Cleaning and Shaping Ability of Gentlefile, HyFlex EDM, and ProTaper Next Instruments: A Combined Micro–computed Tomographic and Scanning Electron Microscopic Study

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ABSTRACT

Introduction: This *ex vivo* study aimed to evaluate the cleaning and shaping ability of a unique stainless steel rotary system (Gentlefile; MedicNRG, Kibbutz Afikim, Israel) compared with 2 nickel-titanium rotary instruments. **Methods:** Thirty human mandibular premolars with a 15° to 25° curvature were equally distributed into 3 groups for final instrumentation with Gentlefile Red (#23/0.04), HyFlex EDM OneFile (#25/0.08∼; Coltene/Whaledent, Altstätten, Switzerland), and ProTaper Next X2 (#25/0.06v; Dentsply Sirona, Ballaigues, Switzerland) (n = 10/each). The untouched canal area, volume changes, and transportation were evaluated on pre- and post-instrumentation micro–computed tomographic images. Five random regions of the canal wall located 1–7 mm from the apical foramen were evaluated with scanning electron microscopy for superficial debris and a smear layer via a 5-point scoring system. Data were compared using the Kruskal-Wallis test with post hoc Dunn's pairwise comparison test with Bonferroni correction and Wilcoxon signed-rank test ($\alpha = 5\%$). **Results:** All instruments generated no overt procedural errors. Untouched area and volume changes did not show any significant differences among the 3 groups ($P > .05$). The Gentlefile exhibited less transportation at the level of 5–7 mm from the apex compared with ProTaper Next ($P < .05$). The Gentlefile showed a smaller debris score than ProTaper Next and better smear layer removal than the others ($P < .05$). Complete cleanliness was not achieved by any of the systems investigated. **Conclusions:** Canals instrumented with the Gentlefile exhibited less transportation at the mid-root level and better cleanliness than those instrumented with HyFlex EDM and ProTaper Next. *(J Endod 2020;46:973–979.)*

KEY WORDS

Centrifugal rotation; endodontic treatment; Gentlefile; micro–computed tomography; scanning electron microscopy

SIGNIFICANCE

The untouched canal area and volume changes were comparable among the Gentlefile, HyFlex EDM, and ProTaper Next. The Gentlefile displayed superior smear layer removal compared with the HyFlex EDM and ProTaper Next. The Gentlefile showed less mid-root transportation and better debris removal than the ProTaper Next.

Cleaning and shaping of the root canal system via chemomechanical preparation should effectively remove intracanal pathogens and debris to treat or prevent apical periodontitis[1]. Nickel-titanium (NiTi) rotary instruments have greatly improved the efficiency of the canal shaping procedure because these instruments have advantages over stainless steel files in terms of flexibility, cutting efficiency, and superior maintenance of the canal geometry[2,3]. The current advancement of NiTi rotary file systems in cross-sectional design[4], motion[5,6], and metallic properties[7] has further contributed to the increased efficiency and reduced the risk of intracanal separation. However, NiTi instruments cannot achieve complete canal cleanliness, particularly in the apical area[8–10]. Cleaning of oval canals is particularly challenging, largely because of the round cutting nature, which inevitably leaves a significant portion of the canal wall untouched[4,10–14].

Gentlefile (GF; MedicNRG, Kibbutz Afikim, Israel) is a unique ultraflexible rotary system made of stainless steel braided wires with an abrasive surface[15]. In the apical portion, the GF instruments consist

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of a central cable on which a second wire is coiled. In the middle and coronal portions, a third wire is coiled on top of the second wire[15]. GF instruments have a 4% taper in the apical portion and a "flamelike" shape with a greater taper in the middle portion because of the wrapping of the third wire. These instruments are operated at a maximum speed of 6500 rpm with a dedicated motor (Gentlefile Drive, MedicNRG) that automatically adapts the rotational speed and torque according to the applied load. In contrast with ordinary endodontic files, GF instruments do not cut into the dentin but rather abrade the root canal dentin walls. GF instruments have been reported to exhibit higher cyclic fatigue resistance and generate smaller vertical forces than NiTi rotary instruments[15]. However, comprehensive knowledge regarding the cleaning and shaping ability of the GF system in comparison with contemporary NiTi rotary instruments is still lacking.

