Article published online: 2024-09-20

The Effect of Canal Curvature and Different Manufacturing Processes of Five Different NiTi Rotary Files on Cyclic Fatigue Resistance

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Abstract

Objectives The aim of this study was to evaluate the cyclic fatigue resistance of ProTaper Universal, ProTaper Next, E-FLEX EDGE, E-FLEX ONE, and ZenFlex nickel-titanium (NiTi) rotary files in 60 and 90 degrees of simulated canal curvature.

Materials and Methods ProTaper Universal, ProTaper Next, E-FLEX EDGE, E-FLEX ONE, and ZenFlex were used in this study. Each system was divided into two groups testing in simulated canals with 60 and 90 degrees of curvature. Both groups were set to rotate under a controlled temperature at 37°C until fracture. The number of cycles to fracture (NCF) was recorded and two fractured files from each group were randomly selected to analyze the fractographic pattern using scanning electron microscopy (SEM).

Statistical Analysis The NCF between the two groups was analyzed statistically using the Mann–Whitney *U* test. The statistical differences between each system at the same degree of artificial canal curvature were analyzed using the Kruskal–Wallis test. A significant difference was set at $p < 0.05$.

Results E-FLEX ONE showed the highest mean NCF ($p < 0.05$) when performed in 60- and 90-degree curvatures. In addition, the file tested in a 60-degree curvature exhibited higher resistance to cyclic fatigue than the one tested in a 90-degree curvature in the mutual NiTi system ($p < 0.05$). The SEM micrographs exhibited a similar crack initiation area, which is the feature of cyclic fatigue failure.

Conclusion E-FLEX ONE showed the greatest resistance to cyclic fatigue in both 60 and 90 degrees of curvature. This study implies that E-FLEX ONE is appropriate for severely curved canals.

Keywords
- blue heat–treated
- cyclic fatigue resistance
- martensitic composition
- metallurgical process
- nickel-titanium rotary file

Introduction

Nickel-titanium (NiTi) rotary instruments are currently used in endodontic procedures.[1–3] Previously, root canal instruments were made of stainless steel, which has great cutting efficiency. However, the inherent stiffness and rigidity of the material increases the iatrogenic failure during root canal preparation including ledges, apical zip, transportation, and perforation. Therefore, rotary NiTi files, which possess relatively superior mechanical properties such as flexibility and

DOI https://doi.org/10.1055/s-0044-1788719.
ISSN 2320-4753.

superelasticity, have been customarily involved in root canal preparation.[1,3,4]

There are many dental manufacturing companies that focus on improving the mechanical properties of NiTi files, the clinical outcome of root canal treatment, shaping ability, and the cleaning efficacy of root canal instrumentation. Manufacturing or surface treatment, structural design, metallurgical development, and motion mode are the four main aspects they proposed for the improvement and evolution of NiTi files. Among these, the remarkable one is metallurgical development, and the most frequently used method is a proprietary heat treatment that imparts specific mechanical properties to the NiTi alloy.[2]

Nevertheless, NiTi files still have a high incidence of file separation due to excessive cyclic fatigue, especially in curved root canals. This decreases the success rate of root canal treatment and becomes a clinical concern.[5–7] Previous studies reported that R-phase NiTi rotary files and M-wire NiTi rotary files had a significantly higher cyclic fatigue resistance than the traditional NiTi rotary files. Another study revealed that EdgeTaper Platinum, which has a high martensitic composition, exhibited a significantly higher cyclic fatigue resistance than ProTaper Gold.[8–10] Recently, ZenFlex (Kerr Corporation, Orange, CA, United States), E-FLEX EDGE (Changzhou Sifary Medical Technology, Changzhou, China), and E-FLEX ONE (Changzhou Sifary Medical Technology) were launched in the market. ZenFlex is a triangular cross-section NiTi file and is manufactured with the proprietary heat treatment process. It has been claimed to have high cutting efficiency, strength, flexibility, and resistance to fracture. Second, E-FLEX EDGE, a heat-treated NiTi file with S cross-section and flat-sided design, has been claimed to have the following properties: controlled memory NiTi wire, high flexibility, variable pitch, which can reduce the screw-in effect, and high resistance to cyclic fatigue. Finally, E-FLEX ONE, a blue heat–treated NiTi file with double S cross-section, has been claimed to have high flexibility, sharp cutting flute, and resistance to cyclic fatigue. From these statements, it is clear that every manufacturer claims that their files are not easily broken and have excellent properties. However, the review of the cyclic fatigue comparison of the blue heat–treated NiTi system and other NiTi rotary file systems is still unavailable and should be elucidated. Therefore, this study aimed to evaluate the cyclic fatigue resistance of ProTaper Universal (Dentsply Maillefer, Ballaigues, Switzerland), ProTaper Next, E-FLEX EDGE, E-FLEX ONE, and ZenFlex NiTi rotary files in simulated severely curved canals.

