Dental Solution

WaveOne® Gold

SCIENTIFIC MANUAL

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Dentsply Sirona

WaveOne® Gold

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Preface by co-designers

The majority of commercially available Nickel Titanium (NiTi) instruments are designed for use in continuous rotation. Whilst the advantages of these instruments are well documented, the problems of cyclic fatigue and torque especially in longer, narrower, and more curved canals remain a concern[1-3].

As an alternative to rotation, reciprocation, has been used to drive endodontic instruments for many years, with a movement of alternating but equal forward and reverse angles where none of the instruments ever completed a full rotation. In 2008, a novel reciprocating movement of four cycles of unequal bidirectional angles that completed a full forward rotation of 360˚ was identified that showed how just one single file can start and fully complete the preparation of a canal to a perfect shape[4]. This technique was clearly shown to reduce both cyclic fatigue and torsional failure preventing broken instruments[5].

This led to the launch in 2011 of WaveOne® (Dentsply Maillefer), one of the first "single file" reciprocating systems with specific and dedicated motors to generate bidirectional and unequal angles of movement.[6] The concept was embraced by many general dental practitioners looking to move into automated canal shaping after years of unsuccessful attempts with manual techniques and valued in terms of safety, time and cost savings.

As a result of clinical feedback, literature conclusions and advances in instrument metallurgy, four of the original clinical expert advisors involved in the initial development of WaveOne®, Dr Sergio Kuttler (USA), Dr Wilhelm Pertot (France), Clifford Ruddle (USA), and Dr Julian Webber (UK) worked in collaboration with the research and development team at Dentsply Maillefer in Ballaigues, Switzerland to further improve the cutting efficiency and mechanical properties of the file and give a new level of confidence to the many clinicians still wary of automated techniques to shape canals.

WaveOne® Gold came to market in 2015 as a new generation of 4 single use reciprocating files, Small, Primary, Medium and Large offering unparalleled safety, effortless efficiency and super simplicity. A progressively tapered and metallurgically enhanced reciprocating WaveOne® Gold Glider (Dentsply Sirona) was introduced in 2017 to cut a safer and more fully tapered expanded glide path to length compared to a fixed tapered stainless steel size 15 file, further reducing overall shaping time[7] and with the advantage of providing more available time to enhance and activate irrigants with sonic and ultrasonic devices, improving their effectiveness[8].

With its distinctive gold finish and patented cross-section WaveOne® Gold has considerable strength and flexibility due to a novel post machining thermal process. Having identified a suitable phase-transition point between austenite and martensite, a more clinically optimal and sophisticated metal than standard NiTi was developed that had a very positive effect on instrument properties[9, 10].

Designed with a reverse cutting helix, the files engage and cut dentine in a counterclockwise (CCW) direction and then disengage in a clockwise (CW) direction before the instrument has a chance to "taper lock" (i.e. bind into the canal). The net reverse file movement is 120°, completing a full rotation of 360° after 3 cycles

of reciprocation. As the CCW angle is less than the elastic limit of each file, the problem of torsional failure is considerably mitigated. Unequal CW/CCW angles also enable a file to more readily advance toward the desired working length without using excessive and potentially dangerous inward pressure[4] and strategically enhances auguring debris out of the canal [11].

The files cannot be sterilised and re-used. Eliminating repeated use decreases the possibility of fracture from both fatigue and torsional failure[12]. Single use eliminates any concerns about cross contamination[13] and removing the cost of disinfecting, cleaning and sterilizing reduces costs overall. As a single reciprocating file is doing the same job that would typically require 3 or more rotary nickel titanium files to accomplish, logic dictates that single use is by far the best solution to reduce the incidence of file breakage.

WaveOne® Gold has now become a globally adopted method for preparing canals, largely supported by clinical and laboratory studies, many of which are included in this scientific manual; and gaining legitimate traction in dental schools, teaching hospitals and private practice. Shaping canals confidently is now a clinical reality for all.

Co-designers, Clinical expert advisors during WaveOne® Gold development

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WaveOne® Gold solution description, with a focus on files

The WaveOne® Gold solution includes a dedicated Glide Path instrument and four shaping instruments (Primary, Small, Medium, Large), as well as Dentsply Sirona Irrigation Needle, the EndoActivator®, absorbent paper points, the AH Plus® Bioceramic sealer, conforming gutta-percha points and carrier-based obturators Guttacore® (see ***Figure 1***).

Instead of a rotary motion, all the WaveOne® Gold instruments are operated in a "back and forth motion", i.e. reciprocating motion, driven by Dentsply Sirona and VDW reciprocating motors. This reciprocation motion engages the instrument and cuts dentin in a counterclockwise direction and then disengages it in a clockwise direction (see ***Figure 2***). The disengagement occurs before excessive torsional stress is transferred onto the metal alloy and before the instrument can bind (taper lock) into the root canal, providing some advantages over continuous rotations systems.

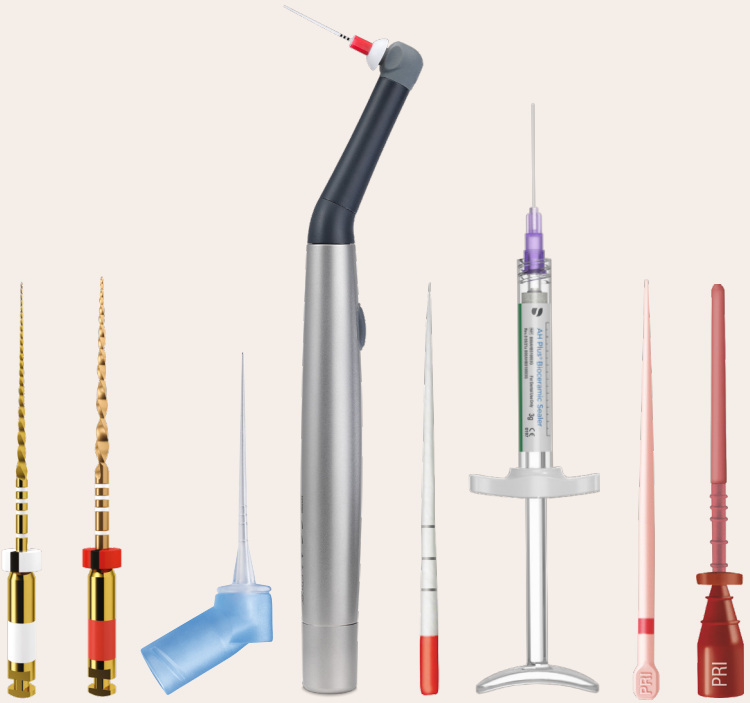

Figure 1:
WaveOne® Gold solution (from left to the right: Glider, Primary shaping file, irrigation needle, EndoActivator®, Primary Paper Points, AH Plus® Bioceramic sealer, Primary Conform® fit Gutta Percha and GuttaCore®).

WaveOne® Gold instruments are based on a series of patent-protected instrument geometries (see ***Figure 2*** illustrating the parallelogram cross-section of the instruments), a Maximum Flute Diameter (MFD) of 1.2 mm in the operative part and a dedicated newly developed heat-treatment. All instruments have a shank of 11 mm in order to give a better access to molars.

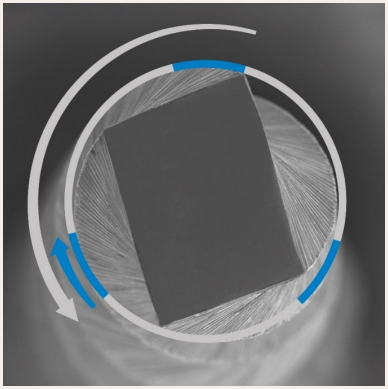

Figure 2:
SEM image of the parallelogram cross-section of a Medium WaveOne® Gold instrument, showing the reciprocating motion (white arrows and lines showing the counterclockwise motion and blue arrows and line showing the clockwise motion).

