INTRODUCTION

Current clinical endodontic treatment (root canal therapy) extensively employs nickel–titanium (NiTi) rotary medical devices (files), which are operated with a special gear-reduced dental handpiece. Introduction of the NiTi alloy to endodontics dates from the pioneering publication by Walia, Brantley, and Gerstein (1988). The low elastic modulus of the near-equiatomic NiTi alloy permits negotiation of curved root canals while the file is in rotation, which is of particular clinical importance for molar teeth. The NiTi files are generally manufactured by machining starting wire blanks. Previously, austenitic stainless steel alloys with much higher elastic modulus were twisted to manufacture files used for hand instrumentation of root canals, and clinical problems were much more common when these files are employed in curved root canals.

In their pioneering study, Walia et al. (1988) investigated hand files that were machined from heavily work-hardened non-superelastic (non-pseudoelastic) martensitic NiTi wires. With advances in NiTi wire processing, manufacturers introduced engine-driven rotary superelastic (pseudoelastic) files fabricated from wires containing substantial austenitic phase, avoiding the use of time-consuming hand instrumentation (Thompson, 2000). New thermomechanical processing protocols (Berendt, 2007) subsequently yielded NiTi wire...
with a stable martensitic structure and improved fatigue resistance, and superelastic M-Wire rotary files (Alapati, Brantley, Iijima, Clark et al., 2009; Johnson, Lloyd, Kuttler, & Namerow, 2008) were introduced. Another rotary NiTi file based on Controlled Memory Technology™ (D&S Dental, Johnson City, TN) (Shen et al., 2011) has also been marketed, in which different proprietary thermomechanical processing also yielded instruments with improved fatigue resistance. A novel metallurgical approach has been employed for the TF™ Twisted File (Kerr Dental Products), which is fabricated by twisting the NiTi wire in the R-phase condition (Kim, Yum, Hur, & Cheung, 2010), rather than machining the NiTi wire.

Considerable literature exists on the structure and properties of as-received and clinically used NiTi rotary instruments. Articles report the SEM examination of file surfaces (Alapati et al., 2005), use of differential scanning calorimetry to investigate the NiTi phases (Alapati, Brantley, Iijima, Schricker et al., 2009; Brantley, Svec, Iijima, Powers, & Grentzer, 2002), fatigue testing in artificial root canals that simulate clinical conditions (Pruett, Clement, & Carnes, 1997), and the use of X-ray diffraction (Shen, Coil, Zhou, Zheng, & Haapasalo, 2013; Shen et al., 2011), transmission electron microscopy (Alapati, Brantley, Iijima, Clark et al., 2009) and Vickers hardness measurements (Alapati et al., 2006) to provide additional details about their metallurgical structure.

New information is reported in this article about the simulated clinical performance of four well-known NiTi instrument products in current use, for which characterization and other property information has been published. To the best knowledge of the authors, no similar study using extracted teeth and serial instrumentation has been reported in the endodontic literature.

2 | EXPERIMENTAL

2.1 | Endodontic instruments selected for study

Four NiTi rotary instrument products were selected: ProFile Vortex™, ProFile Vortex Blue™ and ProTaper Gold™ (all Dentsply Tulsa Dental Specialties), along with HyFlex® CM™ (Coltene/Whaledent). One hundred files were used: five packages of five files across the four brands.

The ProFile Vortex™ product is an M-Wire file (Gao, Shotton, Wilkinson, Phillips, & Johnson, 2010), and served as the control. The subsequently marketed ProFile Vortex Blue™ product is an M-Wire file in which the manufacturer performs a special heat treatment that yields a blue colour from the titanium oxide surface film (Plotino, Grande, Cotti, Testarelli, & Gambarini, 2014; Tsujimoto et al., 2014). The ProTaper Gold™ product is also a subsequently marketed M-Wire file, but subjected to different metallurgical processing (Hieawy, Haapasalo, Zhou, Wang, & Shen, 2015; Uygun et al., 2016). The Coltene HyFlex® CM™ product is a controlled-memory file that is machined from the proprietary-processed CM™ NiTi wire (Shen et al., 2011, 2013).

