The Self-adjusting File (SAF). Part 3: Removal of Debris and Smear Layer—A Scanning Electron Microscope Study

Zvi Metzger, DMD,[*†] *Ehud Teperovich, DMD,*[†] *Raphaela Cohen, DMD,*[†] *Raviv Zary, DMD,*[†] *Frank Paqué, DMD,*[‡] *and Michael Hülsmann, DMD*[§]

Abstract

Aim: The aim of this study was to evaluate the cleaning ability of the Self-Adjusting File (SAF) system in terms of removal of debris and smear layer. **Methodology:** Root canal preparations were performed in 20 root canals using an SAF operated with a continuous irrigation device. The glide path was initially established using a size 20 K-file followed by the SAF file that was operated in the root canal via a vibrating motion for a total of 4 minutes. Sodium hypochlorite (3%) and EDTA (17%) were used as continuous irrigants and were alternated every minute during this initial 4-minute period. This was followed by a 30-second rinse using EDTA applied through a nonactivated SAF and a final flush with sodium hypochlorite. The roots were split longitudinally and subjected to scanning electron microscopy (SEM). The presence of debris and a smear layer in the coronal, middle, and apical thirds of the canal were evaluated through the analysis of the SEM images using five-score evaluation systems based on reference photographs. **Results:** The SAF operation with continuous irrigation, using alternating irrigants, resulted in root canal walls that were free of debris in all thirds of the canal in all (100%) of the samples. In addition, smear layer–free surfaces were observed in 100% and 80% of the coronal and middle thirds of the canal, respectively. In the apical third of the canal, smear layer–free surfaces were found in 65% of the root canals. **Conclusions:** The operation of the SAF system with continuous irrigation coupled with alternating sodium hypochlorite and EDTA treatment resulted in a clean and mostly smear layer–free dentinal surface in all parts of the root canal. *(J Endod 2010;36:697–702)*

Key Words

Apical third of root canal, cleaning debris, irrigation, irrigation protocol, SAF, self-adjusting file, smear layer

The cleaning and shaping of root canals is a key step in root canal treatment procedures. Unless all tissue remnants and debris are removed, the subsequent stage of root canal obturation may also be jeopardized, leading to the potential failure of treatment (1, 2). Any material left between the canal wall and the root canal filling may prevent intimate adaptation between the two and may provide a space for bacterial leakage and bacterial proliferation.

Accordingly, the cleaning efficacy of any endodontic file system is of major importance and has been studied intensively (3, 4). The presence of a significant amount of debris is commonly encountered when either rotary or hand files are used in root canals with flat cross-sections. The debris accumulation in the uninstrumented “fins” may not allow for proper disinfection and may prevent the root canal filling from reaching these recesses, even when warm gutta-percha compaction is applied (1, 2). Such a gross accumulation of debris may readily be visualized even when using light microscopy at a magnification of ×50 (1, 2).

Furthermore, the smear layer and some amounts of debris may be present on the walls of the root canals, even with the simplest morphology. A 5-μm-thick smear layer represents a potential gap between the root canal filling and the root canal wall that may be capable of accommodating approximately five layers of bacteria. Moreover, the smear layer may block or prevent the free access of antibacterial agents to the bacteria that may have penetrated into the dentinal tubules. The evaluation of fine debris and the presence of the smear layer require higher magnification levels (200×-1,000×) that are achievable only through the use of scanning electron microscopy (SEM).

SEM has been applied by numerous investigators to study the efficacy of various rinsing protocols and file systems in the removal of debris and smear layer (5–16). Every available file system generates a smear layer and leaves debris in the root canal, and rinsing with sodium hypochlorite alone is unable to render the canal free of debris and smear layers (5–13, 15, 16). In addition, the application of chelating agents such as EDTA may dramatically improve the overall efficiency of the procedure (8-13). Finally, even when the coronal and middle thirds of the canal are relatively clean, the apical third of the root canal always presents a problem in regard to the ability to achieve the same level of cleanliness (5, 6, 9, 12). This may be of great importance because the presence of a smear layer and debris may prevent sealer adaptation to the canal walls and allow penetration of irritants into the periradicular tissues, initiating or sustaining periradicular inflammation (17, 18).