More into details, the Glider (size 15.02v)("v" is for variable taper), with a progressive taper and a centered parallelogram cross-section design as shown in ***Figure 3***, is used to create a pathway to the canal terminus. WaveOne® shaping files, available in four sizes (Primary 25.07v, Small 20.07v, Medium 35.06v, Large 45.05v and three working lengths (21, 25 and 31 mm)), have a parallelogram cross-section with a variable taper and one or two cutting edges, depending on location along the file.

All instruments are ready-to-use sterile and have an ABS polymer ring on the shank, also called the "anti-reuse ring" that swells in case of autoclaving at the dentist's office. Thus, the instrument cannot be reinserted in the contra-angle. The benefit of such ring is to reduce the risk of cross-contamination, ensure maximum cutting efficiency and safety margin (fatigue resistance potential).

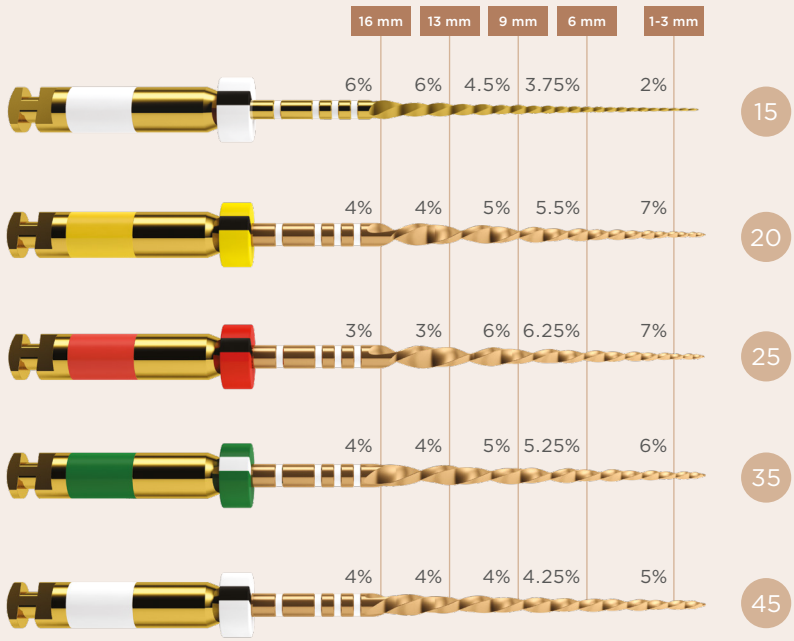

Figure 3:
Glider, Small, Primary, Medium and Large instrument (In circles: ISO sizes).

WaveOne® Gold instruments are manufactured from standard NiTi wires, which are worked by micro milling and finally submitted to a proprietary post machining "gold" heat-treatment. This heat-treatment is done to allow the files to be in the martensitic phase during clinical treatment (i.e. 35°C to 37°C), offering the following clinical advantages:

- Pre-bendable instruments, which can be useful when bypassing ledges,
- Instruments with enhanced fatigue resistance and flexibility for optimized performance in complex curvatures and root canal anatomies...

...when compared to other NiTi instruments which are mostly in a more rigid austenitic phase during clinical treatment[14]. For more information on thermomechanically treated NiTi alloys, Zupanc et al[14]. have published a review, emphasizing their properties, the differences between the austenite and the martensitic phase, and the advantages of both phases from a clinical perspective.

Key literature focus

The WaveOne® Gold system was launched worldwide in 2015 and the WaveOne® Gold Glider instrument later in 2017. So far, more than 200 peer-reviewed scientific papers have been published on this endodontic system, with various topics of interest as shown in *Figure 4*, making WaveOne® Gold one of the most extensively studied NiTi treatment solution in the endodontic field.

This scientific manual provides a synopsis of the key published research findings on WaveOne® Gold system with focus on performance and safety aspects, defined as fatigue resistance (mechanical properties), level of expertise required, shaping ability, quality of obturation and clinical data. Each summary is based on facts retrieved from the original research article. For higher scientific validity, in vitro articles were only included if they had a sample size of ≥10 per group. If further inclusion criteria were defined, these are listed in ***Figure 4***.

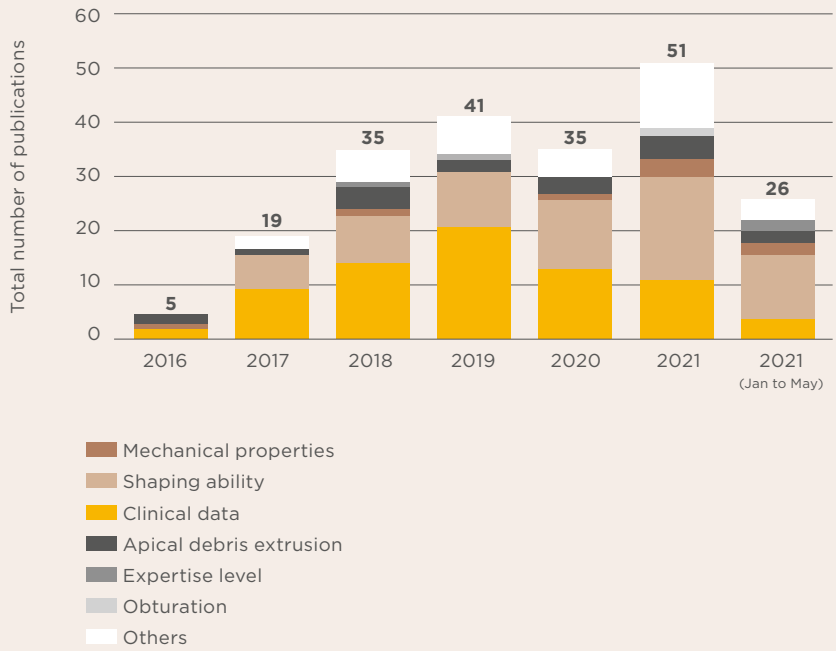

Figure 4:
Total number of publications on the WaveOne® Gold system.

1. Fatigue resistance (mechanical properties)

Includes all studies performed using clinically relevant parameters (37°C, presence of liquid) with comprehensive performance analysis (NCF, SEM and DSC).

2. Level of expertise required

Supporting the dentists in the selection of the most appropriate instrument sequence, according to their level of expertise, is explored in this section.

3. Shaping ability

Includes all microCT studies on extracted teeth, following the WaveOne® Gold instructions for use.

4. Obturation quality

Includes one article studying the filling ability of carrier-based WaveOne® Gold obturators in oval-shaped canals, following WaveOne® Gold instructions for use.

5. Clinical results

Includes all available peer-reviewed clinical studies on WaveOne® Gold and clinical case reports.

Apical debris extrusion

Even though some researches also focus on in vitro apical debris extrusion studies, they were excluded from this manual, as their study models are mostly obsolete, not incorporating the biological circumstances in which extrusion occurs[15]. Moreover, the available WaveOne® Gold clinical studies focusing on post-operative pain (a potential clinically relevant consequence of apical debris extrusion) are reviewed in the "clinical results" chapter.

It's important to emphasis that conclusions drawn from the excluded studies on all topics did not reveal any compromised performance or safety when using WaveOne® Gold following the instructions for use.