For the ProFile Vortex™ and ProFile Vortex Blue™ instruments, the five file sizes (diameter in units of 0.01 mm at the instrument tip) were 20, 25, 30, 35, and 40, and all instruments had the commonly used 0.04 taper (diameter increase along the length of the instrument in units of mm/mm). For the ProTaper Gold™ instruments, the five sizes were S1, S2, F1, F2 and F3. For the HyFlex® CM™ instruments, the five sizes/tapers were 20/0.04, 25/0.04, 20/0.06, 30/0.04 and 40/0.04. All instruments had 25 mm length.

2.2 | Extracted teeth and simulated instrumentation

Extracted posterior teeth (mandibular and maxillary molars and premolars) were de-identified and rinsed in 3% NaOCl solution. Exterior tissue was removed from the roots using a periodontal scaler, and teeth were then stored in water in sealed, opaque jars. Radiographs were taken of all teeth, and canals were divided into classifications of <30°, 30°–45°, 45°–60° and >60° curvature, following the technique employed by Pruett et al. (1997). Teeth were randomly selected for each set of rotary files just prior to simulated clinical endodontic treatment with that set of files. Each file set treated one of each type of tooth.

Rotary instrumentation followed the directions of each manufacturer in terms of rotational speed (rpm) and torque settings (g-cm) (Table 1) and the clinical endodontic protocols. An 8:1 reduction handpiece (TUL-8M, Dentsply Tulsa Dental Specialties) was utilized on a torque-control motor (Aseptico® DTC®, Dentsply Tulsa Dental Specialties). Instrumentation of canals continued to a minimal apical size of 25 or maximum size of 40 (with taper corresponding to the file system used), depending on the anatomy of the individual canal. Root canals were irrigated with approximately 1 ml 3% NaOCl solution per canal with a 27-gauge needle (BD PrecisionGlide™, Becton Dickinson), placed passively into each canal, after every two instruments used. Between the uses of each rotary instrument, a #10 K-File was placed in the root canal to working length to maintain patency. Files were cleaned with a 4 × 4 cotton sponge soaked in 70% isopropyl alcohol after each use and stored in EndoFoam™ (Jordco) during instrumentation of the tooth.

2.3 | Evaluation of instrument wear and statistical analysis

Two experienced endodontists examined and scored SEM (Quanta 200, FEI) images of files for deformation and wear. Files were examined at four discrete, constant, positions along the length of the files

| Brand               | Revolutions per minute | Torque (g-cm) |
|---------------------|------------------------|---------------|
| ProFile Vortex™     | 500                    | 104–132       |
| ProFile Vortex Blue™| 500                    | 104–132       |
| ProTaper Gold™      | 300                    | 400–520       |
| HyFlex® CM™         | 500                    | 245           |
before use and through three simulated clinical procedures. The use of a custom-fabricated jig to hold the files allowed the four discrete sites to be evaluated each time. The maximum score from all four evaluated locations (distance from the tip in mm) on each file (D0, D1, D3 and D5) was used as the final file grade for each use. Scores of 1 (best)—3 represented surface conditions that were considered suitable for clinical use of the instrument (classified as “usable”); a score of 4 was given when the instrument was judged potentially unfit for use as seen at ×200 magnification (“microscopically unacceptable”); and a score of 5 was given for a failed instrument. When disagreement existed between what one observer thought was usable and other observer thought was microscopically unacceptable, the evaluations were discussed and a consensus was obtained.

When performing the data analysis, Kappa statistics for intra-rater and inter-rater reliability were calculated, and Fisher’s exact test used to evaluate root canal curvatures experienced by each file brand. The instrument grading results were tabulated and analysed, performed with repeated-measures logistic regression for visual use and microscopic use. The odds ratios between brands and uses were also calculated. Statistical significance was set at $\alpha = 0.05$. Any file added to the study to replace one that failed was not included in the statistical analysis to ensure that each file examined had an equal chance at being used through the three clinical simulations (use 1, use 2 and use 3).