The purpose of this study was to evaluate the untouched canal area, canal volume changes, transportation, and cleaning ability of the GF system in comparison with the following contemporary NiTi rotary instruments: HyFlex EDM (HEDM; Coltene/Whaledent, Altstätten, Switzerland) and ProTaper Next (PTN; Dentsply Sirona, Ballaigues, Switzerland). The null hypothesis was that there would be no differences among the 3 instruments in terms of analyzed parameters.

MATERIALS AND METHODS

Sample Size Calculation and Tooth Preparation

Based on a previous study[6], an effect size of 0.6, a study power of 80, and an alpha-type error of 0.05 were considered for the sample size calculation using G*Power 3.1.9 (Universität Kiel, Kiel, Germany). The estimated sample size was 10 teeth in each group.

After approval from the Institutional Review Board of Tokyo Medical and Dental University (no. D2014-033-01), 120 mandibular premolars extracted for reasons unrelated to this study were subjected to micro–computed tomographic (micro-CT) imaging (inspeXio SMX-100CT; Shimadzu, Kyoto, Japan) for preliminary evaluation of the canal configuration. Teeth with caries, fracture, restorations, resorption, or an immature apex were not included. First, teeth with an apical size equivalent to a #10 K-file (Zipperer, Munich, Germany) were selected after access opening and negotiation with the #10 K-file. Teeth with a single oval canal (with a buccolingual diameter 2.5 times larger than the mesiodistal diameter at 5 mm from the apex) and having a 15° to 25° canal curvature as determined according to the Schneider method[16] were selected[17]. Samples were decoronated to standardize the working length to 15 mm, and a customized jig for each sample was fabricated. A glide path was achieved to the working length with a #15 K-file. Each sample positioned on the jig was submitted to pre- and post-operative micro-CT scans at 80 kV and 130 μA using a 1-mm-thick aluminum filter with 360° rotation in steps of 0.5°, resulting in images with a voxel size of 0.03 mm[6].

Root Canal Instrumentation

Samples were randomly distributed into 3 groups (GF, HEDM, and PTN; $n = 10$ each). The initial canal volume was not significantly different among groups as verified with Kolmogorov-Smirnov and Shapiro-Wilk normality tests followed by 1-way analysis of variance ($P > .05$). The coronal 8 mm was flared using GF Grey (#22/.04, MedicNRG), HEDM Orifice Opener (#25/.12, Coltene/Whaledent), and ProTaper Gold SX (#19/.04v, Dentsply Sirona) in the corresponding group. The canal instrumentation was performed in a closed apical system. An operator experienced in each system conducted the canal preparation using new instruments.

In the GF group, after instrumentation with a manual GF NiTi file (#17/0.04), a GF Red instrument (#23/0.04, MedicNRG) was inserted into the canal, and the instrument was activated using the Gentlefile Drive at 6500 rpm, applying quick pecking motions with slight apical pressure for 5 seconds. This was repeated until the instrument reached the working length, and the instrument was removed from the canal while it was rotating[18].

In the HEDM group, a HyFlex Glidepath File (#10/0.05, Coltene/Whaledent) and a OneFile (#25/0.08∼, Coltene/Whaledent) were sequentially used at 300 rpm/1.8 Ncm and 400 rpm/2.5 Ncm, respectively. In the PTN group, a ProTaper Next X1 (#17/.04v, Dentsply Sirona) and an X2 (#25/.06v, Dentsply Sirona) were sequentially rotated at 300 rpm/2 Ncm[19]. For each NiTi instrumentation, the X-Smart Plus motor (Dentsply Sirona) using the dedicated program was exercised with in-and-out pecking motions and slight apical pressure.