The Self-Adjusting File system (SAF; ReDent-Nova, Ra’anana, Israel) is different from any available file system in two major respects (19). First, the SAF is a hollow and flexible file that adapts itself three-dimensionally to the shape of the root canal, including the ability to adapt to its cross-section (19). The SAF vibrates when

From the *Department of Endodontology, The Goldschleger School of Dental Medicine, Tel Aviv University, Tel Aviv, Israel; †ReDent-Nova Inc, Ra’anana, Israel; ‡Department of Preventive Dentistry, Peridontology and Cariology, University of Zurich, Zurich, Switzerland; and §Department of Preventive Dentistry, Periodontology and Cariology, University of Goettingen, Goettingen, Germany.

Dr. Ehud Teperovich, Dr. Raphaela Cohen, and Dr. Raviv Zary are employed by ReDent-Nova, manufacturer of the SAF file. Dr Zvi Metzger serves as a scientific consultant to the same company.

Address requests for reprints to Dr Zvi Metzger, School of Dental Medicine, Tel Aviv University, Ramat Aviv, Tel Aviv, Israel. E-mail address: metzger@post.tau.ac.il.

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operated and removes a uniform dentin layer from the canal walls even in oval, flat root canals (19). Rather than machining a central portion of the root canal into a round cross-section, the SAF allows for maintaining a flat canal as a flat canal with slightly larger dimensions. Second, this hollow file allows for the continuous irrigation of the root canal throughout the procedure, with additional activation of the irrigant by its vibrating motion that creates turbulence in the root canal. Irrigation may be provided by any physio-dispenser type of device (ie, NSK Surgic XT Micro Motor System, Kanuma, Japan, or W&H ImplantMed, Burmoos, Austria) or by a special rinsing unit such as the one used in the current study, which delivered the irrigant at a flow rate of 5 mL/min (VATEA, ReDent-Nova).

The adaptation of the file to the root canal's cross-section is expected to limit the potential gross debris accumulation in untreated areas of oval, flat canals. The continuous flow of the irrigant through the file combined with the vibrating motion may have an effect on the cleaning ability of the file in the root canal at large and particularly in its difficult-to-clean cul de sac region, the apical third of the root canal (20). This challenging portion of the root canal may benefit from the unique mode of action of the SAF file.

The present study was designed to evaluate the cleaning ability of the SAF in terms of removal of debris and smear layer, using SEM.

Materials and Methods

Selection of Teeth

Twenty-three single-rooted teeth were selected from a random collection of human teeth that were extracted within the last 3 months and stored in 10% buffered formalin until they were used. Each root was radiographed in buccolingual and mesiodistal projections to evaluate the shape of the root canal and to detect any possible obstruction. The inclusion criteria were single-rooted teeth with straight root canal and an intact pulp chamber, whereas the exclusion criteria were previous root canal treatment and teeth with an irregular root canal anatomy.

Root Canal Treatment

An endodontic access cavity was prepared in each tooth, and the root canal was negotiated using a size 15 K-file. The working length was determined to be 1 mm short of the apical foramen that was sealed from the outside using an impression compound (Kerr, Orange, CA).

A glide path was established by manual instrumentation up to a size 20 K-file using 3% sodium hypochlorite and RC-Prep paste (Premiere, Philadelphia, PA) as a lubricant.

An SAF file (ReDent-Nova) was used for cleaning and shaping the root canal using an in-and-out vibrating handpiece as described by Metzger et al (19). The hollow SAF file allowed for continuous irrigation throughout the procedure. Irrigation was performed via a silicon tube (inner and outer diameters of 1.587×3.175 mm, respectively; Degania-Silicone, Degania, Israel) that was attached to a rotating hub on the shaft of the file (Fig. 1). The irrigant went into the file and freely escaped into the canal through the lattice wall to backflow coronally and escape through the access cavity. No positive pressure was generated in the root canal.