3 | RESULTS AND DISCUSSION

3.1 | File failures and evaluation of instrument wear

Table 2 presents details of the individual file failures, indicating the specific product, the instrument size and taper (size/taper format), the specific use when failure occurred, the mode of failure, the specific tooth type being instrumented when failure occurred, the range of the most severe root curvature for this tooth, and the distance of the failure location from the instrument tip (D0). Twelve files visibly

### Table 2  Detailed information about individual visual file failures

| Brand                  | Size/taper | Use at failure | Failure mode | Tooth type    | Most severe curvature | Failure location |
|------------------------|------------|----------------|--------------|---------------|-----------------------|-----------------|
| ProFile Vortex™        | 25.04      | Tooth 1        | Separation   | Pre-molar     | 45–60°                | 1 mm            |
|                        | 30.04      | Tooth 2        | Separation   | Maxillary molar | 30–45°                | 1 mm            |
| ProFile Vortex Blue™   | 25.04      | Tooth 3        | Deformation  | Maxillary molar | <30°                  | N/A             |
|                        | 35.04      | Tooth 1        | Deformation  | Mandibular molar | 30–45°                | N/A             |
|                        | 30.04      | Tooth 1        | Deformation  | Mandibular, molar | 30–45°                | N/A             |
|                        | 25.04      | Tooth 1        | Separation   | Mandibular molar | 30–45°                | 1 mm            |
| ProTaper Gold™         | S2         | Tooth 1        | Deformation  | Maxillary molar | 30–45°                | N/A             |
|                        | S1         | Tooth 1        | Deformation  | Maxillary molar | 30–45°                | N/A             |
| HyFlex® CM™            | 30.04      | Tooth 1        | Deformation  | Pre-molar     | 30–45°                | N/A             |
|                        | 20.06      | Tooth 3        | Deformation  | Pre-molar     | <30°                  | N/A             |
|                        | 25.04      | Tooth 3        | Deformation  | Pre-molar     | <30°                  | N/A             |
|                        | 20.04      | Tooth 1        | Deformation  | Mandibular molar | <30°                  | N/A             |

### Figure 1 Evaluation summary for the entire study by file brand and tooth sequence use. The vertical axis shows the number of instruments for the four brands in each of the three categories of usable from visual examination, unacceptable from visual examination and unacceptable from scanning electron microscope examination.
failed during the study: three separated (fractured) and nine plastically (permanently) deformed. The majority of these failures occurred during the first use of the file.

Figure 1 presents the evaluation summary from the two observers for the four file products. "Clean" corresponds to the as-received files (as-manufactured condition), "Unacceptable-EM" to files that were judged clinically unacceptable based on SEM images, and "Unacceptable-Visual" to files that were judged clinically unacceptable from examination with the unaided eye.

Repeated-measures logistic regression analysis yielded no significant effects for brand, amount of use and their interaction, for the files remaining visibly useful. For files that were rated microscopically useful, a significant effect was found for the number of uses \((p = 0.0127)\). Contrasts of uses showed statistical significance for use 0 (clean) versus 1, use 0 versus 2 and use 0 versus 3, indicating that unused files were more likely to be microscopically acceptable than used files. Even with the two experienced endodontists as evaluators, the Kappa statistics were much less than desired (0.6809 and 0.7608 for intra-rater reliability; 0.5176 for inter-rater reliability), based on the 1–5 scale used in the study, because of the small amount of surface wear that occurred.