Materials and Methods

ProTaper Universal (Dentsply Maillefer), ProTaper Next (Dentsply Maillefer), E-FLEX EDGE (Changzhou Sifary Medical Technology), E-FLEX ONE (Changzhou Sifary Medical Technology), and ZenFlex (Kerr Corporation) with a 0.25 tip diameter, 0.06 taper, and 21 mm in length were used in this study. Each system consisted of 20 new files and were divided into two groups as shown in ►**Table 1**. A total of 100 files were used in this study.

Table 1 Samples of nickel-titanium (NiTi) rotary files used in this study

ProTaper Universal (20 files)	Group I: 60-degree angle of curvature (10 files)
	Group II: 90-degree angle of curvature (10 files)
ProTaper Next (20 files)	Group I: 60-degree angle of curvature (10 files)
	Group II: 90-degree angle of curvature (10 files)
E-FLEX EDGE (20 files)	Group I: 60-degree angle of curvature (10 files)
	Group II: 90-degree angle of curvature (10 files)
E-FLEX ONE (20 files)	Group I: 60-degree angle of curvature (10 files)
	Group II: 90-degree angle of curvature (10 files)
ZenFlex (20 files)	Group I: 60-degree angle of curvature (10 files)
	Group II: 90-degree angle of curvature (10 files)

The cyclic fatigue resistance test was performed in the stainless steel block with a 2-mm internal diameter, 60- and 90-degree angles of curvature, and a 5-mm radius of curvature.

Cyclic Fatigue Testing

All the files were tested in a simulated canal, which has 60 and 90 degrees of curvature under a controlled temperature water bath at 37°C. The working length of the artificial canal was set at 20.0 mm. ProTaper Universal and ProTaper Next were set to rotate at 300 rpm, 2 N/cm torque, while E-FLEX EDGE, E-FLEX ONE, and ZenFlex were set to rotate at 500 rpm, 2 N/cm torque until fracture. The number of cycles to failure (NCF) was recorded and calculated using the following formula: time to failure (in seconds) × rpm/60 (►**Fig. 1**).

Scanning Electron Microscope

Two fractured files from each group were randomly selected and the pattern of fracture was analyzed using 200X magnification for cross-sectional view and 60X magnification for lateral view.

Statistical Analysis

The statistical analysis was performed using GraphPad Prism 9.4 software (GraphPad by Dotmatics, San Diego, CA, United States). The NCF between the groups was analyzed statistically using the Mann–Whitney *U* test. The statistical differences between each system at the same degree of artificial canal curvature were analyzed using the Kruskal–Wallis test. A significant difference was set at $p < 0.05$.

