F360 and F6 Skytaper: SEM evaluation of cleaning efficiency

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Summary

Aim. Root canal preparation may produce a large quantity of smear layer that covers canal walls. Single-file systems have recently appeared, with the aim of reducing the number of steps and files to reach a correct endodontic treatment. The purpose of this study was to evaluate by SEM the root canal walls after instrumentation with F360 (Komet, Brasseler GmbH & Co., Lemgo, Germany) and F6 Skytaper (Komet, Brasseler GmbH & Co., Lemgo, Germany), in order to evaluate the presence/absence of smear layer and the presence/absence of open tubules on the root canal walls at coronal, middle, and apical third of each sample.

Methods. Twenty single-rooted freshly extracted teeth were selected and divided into 2 groups. For each group root canals were shaped with F360 (Komet, Brasseler GmbH & Co., Lemgo, Germany) and F6 Skytaper (Komet, Brasseler GmbH & Co., Lemgo, Germany) instruments under irrigation with 5,25% NaOCl and 17% EDTA. Specimens were fractured longitudinally and analyzed by SEM at standard magnification of 5000x. The presence/absence of smear layer and the presence/absence of open tubules at the coronal, middle, and apical third of each canal were evaluated using a 5-step scale for scores. Numeric data were analyzed using Kruskal-Wallis and Mann-Whitney U statistical tests and significance was predetermined at $P < 0.05$.

Results. This study did not reveal differences among two groups at the coronal and apical third. The apical third showed the highest values of scores for all Ni-Ti systems used. Significant differences in smear layer scores were recorded among the Ni-Ti systems at middle canal level ($P < 0.05$), where F6 Skytaper showed significantly lower scores than F360.

Conclusions. Within the limitation of this study, F360 and F6 Skytaper rotary instruments seem to be effective in shaping root canals with good debridement from canal walls, without significant differences between the two systems as it regards the coronal third and the apical third, the area where more debris is still visible. Instead, in the middle third F6 Skytaper seems to be more effective than F360, with statistically significant differences between the two systems.

Key words: debris, Ni-Ti, single-use instruments, single-file systems, SEM, smear layer.

Introduction

Effective root canal treatment is based on cleaning, shaping and sealing the root canal system (1) and its aim is the elimination of microorganisms from the root canal system and the prevention of recontamination after therapy (2-5). Irrigating solutions are used to promote the disinfection and the debridement of the root canal and are considered to be crucial for the success of treatment (6-10). The instrumentation alone cannot efficiently eliminate bacteria from the root canal system (11) and modern rotary systems generate a huge quantity of smear layer that covers root canal walls. Many nickel-titanium (Ni-Ti) instruments have been introduced to improve root canal preparation and several studies (12-14) demonstrated that they can create a smooth funnel-form shape with minimal risk of ledging or transporting the canals. Irrigating solutions are needed to facilitate the debridement of the canals during mechanical preparation (11, 15). Sodium hypochlorite (NaOCl) is the most commonly used irrigant and although it is a highly effective antimicrobial agent, it does not remove the smear layer from the dentin walls (16-22). EDTA is considered a moderate antibacterial agent but it is appreciated for its ability to chelating hard tissue as decalcifying agent (1).

Numerous attempts have been made to further improve and facilitate mechanical root canal preparation with different Ni-Ti instruments being available to achieve this goal (23). Actually new single-file and

single-use Ni-Ti systems have been launched to make the root canal treatment easier (due to the reduction of the files necessary for complete root canal shaping) and safer (due to the reduction of stresses related to reuse, to disinfecting procedures and to thermal cycles in autoclave).

The first single-use and single-file systems launched were made for reciprocating motion. But reciprocating files showed a marked tendency to produce debris along dentinal walls of root canals, much more than rotating instruments (24, 25). So new single-file and single-use systems made for rotary motion were recently launched.

The F360 (Komet, Brasseler GmbH & Co., Lemgo, Germany) is a new single-use and multi-file Ni-Ti system: basic sequence is based on two files with tip diameter of 25 and 35 and taper 0.04; accessory files for apical shaping are available with the same taper and tip diameter of 45 or 55. The files are made of a conventional austenite 55-45 Ni-Ti alloy. A modified S-shaped cross sectional design is used for the entire working part of the file.