| TABLE 3 | ProFile Vortex™ evaluation summary |
|---------|-----------------------------------|
|         | Visually unacceptable | Microscopically unacceptable | Usable | Total |
| Unused  | 0                     | 3                         | 22     | 25    |
| 20.04   | 0                     | 0                         | 5      | 5     |
| 25.04   | 0                     | 2                         | 3      | 5     |
| 30.04   | 0                     | 1                         | 4      | 5     |
| 35.04   | 0                     | 0                         | 5      | 5     |
| 40.04   | 0                     | 0                         | 5      | 5     |
| Tooth 1 | 1                     | 3                         | 21     | 25    |
| 20.04   | 0                     | 0                         | 5      | 5     |
| 25.04   | 1                     | 1                         | 3      | 5     |
| 30.04   | 0                     | 1                         | 4      | 5     |
| 35.04   | 0                     | 0                         | 5      | 5     |
| 40.04   | 0                     | 0                         | 5      | 5     |
| Tooth 2 | 1                     | 2                         | 21     | 24    |
| 20.04   | 0                     | 0                         | 5      | 5     |
| 25.04   | 0                     | 1                         | 3      | 4     |
| 30.04   | 1                     | 1                         | 3      | 5     |
| 35.04   | 0                     | 0                         | 5      | 5     |
| 40.04   | 0                     | 0                         | 5      | 5     |
| Tooth 3 | 0                     | 3                         | 20     | 23    |
| 20.04   | 0                     | 1                         | 4      | 5     |
| 25.04   | 0                     | 1                         | 3      | 4     |
| 30.04   | 0                     | 1                         | 3      | 4     |
| 35.04   | 0                     | 0                         | 5      | 5     |
| 40.04   | 0                     | 0                         | 5      | 5     |
| Total   | 2                     | 11                        | 84     | 97    |

| TABLE 4 | ProTaper Gold™ evaluation summary |
|---------|-----------------------------------|
|         | Visually unacceptable | Microscopically unacceptable | Usable | Total |
| Unused  | 0                     | 1                         | 24     | 25    |
| S1      | 0                     | 1                         | 4      | 5     |
| S2      | 0                     | 0                         | 5      | 5     |
| F1      | 0                     | 0                         | 5      | 5     |
| F2      | 0                     | 0                         | 5      | 5     |
| F3      | 0                     | 0                         | 5      | 5     |
| Tooth 1 | 2                     | 2                         | 21     | 25    |
| S1      | 1                     | 1                         | 3      | 5     |
| S2      | 1                     | 1                         | 3      | 5     |
| F1      | 0                     | 0                         | 5      | 5     |
| F2      | 0                     | 0                         | 5      | 5     |
| F3      | 0                     | 0                         | 5      | 5     |
| Tooth 2 | 0                     | 1                         | 22     | 23    |
| S1      | 0                     | 1                         | 3      | 4     |
| S2      | 0                     | 0                         | 4      | 4     |
| F1      | 0                     | 0                         | 5      | 5     |
| F2      | 0                     | 0                         | 5      | 5     |
| F3      | 0                     | 0                         | 5      | 5     |
| Tooth 3 | 0                     | 2                         | 21     | 23    |
| S1      | 0                     | 1                         | 3      | 4     |
| S2      | 0                     | 1                         | 3      | 4     |
| F1      | 0                     | 0                         | 5      | 5     |
| F2      | 0                     | 0                         | 5      | 5     |
| F3      | 0                     | 0                         | 5      | 5     |
| Total   | 2                     | 6                         | 88     | 96    |

Tables 3–6 present the information in Figure 2 in a detailed manner for the individual ProFile Vortex™, ProTaper Gold™, ProFile Vortex Blue™ and Coltene HyFlex® CM™ instruments, respectively. When considering these evaluation summaries in Tables 3–6, it is important to note that, with the study protocol employed, microscopically unacceptable grades (score of 4) do not directly correlate to individual files. For example, a total of 10 Coltene HyFlex® CM™ files were graded microscopically unacceptable for the unused condition and through three uses (Table 6). This could represent 10 different files with all receiving the same score, but it could also represent the same files receiving multiple microscopically unacceptable scores throughout multiple uses. Also, a file graded as microscopically unacceptable after use 1 may have been graded as usable after subsequent instrumentation (use 2 or 3) on additional teeth.

