution of results across examiners, root tertiles, and magnification rates; similar intra-class correlation of scores from the same tooth; and the same sample size as the current study would have a power of at least 80% to detect a significant difference between techniques at an alpha level of 0.05 if the corresponding odds ratio was at least 4.3. The power of such a study to detect an odds ratio of 3.9 (as observed in our study) would be 72.9%. These results suggest that based on the current sample size and design, the power of our study was satisfactory but that the subgroup analyses are underpowered.

Discussion

We selected single-rooted permanent human premolars for this study. Premolars with one root canal have an oval diameter, especially at the coronal and middle levels. To reduce variables between groups, we only used oval canals (a maximum diameter of up to 2 times the minimum diameter), excluding long oval ones (with a maximum diameter of 2 to 4 times the minimum diameter) [16]. Considering the difficulties in cleaning this type of canal, especially their buccal and lingual extensions [5], the selected teeth were suitable choices for examining the cleaning efficacy of two single-file systems, the SAF and WaveOne.

This study addressed root canal cleanliness through observation under an optical microscope. Nearly every other similar study has used a Scanning Electron Microscope (SEM), because it provides greater resolution (the minimum distance that can be separated as two distinguishable points in an SEM image) and thus has higher magnification [17]. In addition, SEM has a greater depth of field compared with light microscopes due to the nature of electrons. These are desirable attributes when examining a small, curved surface, such as the inside of a root canal [17].

However, SEM has major disadvantages that are often overlooked. De-Deus et al. in their critical appraisal of smear layer removal studies [18], addressed some of these problems. Although a detailed analysis of the working principles of SEM are beyond the scope of this study, we briefly discuss these issues to justify the use of optical microscopy:

Specimens that are observed by SEM require a surface staining with metals (usually gold) for electron conduction. If the coating is too thick, its particles become visible while the structures of interest might be obscured. Optical microscopy has the advantage of observing a surface as it actually is, without altering its surface with another material, however thin it might be, and in its true colors.

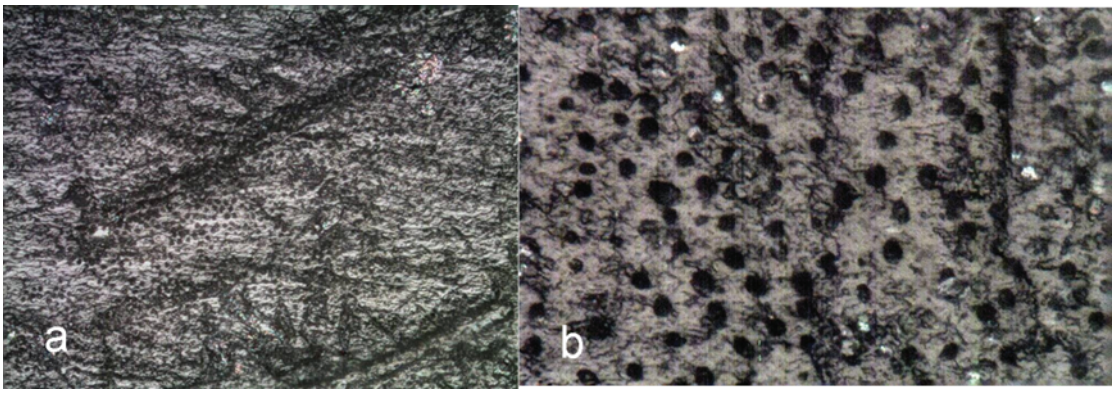

Figure 1: Canal wall after preparation with the SAF, representative of a Score of 1 at, a. 200x and b. 500x magnification.