The F6 Skytaper is a new single-use and single-file Ni-Ti system: only one instrument, available in five different sizes (of 20, 25, 30, 35, and 40) with a constant taper of 0.06 is necessary for root canal shaping. Each file is characterized by the same cross-sectional design of F360, a S-shaped section.

Both F360 and F6 Skytaper instruments are developed for use in continuous clockwise rotation.

The purpose of this *ex vivo* study is to investigate by SEM image the endodontic dentinal surfaces after canal shaping with both the single-use Ni-Ti systems, under irrigation with 5,25% NaOCl and 17% EDTA solutions, in order to evaluate the presence/absence of smear layer and the presence/absence of open tubules on the root canal walls at the coronal, middle, and apical third of each canal.

The null hypothesis of the study is that there are no significant differences in debris scores and open tubules scores among the two systems.

Material and methods

Twenty single-rooted human teeth freshly extracted for periodontal reasons were selected for this study and placed in saline at room temperature immediately after extraction. The inclusion criteria are: morphological similarity, single-canal roots, straight roots, absence of root decay, absence of previous endodontic treatment, root length of at least 13 mm and apical diameter of at least #20.

The crown of each tooth was removed at the level of the cementum-enamel junction (CEJ) in order to obtain root segments similar in length. Two longitudinal grooves were prepared on the palatal/lingual and buccal surfaces of each root with a diamond bur used with a high-speed water-cooled handpiece to facilitate vertical splitting with a chisel after canal instrumentation.

All the roots were randomly assigned to two groups of 10 specimens each.

Samples were prepared by the same trained operator. The root canals were preliminary scouted using a stainless steel #10 K-file (KometBrasseler GmbH & Co., Lemgo, Germany) and then instrumented with 015 PathGlider rotary Ni-Ti instrument (KometBrasseler GmbH & Co., Lemgo, Germany) in order to create a glide path, and then shaped with two different Ni-Ti rotary systems:

- group A) F 360 (KometBrasseler GmbH & Co., Lemgo, Germany)
- group B) F6 Skytaper (KometBrasseler GmbH & Co., Lemgo, Germany).

All instruments were set into permanent rotation with 6:1 contra-angle handpiece (Sirona, Bensheim Germany) powered by a torque-limited electric motor (VDW Silver Reciproc motor; VDW). For each rotary file, the individual torque limit and rotational speed programmed in the file library of the motor were used. The root canals of group A were prepared using the F 360 system at 300 rpm and 1.8 N/cm torque. The instrumentation sequence was: first red instrument (25/04) and then green instrument (35/04). All instruments were used at WL with gentle in- and out-motion. For each root canal, a new set of F 360 instruments was used.

The root canals of group B were prepared using the F6 Skytaper system at 300 rpm and 2.2 N/cm torque. The instrument (25/06) was used at WL with gentle in- and out-motion. For each root canal, a new F6 was used.

The flutes of each instrument were cleaned after three in-and-out movements and root canals were irrigated with 1 ml of 5.25% NaOCl and with 1 ml of 17% EDTA. After preparation 4 ml of 17% EDTA were left *in situ* for 120 sec followed by 1 ml of 5.25% NaOCl for 60 sec as final rinse. The same manufacturer (Ogna Laboratori Farmaceutici, Muggiò, Italy) prepared the endodontic irrigating solutions. The irrigating solutions were frequently replaced to maintain their effectiveness. Small 27G endodontic needleless (Kendall Monoject, Mansfield, Ma, USA) allowed to reach the apical third with the reflux of irrigating solutions. At the end all the canals were washed with ethanol for 30s and dried with calibrated paper points (Absorbent Paper Points, Dentsply-Maillefer, Konstanz, Germany).

SEM preparation and examination

Each sample were dipped in liquid nitrogen immediately after canal preparation and split longitudinally into two halves with a stainless steel chisel. The sections were then prepared for SEM analysis. The sections were then allowed to air-dry overnight in a desiccator at room temperature, sputter-coated with gold and prepared for SEM analysis (EVO MA 10 Carl Zeiss SMT AG, Germany).

SEM observations were obtained at standard magnification of 5000X. Six photomicrographs were taken in three areas (coronal, middle and apical). In a blind manner, three trained operators scored the presence or absence debris and smear layer on the surface of the root canal at the coronal, middle, and apical portion of each canal. The rating system was proposed

by Hulsmann et al. and the criteria for the scoring are reported following (26).