The irrigation was performed continuously during the operation using a special irrigation apparatus (VATEA Irrigation Device). This apparatus contained two separate irrigation fluid reservoirs, each with its own irrigation tubing, which was attached to the hollow SAF file via a dual silicone tube with a Y-type ending that allowed each irrigant to be separated from the other until the delivery point.

The SAF file was operated in two cycles of 2 minutes each for a total of 4 minutes. The SAF was removed for inspection after each cycle.

Figure 1. The SAF file with its irrigation tube. The file was operated with a KaVo (Biberach Riss, Germany) vibrating handpiece. An irrigation tube with an on-off switch (white) was attached to a continuous-flow source (VATEA, ReDent-Nova, [19]) that provided either 3% sodium hypochlorite or 17% EDTA at 5 mL/min.

During the first minute of each cycle, sodium hypochlorite (3%) was used as the irrigant, wheras EDTA (17%) was used during the second minute. The flow rate of the irrigants was set at 5 mL/min, resulting in a total volume of 10 mL of each irrigant used during the procedure. After completion of the two cycles, an additional irrigation with EDTA (17%) was performed for 0.5 minutes with the vibrational mechanism turned off followed by a final flush with sodium hypochlorite (3%, 5 mL) in order to remove the remaining EDTA. The root canal was dried using paper points, and the tooth was left to dry at room temperature for 24 hours before being prepared for the SEM examination. The experimental group was composed of 20 roots, which were subjected to the protocol described previously. Three roots were used as a positive control for the smear layer in which only sodium hypochlorite (no application of EDTA) was used as an irrigant through the total 4-minute period of the SAF operation.

SEM

Each root was split longitudinally and subjected to SEM processing and examination. The samples were dried and coated with gold (Polaron SEM Coating Unit E5100; Quorum Technologies, East Sussex, UK) and examined using a JEOL JSM 840A scanning electron microscope (JEOL, Tokyo, Japan). Representative sections of the coronal, middle, and apical thirds of the canal were used for evaluation at a magnification of 200× and 1,000×.

Selection of Representative Sections

After the central beam of the SEM had been directed to the center of the object by the SEM operator at 10× magnification, the magnification was increased to 200× and subsequently 1,000×, respectively, and the canal wall region appearing on the screen was photographed (5).

SEM Image Analysis and Scoring

The cleaning ability of the SAF file was evaluated using the debris and smear layer score systems introduced by Hülsmann et al (5). These scoring systems were applied to the coronal, middle, and apical thirds of the canal. Three examiners independently scored each of these images, which were coded and randomly mixed so that the examiners were blinded to the area from which a given sample originated. The reference set of SEM images that was used by Hülsmann et al (5), Versümer et al (9), and Paqué et al (12) was also available and was used in the present study. The examiners were initially calibrated using the reference SEM images.

When all three examiners independently agreed on a score, it was recorded. When disagreement occurred, all three discussed the sample and its scoring, and an agreed score was reached.

The presence of debris was evaluated from images at 200× magnification using a scale of 5 scores (5) as follows: (1) score 1: clean root canal wall and only a few small debris particles, (2) score 2: a few small agglomerations of debris, (3) score 3: many agglomerations of debris covering less than 50% of the root canal wall, (4) score 4: more than 50% of the root canal walls were covered with debris, and (5) score 5: complete or nearly complete root canal wall coverage with debris.

The results were then dichotomized into "clean canal wall" that included scores 1 and 2 or "debris present" that included scores of 3, 4, and 5.