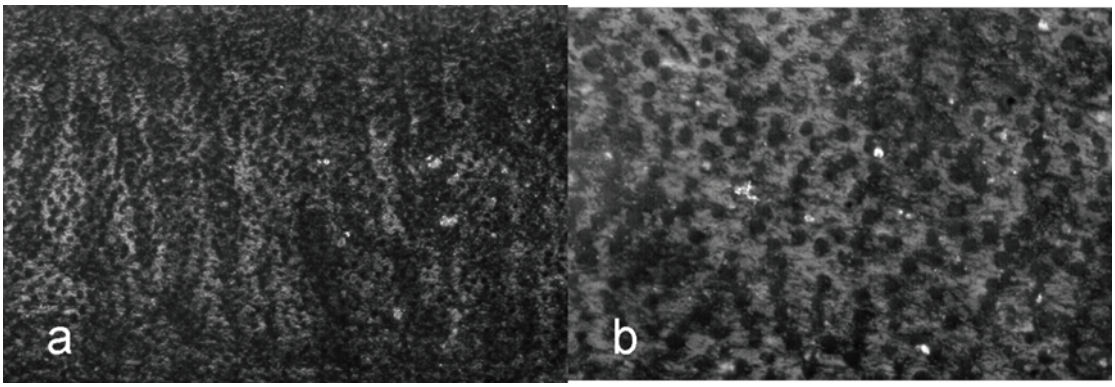

Figure 2: Canal wall after preparation with the WaveOne, representative of a Score of 1 at, a. 200x and b. 500x magnification.

Table 1: Results of multivariate ordinal logistic regression model Data from all tertiles, magnifications, and examiners.

Factor	Odds Ratio	95% C.I.	p-value
Group			
SAF*	1		
WaveOne	3.88	(1.51, 9.95)	0.005
Magnification			
x200 (Debris)*	1		
x500 (Smear layer)	5.77	(3.34, 9.94)	<0.001
Tertile			
Cervical*	1		
Middle	2.17	(0.89, 5.32)	0.090
Apical	1.23	(0.34, 4.52)	0.752
Examiner			
1*	1		
2	0.94	(0.69, 1.28)	0.691
3	1.29	(0.88, 1.89)	0.186

* Reference category
- Global test for differences by tertile: p=0.089
- Global test for differences by examiner: p=0.182
- Test for interaction between group and magnification: p=0.818
(Test nonsignificant; i.e., group differences are similar at both x200 and x500)
- Test for interaction between group and tertile: p=0.139
(Test nonsignificant; i.e., group differences are similar in all tertiles)

In SEM, an electron beam is focused into a small probe and is rastered across the surface of a specimen. At higher accelerating voltages, the beam penetration and diffusion area become larger, resulting in unnecessary signals (e.g., backscattered electrons) that are generated from within the specimen. These signals reduce the image contrast and obscure fine surface structures. When analyzing a surface area such as root dentin with small dentinal tubules of various sizes and depths, it can be assumed that these variations interfere with the resulting image [19].

Images that are produced by SEM experience a phenomenon, termed the "edge effect," which is the result of a specimen's surface morphology, wherein edges and ridges of an observed sample emit more secondary electrons and thus appear brighter in the image that is taken. Thus, areas inside of the root canal, notably the circumference of the openings of dentinal tubules, can appear brighter than others, interfering with the scoring process.

These disadvantages do not apply to optical microscopy. Rather, an optical microscope provides direct, true-color imaging with no need for sample pretreatment. As discussed, an optical microscope has lower resolution (primarily due to the light diffraction limit) than SEM and is thus capable of smaller magnification. Such levels of magnification are adequate for examining debris and smear layers, according to most similar studies [20,21].

The main deficiency, however, and the reason why optical microscopy is not used in cleaning efficacy studies is "depth of focus." In an optical microscope, depth of focus is the distance above and below the image plane over which the image appears in focus. As the

magnification increases in an optical microscope, the depth of focus declines. As a result, and because the inside of a root canal is not a flat but rather a curved surface, only part of the image is in focus (sharp) using a variety of slants.

In our study, the use of a program, Helicon Focus (Helicon Soft Ltd), was advocated to overcome this problem. Using this software as described in the experimental section, we were able to blend all of the sharp areas of many pictures of the same root wall area and merge them into as single, sharp image.

Larger volumes of NaOCl and EDTA can result in significantly cleaner root canal walls compared with smaller volumes [22]. The duration of exposure also influences the tissue-dissolving ability of NaOCl [23]. The volumes of irrigants and the time that they were in contact with canal walls could not be standardized per the manufacturer's recommendations for each file system. A decision was made to ensure equal volumes of both irrigants in both groups-22 mL 2.4% NaOCl (2 mL during glide path preparation, 10 ml during instrumentation, and 10 mL final flushing) and 10 mL 17% EDTA-and to follow the clinical protocols that have been proposed by the manufacturers to simulate clinical conditions. These steps resulted in disparate times of exposure and activation for the two irrigants between groups, which might have affected the final results.