Score of the debris:

- Score 1: clean root canal wall, only few small debris particles.
- Score 2: few small agglomerations of debris.
- Score 3: many agglomeration of debris covering less than 50% of the root canal wall.
- Score 4: more than 50% of the root canal wall covered by debris.
- Score 5: complete or nearly complete root canal wall covered by debris.

Score of the smear layer:

- Score 1: no smear layer, orifices of dentinal tubules open.
- Score 2: small amount of smear layer, some dentinal tubules open.
- Score 3: homogenous smear layer covering the root canal wall, only few dentinal tubules open.
- Score 4: complete root canal wall covered by a homogenous smear layer, no open dentinal tubules.
- Score 5: heavy, homogenous smear layer covering the entire root canal wall.

Statistical analysis

Statistical analysis was performed with Stata 12.0 software (Stata, College Station, Texas, USA). Descriptive statistics for ordinal data, including the medi-

an, minimum and maximum values were calculated for all groups.

A non-parametric analysis of variance (Kruskal-Wallis ANOVA) and the post-hoc Bonferroni test were applied to investigate significant differences among treatments and among the three thirds of the canals. Significance for all statistical tests was predetermined at $P < 0.05$.

Results

Data derived from scoring are reported in Tables 1 and 2, respectively for debris and smear layer scores. Kruskal-Wallis ANOVA for debris and smear layer scores showed significant differences among the three thirds of the canal ($P < 0.05$). The apical third showed the highest values of scores for all Ni-Ti systems used. As reported in Table 3, significant differences in smear layer scores were recorded among the Ni-Ti systems at middle canal level ($P < 0.05$).

Figures 1 to 4 show representative samples of scanning electron micrographs at different magnifications (2500x and 5000x) of the root canal dentine surface of groups A and B.

Discussion and conclusion

The null hypothesis of the present study has been partially accepted. No significant differences were found be-

Table 1. Summary score of the debris.

Group	Canal level	Score=1	Score=2	Score=3	Score=4	Score =5
F360	Coronal	7	1	2	0	0
	Middle	6	2	2	0	0
	Apical	2	3	3	2	0
F6	Coronal	7	2	1	0	0
	Middle	7	3	0	0	0
	Apical	2	3	4	1	0

Table 2. Summary score of the smear layer.

Group	Canal level	Score=1	Score=2	Score=3	Score=4	Score =5
F360	Coronal	7	2	1	0	0
	Middle	6	1	2	1	0
	Apical	3	3	2	2	0
F6	Coronal	7	2	1	0	0
	Middle	8	1	1	0	0
	Apical	3	4	2	1	0

Table 3. Comparison between the Ni-Ti systems at the same canal level.

F6			
	Canal level	Coronal	Middle Apical
F360	Coronal	0.388	
	Middle		0.012*
	Apical		0.124

* significant differences

Figure 1. Representative samples of scanning electron micrographs of the root canal dentin surface instrumented with F360 (group A) at coronal (a), middle (b) and apical (c) third of the root (2500 $\times$). Dentinal tubules are visible at the coronal and middle third (Smear layer score = 2). The apical third is the area where more debris is still visible (Debris score = 4).

Figure 2. Representative samples of scanning electron micrographs of the root canal dentin surface instrumented with F360 (group A) at coronal (a), middle (b) and apical (c) third of the root (5000 $\times$).

Figure 3. Representative samples of scanning electron micrographs of the root canal dentin surface instrumented with F6 Skytaper (group B) at coronal (a), middle (b) and apical (c) third of the root (2500 $\times$). Dentinal tubules are visible at the coronal third, but at the middle third there are smear layer and some open tubules (Smear layer score = 2). At the apical third more than 50% of the root canal wall covered by debris (Debris score = 4).

Figure 4. Representative samples of scanning electron micrographs of the root canal dentin surface instrumented with F6 Skytaper (group B) at coronal (a), middle (b) and apical (c) third of the root (5000 $\times$).

tween the two groups of Ni-Ti rotary instruments at the coronal and at the apical third. Significant differences were found at the middle third of the samples, where F6 Skytaper showed significantly lower scores than F360.