The smear layer was evaluated from images at 1,000× magnification on a scale of the following five scores (5): (1) score 1: no smear layer, and all dentinal tubules were open; (2) score 2: a small amount of smear layer, and some dentinal tubules were open; (3) score 3: homogenous smear layer covering the root canal wall, and only a few dentinal tubules open; (4) score 4: complete root canal wall covered by a homogeneous smear layer, and no open dentinal tubules were observed; and (5) score 5: heavy, homogeneous smear layer covering the complete root canal wall.

The results were then dichotomized into "clean canal wall" that included scores 1 and 2 and "smear layer present" that included scores 3, 4, and 5.

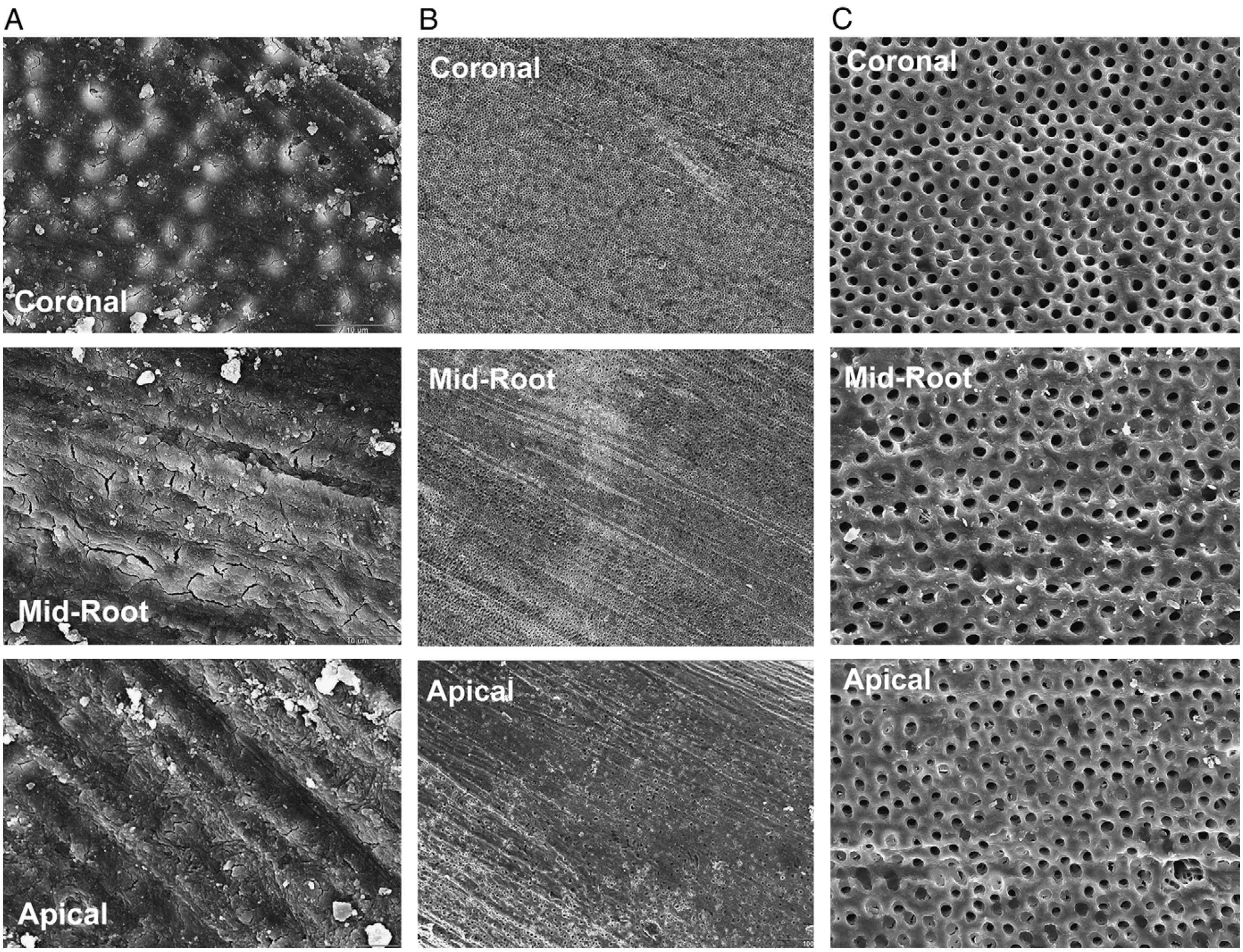

Figure 2. (*A*) The smear layer in a root canal treated using the SAF file and sodium hypochlorite alone. When sodium hypochlorite alone was used as the irrigant, the smear layer was present in the coronal, midroot, and apical portions of the root canal. A representative case from the positive control group. Smear layer scores: coronal = 4 and midroot and apical = 5 using the Hülsmann smear layer score system (5). Original magnification: 1,000×. (*B*) A root canal surface free of debris in a root canal which was treated using the SAF system and the alternating irrigation protocol. The coronal, midroot, and apical thirds of the canal recieved all a score of 1 using the debris scoring system described by Hülsmann et al (5). A representative case from the experimental group. Original magnification: 200×. (*C*) The smear layer-free surface in a root canal treated using SAF and the alternating irrigation protocol. The coronal, midroot, and apical thirds of the canal received a score of 1 using the smear layer scoring system of Hülsmann et al (5). A representative case from the experimental group. Original magnification: 1,000×.

Results

Examiner Agreement

Initial independent agreement of all three examiners was 78% and 58% for debris and smear layer scores, respectively. As for debris scoring, in an additional 17% of the cases, there was initial agreement between two examiners and in only 5% of the cases was there a difference between examiners by more than one level of scoring. When scoring smear layer, in an additional 22% of the cases, there was agreement between two examiners, and in no case was the difference between the examiners by more than one level of scoring.