The total instrumentation time was recorded. Aqueous 17% EDTA (BSA Sakurai, Nagoya, Japan) was used as a lubricating agent[20,21], and irrigation was performed throughout the preparation procedure with 5 mL 3% sodium hypochlorite (Takasugi Pharmaceutical, Fukuoka, Japan) using a 30-G needle (Dentsply Sirona) placed 2 mm short of the working length. Finally, canals were flushed with 3 mL 3% sodium hypochlorite and 2.0 mL saline for 1 minute (Otsuka Pharmaceutical, Tokushima, Japan). Postoperatively, specimens were stored in 100% relative humidity at 37°C until further use.

Evaluation of Canal Preparation

The canal volume changes and transportation were calculated using Amira 5.4.4 software (Visage Imaging GmbH, Berlin, Germany) in accordance with a previous study[6]. Briefly, the voltex module in colormap was fixed for each sample to minimize manual errors during image reconstruction. The root canal volume at 1–4 mm and 4–7 mm from the apical foramen, referred to as the apical and middle regions, respectively, were separately calculated by subtracting the pre- from the post-instrumentation volume. To measure canal transportation values, 2-dimensional coregistered slices of 1–7 mm were selected, and the values were calculated by subtracting the width of canal movement on one side from the opposite side; a result of 0 indicates no canal transportation. The amount of untouched area was evaluated from the superimposed images of pre- and post-instrumentation using ImageJ/Fiji version 1.48c (National Institutes of Health, Bethesda, MD).

Scanning Electron Microscopic Analysis

Two longitudinal grooves were prepared on the buccal and lingual surfaces of the root[22], taking care that the grooves followed the curvature without penetration into the canal. The roots were then split with 2 flat-head screwdriver–type instruments (Core Removable Tactics Drivers; Forest-One, Funabashi, Japan).

Specimens were desiccated in ethanol with ascending concentrations, sputter coated with platinum under a vacuum, and examined with scanning electron microscopy (S-4500/EMAX-7000; Hitachi, Hitachinaka, Japan) at an accelerating voltage of 15 kV. In each specimen, images were taken in 5 randomly chosen regions (1–7 mm from the apical foramen), and the canal cleanliness was blindly evaluated by 2 calibrated investigators using a 5-point scoring system as described previously[13,23,24]. Briefly, debris and smear scores were evaluated on 100× and 500–1000× magnified images, respectively. Debris scoring was as follows (Supplemental Fig. S1 is available online at www.jendodon.com):

