

In vitro evaluation of the mechanical properties of newly developed orifice openers

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Abstract

The present study aimed to evaluate the morphology and mechanical properties of two orifice openers produced by the same manufacturer, with the same design and heat treatment but different dimensions. Twenty I-File/Onyx Orifice Openers for each of the following sizes (09.09 versus 20.07) were selected for the study. The instruments were initially examined with SEM at x200 and measured to ensure dimensional accuracy. Then they were randomly divided into two identical groups (n=10). For each size, one group was tested for cyclic fatigue and the other for ISO torsional resistance, using methods already validated in the authors' previous studies (16-20). The same expert operator performed each test to minimize errors caused by differences in operator skill. For each size and test, 10 instruments were analyzed for each brand. The data were collected and statistically analyzed using 1-way ANOVA followed by a post hoc Tukey test at the 95% confidence level. The D0 diameters showed very good dimensional accuracy, with small standard deviations and mean values compatible with ISO dimensional tolerance (0.02). No significant statistical differences were noted between the two groups for maximum torque at failure (TAF) ($P>0.05$). In contrast, significant differences were noted for the deflection angle and resistance to cyclic fatigue ($P<0.05$). In both cases, the 09.09 orifice opener performed better. The newly developed 09.09 orifice opener showed very interesting mechanical properties compared with a more traditional orifice opener, suggesting its possible routine use, with the majority of benefits in more complex cases. The present study also showed precise manufacturing despite a very small tip size and a heat treatment.

Keywords: nickel titanium, instruments, dimensions, orifice opener

Introduction

The clinical performance and mechanical properties of nickel-titanium (NiTi) instruments (1-7) are primarily determined by three factors. The first is the design, the second is the manufacturing process, including alloys and heat treatments, and the third concerns dimensions. For many years, the design of nickel-titanium rotary files has been the primary determinant of their performance and properties, and, due to differences in design, these instruments have been called by different names. An orifice opener is a nickel-titanium (NiTi) rotary instrument used early during root canal treatment to



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enlarge and shape the coronal third of the root canal system. The objectives are to create a smooth, straight-line access into the canal, to remove constricting dentine at the canal entrance and, thus, reduce coronal interference in the coronal (mainly) and middle third, allowing shaping instruments to reach apical segments with less stress (11-13). NiTi orifice openers typically have larger tapers and more aggressive cutting profiles than standard shaping files to achieve rapid coronal enlargement. By selectively enlarging the coronal third, torsional and flexural loads on subsequent shaping files are reduced, and irrigant penetration is improved. NiTi alloy is favoured for these instruments because of its flexibility and resistance to cyclic fatigue compared with stainless steel when cutting curved canals.

While manufacturers vary, orifice openers share some common design features (14-15):

- a. Shorter overall/working length: Many orifice openers are manufactured in shorter working lengths (e.g., 15–19 mm) compared with full-length shaping files (21–25–31 mm). The shorter length improves control and reduces the risk of inadvertently plunging apically while opening the coronal third.
- b. Dimensions (D0 and taper): D0 refers to the nominal diameter of the instrument at its absolute tip, and this value is the primary identifier of the instrument size. Most orifice openers use a large ISO tip (e.g., 20 or 25) and a large taper, depending on the system philosophy. In contrast, others use smaller tip diameters (e.g., ISO 17 or 19) but larger tapers. Tapers of 0.08 to 0.12 (8–12%) are common for orifice openers. In many cases, taper is variable rather than constant. For example, ProTaper SX and Edge Taper Platinum SX are described as having a nominal tip size of approximately 0.19 mm and a variable taper designed for coronal shaping. These aggressive tapers allow quick coronal enlargement.
- c. Robust cross-section and cutting flutes: To cut dentine efficiently, orifice openers tend to have more aggressive cutting edges, variable rake angles, and larger flute volumes to remove debris. Currently, most of them are manufactured using special heat treatments or EDM processes to improve mechanical properties, particularly flexibility and resistance to fatigue.
- d. Variable working depth recommendations: Clinicians are advised to limit penetration of the orifice opener to the straight coronal portion and avoid passing into curved canal segments. Some manufacturer instructions emphasize “work above the curve” and re-establish a glide path before deeper shaping.