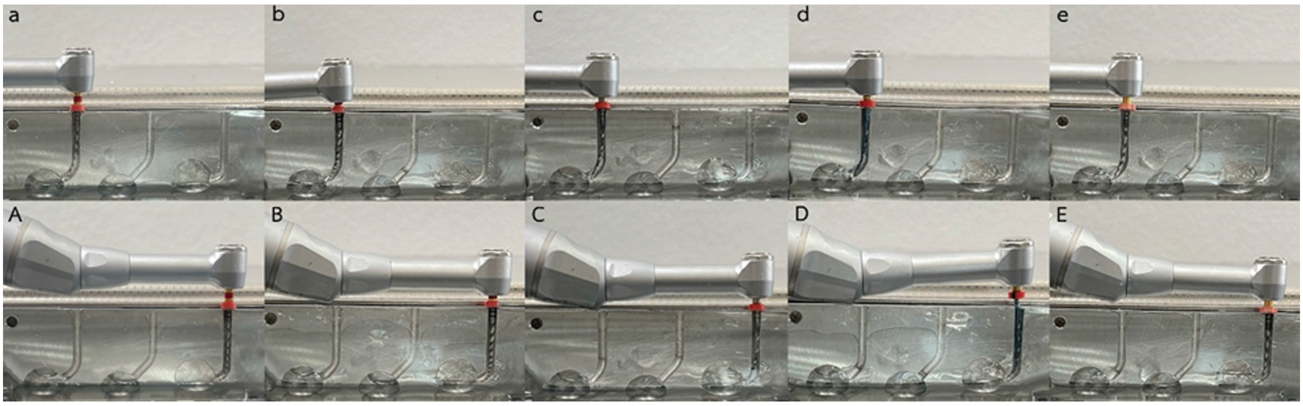

Fig. 1 Schematic of cyclic fatigue testing device adapted from Phumpatrakom et al.[10] Nickel-titanium (NiTi) rotary instruments in an artificial 60-degree curvature canal (upper row) and 90-degree curvature canal (lower row). NiTi rotary instruments were immersed in 37°C water bath: (**a, A**) ProTaper Universal, (**b, B**) ProTaper Next, (**c, C**) E-FLEX EDGE, (**d, D**) E-FLEX ONE, and (**e, E**) ZenFlex.

Table 2 Mean values (±SE) for NCF according to the NiTi system

	ProTaper Universal	ProTaper Next	E-FLEX EDGE	E-FLEX ONE	ZenFlex
Group I (60 degrees)	2,937 ± 123.67	3,083 ± 16.67	38,433 ± 1,599.61	107,545.5 ± 3,984.83	80,363.6 ± 2,412.22
Group II (90 degrees)	170.5 ± 12.5	287 ± 9.67	245.5 ± 4.17	1,424.5 ± 52.83	941.3 ± 15.10

Abbreviations: NCF, number of cycles to fracture; NiTi, nickel-titanium; SE, standard error.

Results

The mean ± standard error (SE) of the NCF from the cyclic fatigue tests is shown in ►**Table 2**. This study revealed that E-FLEX ONE had the highest NCF, followed by ZenFlex, E-FLEX EDGE, ProTaper Next, and ProTaper Universal in group I. For group II, E-FLEX ONE had the highest NCF, followed by ZenFlex, ProTaper Next, E-FLEX EDGE, and ProTaper Universal.

For group I, E-FLEX ONE, ZenFlex, and E-FLEX EDGE exhibited significant difference in the NCF compared with each system ($p < 0.05$). Additionally, these three systems had a significant difference compared with ProTaper Universal and ProTaper Next ($p < 0.05$). Conversely, ProTaper Universal and ProTaper Next had no significant difference in the NCF ($p < 0.05$). For group II, E-FLEX ONE showed the highest NCF compared with the other NiTi file systems. Moreover, there were statistically significant difference between E-FLEX ONE, ZenFlex, ProTaper Next, E-FLEX EDGE, and ProTaper Universal (►**Fig. 2**).

This study has shown that the NCF of all samples in group I had a statistically significant difference compared with that of the samples in group II. The SEM micrographs show the fractographic pattern of fractured surfaces in ►**Figs. 3** and **4**.