1. Fatigue resistance

Fatigue resistance remains a major concern of dentists, even though NiTi instruments can withstand several hundred flexural cycles before they fracture via metal fatigue[16]. Furthermore, with a reciprocating motion, the alternating changes in direction of rotation is expected (i) to stress less on the elastic limit of the instruments and (ii) to produce different stress points on the instruments vs. one single stress point, when compared with a consistent rotation motion[5]. Thus, reciprocating motion is expected to promote higher cyclic fatigue resistance than rotary motion[17].

Resistance to cyclic fatigue of reciprocating instruments determined at body temperature and phase transformation analysis[18].

Authors: R. Scott, A. Arias, J. C. Macorra, S. Govindjee and O. A. Peters

Published in: Australian Endodontic Journal 2019 Vol. 45 Issue 3 Pages 400-406

The goal of this study was to compare the fatigue resistance of 3 reciprocating instruments, WaveOne® Primary, WaveOne® Gold Primary and EdgeFile® X1 (EdgeEndo®).

A total of 60 instruments (n = 20) were evaluated in an artificial canal with 60° curvature and 3 mm of radius located at 5 mm from the instrument tips, in deionized water at body temperature (37+/-1°C). Fracture patterns after fatigue tests were assessed using Scanning Electron Microscopy. The study also included Differential Scanning Calorimetry (DSC) testing on new instruments of each system in order to analyze their thermal behavior: austenite transformation start and finish points (As and Af) and the martensitic start and finish points (Ms and Mf).

THE OUTCOMES ARE:

- WaveOne® Gold was the most predictable instrument, i.e. foreseeable time to failure of 199.4 s, showing the highest β value. WaveOne® Gold was also found significantly more fatigue resistant than WaveOne® with 157.9 s to failure (see ***Table 1***).

- EdgeFile® X1 was significantly more cyclic fatigue resistant than WaveOne® Gold and WaveOne®, but showing the least predictable fatigue resistance behaviour (see the smallest β value in ***Table 1***, meaning occurrence of unexpected early failure) attributed to surface and/or mass defects. SEM images

revealed that the surface of EdgeFile® X1 at the fracture site was the smallest, explaining higher cyclic fatigue resistance.

- DSC analysis revealed that WaveOne® and WaveOne® Gold are 50% martensitic while EdgeFile® X1 has less of a martensitic phase, all at body temperature. Therefore, the cyclic fatigue resistance of the three evaluated instruments was not linked to their martensitic phase but rather to their design and tapers.

Table 1:
Mean life (average time to failure), beta (failure rate behavior) and eta parameters (characteristic life of the instruments) and their 95% confidence intervals for the three instruments tested.

Instrument	Mean Life (CI 95%)	β (CI 95%)	η (CI 95%)
WaveOne®	157.9 s (141.8 – 175.9)	4.8 (3.4 – 6.8)	172.5 s (156.6 – 190)
WaveOne® Gold	199.4 s (187.4 – 212.3)	9.1 (6.6 – 12.5)	210.5 s (199.8 – 221.8)
EdgeEndo Reciprocating	242.9 s (211 – 279.6)	4.2 (3.1 – 5.7)	267 s (236.8 – 301.1)

Effect of canal curvature location on the cyclic fatigue resistance of reciprocating files[19].

Authors: Sobotkiewicz T, Huang X, Haapasalo M, et al.

Published in: Clinical Oral Investigations 2021;25(1):169-177

In this in vitro study, the fatigue resistance of 4 reciprocating NiTi instruments (WaveOne® Primary (WO), WaveOne® Gold Primary (WOG), Reciproc® 25/0.08 (Rec) (VDW, Munich, Germany), and Reciproc® Blue 25/0.08 (RecB) (VDW, Munich, Germany) files) was compared in artificial canals with different curvature locations (see ***Figure 5***). 50 instruments per system were used (n = 10 per canal with dedicated curvature location) and tests were performed in saline water at 37 +/- 2°C. The number of cycles to failure was calculated for each file, the length of fractured instruments was measured and Scanning Electron Microscopy (SEM) images of fractures surfaces were performed. The study also included Differential Scanning Calorimetry (DSC) testing on new instruments of each system in order to analyze their thermal behavior: austenite transformation start and finish points (As and Af) and the martensitic start and finish points (Ms and Mf).

OUTCOMES ON THE NUMBER OF CYCLES TO FAILURE

- All evaluated instruments showed lower fatigue resistance in canal with middle or coronally curvatures ("a", "b", "c", curvature locations) compared to apically located curvatures ("d", "e", curvature locations) (see ***Figure 6***). This is mainly attributed to the larger diameter at the coronal and middle parts of the instruments than at the apical area (see ***section 3*** for more details on the geometry of WaveOne® Gold instruments).

- WaveOne® Gold and Reciproc® Blue both showed superior fatigue resistance compared to the WaveOne® and Reciproc® instruments.

- The number of cycles (360°) to failure of WaveOne® Gold instruments was between approximately 200 cycles ("b" curvature location, see ***Figure 6*** to more than 900 cycles ("e" curvature location, see ***Figure 6***).

OUTCOMES ON THE LENGTH OF FRACTURES

- All the instruments broke at, or close to, the point of maximum curvature for each canal.

- SEM images revealed a fatigue failure mode with a crack initiation point located at the stress concentration areas (i.e. cutting edges).

EXPLANATION AND OUTCOMES ON THE PHASE TRANSFORMATION

For a maximum possible fatigue resistance, As and Af of NiTi instruments shall be above clinical intracanal temperature, 35 +/- 1°C. Thus, instruments are in a martensite phase during treatment, with superior flexibility and fatigue

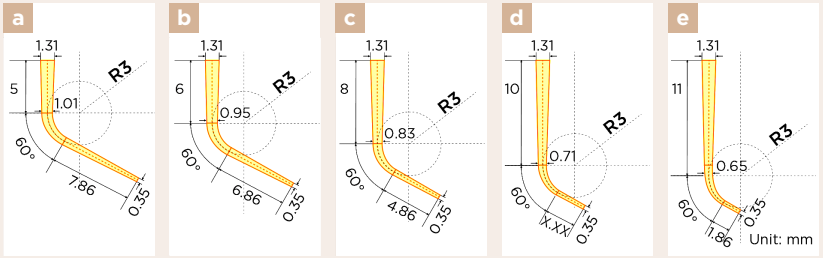

Figure 5:
Schematic diagrams of five curvature locations on the canals. The distance from the orifice to the curvature of 5 mm (A), 6 mm (B), 8 mm (C), 10 mm (D), and 11 mm (E).