The clinical use of orifice openers is highly suggested in molars with constricted pulp chambers, heavy coronal calcification that limits entry of small hand files, cases where a straight-line entry is difficult due to coronal anatomy, or when using large tapered shaping files that would otherwise engage on coronal interferences. When selecting an orifice opener for a case, clinicians

should consider that in straight, wide canals, a larger tip (e.g., ISO 20 or 25) and higher taper (e.g., .08–.12) may be appropriate. However, for canals with pronounced curvature or thin cervical dentine, they should choose a less aggressive instrument or limit penetration depth. Due to their dimensions, orifice openers are more rigid, and in such complex cases, they could more easily make iatrogenic errors. To reduce these risks, heat treatments are becoming more popular in the manufacturing of orifice openers. Nevertheless, many manufacturers recommend a patent glide path before introducing NiTi rotary orifice openers to reduce the risk of iatrogenic complications.

To improve safety and efficiency of orifice openers, more precisely to maximize their advantages also in thin calcified canals, in complex coronal curvatures and in those complex cases when preflaring is recommended to make manual negotiation less stressful a new Orifice Opener with a very small tip (ISO 09) and a big constant taper (.09) has been developed by Henry Schein Endodontics (I-file / Onyx, Edge Endo, USA). The instrument can be used with caution even before a manual glide path and can be gently pushed beyond mild curvatures, thereby facilitating the following instrumentation steps. A major concern was the manufacturing accuracy and strength of such a small tip. The present study aimed to evaluate the morphology and mechanical properties of two orifice openers produced by the same manufacturer, with the same design and heat treatment but different dimensions: 09.09 versus 20.07.

Materials and Methods

Twenty I-File/Onyx Orifice Openers produced by the same manufacturer's factory, with the same design and heat treatment for each of the following sizes (09.09 versus 20.07), were selected for the study. Exclusion criteria were the presence of visible defects, but no instruments were discarded. The instruments were initially examined using SEM at x200 and measured to ensure dimensional accuracy (Figs. 1-2).

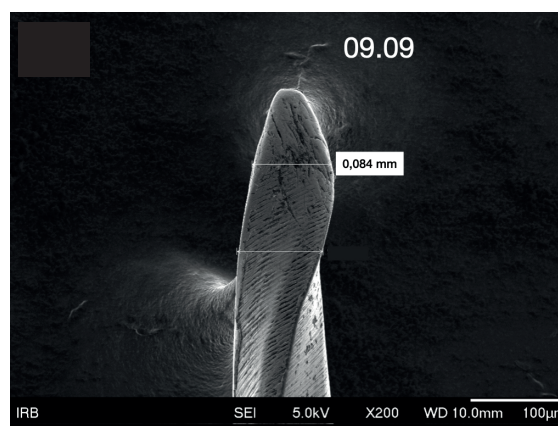


Figure 1. I-File/Onyx 09.09 Measurement of one sample with SEM

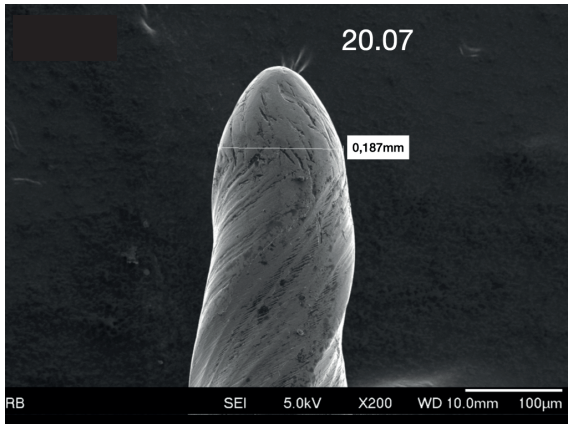


Figure 2. I-File-Onyx 20.07 Measurement of one sample with SEM

Then they were randomly divided into two identical groups (n=10). For each size, one group was tested for cyclic fatigue and the other for ISO torsional resistance, using methods already validated in the authors' previous studies (16-21). The same expert operator performed each test to minimize errors caused by differences in operator skill. For each size and test, 10 instruments were analyzed for each brand, and the data were collected.

The torsional test was conducted according to ISO standard 3630-1 by blocking the instrument at 3 mm from the tip and rotating it at 2 rpm. Maximum torque at failure (MAF) was evaluated and recorded for each instrument. In the torsional test, the higher the value, the greater the resistance. Moreover, the deflection angles (DA) were also recorded. During the same test, it is also possible to measure how much rotation a blocked instrument can still perform before breaking. The larger the angle, the more resistant the instrument is to torsional stress.