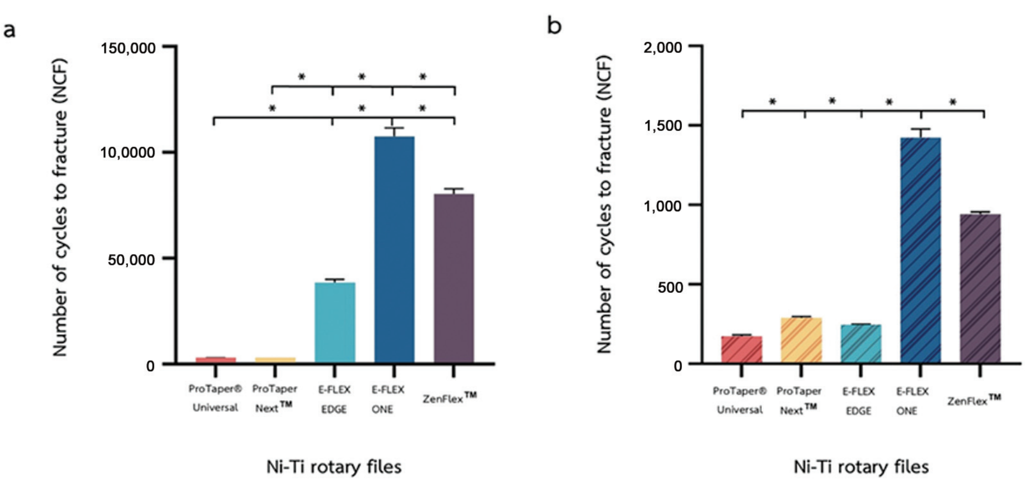

Fig. 2 Mean values ± standard error (SE) for number of cycles to fracture (NCF) of (**a**) group I and (**b**) group II from ProTaper Universal, ProTaper Next, E-FLEX EDGE, E-FLEX ONE, and ZenFlex. The asterisk symbol (*) Indicates a significant difference ($p < 0.05$).

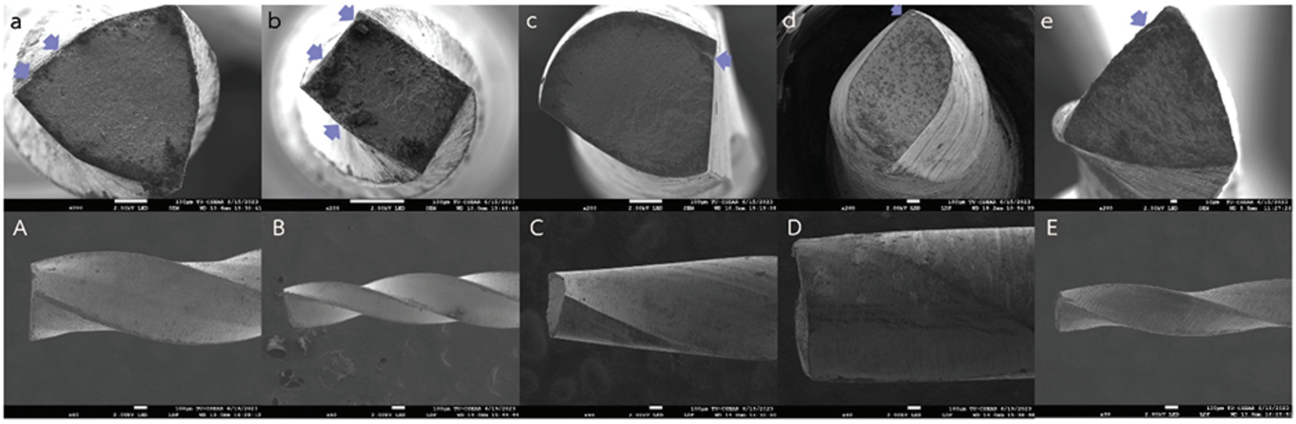

Fig. 3 Scanning electron microscopy (SEM) of group I from (**a, A**) ProTaper Universal, (**b, B**) ProTaper Next, (**c, C**) E-FLEX EDGE, (**d, D**) E-FLEX ONE, and (**e, E**) ZenFlex. The *arrows* indicate the crack initiation site of the files.

