

Fracture incidence of waveone gold and reciproc blue files when used in up to three clinical cases: a prospective study

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Abstract

Objective: Reuse of endodontic files remains an open issue in clinical practice. This study was designed to evaluate the fracture strength of WaveOne Gold (Dentsply Maillefer, Ballaigues, Switzerland) and Reciproc Blue (VDW, Munich, Germany) files with successive reuse for root canal shaping in up to three molars. **Material and Methods:** Prospective clinical study carried out by five calibrated endodontists who treated 384 molars (1291 canals) with a curvature $<45^\circ$ over a 12-month period. A total of 128 instruments were used (64 Reciproc Blue and 64 WaveOne Gold). Each instrument was used to treat three posterior teeth. After each use, the instruments were observed under an operating microscope at 8× magnification. Data were tabulated and a chi-square test was applied. Significance was accepted at the 5% level. **Results:** Two instruments (one from each group) separated, both on the third use and during instrumentation of a mandibular first molar. In other words, instrument separation occurred in 0.52% of teeth and 0.16% of treated root canals. **Conclusions:** There was a low incidence of instrument fracture when reciprocating files were used for up to three endodontic treatments in molars.

Keywords: Endodontics; Instrument fracture; Molars; Reciprocating movement; Reciproc Blue; WaveOne Gold.



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Introduction

In recent decades, NiTi rotary instruments have become increasingly popular as a result of their greater flexibility and strength compared to stainless steel instruments¹. However, despite their numerous advantages, these instruments carry a higher risk of fracture during use, especially in curved canals, which can jeopardize the prognosis of root canal treatment². Different alloys and cross-sectional designs have been proposed to increase the flexibility and cyclic fatigue resistance of endodontic instruments^{3, 4}.

The advent of the WaveOne (Dentsply Maillefer, Ballaigues, Switzerland) and Reciproc (VDW, Munich, Germany) systems introduced the concept of single-file root canal preparation to endodontic practice⁵. These are reciprocating instruments, i.e., their kinematics alternate between counterclockwise (cutting direction) and clockwise (release) movement⁶, and have proven safer than rotary instruments in relation to both cyclic fatigue and torsional strength^{7,8}. As a result, the service life of reciprocating instruments also appears to be longer⁹⁻¹¹.

When compared to the original WaveOne instruments, the WaveOne Gold system (Dentsply Maillefer, Ballaigues, Switzerland) has a modified cross section, with an off-centered parallelogram design, and different tapers; files also undergo a complex heat treatment^{12,13}.

Reciproc Blue instruments (VDW, Munich, Germany) also undergo a modified heat treatment protocol, which changes their molecular structure to increase cyclic fatigue resistance and also gives the instrument its characteristic blue color. According to the manufacturer, Reciproc Blue files are approximately twice as resistant to cyclic fatigue as conventional Reciproc instruments, without any change in their cross-section¹⁴.

The number of times an endodontic file can be used is a highly controversial topic in the literature. Despite countless

improvements to instrument design and alloy composition, instrument separation during root canal shaping remains a concern. This phenomenon can occur at any time, even without visible signs of file deformation¹⁵. According to their manufacturers, endodontic files - whether rotary or reciprocating - are single-use instruments and must be discarded after their first use. One of the reported contraindications to the reuse of instruments would be the cumulative damage and the impossibility of assuring that the factory preset movement cycle of the motor will remain within the elastic range of the material¹⁶.

However, it appears reasonable to assume that the wear sustained by an instrument when used in a tooth with only one canal will be less than that observed when it is used in a tooth with three canals. Based on this reasoning, one may admit the possibility of using the same reciprocating instrument in more than one case, particularly in regions where the high cost of endodontic instruments can be a hindrance to treatment¹⁷.

Within this context, the present prospective clinical study aimed to assess the incidence of fracture in Reciproc Blue and WaveOne Gold files during root canal preparation in up to three molars.