The cyclic fatigue test did not follow ISO standards and was therefore performed using a device, as in many previous tests, as used by the authors. All instruments were used at body temperature under the same parameters (300 rpm) in an artificial canal with a 75° curvature and a 5 mm radius. Each instrument was rotated inside the canal until a visible and/or audible sign of fracture was detected. Therefore, the time to fracture was measured using a digital chronometer with a sensitivity of 0.01 seconds. The longer the time, the more resistant the instrument.

Statistical analysis

For each of the three tests, mean values and standard deviations were recorded. Then, statistical analysis was performed using a 1-way ANOVA followed by a post hoc Tukey test, with significance set at the 95% confidence level.

Results

Results are shown in Table 1. The D0 diameters showed very good dimensional accuracy, with small standard deviations and mean values compatible with ISO dimensional tolerance (0.02). No significant statistical differences were noted between the two groups for maximum torque at failure (TAF) (P>0.05). In contrast, significant differences were noted for the deflection angle and resistance to cyclic fatigue (P<0.05). In both cases, the 09.09 orifice opener performed better.

Discussion

Results from the present study showed precise manufacturing despite a very small tip size and a heat treatment. A very small tip can be very delicate. It may deform easily, but this is probably less common in orifice openers because the large increase in taper provides greater rigidity. Both files showed dimensional compatibility with ISO standards, and the small standard deviations indicated consistent production quality. Torsional resistance was similar despite differences in tip diameters. A possible explanation is that instruments were blocked at 3 mm from the tip, and due to the difference in tapers, the actual dimensions at 3 mm were 0.08 + 0.27 = 0.35 for 09.09, while the 20.07 had 0.20 + 0.21 = 0.41. Such a difference disappears after 6,5 mm. This allows the small instrument to have mass and strength suitable for an orifice opener, even if the tip is smaller (half size). Such a small tip, however, is very helpful in narrow canals to facilitate progression and is less dangerous when curvatures are present, allowing wider and more predictable use, even without a manual glide path.

Cyclic fatigue resistance was higher for the smaller instruments, which is consistent with the fact that bending stress is localized at the midcurvature; therefore, a smaller apical portion with less mass could be beneficial. The same could happen for the deflection angle, which may also suggest slightly more flexibility in the apical portion of the file.

Historically, coronal flaring was commonly performed with stainless steel Gates-Glidden drills in a low-speed

Table 1. Mean values and SD (* significant difference)

Instruments.	D0 diameters (mm)	Torsional Resistance TAF (Ncm)	Deflection Angle (°)	Fatigue resistance. (sec)
09.09.	0,086 (0,006)	1, 31 (0,241)	490 ° (36,59)*	395 (46,2)*
20.07	0,193 (0,011)	1, 39 (0,275)	411 ° (31,45)	309 (39,4)

handpiece (12-13). In recent decades, NiTi orifice openers have become the most popular instruments for coronal shaping (22) due to several factors: NiTi resists flexural deformation better than stainless steel. Clinicians emphasize the need to preflare coronal to curves to reduce the risk of ledging, but hidden curvatures can sometimes be present in the middle and coronal parts of the canals, especially when access is poor. Many clinicians prefer using a single NiTi orifice opener for rapid coronal shaping rather than using sequential GG sizes. As a consequence, the proper choice of the alloy, design, and dimensions can be very beneficial for maximizing efficiency and minimizing errors.

The newly developed 09.09 showed very interesting mechanical properties compared to a more traditional orifice opener (20.07), suggesting its possible routine use, with the majority of benefits in more complex cases. Clinicians should also be aware that large tapers (8–12%) can remove substantial cervical dentine when used indiscriminately, increasing the risk of strip perforation in thin roots. Clinicians must be conservative and aware of canal anatomy, as enlargement is more risky in roots when dentine width is reduced. NiTi may fracture if used without a glide path, with excessive torque, or when forced into curved canal sections. Manufacturers' protocols typically emphasize glide path establishment, limiting penetration depth. Nevertheless, the good mechanical properties shown by the new 09.09 may suggest a different, but cautious, use, increasing penetration depth and reducing the need for manual glidepath. This statement must be proven by clinical studies demonstrating the feasibility of these new clinical approaches.

Hence, we may conclude that the newly developed 09.09 orifice openers exhibited very interesting mechanical properties compared with a more traditional orifice opener, suggesting their routine use, with the majority of benefits in more complex cases. The present study also showed precise manufacturing despite a very small tip size and a heat treatment.

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