A total of eight files were graded as visually unacceptable after their first use. Most instrument failures occurred during the first use; fewer instrument failures were seen in uses 2 and 3. The total number of files graded as microscopically unacceptable at each use stayed relatively similar, ranging from 8.0% in the clean (unused) file group to 11.0% in tooth (use) 3. The instruments of each brand that were graded as usable in each simulated clinical use ranged from...
TABLE 5  ProFile Vortex Blue™ evaluation summary

| Instrumentation | Visually unacceptable | Microscopically unacceptable | Usable | Total |
|-----------------|-----------------------|------------------------------|--------|-------|
| Unused          | 0                     | 1                            | 24     | 25    |
| 20.04           | 0                     | 0                            | 5      | 5     |
| 25.04           | 0                     | 0                            | 5      | 5     |
| 30.04           | 0                     | 0                            | 5      | 5     |
| 35.04           | 0                     | 0                            | 5      | 5     |
| 40.04           | 0                     | 1                            | 4      | 5     |
| Tooth 1         | 3                     | 3                            | 19     | 25    |
| 20.04           | 0                     | 0                            | 5      | 5     |
| 25.04           | 1                     | 0                            | 4      | 5     |
| 30.04           | 1                     | 2                            | 2      | 5     |
| 35.04           | 1                     | 0                            | 4      | 5     |
| 40.04           | 0                     | 1                            | 4      | 5     |
| Tooth 2         | 0                     | 1                            | 21     | 22    |
| 20.04           | 0                     | 0                            | 5      | 5     |
| 25.04           | 0                     | 0                            | 4      | 4     |
| 30.04           | 0                     | 1                            | 3      | 4     |
| 35.04           | 0                     | 0                            | 4      | 4     |
| 40.04           | 0                     | 0                            | 5      | 5     |
| Tooth 3         | 1                     | 2                            | 19     | 22    |
| 20.04           | 0                     | 0                            | 5      | 5     |
| 25.04           | 1                     | 0                            | 3      | 4     |
| 30.04           | 0                     | 1                            | 3      | 4     |
| 35.04           | 0                     | 0                            | 4      | 4     |
| 40.04           | 0                     | 1                            | 4      | 5     |
| Total           | 4                     | 7                            | 83     | 94    |

92.0% in the clean (unused) file group to 86.0% in tooth (use) 3. Additional details about the grading results for these instruments are available elsewhere (Burke, 2016).

3.2  | SEM examination of instruments

Figures 2–6 present representative SEM images of the files, showing the unused condition of an as-manufactured instrument (Figure 2), the ductile torsional fracture (Luebke & Brantley, 1991) of an instrument that separated during the first use (Figure 3), the extent of instrument surface wear after the third use (Figures 4 and 5) and the appearance of an instrument that had undergone plastic deformation during the simulated clinical use (Figure 6). The machining grooves on the spiral cutting flutes are evident, along with rollover (Walia et al., 1988) of deformed metal at the edges of the flutes. Manufacturing defects, known to lead to clinical instrument failure (Alapati et al., 2005), can also be noted on the instrument surfaces.

Even though SEM studies of the wear of NiTi rotary instruments have been reported (Arantes et al., 2014; Shen et al., 2015; Trojan,

FIGURE 2  Unused size 30.04 ProFile Vortex™ file, showing edge rollover and edge defects

TABLE 6  Coltene HyFlex® CM™ evaluation summary

| Instrumentation | Visually unacceptable | Microscopically unacceptable | Usable | Total |
|-----------------|-----------------------|------------------------------|--------|-------|
| Unused          | 0                     | 3                            | 22     | 25    |
| 20.04           | 0                     | 0                            | 5      | 5     |
| 25.04           | 0                     | 3                            | 2      | 5     |
| 30.04           | 0                     | 0                            | 5      | 5     |
| 35.04           | 0                     | 0                            | 5      | 5     |
| 40.04           | 0                     | 0                            | 5      | 5     |
| Tooth 1         | 2                     | 1                            | 22     | 25    |
| 20.04           | 1                     | 0                            | 4      | 5     |
| 20.06           | 0                     | 1                            | 4      | 5     |
| 25.04           | 0                     | 0                            | 5      | 5     |
| 30.04           | 1                     | 0                            | 4      | 5     |
| 40.04           | 0                     | 0                            | 5      | 5     |
| Tooth 2         | 0                     | 3                            | 20     | 23    |
| 20.04           | 0                     | 1                            | 3      | 4     |
| 20.06           | 0                     | 2                            | 3      | 5     |
| 25.04           | 0                     | 0                            | 5      | 5     |
| 30.04           | 0                     | 0                            | 4      | 4     |
| 40.04           | 0                     | 0                            | 5      | 5     |
| Tooth 3         | 2                     | 3                            | 18     | 23    |
| 20.04           | 0                     | 1                            | 3      | 4     |
| 20.06           | 1                     | 2                            | 2      | 5     |
| 25.04           | 1                     | 0                            | 4      | 5     |
| 30.04           | 0                     | 0                            | 4      | 4     |
| 40.04           | 0                     | 0                            | 5      | 5     |
| Total           | 4                     | 10                           | 82     | 96    |
Só, Figueiredo, & Oliveira, 2006], this was the first study in which detailed scoring of instrument wear was obtained for clinically simulated sequential instrumentation (three uses) of a large number of extracted teeth.