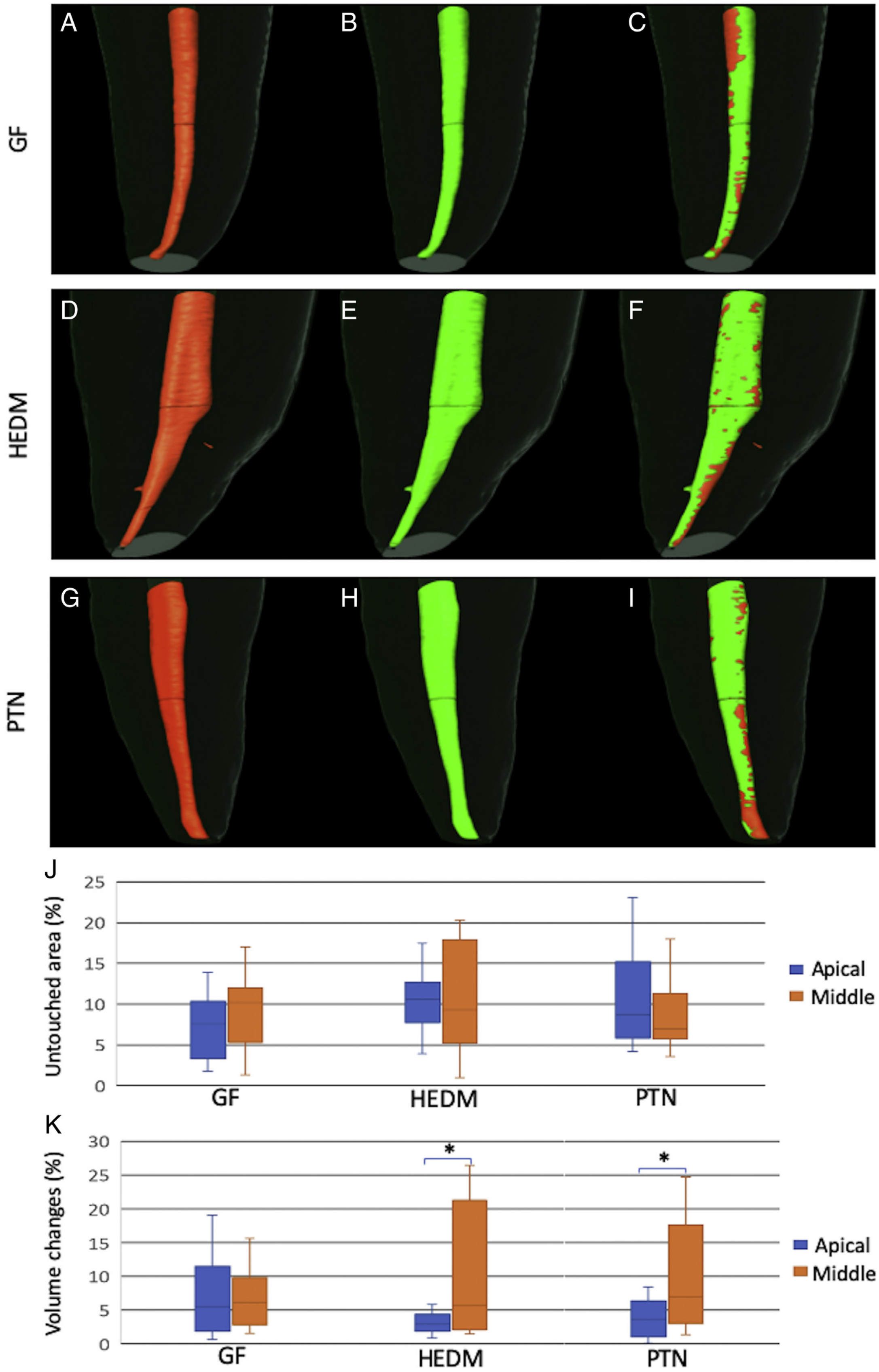

FIGURE 1 – Representative (*A*, *D*, and *G*) preoperative (*red*), (*B*, *E*, and *H*) postoperative (*green*), and (*C*, *F*, and *I*) superimposed micro-CT images of the root canals instrumented with (*A–C*) GF, (*D–F*) HEDM, and (*G–I*) PTN instruments. Maximum, 75th percentile, median, 25th percentile, and minimum values of the (*J*) untouched area and (*K*) volume changes for all tested groups. $^{*}P < .05$ (the Wilcoxon signed-rank test).

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

Smear layer scoring was as follows (Supplemental Fig. S2 is available online at www.jendodon.com):

- Score 1: All dentinal tubules open
- Score 2: 25%–75% of dentinal tubules open
- Score 3: <25% of dentinal tubules open, a homogeneous smear layer covering the canal wall
- Score 4: no dentinal tubules open, a homogeneous smear layer completely covering the canal wall
- Score 5: a heavy, inhomogeneous smear layer covering the canal wall

Statistical Analysis

Data were statistically compared using statistical software (SPSS v22.0; IBM Corp, Armonk, NY). The Kruskal-Wallis test with the post hoc Dunn's pairwise comparison test with Bonferroni correction was used for inter-group comparisons, and Wilcoxon signed-rank test was used for intra-group comparisons. A level of $P < .05$ was considered significant.