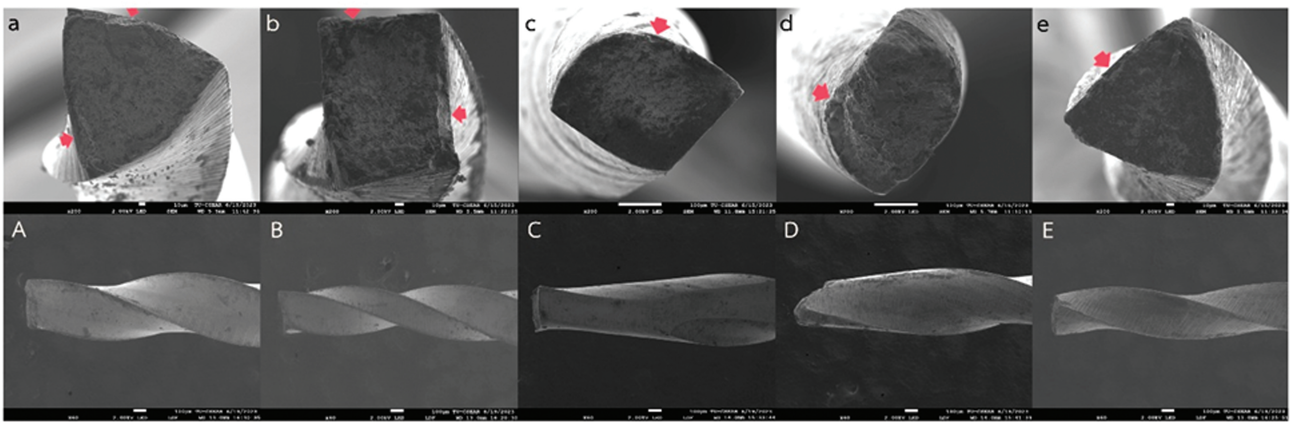

Fig. 4 Scanning electron microscopy (SEM) of group II from (**a, A**) ProTaper Universal, (**b, B**) ProTaper Next, (**c, C**) E-FLEX EDGE, (**d, D**) E-FLEX ONE, and (**e, E**) ZenFlex. The *arrows* indicate the crack initiation site of the files.

The typical features of cyclic fatigue failure are characterized by a crack initiation site, fatigue zone, and overload fast fracture zone. The fractographic analysis of cross-sectional fractured surfaces revealed crack sites at the peripheral surface, which indicated an initiation point of cyclic fatigue fracture. Crack propagation toward the fatigue zone was characterized by striations, followed by an overload fast fracture zone with abundant dimples and microvoids.

Discussion

Cyclic fatigue implicates the unpredictable separation of NiTi rotary instruments. It is influenced by the differences in the manufacturing process of the NiTi instruments and the root canal geometry. Cyclic fatigue occurs when the instrument rotates inside a curved root canal over an excessive number of tension-compression strain cycles in the maximum curvature region. Changing the NiTi alloy, file design, and innovating kinematics of the rotary NiTi files helped improve cyclic fatigue resistance. Applying different machining techniques and different heat treatments of the NiTi files has also affected cyclic fatigue resistance. Raising the temperature causes phase transformation into a more austenite form, which lowers the cyclic fatigue resistance.[11] The separated instrument leads to inadequate root canal preparation and alters the outcome of root canal treatment.[12–17] To compare the properties of NiTi from different manufacturing processes, five specific brands were selected for this study. ProTaper Universal represented the NiTi file from the conventional grinding method. ProTaper Next represented NiTi files made from M-wire. Finally, E-FLEX EDGE, E-FLEX ONE, and ZenFlex represented NiTi files made from different heat treatment methods. Consequently, this study was conducted to investigate the effect of canal curvature and different manufacturing processes of the NiTi rotary on cyclic fatigue resistance.

The result of this study shows that in group I E-FLEX ONE had the highest cyclic fatigue resistance followed by ZenFlex, E-FLEX EDGE, ProTaper Next, and ProTaper Universal. E-FLEX ONE, ZenFlex, and E-FLEX EDGE exhibited a statistically significant difference in the NCF compared with each system, while ProTaper Universal and ProTaper Next did not have a statistically significant difference in the NCF. In group II, E-FLEX ONE showed the highest NCF compared with other NiTi files. All tested NiTi systems had a statistically significant difference in the NCF. The result is consistent with a previous study that reported that the CM wire (controlled memory NiTi wire) has higher fatigue resistance than the M wire and the conventional NiTi file. This is because the CM wire contains a lower percentage of nickel content and exhibits a primarily steady martensitic crystalline structure compared with the traditional NiTi alloy.[18,19] The other factor could be the improved flexibility as the critical stress required to induce martensite transformation is much higher than that required to induce martensite re-orientation in the CM wire. Moreover, other studies suggest that blue heat treatment was significantly more resistant than the M wire because the blue heat–treated NiTi mainly consists of martensite phase, exhibits greater flexibility compared with the M wire, has improved wear resistance due to physical vapor deposition of the titanium oxide layer, and compensates the microhardness lost during the process.[20–25]