It is well known that during root canal preparation the action of endodontic instruments produces debris and smear layer, which is compacted along dentinal walls (3). Its elimination seems to be of great importance, since it could allow NaOCl to penetrate into the dentinal tubules, thus enhancing its bactericidal action (7, 10). Moreover, smear layer may affect the sealing efficiency of root canal filling materials, acting as physical barrier to sealers (4, 5). All Ni-Ti rotary instruments have been shown to produce smear layer that needs to be removed with the use of irrigating solutions (27). The chelating agents like EDTA are currently used to remove the smear layer formed during preparation of the root canals. The association of EDTA and NaOCl solutions is the gold standard in chemo-mechanical preparation of the root canals. EDTA acts upon the inorganic components of the smear layer and decalcifies the peri- and intertubular dentine and leaves the collagen exposed. Subsequently, the use of NaOCl dissolves the collagen, leaving the entrances of the dentinal tubules open. For this reason an irrigation regimen similar to the methodology purposed by Foschi et al. was used, with alternation of EDTA and NaOCl at each change of instrument.

The first single-file and single-use files launched on the market were made for reciprocating motion. Although single-file reciprocating systems have been shown to offer advantages over multi file rotary systems, greater amounts of debris were packed laterally over dentinal walls and in isthmuses and protrusions of the root canals, and this may be clinically significant finding because this debris may harbor bacteria (24). The continuous forward motion of the rotary file enables constant exit of debris up the flute of the file; however, each back ward motion of the reciprocating file might provide the opportunity for debris to build up in protrusions and isthmus areas (25). In addition, the reciprocating motion of the file may not allow the blade to cut into the dentine as cleanly, resulting in a burnishing-type effect and pushing debris into recesses and isthmuses (24). Today the last single-use systems are developed for continuous rotation and not for reciprocating motion. F360 and F6 Skytaper belongs to them. They are made by the same manufacturer, with the same cross section but two main differences: F360 is a multi-file system (two files are required for the root canal shaping) with 4% tapered instruments; F6 Skytaper is a single-file system with 6% tapered files.

All tested instruments were evaluated in accordance with the manufacturers' direction. All protocol sequences and instruments operative settings were respected: irrigation procedures were standardized for all experimental groups and the same trained operator shaped all root samples.

SEM analysis revealed that F360 and F6 Skytaper associated to EDTA and NaOCl irrigation leave dentine surfaces substantially free from smear layer. De-

spite some structural differences, single-file rotating Ni-Ti instruments are able to remove smear layer produced during instrumentation and subsequently dissolved by EDTA. Previous SEM studies investigated the effect of other Ni-Ti rotary instruments on dentine and obtained similar results (27-30). The combination of NaOCl and EDTA was probably responsible for the removal of smear layer and for the removal of a great portion of circumferential dentine collagen and mineralized dentine wall from the most part of tubules, as confirmed by Foschi et al. The present study also confirmed that the apical third is the area where more debris is still visible under SEM inspection (30).

Rotary Ni-Ti instruments produced fine dentine particles and shavings that were spread and compacted along dentine walls and then partially dissolved by EDTA and removed coronally via flute spaces. F360 and F6 Skytaper, thanks to their cross section, favorite debris elimination and gave SEM images generally free from smear layer, with major part of dentinal tubules completely opened. Both of them have a S-curve design with two blades and a thin instrument core to deliver a high level of cutting efficiency while respecting natural root canal morphology.

The main differences between these two systems are the taper, F360 0.04 and F6 Skytaper 0.06, and the number of instrument used: F360 requires two file to shape the canal, while F6 Skytaper is characterized by only one instrument (27). The 0.06 taper of F6 Skytaper can explain the better debridement of the middle third of the root canals.

The pre-sterilized, single-use files are designed to prevent cross-contamination, eliminate the need to clean, disinfect and sterilize the instruments and reduce the risk of fracture due to cyclic fatigue (31).

In conclusion, within the limitation of this study, F360 and F6 Skytaper rotary instruments seem to be effective in shaping root canals with good debridement from canal walls, without significant differences between the two systems as it regards the coronal third and the apical third. Instead, in the middle third, F6 Skytaper seems to be more effective than F360, probably thanks to the increased taper.

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Conflict of interest statement

The Authors of this study have no conflict of interest to disclose.

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