Control Group

A smear layer and much debris were found in all three root canals that were treated using the SAF with sodium hypochlorite alone (Fig. 2*A*). The smear layer and debris were present in the coronal, midroot, and apical parts of the root canals.

Debris

Root canal preparation using the SAF combined with the alternating irrigation protocol rendered all root canals clean of debris (Fig. 2*B*). Debris evaluation of the root canal dentinal surfaces resulted in debris scores of 1 or 2, representing a clean root canal surface in 100% of the cases in the coronal, midroot, and apical thirds of the root canals (Table 1). None of the samples were characterized as having debris score of 3 to 5.

Smear Layer

The combined action of the SAF with the continuous irrigation regimen resulted in a root canal surface clean of smear layer (Fig. 2*C*). In the coronal and midroot areas, 20 out of 20 (100%) and 16 out of 20 (80%) samples were scored as either 1 or 2, respectively, representing a clean dentin surface (Table 2). Notably, no samples were characterized with scores of 3 to 5 in the coronal part, and only 4 of 20 (20%) had these scores in the middle third of the root.

In the apical third of the canal, scores of 1 or 2, representing clean canal walls, were reported for 13 of 20 (65%) of the samples, whereas smear layer scores of 3 to 5 were reported for only 7 of 20 (35%) of the samples.

Discussion

The SAF, as any mechanical device that is designed to remove dentin layers, produces a smear layer when operated in conjunction with sodium hypochlorite alone (15,16). This occurred despite the continuous irrigation method used by the SAF (Fig. 2*A*). Nevertheless, the application of an irrigation protocol with alternating administration of 3% sodium hypochlorite and 17% EDTA rendered the root canal dentin surface free of the smear layer. Similar results could also be achieved in the coronal and midroot areas with other instruments and protocols using EDTA or other chelator preparations to remove the smear layer (9-14). However, although several studies indicate that achieving this goal in the apical third of the root canal may be difficult if not impossible, the use of the SAF in combination with the current irrigation protocol resulted in a clean dentin surface in the apical portion of most root canals.