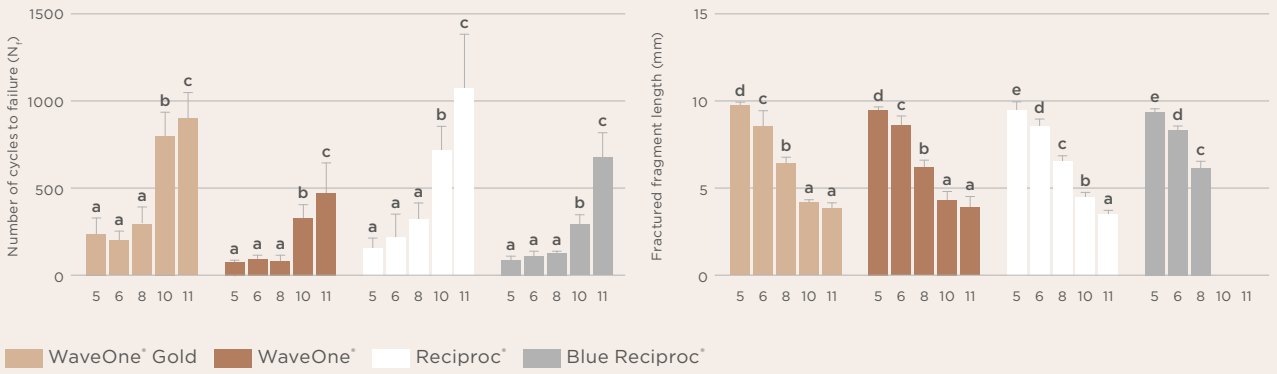

Figure 6:
First graph on the left: *The Nf of instruments at different curvature locations.*
Second graph: *the mean length of the fractured fragments of instruments at different curvature location. Letters indicate statistically significant differences within each group ($p < 0.05$).*

resistance compared to their state in the austenitic phase (see also ***section 3*** for more details on thermomechanically treated NiTi alloys).

In this study, the average As was 35.4°C for WaveOne® Gold, 26.22°C for WaveOne®, 26.6°C for Reciproc® and 30.2°C for Reciproc® Blue, suggesting that WaveOne® Gold is completely in the martensic phase during treatment (i.e. showing enhanced flexibility and fatigue resistance). See ***Table 2*** for more details on the austenite transformation start and finish points, As and Af, and on the martensitic start and finish points (Ms and Mf) of the evaluated instruments.

The ***Figure 7*** provides a visualization on the thermal behavior of NiTi alloy for a deeper understanding of the two summarized research studies above. Temperature hysteresis diagram showing the transformation temperatures.

Table 2:
Mean phase transformation temperatures (± standard deviation) of the reciprocating systems when the coronal and apical fragments were combined into one group. Austenite transformation start and finish points (As and Af) and the martensitic start and finish points (Ms and Mf).

	Cooling		Heating	
File system	Ms (°C)	Mf (°C)	As (°C)	Af (°C)
WaveOne®	45.10 ± 1.38	22.54 ± 1.01	26.22 ± 1.82	48.70 1 1.67
WaveOne® Gold	44.40 ± 0.30	26.26 ± 1.00	35.36 ± 0.80	47.26 ± 1.02
Reciproc®	44.88 ± 0.64	23.72 ± 2.09	26.76 ± 1.23	51.42 ± 1.62
Reciproc® Blue	32.55 ± 1.00	24.09 ± 1.23	30.24 ± 0.22	37.08 ± 0.60

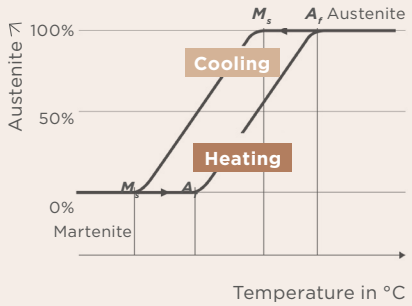

Figure 7:
Temperature hysteresis of NiTi alloy, (Ms) martensite start temperature, (Mf) martensite finish temperature, (As) austenite start temperature, (Af) austenite finish temperature.

Take home message on WaveOne® Gold and fatigue resistance

- WaveOne® Gold instruments show a very predictable and constant resistance to cyclic fatigue[18], emphasizing their reliability and safe use, and an increased cyclic fatigue resistance compared to its predecessor WaveOne®[18, 19].
- WaveOne® Gold instruments are mostly in their martensitic phase during canal treatment, promoting their fatigue resistance (compared to a non-heat-treated instrument)[19].
- The root canal curvature's location can influence the fracture resistance of the instruments. Coronal and middle curvatures put more stress on root canal instruments than apical curvatures. This is addressed by WaveOne® Gold thanks to its gold heat-treatment, again promoting the martensite phase. Thus, both its flexibility and fatigue resistance are enhanced (compared to a non-heat-treated instrument)[19]. Finally, the safety of use of WaveOne® Gold instruments was largely confirmed by a clinical study evaluating their fracture incidence[20] (see ***Section 5 'clinical results'*** for the summary of this study).

2. Level of expertise required

Supporting the dentists in the selection of the most appropriate instrument sequence, according to their level of expertise, is explored in this section with one original recent publication.

Influence of operator expertise on glide path and root canal preparation of curved root canals with rotary and reciprocating motions[21].

Authors: Dablanca-Blanco AB, Arias A, Ginzo-Villamayor MJ, Pérez MC, Castelo-Baz P, Martín-Biedma B.

Published in: Aust Endod J. 2022 Apr;48(1):37-43.

The goal of this study was to evaluate the impact of operator training on root canal shaping outcome based on instrument breakage incidence and preparation time.

Thus, two expert operators and two non-expert operators prepared selected curved root canals from extracted teeth (angle > 30°, radius < 6 mm) with rotary instruments (ProGlider™ for glide path and ProTaper® Next, X1 and X2 for shaping) and reciprocating instruments (WaveOne® Gold Glider for glide path and WaveOne® Gold Primary for shaping). Expert operators had more than ten years of experience in endodontics while non-expert operators were undergraduate students with a prior training of shaping 10 canals with each evaluated system. A total of 400 instruments were tested on 160 root canals.

Regarding the results on time required for glide path and shaping (see ***Table 3***), no statistically significant differences in the time required for glide path for both experts and non-experts, but all users required significantly more time with ProGlider™ compared to WaveOne® Gold Glider. Then, non-experts required significantly more time for shaping with ProTaper® Next than experts but the time with WaveOne® Gold was similar for experts and non-experts.

Regarding fracture incidence (see ***Table 3***), 3 ProGlider™ instruments broke during the glide path performed by non-experts while none of the WaveOne® Glider instruments fractured in this study, neither with experts nor non-experts dentists. During the shaping step, non-experts broke 4 ProTaper® Next and 2 WaveOne® Gold instruments, experts did fracture 2 ProTaper® Next but 0 WaveOne® Gold. SEM images revealed that all evaluated instrument systems fractured via flexural cyclic fatigue failure but ProTaper® Next and WaveOne® Gold also broke via torsional fracture patterns.

Table 3:
Number of instruments fractured and time (mean and SD) to achieve glide path and complete root canal preparation for the two levels of expertise of operators.

		Expert operators		Non-expert operators	
	System	Time (s)	Fracture (n)	Time (s)	Fracture (n)
Glide Path	ProGlider™	67.40 ± 24.36	-	74.43 ± 26.89	3
	WaveOne® Glider	48.32 ± 4.55	-	47.75 ± 3.20	-
Root canal prep	ProTaper® Next	109.54 ± 59.60	2	157.18 ± 74.57	4
	WaveOne® Gold	91.93 ± 32.27	-	112.96 ± 54.16	2

Finally, WaveOne® Gold sequence of instruments in the hand of both experts and novel users showed:

- A faster Glide path preparation with all users, expert and non-experts, compared to ProGlider™, which can be attributed to the reciprocating motion;
- A faster shaping time with WaveOne® Gold for novel users, compared to ProTaper® Next;
- 0 fractures of WaveOne® Gold Glider with all users;
- 0 fractures of WaveOne® Gold Primary with expert users;
- Significantly more fractures of ProGlider™ in the hands of novel users compared with expert users.

Take home message on WaveOne® Gold and and its required level of expertise

A common belief is that non-expert users require more time than experts using the same tools and may even experience more instrument fractures.