Materials and methods

The present study was approved by the local Research Ethics Committee (protocol no. 2.332.686). It was conducted in full compliance with ethical principles, including the provisions of the World Medical Association Declaration of Helsinki (2008 version). All patients or their legal representatives agreed to participate and provided written informed consent.

Patients were recruited from the dental practice of the authors over a 12-month period. A total of 384 maxillary and mandibular molars (1291 root canals) with indications for conventional endodontic treatment for curative or prosthetic purposes, were

included. Patients who did not agree to participate were excluded from this study, as were those teeth with: incomplete rhizogenesis; markedly curved ($>45^\circ$) canals¹⁸; a radiographically visible double curvature; previous endodontic treatment; calcified canals; and canals in which apical patency could not be established with #10 K-files.

The sample size of 192 teeth per group was obtained from the chi-square statistical test, with an estimated chi-square value of 4.08, 1 degree of freedom, a statistical power of 0.80, and an alpha of 0.05.

The study was conducted by five specialist endodontists who routinely work with the systems proposed in this study—Reciproc Blue (VDW, Munich, Germany) and WaveOne Gold (Dentsply Maillefer, Ballaigues, Switzerland)—and were given a technical sequence to follow, consisting of pre-established protocols, including regarding instrument kinematics.

Access to the pulp cavity was established with round diamond burs of a size consistent with each pulp chamber. Then, rubber dam isolation of the operative field was performed and access to the root canal system was established. The canals were first explored with #8 or #10 K-files (Dentsply Maillefer, Ballaigues, Switzerland), depending on the initial diameter and curvature, in a watchwinding (“twiddling”) motion. Exploration was stopped 2 mm short of the radiographic apex.

After this stage, 128 instruments were used (64 Reciproc Blue and 64 WaveOne Gold). The cervical third of the canals was prepared with reciprocating instruments, using three in-and-out (pecking) motions, followed by a final brushing motion against the canal walls, always taking into account the safety zone. At each instrument change, the root canal was irrigated with 5 mL of sodium hypochlorite 2.5%. The middle third was prepared as for the cervical third.

Working length was determined 1 mm short of the apical foramen using a Mini Root ZX II electronic apex locator (J Morita Corp, Fushimi-ku, Kyoto, Japan). Finally, the apical third of the root canals was prepared, using the same envelope of motion, until the previously established working length was reached, and a #25 K-file was used to full length.

When the anatomical variation of the canal required supplemental instrumentation in addition to the WaveOne Gold Primary (25/.07) or Reciproc R25 files to achieve optimal enlargement and shaping of the root canal system, WaveOne Gold Medium (35/.06) and Large (45/.05) or Reciproc Blue R40 and R50 files were used.

Throughout the instrumentation process, the root canals were abundantly irrigated with 2.5% sodium hypochlorite, dispensed through a NaviTip 31G needle (Ultradent Products Inc, South Jordan, UT), for a total volume of 25 mL irrigating solution on average at the end of instrumentation.

Gentle pecking and brushing motions were performed for controlled dentin cutting, without deviating from the original shape of the canal. Files were driven by an X-Smart Plus endodontic motor (Dentsply Maillefer, Ballaigues, Switzerland) in “WAVE ONE GOLD” AND “RECIPROC” modes, with pre-programmed speed and torque settings, respectively, depending on the instrument. Apical patency was maintained with a #10 K-file throughout the instrumentation process. After each use, the instruments were observed under an Opmi Pico operating microscope (Carl Zeiss, Göttingen, Germany) at 8× magnification.