In our study, SAF yielded better results than WaveOne, especially at the coronal third (odds ratio 12.59). One explanation of this finding is that the SAF effected a higher mean increase in root canal area and volume, along with the percentage of prepared walls, at the coronal third [24]. The statistically insignificant differences in the middle and apical portions might be explained by the initially small diameter of the canal between ISO #10 to #20, and the possibility of the WaveOne instrument creating a round canal from an oval one during enlargement. Future research should compare these systems in long oval canals with a primary diameter of more than 0.2 mm.

Activation of the final rinse has beneficial effects on canal cleanliness. Due to its unique design, the SAF has the advantage of allowing this activation throughout the entire cleaning and shaping process. As suggested by De-Deus et al. [18], vibration of the SAF file at 5 kHz, induces sonic activation of the irrigant (NaOCl or EDTA) during the entire procedure. Moreover, chlorine, which is responsible for the dissolution of organic tissue and the antimicrobial effects of NaOCl [25], quickly inactivates when it comes into contact with dentine [26]. The continuous replenishment of fresh NaOCl when using the SAF can presumably deliver sufficient free chlorine, thus optimizing debridement. These two parameters might also have contributed to the better results that were achieved by the SAF. Notably, however, according to de Gregorio et al. [27], the pecking motion of the SAF files allowed for further penetration of the irrigants but could not reach the working length.

Although sonic activation is inherent in the SAF system, preparation with the WaveOne system was followed by the application of EndoActivator (Advanced Endodontics, Santa Barbara CA, USA), which also uses sonic energy (10 kHZ) to irrigate root canal systems. We placed the EndoActivator tip 2 mm short of the working length, according to the manufacturer's protocol. In a recent study, de Gregorio et al. [28], using sonic (EndoActivator) activation in simulated lateral canals, reported better irrigation in the apical third (4.5 and 2 mm from the working length) than with traditional needle irrigation alone. The hydrodynamic phenomenon that is produced by vibrating the tip, in combination with moving the tip up and down in short vertical strokes, might be more powerful near the tip (apical third), thus providing another explanation for our findings. Actually, the whiplash motion that is created, according to Newton's first law, accelerates the end of the tip more compared with the body of the plastic file, making it more efficient.

No study has compared these two systems directly using a similar method (optical microscopy) as ours. Three studies have compared SAF and WaveOne, examining horizontal sections in the mesial root of mandibular molars [29], performing micro-computed tomography analysis [30], and analyzing the removal of radiopaque material from mandibular central incisors [31].

The majority of cleanliness studies (SEM) concerning the SAF agrees with our results [7,32,33]. In contrast with our results and with the aforementioned studies, Paranjipe et al. reported significantly better results for the ProTaper group compared to the SAF group in general [34]. Notably, scores were 4 to 5 for debris and above 4 for smear layers. The results for the ProTaper group were also high. This finding is not consistent with the majority of the most recent cleaning efficacy studies.

Concerning the WaveOne, a study compared its cleaning efficacy with the ProTaper system on single-rooted teeth (but not strictly oval) under two protocols [35]. Each of the two systems was assessed with and without the use of a flexible micro brush (CanalBrush; Coltene Whale dent GmbH+ Co KG, Langenau, Germany). Overall, better results were achieved for the coronal than the middle and apical thirds and for the group that used the WaveOne and CanalBrush. None of the groups achieved complete cleanliness.

In general, for all aforementioned studies, the differences in many parameters (tooth type, root curvature, preparation protocol, method of observation, and scoring system) prevent us from making strict comparisons with the results of our study.

Conclusion

Within the limitations and under the conditions of this study, we conclude that:

- Instrumentation with neither of the two systems generates completely cleaned root canals
- Both the SAF system and the WaveOne followed by the EndoActivator system yielded scores ranging from 1 to 3 (on a 5-point scale), meaning that in general, root canal walls showed relatively minimal amounts of remaining debris and smear layer in both groups.
- In the cervical root third, the SAF group exhibited statistically significant better cleaning efficacy compared with the WaveOne-group.
- No significant differences between systems were noted in the middle and apical thirds.
- We observed statistically significant higher scores for the smear layer versus debris in both groups.

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