This well-designed study highlights that the experience with WaveOne® Gold is different:

- Experts and non-experts perform root canal preparation in similar time frame. Non-experts prepared root canals faster with WaveOne® Gold when compared to rotary instruments.
- Non-expert users did not fracture any WaveOne® Gold Glider, and fractured significantly more rotary instruments when compared to expert users.

All together, these outcomes emphasize the forgiving experience with WaveOne® Gold for novel users.

3. Shaping ability

An ideal mechanical objective of root canal instrumentation is complete and centered incorporation of the original canals into the prepared shape, meaning that all root canal surfaces are mechanically prepared[16]. This theoretical goal is not achievable in most clinical cases, considering the complex internal anatomy of root canals.

Therefore, the "shaping ability" of endodontic instrument is often described in literature but without any clear definition of it. It is nonetheless often expressed as a minimal canal transportation, a good centering ability and a sufficient amount of root canal wall removed during canal preparation while retaining as much as possible cervical and radicular dentin.

In this section, seven scientific studies are summarized, exploring the "shaping ability" of WaveOne® Gold in terms of canal transportation, centering ability but also studying dentinal microcracks incidence and severity. To these purposes, microcomputed tomography (MicroCT) was used, as it is the state-of-the-art tool for analysis of canal shaping outcomes, thanks to its non-destructive and reproducible analysis of high-resolution scans before and after treatment.

Micro-CT evaluation of rotary and reciprocating glide path and shaping systems outcomes in maxillary molar curved canals[22].

Authors: Alovisi M, Pasqualini D, Scotti N, Carpegna G, Comba A, Bernardi M, Tutino F, Dioguardi M, Berutti E.

Published in: Odontology. 2022 Jan; 110(1):54-61.

The goal of this study was to compare the shaping ability of rotary and reciprocating glide path and shaping systems via MicroCT.

In total, 30 extracted maxillary first molars were scanned before, after glide path, and after shaping with either WaveOne® Gold Glider and WaveOne® Gold Primary (WOGG-WOG), or with rotary system ProGlider™ and ProTaper® Next X1, X2 (PG-PTN) (n = 15). 5% NaOCl and 10% EDTA were used as irrigants. Increase in canal volume and surface area, percentage of removed dentin from the inner curvature, centroid shift and canal geometry variation via Ratio of Diameter Ratios (RDR which represents the instrument tendency to asymmetrically enlarge the root canal in one direction. Values close to 1 correspond to a better maintenance of the original canal geometry) and Ratio of cross-sectional Areas (RA which quantifies

Table 4:
Parameters utilized for post-shaping analysis in each group (PTN = ProTaper Next; WOG = WaveOne Gold; RDR = Ratio of Diameters Ratios; RA = Ratio of Cross-Sectional Areas).

	Increase in canal volume (mm^3)	Increase in canal surface area (mm^2)		Dentinal removal from inner curvature (%)	Centroid shift (mm-1)	RDR (ratio)	RA (ratio)
Group	Mean ± SD	Mean ± SD	Level of analysis	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
PTN			Coronal		0.61 ± 0.36a	0.85 ± 0.27a	2.80 ± 0.50a
	0.87 ± 0.50a	2.77 ± 2.04a	Middle	11.20 ± 10.39a	0.73 ± 0.26a	0.95 ± 0.24a	1.93 ± 0.62a
			Apical		0.45 ± 0.29a	0.90 ± 0.17a	1.61 ± 0.34a
WOG			Coronal		1.03 ± 0.37a	0.49 ± 0.21a	1.75 ± 1.35a
	2.14 + 1.16b	4.79 ± 3.44b	Middle	19.61 ± 9.62b	1.14 ± 0.41a	0.66 ± 0.17a	3.31 ± 1.35b
			Apical		0.58 ± 0.45a	0.96 ± 0.39a	1.19 ± 1.17a

Different superscript letters (a,b) in the same column indicate significant differences between groups (P <0.05). For centroid shift, RDR and RA, % dentin removal, significance was compared for the same level of analysis (coronal, middle or apical) except for the parameter % dentin removal (inner curvature), which was evaluated only for the middle (M) level.

the ability of the instrument to enlarge the root canal space. Values close to 1 correspond to a reduced difference between post and pre-instrumentation measurements) were measured in the apical and coronal levels and at the point of maximum curvature.

THE OUTCOMES ARE:

- ProGlider™ combined with ProTaper® Next and reciprocating system WaveOne® Gold Glider combined with WaveOne® Gold both produced a well-centered preparation respecting the original canal anatomy.
- Post-glide path analysis revealed that, in the coronal third, ProGlider™ produced less transportation. On the other hand, a more conservative preparation was observed with WaveOne® Gold Glider, in the apical third.
- Post-shaping analysis showed a higher volume and surface increases with WaveOne® Gold Glider combined with WaveOne® Gold, attributed to the higher number of pecking motion up to working length.

Shaping ability of reciprocating and rotary systems in oval-shaped root canals: a microcomputed tomography study[23].

Authors: de Medeiros TC, de Lima CO, Barbosa AFA, et al

Published in: Acta Odontologica Latinoamericana: AOL. 2021;34(3): 282-288

The goal of this study was to compare the shaping ability of single-file WaveOne® Gold and multi-files Mtwo® (VDW, Munich, Germany) in oval shaped canals via MicroCT.

In total, 30 mandibular oval-shaped canine canals with 10 to 20° curvatures were scanned before and after canal preparation with either WaveOne® Gold or Mtwo® up to size 25 (n = 15), with 2,5% NaOCl and 17% EDTA as irrigants. The images were analyzed in order to quantify the shaping ability in terms of percentage of surface touched/ untouched, canal transportation and centering ratio.

THE MAIN OUTCOMES ARE:

- Both evaluated systems showed similar shaping ability and centering ability (see ***Table 5***).
- WaveOne® Gold showed significantly less canal transportation at 5 mm from the apex vs. Mtwo® (see ***Table 6***). This is attributed to its gold heat-treatment, promoting the martensitic phase that is more flexible than conventional NiTi files such as Mtwo®.

Table 5:
Median, minimum and maximum values of percentage of unprepared canal area in root canal and apical third, after the different root canal preparations in WaveOne® Gold and Mtwo® Groups. Different uppercase letters indicate statistically significant differences between rows (p<0.05).

	Root canal		Apical third	
	WaveOne® Gold	Mtwo®	WaveOne® Gold	Mtwo®
Unprep. Canal area	7.96 (3.00 - 77.64)^{A}	10.18 (1.51 - 71.90)^{A}	11.33 (3.12 - 18.12)^{A}	11.79 (4.05 - 21.73)^{A}

Table 6:
Canal transportation and centering ability (mm) in the root canals sections after preparation for the two instrumentation systems. The closer the value is to 0, the lower the transportation. Different lowercase letters in each column indicate statistically significant differences within the same group between all evaluated sections. Different uppercase letters in each column indicate statistically significant differences between groups for each evaluated canal section.

		Transportation	Centering ability
Instrumentation syem	Level (mm from the apex)	Median (min - max)	Median (min - max)
WaveOne® Gold	3 mm	0.06 (0.00 - 0.19)^{aA}	0.05 (0.00 - 0.23)^{aA}
	5 mm	0.07 (0.00 - 1.09)^{aB}	0.03 (0.00 - 0.12)^{aA}
	7 mm	0.04 (0.00 - 0.28)^{aA}	0.03 (0.00 - 0.27)^{aA}
Mtwo®	3 mm	0.52 (0.01 - 1.00)^{aA}	0.52 (0.01 - 1.00)^{aA}
	5 mm	0.42 (0.00 - 0.88)^{aA}	0.30 (0.00 - 1.00)^{aA}
	7 mm	0.42 (0.00 - 0.87)^{aA}	0.48 (0.01 - 1.00)^{aA}

Micro-computed tomography evaluation of dentinal microcracks following canal preparation with thermomechanically heat-treated engine-driven files[24].