To control the number of times each instrument was used, a visual criterion was adopted: for its first use, a file was removed from its blister packaging and thus had its silicone stopper still intact. After the first use, the instrument was sterilized, which involved individual packaging in sterilization wrap and autoclaving at 134 °C for 24 minutes (2340EK; Tuttnauer USA Co, Hauppauge, NY) with Attest™ 1492V Biological Indicator (3M, Indaiatuba, São Paulo, Brazil). For the second use, the instrument was removed

from the sterilization wrap and its silicone stopper, deformed by autoclaving, was cut off. For the third use, the file was already lacking its silicone stopper when removed from the sterilization wrap. The file to be used in each treatment was selected randomly, with the aid of the www.random.org website.

Once the entire root canal instrumentation process was complete, a final irrigation step was carried out with 5 mL of 17% EDTA, which was kept inside the canal for 3 minutes, followed by irrigation with 5 ml of 2.5% sodium hypochlorite. For this final irrigation procedure, passive ultrasonic irrigation (PUI) was also performed with an Irrisonic tip (Helse Ultrasonic, São Paulo, Brazil). PUI was repeated 3 times for 20 seconds each. Final aspiration was performed with a capillary tip (25.0 x 0.35 mm), and canals were dried with appropriately sized absorbent paper points.

Obturation was performed with gutta-percha cones sized appropriately for the tip and taper of the file used to instrument the canal, using AH Plus endodontic cement (Dentsply, Konstanz, Germany) and Tagger's hybrid technique. The access opening was sealed with Filtek XT Z350 composite resin (3M, São Paulo, Brazil). All treatments were performed in a single session.

After completion of endodontic treatment, the operators filled out a questionnaire designed to capture patient information. In case of instrument fracture or deformation, the operator was asked to provide details about the fractured instrument, fragment size (mm), fracture site (cervical, middle, or apical third), and whether the fracture occurred during the first, second, or third use. The results were tabulated and analyzed as relative frequencies (percentages).

Statistical analysis

Results were analyzed in the Biostat 4.0 software environment. The chi-square test was performed. Statistical significance was accepted at the 5% level ($p \leq 0.05$).

Results

The sample profile is described in Table 1. Proportionate to the number of teeth and canals treated, the fracture rate was 0.53% and 0.16%, respectively.

Among 1291 root canals treated and 128 instruments used, only two instruments (one Reciproc Blue and one WaveOne Gold) separated, both during the third use and both while treating mandibular first molars (fracture rate: 0.52%). The Reciproc Blue instrument separated in the middle third and WaveOne Gold instrument in the apical third, both in mesial channels of mandibular molars. There was no significant difference in fracture rate when comparing the Reciproc Blue and WaveOne Gold systems ($p=1.00$, Table 2).

TABLE 1 · Distribution of teeth and canals in the study sample

Tooth	N
Maxillary first molar	126 (32.81%)
Maxillary second molar	86 (22.40%)
Maxillary third molar	2 (0.52%)
Mandibular first molar	105 (27.34%)
Mandibular second molar	63 (16.41%)
Mandibular third molar	2 (0.52%)
Total teeth	384 (100%)
Total root canals	1291

TABLE 2 · Number, location, and fragment size of instrument fractures according to number of uses (chi-square test).

System	File	Tooth	Number of fractures	Number of uses	Fragment size	Third	(p)
RB	R25	Mandibular first molar	1 (0.52%)	3	3 mm	middle	1.00
WOG	Primary	Mandibular first molar	1 (0.52%)	3	4 mm	apical	1.00

RB: Reciproc Blue; WOG: WaveOne Gold.

Discussion

Reciprocating systems were developed for use as single-file systems, i.e., to allow preparation of the entire root canal with only one instrument¹⁹. Furthermore, it has been proposed that these files should be discarded after a single use²⁰. Although the cost of these systems has come down over time, it is still very high for some practitioners, especially in lower-income regions. Within this context, the present study sought to assess the possibility of instrument reuse so as to reduce the cost of endodontic treatment and facilitate access to these systems by more endodontists.