Only a small amount of wear was observed for the four brands during the three uses. Accordingly, there were some disagreements among the two experienced evaluators about scoring the amount of wear. This situation was exacerbated with the initial study plan of having four evaluators, resulting in the decision to have two evaluators grade the instrument quality and wear. There was generally excellent visual quality for the manufactured files. Only a small number of as-received files were judged not to be clinically usable, as the SEM examination of the rotary instruments revealed machining grooves and other surface defects from the manufacturing process.

There were unique SEM observations for the ProFile Vortex Blue™ files. Multiple instruments of this brand displayed characteristic surface defects that had the appearance of extensive pitting. This condition appeared to worsen with continued use (Figure 4), as if the instrument surface was chipping off, and examiners frequently scored this appearance as severe instrument wear (score of 4). While the titanium oxide coating on these files may compensate for the surface hardness decrease from the heat treatment process (Gao et
al., 2010), the resulting surface is evidently prone to wear. The wear pattern appeared as voids in the surface layer that was progressively removed through continued use. This observation suggests that repeated use of ProFile Vortex Blue™ files can potentially result in significant surface defects that are not detectable by visual inspection, causing reduction in hardness and overall cutting efficiency; this supports the manufacturer recommendation for single use of the file. However, in this study no Vortex Blue™ files were observed to fracture or visibly deform because of this type of defect.

3.3 | Instrument failure and study perspective

As previously noted in Section 3.1, the observed instrument failure modes were plastic deformation (nine files) and fracture (three files). Hence, 12% of the 100 files utilized in the study underwent failure during the clinically simulated instrumentation. The overall separation rate for all four instrument brands was 3.0%. Separation, which is of great concern to the patient, presents a challenge for the endodontist to remove the instrument fragment from the root canal (Suter, Lussi, & Sequeira, 2005). Figure 3 shows fracture of the file at approximately 1 mm from the tip (D1 position). Two extensive studies of clinical rotary instrument fracture have reported that separation occurs near the tip, yielding fragments of 2–3 mm in length (Di Fiore, Genov, Komaroff, Li, & Lin, 2006; Wu et al., 2011). The results from the present study suggest that clinical wear is not a problem with current NiTi rotary instruments, although there is some concern about instrument separation during root canal therapy. Limitations of this in vitro investigation were the inability to simulate fully in vivo conditions during root canal therapy and difficulty of determining the precise amount of wear during instrumentation. The recommendation of manufacturers that the NiTi rotary files be used only one time clinically is supported by the present study.

4 | CONCLUSIONS

Under the conditions of this in vitro investigation that simulated clinical endodontic use, it was found that none of four brands of rotary NiTi files showed significantly more or less wear, which occurred at a low level during instrumentation. Files that were initially evaluated as microscopically unacceptable rarely (only one time) progressed to visually unacceptable in subsequent uses, suggesting that a poor surface condition is not necessarily a precursor to instrument failure. Some files evaluated in this study separated during the simulated clinical instrumentation. When and how a file will fail during clinical use appears to be multimodal, involving instrument surface quality/hardness, wear and permanent deformation.

ORCID

William A. Brantley https://orcid.org/0000-0002-0932-5683

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