RESULTS

Figure 1*A–I* shows representative micro-CT images. There were no significant differences among the 3 instruments regarding the untouched area and canal volume changes in each region ($P > .05$, Fig. 1*J* and *K*). However, the HEDM and PTN groups showed significantly larger canal volume changes in the middle region compared with the apical region ($P < .05$, Fig. 1*K*).

As shown in Table 1, the PTN group presented larger transportation values at 5-, 6-, and 7-mm levels compared with the GF group ($P < .05$), whereas no significant differences up to the 4-mm level were noted among the groups ($P > .05$).

Scanning electron microscopic analysis (Fig. 2*A–H*) showed that the GF group had significantly smaller debris scores than the PTN group and smaller smear layer scores than the other groups ($P < .05$). However, no sample was completely cleaned.

The GF group showed the longest instrumentation time compared with the other groups. The median values were 158, 109, and 127 seconds for the GF, HEDM, and PTN groups, respectively ($P < .05$). No instrument separation occurred.

DISCUSSION

To the best of our knowledge, no available information exists regarding the cleaning and shaping ability of the GF system in comparison with HEDM and PTN instruments. The null hypothesis was partly rejected because the GF group exhibited superior smear layer removal compared with the other groups and less remaining debris and canal transportation at the mid-root level than the PTN group. Our findings suggest that the properties of the GF system, especially ultraflexibility, high rotational speed, and shaping by abrading, helped to achieve better cleanliness and reduce the risk of overflaring compared with contemporary NiTi instruments of comparable sizes.

Micro-CT imaging was used because it is nondestructive and gives high-resolution images to evaluate the untouched area, volume changes, and transportation[10,11,13]. Scanning electron microscopic examination is suited to analyzing debris and smear layer removal[8,23,25,26]. The apical 7 mm of the canal was evaluated because only this region was instrumented with the test instruments. One limitation of this study would be that the samples had a moderate curvature. Thus, further studies using severely curved canals would be needed to evaluate the performance of the GF system.

In this study, the median percentages of the untouched areas ranged from 6.9%–10.6% and 8.7%–10.2% for the apical and middle regions, respectively (Fig. 1*J*). This result agrees with previous micro-CT–based studies reporting that portions of canal areas remain untouched after instrumentation of oval-shaped canals[4,10–14]. In particular, 1 study using mandibular premolars has shown that 17.6% and 34.6% of canal areas remain untouched in the apical 4 mm and 10 mm, respectively, after NiTi rotary instrumentation[10]. There was no significant difference among the 3 groups, indicating that the GF and NiTi rotary systems do not differ in terms of creating unprepared surfaces in oval canals.

The amount of canal volume changes did not differ among the 3 groups (Fig. 1*K*). This is consistent with a study showing that HEDM and PTN exhibit similar canal volume changes[27], whereas another study showed that the PTN instrument causes significantly larger canal volume changes than One Shape (Micro-Mega, Besançon, France) and WaveOne Gold (Dentsply Sirona) instruments[28]. Moreover, the amount of canal volume changes in the apical region was significantly smaller than that of the middle region in the NiTi groups. This can be attributed to the larger-tapered design of the NiTi instruments, which allow more dentin removal in the middle region than in the apical region.