The first reciprocating systems were manufactured from M-Wire alloy, a material in which fracture secondary to cyclic fatigue was the main concern, especially in curved canals²¹. In recent years, the Reciproc Blue (VDW, Munich, Germany) and WaveOne Gold (Dentsply Maillefer, Ballaigues, Switzerland) systems were introduced as a means of improving fracture strength and performance during instrumentation^{11,22,23}.

The present study evaluated the incidence of instrument fracture in Reciproc Blue and WaveOne Gold files during root canal preparation in molars, without prior manual or rotary preparation, following the manufacturers' recommendations, i.e., single-file instrumentation of the cervical, middle, and apical thirds. A total of 384 clinical cases with indications for conventional endodontic treatment were selected for this purpose. The advantage of conducting a clinical study is the possibility of obtaining results directly applicable to clinical practice, whereas the findings of laboratory or bench studies do not always translate to the clinic¹⁷.

The instruments were driven by an endodontic motor using preset program modes for the WaveOne Gold and Reciproc systems. Nevertheless, previous work by Kiefner *et al.*⁶ (2014), Plotino *et al.*²⁴ (2014), and Higuera *et al.*²⁵ (2015) found no significant difference between preset motor rotation programs. After each use,

the instruments were observed under an operating microscope at 8× magnification to detect any distortions or fractures. This level of magnification was selected because it is the same used during the clinical procedure. Despite divergent reports in the literature, Cunha *et al.*²⁶ (2014) recommend 8× magnification because it is the magnitude most commonly used by operators.

Pirani *et al.*⁹ (2014) conducted a scanning electron microscopy study to assess superficial changes that occurred after the third sequential use of Reciproc and WaveOne Primary instruments in extracted single-rooted teeth and found that both instruments exhibited only limited changes, such as tip deformation and some surface wear. Under light microscopy, no signs of plastic deformation were observed, as in the present study, corroborating that both files are safe for use in endodontic treatment of teeth with multiple roots.

A topic of great controversy in the literature concerns the extent to which files may be reused. According to their manufacturers, these instruments must be discarded after a single use. However, it is impossible to consider that the wear on the instrument after use in a tooth with a single root canal would be equal to the stress caused after use on a single tooth with three root canals. In the present study, the instruments were used in up to three clinical cases, a number believed to be safe, effective, and associated with a low fracture rate, according to Gavini *et al.*²⁷ (2012), Plotino *et al.*²⁸ (2012), Muñoz *et al.*²⁹ (2014) and Bueno *et al.*¹⁷ (2017).

Cunha *et al.*²⁶ carried out a prospective study in which four calibrated endodontists evaluated the incidence of WaveOne file separation in posterior teeth over an 18-month period. The incidence was determined based on the number of teeth and canals instrumented during that period with single use of the files. A total of 2,215 canals (711 teeth) were treated, and only three instruments separated during use. The overall incidence of instrument fracture in relation to the number of shaped canals

was 0.13%, demonstrating a high degree of safety in single use. In the present study, the incidence of separation in relation to the number of canals treated was 0.16% after three clinical uses per instrument. Based on these results, we conclude that the incidence of reciprocating file separation after reuse in posterior teeth is also very low.

Ehrardt *et al.*³⁰ (2012), in a clinical study, assessed the incidence of separation in Mtwo files used in up to five posterior teeth. They reported a fracture rate of 1.98% in relation to the number of treated teeth. The preparation protocol included preflaring of the cervical third with hand files and Gates-Glidden drills. In the present study, the relative fracture rate was 0.53% and the comparison further favors the use of reciprocating instruments as a single file for all instrumentation, including for initial cervical enlargement, as they allow a more conservative preparation of this region, reduce operative time, and obviate the need for prior preparation.

The use of stainless steel hand files or a mechanized glidepath system to maintain patency throughout the canal instrumentation process is firmly established as a desirable practice in contemporary endodontics³¹. This reduces torsional stress and cyclic fatigue on the canal preparation instruments, thus decreasing the risk of separation³². In addition, these files are important because they promote a superior access path for canal-shaping instruments. Thus, the importance of their use as a protocol in the present study is worth stressing, as is their relationship with the results obtained.