Conversely, recent studies reported that the M-wire and CM wire showed higher resistance than the blue heat–treated wire. This is quite in contrast to the findings of this study because of operator-related factors, variation in cyclic fatigue testing devices, and NiTi instrument–related factors. First, previous studies recorded the time to fracture (TTF) through an observer, whereas our study used video recording, which could result in a more precise time record for NCF calculation than the TTF method. Second, previous studies performed the test under room temperature (25°C) and used lubricants, which do not replicate the actual clinical condition and do not represent the actual phase of NiTi files at body temperature (37°C), and the smaller simulated canal diameter resulted in increased friction. Finally, previous studies used NiTi file with different specifications from our study such as file length, taper, rotational speed, torque, alloy composition, manufacturing methods including brand-specific thermomechanical processing, and cross-sectional geometry resulting in dissimilarity of the results.[20,21]

ProTaper Universal and ProTaper Next have a variable taper, whereas E-FLEX EDGE, E-FLEX ONE, and ZenFlex possess a constant taper. Generally, when compared with the NiTi file at the same tapered size, the NiTi file with a variable taper should have a higher flexibility than the NiTi file with a constant taper. This implies that the file with a variable taper may have a higher cyclic fatigue resistance compared with the file with a constant taper. However, this study found that E-FLEX ONE exhibited a significantly higher resistance than ProTaper Universal, ProTaper Next, E-FLEX EDGE, and ZenFlex in both 60 and 90 degrees of curvature. Moreover, the mutual file system shows a significantly higher resistance at 60 degrees of curvature than at 90 degrees due to increased stress placed on the file when the degree of curvature increased, resulting in higher file breakage.[5,18] There are several factors affecting the cyclic fatigue resistance including surface treatment, flexibility, microstructural phase, and phase transformation behavior.[22–24] The greater austenitic finish temperature, a stable martensitic phase structure, a low nickel percentage, and brand-specific manufactural proprietary process could be the reason for increased cyclic fatigue resistance.[16] Furthermore, the mechanical properties of NiTi instruments are influenced by various factors, including size, taper type, rotational speed, environmental temperature, cross-sectional geometry, pitch, flute design, properties of raw materials, and manufacturing processes.[22–25]

Consequently, this study used the files with a similar size, taper, and environmental temperature at 37°C corresponding to the clinical practice and manufacturer recommendation to minimize the differences that could be caused by these confounding variables.[19,26] Besides, the files were tested in a static mode to surpass the confounding factors like the subjectivity of pecking movements, which in clinical practice enormously varies among clinicians.[25] Then, more precise time measurements and the ability to retrospectively observe the file are provided through digital video camera recording.[21]

The SEM fractographic appearance of the fractured files exhibits surface irregularities from the manufacturing process, which is the stress concentration point for crack initiation.[13,27,28] Crack seems to propagate along the surface with the presence of microvoid coalescence.[29,30] Hence, the higher amounts of microvoids and crack initiation sites within the cross-section of ProTaper Universal and ProTaper Next reflect the lower resistance to cyclic fatigue. Moreover, the blue heat–treated NiTi file showed tearing edges, indicating plastic deformation, exhibiting higher ductility and resistance to fatigue.[31]

As mentioned earlier, our study was performed under static conditions, which do not replicate the actual clinical condition and appear to reduce the cyclic fatigue resistance of the files. This study suggests that circumstances simulating the clinical condition should be covered by a dynamic framework that provides greater reliability for cyclic fatigue testing as the movement replicates the actual stress on the files in a clinical setting.[19,32,33] Furthermore, the certain percentage in the weight of nickel and phase transformation behavior depending on brand-specific manufacturing process has been questioned. Hence, an analysis of the file composition and structural phase transformation behavior of different NiTi systems during cyclic fatigue test is recommended in future studies.

An artificial stainless steel canal was used to standardize the anatomical variation of the extracted teeth. However, there are still no specifications or international standard block to ensure uniformity of methodology and comparable results for cyclic fatigue testing. Thus, a prototype of simulated three-dimensional (3D) printing teeth might be an alternative for fatigue test simulating the clinical environment.[34]

Conclusion

E-FLEX ONE, which is a blue heat–treated system, showed the greatest resistance to cyclic fatigue in both 60 and 90 degrees of curvature. Thus, this study implies that E-FLEX ONE is appropriate for use in severely curved canals. Future studies should be focused on 3D printing teeth with dynamic cyclic fatigue models to mimic the actual clinical context.

Funding
This study was supported by the Faculty of Dentistry, Thammasat University Fund.

Conflict of Interest
None declared.

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