Authors: S. Arumugam, H. Z. Yew, S. A. Baharin, J. Qamaruz Zaman, A. Muchtar and S. Kanagasingam

Published in: Aust Endod J 2021 Vol. 47 Issue 3 Pages 520-530

The aim of this study was to compare the microcracks incidence and severity following canal shaping with rotary or reciprocating NiTi instruments.

In total, 40 extracted mandibular premolars (n=10) from patients aged between 20 to 40 years old were scanned before and after preparation with ProTaper® Next, ProTaper® Gold, WaveOne® Gold and Reciproc® Blue (VDW, Munich, Germany) up to size 25, with NaOCl 3% as irrigation solution. 113'000 cross section images were analyzed in terms of microcracks frequency and were classified in three types of defect severity:

- Score 1: craze line (from the outer surface into the dentin),
- Score 2: incomplete crack (from canal wall into dentin),
- Score 3: complete crack (from canal wall to the outer surface).

THE OUTCOMES ARE:

- The scan before preparation revealed the presence of dentinal microcracks in 16.7%, in apical third and middle root regions, but not in the coronal third.
- The scan after instrumentation revealed no newly created cracks for all NiTi systems. Only slight microscopic crack propagation were detected, not associated with any changes in scoring.
- No correlation between the types of dentinal defects, files motions or file sequences was shown.

Micro-computed tomography evaluation of the shaping ability of 3 reciprocating single-file nickel-titanium systems on single- and double-curved root canals[25].

Authors: F. Haupt, J. R. W. Pult and M. Hülsmann

Published in: J Endod 2020 Vol. 46 Issue 8 Pages 1130-1135

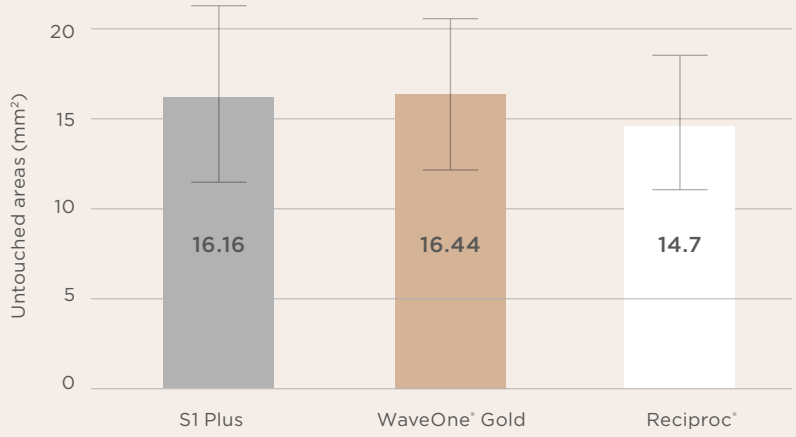

Figure 8:
Similar percentages of untouched areas.

The goal of this study was to compare the shaping ability of three reciprocating NiTi systems S1 Plus Standard (Sendoline, Täby, Sweden), WaveOne® Gold Primary (Dentsply Sirona, Ballaigues, Switzerland), and Reciproc® R25 (VDW, Munich, Germany) in single and double-curved canals via microCT.

In total, 75 curved mandibular molars with 2 separate mesial root canals (n = 25 per group) were scanned before and after preparation with the evaluated systems, and using NaOCl 3% and citric acid as irrigants. The images were analyzed in order to quantify the shaping ability in terms of changes in canal geometry (changes in volume of root canal and surface area, percentage of surface touched/untouched, canal transportation and centering ratio).

THE MAIN OUTCOMES ARE:

- All preparation systems showed similar percentages of untouched areas: S1 Plus = 16.16 +/- 9.79 mm^2, WaveOne® Gold = 16.44 +/- 8.32 mm^2 and Reciproc® = 14.70 +/- 7.81 mm^2 (see ***Figure 8***)
- All systems show similar transportation and centering ratio, up to 0.35 mm in the apical zone.
- No instruments breakage was experienced. Only one S1 Plus instrument showed unwinding after an S-shaped preparation.
- The 3 investigated NiTi reciprocating system equally prepared moderately single and double curved canals, from both safety and performance perspectives.

Micro-computed Tomographic Assessment and Comparative Study of the Shaping Ability of 6 Nickel-Titanium Files: An In Vitro Study[26].

Authors: M. L. N. Perez Morales, J. A. Gonzalez Sanchez, J. G. Olivieri, F. Elmsmari, P. Salmon, D. E. Jaramillo, et al.

Published in: J Endod 2021 Vol. 47 Issue 5 Pages 812-819

The shaping ability of WaveOne® Gold (Dentsply Sirona, Ballaigues, Switzerland), the Reciproc® Blue (VDW, Munich, Germany), TRuShape™ (Dentsply Sirona, Tulsa, USA), XP-Endo® Shaper (FKG, La Chaux-de-Fonds, Switzerland), iRace (FKG, La Chaux-de-Fonds, Switzerland), and TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland) NiTi files was compared in moderately curved canals via micro-computed tomography. 10 extracted lower molars (20 canals in mesial roots) per group were scanned before and after preparation, and the images were analyzed in order to quantify the shaping ability in terms of changes in canal geometry (structure thickness, volume of root canal, percentage of surface touched/untouched, centroids, etc.).

WaveOne® Gold and TruShape™ touched the largest canal surface (73 and 81% respectively), while TruNatomy® and XP-Endo® Shaper respected the canal anatomy better than the other evaluated systems, touching 50 and 58% respectively of the canal walls. At the same time, WaveOne® Gold was shown, as all evaluated files system, to be able to clean and shape the canal, with a minimal apical transportation (no significant differences).

Root Canal Shaping Using Nickel Titanium, M-Wire, and Gold Wire: A Micro-computed Tomographic Comparative Study of One Shape, ProTaper Next, and WaveOne Gold Instruments in Maxillary First Molars[27].

Authors: P. J. van der Vyver, F. Paleker, M. Vorster and F. A. de Wet

Published in: J Endod 2019 Vol. 45 Issue 1 Pages 62-67

The goal of this study was to compare the shaping ability of three NiTi shaping instruments combined with different glide path preparations via microCT.

Thus, glide path preparation with K-files (KF) (Dentsply Sirona, Ballaigues, Switzerland), One G (OG) files (Micro-Mega, Besançon, France), and ProGlider™ (PG) files (Dentsply Sirona) were randomly associated with 3 systems of instrumentation, ProTaper® Next (PTN, Dentsply Sirona), One Shape (OS, Micro-Mega), and WaveOne® Gold (WOG, Dentsply Sirona) systems.

Table 7:
Centering Ratio Values for the Tested Groups. KF, K-file; OG, One G; OS, One Shape; PG, ProGlider; PTN, ProTaper NEXT; WOG, WaveOne Gold; SD, standard deviation. The closer the value is to 1, the better the centering ability. Highlighted in orange: WaveOne Gold combinations.