Previously published studies that used the same scoring system as used in the present study (9, 12) showed that debris scores of 3 to 5 were recorded in the coronal, middle, and apical thirds of the root canal in 24% to 50%, 32% to 48%, and 40% to 73% of the samples, respectively. The results in the SAF-treated root canals were clearly different; scores of 1 or 2 were recorded in all samples in all parts of the root canals with no 3 to 5 scores.

Similar analysis of these studies (9, 12) showed that smear layer scores of 3 to 5, representing a substantial smear layer, were reported for the coronal and middle thirds of the canal in 46% to 82% and 60% to 68% of the cases, respectively. In these aforementioned studies, the smear layer scores of 3 to 5 were reported for the apical third of the root canal in 48% to 95% of the samples. The results of the current study were clearly different; scores of 1 or 2, representing root canal wall free of smear layer, were recorded in 100% of the coronal third of the samples, whereas this score was recorded in 80% and 65% of the samples in the midroot and apical thirds of the root canal, respectively.

The cul de sac portion of the root canal presents a distinct challenge for any irrigation method. A syringe and needle will only be effective if the tip of the needle reaches the end of the prepared canal (20). The process of simply injecting the fluid into the canal will not achieve any results more than 1 or 2 mm beyond the tip of the needle. This presents a problem particularly in curved canals. Inserting an irrigation needle deep into the root canal coupled with the application of positive pressure may enhance the risk for injecting the irrigation solution beyond the apex, potentially causing a "sodium hypochlorite accident" (21). This recently led to the development of alternative irrigation devices based on negative pressure to overcome this problem (20, 22).

The SAF operates in a totally different manner than syringe and needle irrigation. The hollow file is operated with continuous irrigation provided by a special device (VATEA). The chosen irrigation fluid enters the file through a free-rotating hub and is continuously replaced throughout the procedure, thus providing a fresh, fully active, supply of sodium hypochlorite and chelator solution (eg, EDTA). The operator has a choice of which of the two solutions to use at a given moment and at what flow rate to infuse the canal. No positive pressure can develop in the root canal because the solution can always easily escape through openings in the lattice of the file (19, 23).

The fluids in the apical part of the root canal are effectively replaced by the SAF file even in simulated canals that are curved (19). This occurs, most probably, not because of the apical flow of the

TABLE 1. Debris Scores of Root Canals Treated Using the SAF File

Coronal third					Middle third					Apical third				
Clean		Debris present			Clean		Debris present			Clean		Debris present		
1*	2	3	4	5	1	2	3	4	5	1	2	3	4	5
20/20[†]	0	0	0	0	16/20	4/20	0	0	0	14/20	6/20	0	0	0
20/20 (100%)[‡]		0 (0%)			20/20 (100%)		0 (0%)			20/20 (100%)		0 (0%)		

SAF, self-adjusting file.

*Debris scores (Hülsmann et al, 1997 [5]).

[†]Number of canals presenting with a given score.

[‡]Dichotomized scores: scores 1 to 2 (clean canal wall) versus 3 to 5 (debris present).

TABLE 2. The Smear Layer Scores of Root Canals Treated Using the SAF File

Coronal third					Middle third					Apical third				
Clean		Smear layer present			Clean		Smear layer present			Clean		Smear layer present		
1*	2	3	4	5	1	2	3	4	5	1	2	3	4	5
14/20†	6/20	0	0	0	10/20	6/20	3/20	1/20	0	3/20	10/20	5/20	2/20	0
20/20 (100%)‡		0 (0%)			16/20 (80%)		4/20 (20%)			13/20 (65%)		7/20 (35%)		

SAF, self-adjusting file.

*Smear layer scores (Hülsmann et al, 1997 [5]).

†Number of canals presenting with a given score.

‡Dichotomized scores: scores 1 to 2 (clean canal wall) versus 3 to 5 (smear layer present).

solution but rather because of the vibrating motion of the file's delicate mesh within the fluid that is continuously replaced.