This study was carried out by practicing specialist endodontists who had prior experience with the studied systems, and of the 128 tested instruments, only two files fractured (both on the third use). Villela *et al.*³³ (2017) conducted a retrospective study in which they assessed the incidence of separation of reciprocating instruments (R25) during root canal treatments performed by endodontics students. Their analysis included 1,958

treatments of premolars and molars. Twelve fractures occurred (three in premolars and nine in molars). This is an important finding, which highlights that, even when instrumentation is performed by graduate students, the fracture rate of reciprocating instruments is low. Shen *et al.*³⁴ (2016) identified an incidence rate of 0.5% for single-use WaveOne instruments, and found no significant difference in fracture rates among professionals with different levels of clinical experience. Caballero-Flores *et al.*³⁵ (2019) recorded a fracture incidence of 0.92% for Reciproc and WaveOne instruments used several times by students of a postgraduate program in endodontics, and recommended that these instruments be used in no more than six root canals, noting that most separations occurred after that number of uses.

A total of 1,291 canals were treated (384 molars, including some with four canals), and a low separation rate in relation to the number of treated canals was observed (0.16%). Both fractures occurred in lower molars and during the third use of the file (one in the middle third, one in the apical third). The separated instruments could not be removed, and were thus bypassed for successful completion of treatment. Studies such as those by Bueno *et al.*¹⁷ (2017), who reused Reciproc and WaveOne reciprocating instruments multiple times in molars and premolars, observed a relatively low fracture rate as well (0.26% relative to the number of canals). This further demonstrates the safety of reusing reciprocating files in posterior teeth.

The metal alloy used in manufacturing WaveOne Gold and Reciproc Blue files undergoes a specific, predominantly martensitic heat treatment during the machining process, with advantages such as high flexibility and increased fracture strength, which are expected to provide greater safety when these files are reused in molars. The findings of the present study corroborate this.

Conclusion

Under the clinical conditions of this study, reuse of Reciproc Blue and WaveOne Gold files in up to three molar cases was safe and feasible, with a low rate of instrument separation.

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Incidência de fratura dos instrumentos waveone gold e reciproc blue quando utilizadas em até três casos clínicos: estudo prospectivo

Resumo

Objetivo: Avaliar a resistência à fratura das limas WaveOne Gold (Dentsply Maillefer, Ballaigues, Switzerland) e Reciproc Blue (VDW, Munich, Germany) de acordo com o número de utilizações durante a modelagem dos canais radiculares em até três molares. **Material e Métodos:** O estudo clínico prospectivo foi realizado por cinco especialistas em endodontia, calibrados, que realizaram o tratamento de 384 molares (1291 canais), com curvatura inferior a 45°, durante o período de 12 meses. Foram utilizados 128 instrumentos, dos quais 64 eram Reciproc Blue e 64 eram WaveOne Gold, os instrumentos foram utilizados para o tratamento de três dentes posteriores. Após cada uso, os instrumentos foram observados sob microscópio operatório com uma ampliação de 8x. Os dados foram tabulados e foi utilizado o teste estatístico de Qui-quadrado com significância de 5%. **Resultados:** Dois instrumentos, uma Reciproc Blue e outro WaveOne Gold fraturaram, todas no terceiro uso e em primeiros molares inferiores, com uma porcentagem de 0,52% em relação a quantidade de dentes e de 0,16% em relação a quantidade de canais tratados. **Conclusão:** Pode-se concluir que houve uma baixa incidência de fraturas quando os instrumentos reciprocantes foram utilizados em até três casos de tratamento endodôntico em molares.

PALAVRAS-CHAVE: Endodontia; Fratura de instrumento; Molares; Movimento reciprocante; Reciproc Blue; WaveOne Gold.

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