	Apical		Midroot		Coronal	
System	Mean ± SD	Min. - max.	Mean ± SD	Min. - max.	Mean ± SD	Min. - max.
KF/OS	0.52 ± 0.36	0.058 - 1.276	0.49 ± 0.29	0.002 - 1.178	0.33 + 0.27	0.096 - 1.166
KF/PTN	0.55 ± 0.41	0.068 - 1.543	0.45 ± 0.34	0.082 - 1.275	0.35 + 0.34	0.025 - 1.443
KF/WOG	0.59 ± 0.35	0.033 - 1.421	0.43 ± 0.30	0.125 - 1.415	0.52 ± 0.33	0.156 - 1.418
OG/OS	0.53 ± 0.28	0.103 - 1.353	0.44 ± 0.25	0.76 - 1.043	0.35 ± 0.32	0.051 - 1.296
OG/PTN	0.56 ± 0.33	0.068 - 1.167	0.50 ± 0.39	0.004 - 1.377	0.37 ± 0.29	0.062 - 1.143
OG/WOG	0.60 ± 0.32	0.115 - 1.376	0.45 ± 0.29	0.122 - 1.328	0.56 ± 0.16	0.301 - 0.855
PG/OS	0.55 ± 0.33	0.103 - 1.254	0.54 ± 0.35	0.002 - 1.271	0.34 ± 0.28	0.059 - 1.197
PG/PTN	0.60 ± 0.32	0.144 - 1.334	0.47 ± 0.29	0.43 - 1.223	0.44 ± 0.34	0.043 - 1.168
PG/WOG	0.62 + 0.33	0.121 - 1.276	0.44 ± 0.29	0.136 - 1.279	0.58 ± 0.34	0.089 - 1.301
P value	.996		.998		.09	

In total, 135 mesiobuccal canals of maxillary molars (n = 15 per group) were scanned before and after preparation, and the images were analyzed in order to quantify the shaping ability in terms of changes in canal geometry, transportation and centering ratio.

THE MAIN OUTCOMES, ALL PRESENTED IN THE ***TABLES 7, 8, 9***, CAN BE SUMMARIZED AS FOLLOWED:

- The centering ratios were similar for all groups.
- ProGlider™ combined with WaveOne® Gold preparation showed the lowest canal transportation, in the apical third, midroot level and coronal third.
- ProGlider™ combined with WaveOne® Gold preparation also showed the lowest change in canal volume.
- K-file combined with ProTaper® Next preparation showed the highest transportation in the apical third, midroot level and coronal third.
- No matter the glide path instrument used, ProTaper® Next showed the highest volume of dentin removal.

In conclusion, ProGlider™ combined with WaveOne® Gold preparation showed a beneficial shaping ability regarding transportation, centering ratio and dentinal removal.

Table 8:
ransportation (mm) for the Tested Groups. KF, K-file; OG, One G; OS, One Shape; PG, ProGlider; PTN, ProTaper NEXT; WOG, WaveOne Gold; SD, standard deviation. The closer the value is to 0, the lower the transportation. Highlighted in orange: WaveOne Gold combinations.

Apical: *aStatistically significantly different from KT/WOG, OG/OS, OG/PTN, OG/W0G, PG/OS, PG/PTN, and PG/WOG. bStatistically significantly different from KF/WOG, OG/WOG, and PG/WOG. cStatistically significantly different from PG/WOG. dStatistically significantly different from KF/OS, KF/PTN, and OG/PTN.*

Midroot: *aStatistically significantly different from KF/WOG, OG/W0G, PG/OS, and PG/WOG. bStatistically significantly different from KF/WOG, OG/PTN, OGAVOG, PG/OS, PG/FIN, and PGAVOG. cStatistically significantly different from PG/OS and PGAVOG. dStatistically significantly different from KF/OS, KF/PTN, and OG/OS.*

Coronal: *aStatistically significantly different from PG/WOG. bStatistically significantly different from KF/WOG, OG/WOG, and PG/WOG. cStatistically significantly different from KF/OS and KF/PTN.*

	Apical		Midroot		Coronal	
System	Mean ± SD	Min. - max.	Mean ± SD	Min. - max.	Mean ± SD	Min. - max.
KF/OS	0.107a ± 0.046	0.035 - 0.219	0.118a ± 0.036	0.036 - 0.174	0.167a ± 0.037	0.084 - 0.259
KF/PTN	0.096b ± 0.033	0.030 - 0.168	0.132b ± 0.038	0.050 - 0.219	0.172b ± 0.040	0.072 - 0.270
KF/WOG	0.078 ± 0.025	0.037 - 0.128	0.093 ± 0.021	0.053 - 0.128	0.148 ± 0.036	0.074 - 0.212
OG/OS	0.083 ± 0.020	0.054 - 0.128	0.113c ± 0.027	0.060 - 0.162	0.158 ± 0.027	0.133 - 0.230
OG/PTN	0.085c ± 0.026	0.035 - 0.136	0.107 ± 0.030	0.050 - 0.157	0.161 ± 0.032	0.127 - 0.250
OG/WOG	0.068 ± 0.026	0.022 - 1.126	0.093 ± 0.027	0.049 - 1.127	0.147 ± 0.029	0.130 - 0.203
PG/OS	0.081 ± 0.020	0.041 - 0.127	0.089 ± 0.023	0.052 - 0.151	0.154 ± 0.026	0.093 - 0.201
PG/PTN	0.084 ± 0.023	0.030 - 0.128	0.104 ± 0.033	0.23 - 0.171	0.151 ± 0.030	0.091 - 0.221
PG/WOG	0.065d ± 0.026	0.040 - 0.136	0.086d ± 0.020	0.054 - 0.120	0.140c ± 0.027	0.072 - 0.202
P value	.003		.0003		.011	

Table 9:
Changes in Canal Volume (in mm^3) with Shaping Instruments. KF, K-file; OG, One G; OS, One Shape; PG, ProGlider; PTN, ProTaper NEXT; WOG, WaveOne Gold; SD, standard deviation. Mean values with the same superscript letters were not statistically different at P < 0.05 using the Kruskal-Wallis H test. Highlighted in orange: WaveOne Gold combinations.

Shaping Method	Mean	Standard deviation	Minimum value	Maximum value
KF/OS	3.034a	0.903	2.053	5.629
KF/PTN	3.456b	1.394	2.013	6.581
KF/WOG	3.078a	0.567	1.882	3.822
OG/OS	3.211a	1.263	1.672	5.346
OG/PTN	3.616b	1.228	1.180	5.445
OG/WOG	3.025a	1.097	1.453	5.342
PG/OS	2.875a	0.772	1.692	4.274
PG/PTN	3.631b	1.674	1.709	7.143
PG/WOG	2.646a	1.518	1.027	5.755

Synchrotron radiation-based micro-computed tomographic analysis of dentinal microcracks using rotary and reciprocating file systems: An in vitro study[28].

Authors: H. Vemisetty, N. T. Priya, B. Singh, P. Yenubary, A. K. Agarwal and J. R. Surakanti

Published in: J Conserv Dent 2020 Vol. 23 Issue 3 Pages 309-313

The aim of this study was to assess the dentinal microcracks incidence after canal shaping with 4 NiTi systems, ProTaper® Gold (Dentsply Sirona, Ballaigues, Switzerland), Hyflex EDM (Coltène-Whaledent, Altstätten, Switzerland), Reciproc® (WVD, Munich, Germany) and WaveOne® Gold in extracted teeth via synchrotron radiation-based micro-computed tomography (SR-µCT).

In total, 40 extracted curved mandibular molars from patients between 40 and 60 years old (n = 10 per group) were scanned before and after preparation up to size 25, with NaOCl 2.5% as irrigation solution. 81'747 cross section images were analyzed in terms of microcracks frequency.

THE MAIN OUTCOMES, PRESENTED IN THE *TABLE 10*, CAN BE SUMMARIZED AS FOLLOWED:

- Very few microcracks were observed for all instrumentation systems.
- No correlation between the types of dentinal defects, files motions or file sequences was shown.