During instrumentation, preservation of the original curvature of the root canal system is crucial for achieving a favorable treatment outcome[29,30]. The present study showed that canal transportation values were not significantly different in the apical region among the groups (Table 1). The values did not seem critical, indicating that all instruments effectively maintained the apical canal curvature. However, in the middle region, the PTN group produced significantly greater canal transportation values than the GF group. This may be because of the greater stiffness and larger vertical force generation of the PTN instruments[15], both of which may induce greater force on the canal wall, resulting in a tendency to cut toward the outer curvature[31]. The PTN instruments exhibited a shorter working time and thus removed dentin more efficiently than the GF instruments. Moreover, in the PTN group, the canal volume showed a greater change in the middle region compared with the apical region (Fig. 1*K*), indicating a

TABLE 1 - The Median and Interquartile Range of Canal Transportation Values (mm)

Level from the apical foramen	GF	HEDM	PTN
1 mm	.0000 (.0000–.0000)[a]	.0000 (.0000–.0000)[a]	.0000 (.0000–.0000)[a]
2 mm	.0000 (.0000–.0157)[a]	.0000 (.0000–.0365)[a]	.0000 (.0000–.0197)[a]
3 mm	.0000 (.0000–.0307)[a]	.0000 (.0000–.0525)[a]	.0325 (.0000–.0632)[a]
4 mm	.0015 (.0000–.0402)[a]	.0000 (.0000–.0557)[a]	.0330 (.0000–.0495)[a]
5 mm	.0000 (.0000–.0110)[b]	.0315 (.0000–.0922)[ab]	.0440 (.0180–.0770)[a]
6 mm	.0000 (.0000–.0130)[b]	.0150 (.0000–.0657)[ab]	.0495 (.0280–.0802)[a]
7 mm	.0000 (.0000–.0277)[b]	.0130 (.0000–.0740)[ab]	.0285 (.0097–.0930)[a]

GF, Gentlefile; HEDM, Hyflex EDM; PTN, ProTaper Next.
Different letters in the row are significantly different ($P < .05$).