The concept that the vibration of the irrigation solution has beneficial effects has been widely recognized and, as such, has led to the development of a variety of "activating" devices for the final irrigation once the canal preparation has been completed (20, 24). The SAF is the first device that activates the irrigation solution throughout the entire procedure. This, in addition to the continuous replacement of the irrigant, may explain the excellent cleaning efficiency observed in the present study. The canal was rendered free of even ultramicroscopic debris that have a tendency to accumulate during the root canal preparation, especially in the apical portion of the root canal, when other protocols are used (5, 9, 12).

Even though the total irrigation time with each of the irrigants in the current study was relatively short (2 minutes for sodium hypochlorite and 2.5 minutes for EDTA), it resulted in an extremely clean root canal wall. It is likely that the efficacy of the sodium hypochlorite treatment was also enhanced by the removal of the smear layer during this procedure, which provides a better access of the sodium hypochlorite and better access into the openings of the dentinal tubules, thus potentially increasing its range of antibacterial activity. Nevertheless, this issue is beyond the scope of the present study and requires further investigation.

In addition to effectively replacing the irrigant from the apical portion of the root canal and the simple activation of the irrigant through the creation of turbulence, the SAF file also induces a scrubbing motion on the canal walls that must have obviously contributed to the exceptionally clean surface that resulted even in the cul de sac portion of the canal.

Comparing the results of the various studies that addressed the issue at hand is complicated because many of them used a great variety of evaluation methods. From the numerous studies published on this subject, we compared the current results with those of the two studies that used the same evaluation methods for the smear layer and for the presence of debris (9, 12). Furthermore, two of the evaluators of the present study (MH and FP) were also involved in the scoring of both the present study and the previous studies to which the current data were compared. Even though the experimental design of these studies was quite different from the current one, this comparison showed that the conventional rotary file systems used in conjunction with sodium hypochlorite and with either RC-Prep or a Calcinase-Slide chelator paste (Lege Artis, Dettenhausen, Germany), which were both used with each new file (9, 12), failed to render the canal free of debris and of the smear layer. The difference was particularly pronounced in the apical portion of the canal in which the protocols used in these two studies, as well as those used in other studies, failed to achieve clean canals walls in a manner equivalent to those achieved in the more coronal portions of the root canal.

A recent study by Lottanti et al (14) has questioned the validity of the previously published data that indicated that the smear layer is difficult to remove from the apical portion of the root canal. This study suggested that sclerotic dentin, which is more common in the apical portion of the root, may have been mistaken for a smear layer. This could be true when an evaluation method based on simple counting of the number of tubules per unit area was the only criterion. Nevertheless, the finding that the current cleaning protocol was able to render the apical portion of the root canals free of the smear layer and of debris offers indirect support to the previously published data and those of the two studies that used the same evaluation method and were used as a source of comparison with the current study (9, 12). The effective removal of the smear layer observed by Lottanti et al (14) most probably resulted from the wide apical preparations used in this study and from the relatively short root canals (12 mm) with the coronal portion of the tooth removed. Long irrigation times (15 minutes during instrumentation and 3 minutes after) may also have contributed to the observed results.

Several methods were recently introduced to try to overcome the problem of debris accumulation in the apical part of root canals during root canal treatment (22, 24). It would be of interest to compare their cleaning efficacy in this challenging part of the root canal with that of the SAF system. A recent report about massive accumulation of debris in the isthmus area of root canals treated with rotary file systems (25) presents yet another challenge to these new irrigation methods and should also be addressed in such comparative studies.

Conclusions

The SAF, operated with the continuous flow of irrigants alternating between sodium hypochlorite and EDTA, resulted in root canals that were free of debris and almost completely free of the smear layer.

The results were better than those previously published for the coronal and midroot portions of the root canal.

The difference was also pronounced in the apical third of the canal, in which previously published protocols failed to adequately clean the canal, whereas the SAF protocol resulted in debris-free canal walls in all samples and smear layer-free surfaces in most of the samples.

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