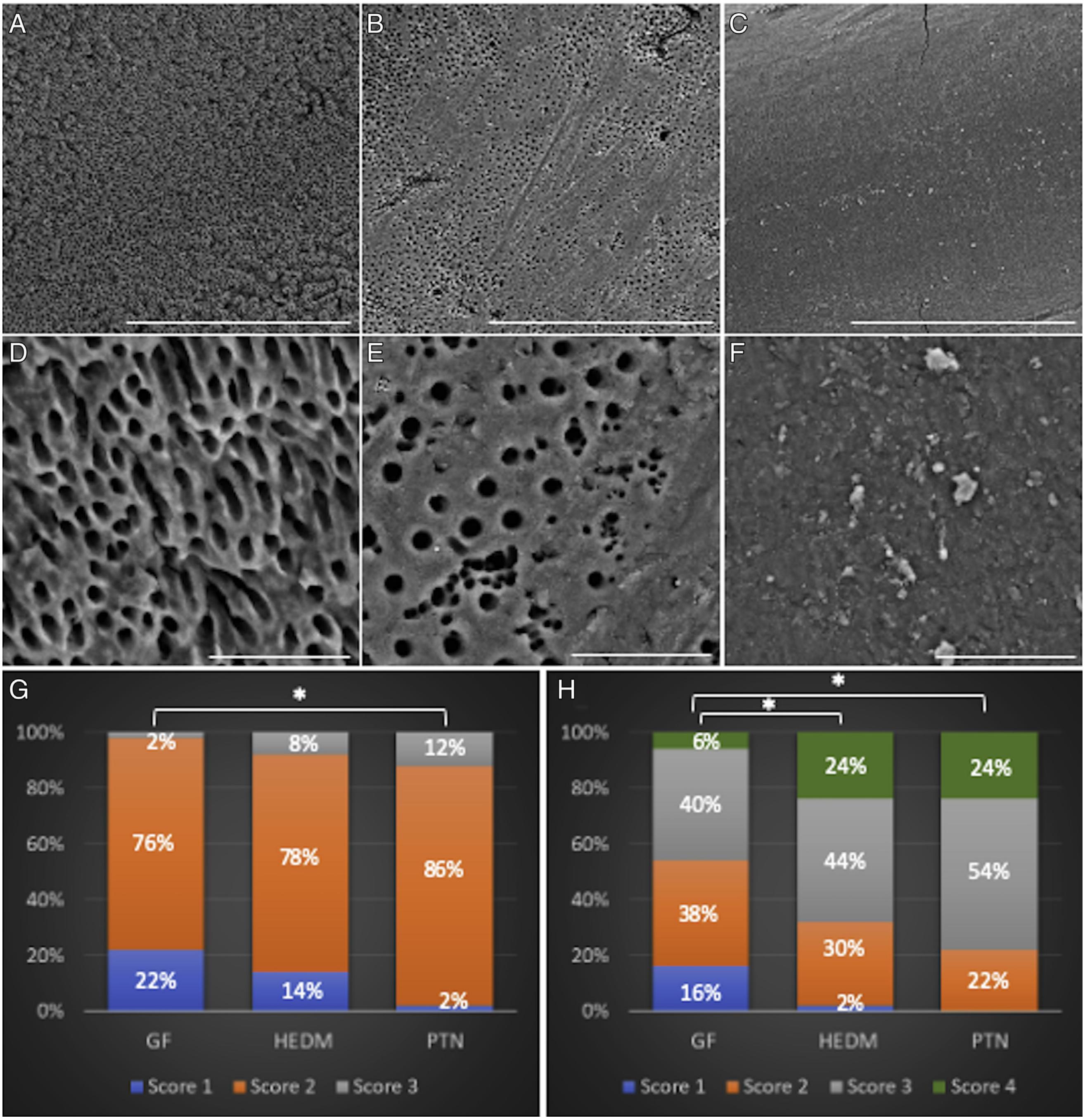

FIGURE 2 – Representative scanning electron microscopic images of the root canal walls in the (*A* and *D*) GF, (*B* and *E*) HEDM, and (*C* and *F*) PTN. (*A–C*) Lower magnification views for debris evaluation. (*A* and *B*) Score 1 and (*C*) 2. Bar = 300 μm. (*D–F*) Higher magnification views for smear layer evaluation. (*D*) Score 1, (*E*) 2, and (*F*) 4. Bar = 30 μm. Percent distribution of (*G*) debris scores and (*H*) smear scores in each group. *$P < .05$ (Kruskal-Wallis test with the post hoc Dunn's test).

tendency to selectively cut the coronal part of the canal. This could also be associated with the greater tendency for mid-root transportation in PTN instruments[19,32]. Our present findings indicate that the GF instruments were flexible enough to maintain the canal anatomy and may reduce the risk of overflaring, which could jeopardize tooth stiffness. Additionally, although statistically insignificant, the HEDM instruments produced slightly lower transportation values than the PTN instruments at all levels. This may be because the HEDM instruments are more flexible than M-Wire instruments of the same size and taper[27].

The GF group achieved smaller smear layer scores than the NiTi-instrumented groups and smaller debris scores than the PTN groups, indicating the superior cleaning ability of the GF instruments. Irrigation of the canal system with a needle and syringe does not produce adequate hydrodynamic shear stresses to dislodge the adherent material from the root canal walls[33,34]. However, 1 study has reported no significant difference in root canal debridement between GF and NiTi rotary instruments[34]. This inconsistency could be ascribed to the difference in methodology because the previous study used histologic examination of the remaining pulp tissues. The GF Drive (MedicNRG) rotates up to 6500 rpm and generates vibration effects that induce agitation of the irrigant throughout the procedure. Collectively, it seems reasonable to assume that the combined effect of the high rotational speed, the vibration effect, and the ultraflexibility of GF create faster movement of the irrigant with a centrifugal effect, which may contribute to achieving better cleaning in oval canals[25,34].

CONCLUSION

Within the limitations of this study, it can be concluded that canals instrumented with GF instruments exhibited less transportation and better cleanliness than those instrumented with HEDM and PTN instruments.

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The authors deny any conflicts of interest related to this study.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found in the online version at www.jendodon.com (10.1016/j.joen.2020.03.027).

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