Table 10:
Number of microcracks determined as a percentage for each group.

Variables	Total slices	Cracks	Percentage
ProTaper® Gold	20,301	399	1.965
Hyflex EDM	21,984	200	0.909
Reciproc®	19,310	256	1.325
WaveOne® Gold	20,152	210	1.042

Take home message on WaveOne® Gold and its shaping ability

Regarding shaping ability, WaveOne Gold® performed similarly to other files, maintaining the original canal curvature, not creating new dentinal microcracks and can even performed better than other file systems in terms of dentin removal from the canal walls when combined with a glide path instrument[23, 24, 27]. Still, the studies summarized above confirmed that engine-driven NiTi instrumentation systems, in reciprocating or rotary motions, are unable to contact 100% of the root canal wall[26]. Such results are nevertheless expected, and in alignment with another peer-reviewed publication indicating that 35% or more of canal surface remains untouched after mechanical instruments, mainly due to the anatomical complexity of the root canal system[29]. Thus, biofilms remain on these inaccessible root canal walls and may recolonize the root canal system, which adversely affects treatment outcome. Irrigation is therefore an essential part of root canal debridement to achieve intracanal disinfection, to dissolve and to remove pulp tissue, dentinal debris, smear layer, microorganisms and their by-products[30]. In this framework, the Dentsply Sirona's Irrigation Needle (4% taper, 30 gauge closed end tip, 27 mm working length) can be of great support (see ***Figure 1***). It is made in soft polypropylene, allowing the needle to curve and flex easily to follow the root canal anatomy. Moreover, the back-to-back 2-sided vent design maintains a balanced irrigation solution volume for greater control throughout the canal.

4. Obturation quality

Most of the literature supports the importance of the shaping and cleaning steps, but very few studies focus on the filling step. The goal of the canal filling is to seal against bacterial penetration and allow for periapical healing.

Microscopic and Chemical Assessments of the Filling Ability in Oval-Shaped Root Canals Using Two Different Carrier-Based Filling Techniques[31].

Authors: D. Mancino, N. Kharouf, J. Hemmerlé and Y. Haïkel

Published in: Eur J Dent 2019 Vol. 13 Issue 2 Pages 166-171

The purpose of this study was to explore the tridimensional seal of both Guttacore® and Thermafil® carrier-based obturators after shaping with ProGlider™ and WaveOne® Gold Primary instruments.

In total, 24 extracted human mandibular premolars with one oval canal were included in this study, then divided in two groups (n = 12) for the obturation with either Guttacore® and Thermafil®, and AH Plus® sealer. Proportions of gutta-percha filled areas, sealer filled areas, void areas were assessed via optical numeric microscope. Maximal dentinal tubules penetration was measured via scanning electron microscopy. Energy-dispersive X-rays was used as a chemical analysis to confirm the image observations of carrier-based obturators vs. sealer at 2 mm (WL-2) and 5 mm (WL-5) from the apex.

THE MAIN OUTCOMES ARE:

- Both techniques showed similar filling ability at 2 mm and 5 mm from the apex (see details in ***Table 11***).
- The maximal dentinal tubules penetration at 5 mm and 2 mm from the apex was, respectively, 96 and 48µm, for Guttacore®, whereas is was 109µm and 55µm, respectively, for Thermafil®.

Table 11:
Filling ability of GuttaCore® vs. Thermafil®.

	Gutta percha filled areas		Sealer filled areas		Void areas	
	2 mm from the apex	5 mm from the apex	2 mm from the apex	5 mm from the apex	2 mm from the apex	5 mm from the apex
GuttaCore®	98.76 ± 0.004%	99.19 ± 0.003%	1.09 ± 0.004%	0.61 ± 0.003%	0.15 ± 0.001%	0.20 ± 0.001%
Thermafil®	98.33 ± 0.04%	99.04 ± 0.02%	1.54 ± 0.01%	0.74 ± 0.003%	0.13 ± 0.004%	0.22 ± 0.001%

- No statistical differences were observed between the two evaluated carrier-based techniques.

In conclusion, both techniques can fill oval canals shaped with WaveOne® Gold. It should be noted that the authors state Guttacore® technique was less technique sensitive and less difficult compared to Thermafil®.

Take home message on WaveOne® Gold and obturation

Very few ex vivo studies on obturation quality have been published using WaveOne® Gold system. Nonetheless, it was clearly shown that oval shaped canals can be successfully filled with Guttacore® or Thermafil® following a canal preparation with WaveOne® Gold, showing dentinal tubule penetration and minimal void space.

Clinical results

Five prospective in vivo studies, focusing on breakage of the instruments or on post-operative pain are available on WaveOne® Gold system. Challenging clinical cases are also presented hereafter, including curved canals management.

Fracture incidence of WaveOne® Gold files: a prospective clinical study[20].

Authors: C. S. P. Bueno, D. P. Oliveira, R. A. Pelegrine, C. E. Fontana, D. G. P. Rocha, J. L. Gutmann, et al.

Published in: International Endodontic Journal, 2020. 53(9): p. 1192-1198.

The aim of this prospective clinical study was to evaluate the incidence of instrument breakage. The WaveOne® Gold system was used on 750 maxillary or mandibular molar teeth (i.e. 2691 root canals; 1104 instruments; 2.43 canals/file; maximum of four canals/file) from patients aged between 15 and 60 years old, with fully formed apices and canal curvatures less than 45°, assessed by Xrays. Three endodontic specialists who are experienced WaveOne® Gold users performed the treatments, starting the scouting/glide path with size 10 or 15 K-files, followed by the WaveOne® Gold Primary instrument and then Small, Medium or Large sizes when necessary (see ***Figure 9*** showing the sampling of the file sizes) in a 2,5% NaOCl solution. Each instrument, after each use, was observed via a dental microscope, at 8x magnification.

In a total of 2691 root canals, none of the 1104 WaveOne® Gold instruments fractured, i.e. none of the 38 Small size - 750 Primary size - 228 Medium size and 88 Large size have broken.

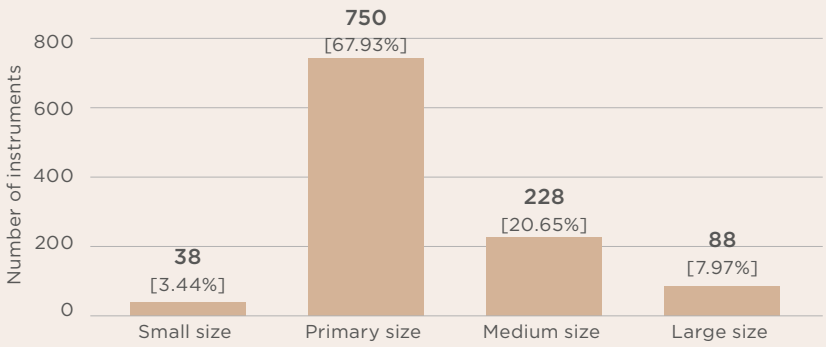

Figure 9:
Composition (n[%]) of the study sample in terms of the final file sizes used for endodontic instrumentation.

Comparison of the incidence of postoperative pain after using a continuous rotary system, a reciprocating system, and a Self-Adjusting File system in single-visit endodontics: A prospective randomized clinical trial[32].

Authors: Saha SG, Gupta RK, Bhardwaj A, Misuriya A, Saha MK, Nirwan AS.

Published in: J Conserv Dent. 2018 May-Jun;21(3):333-338.

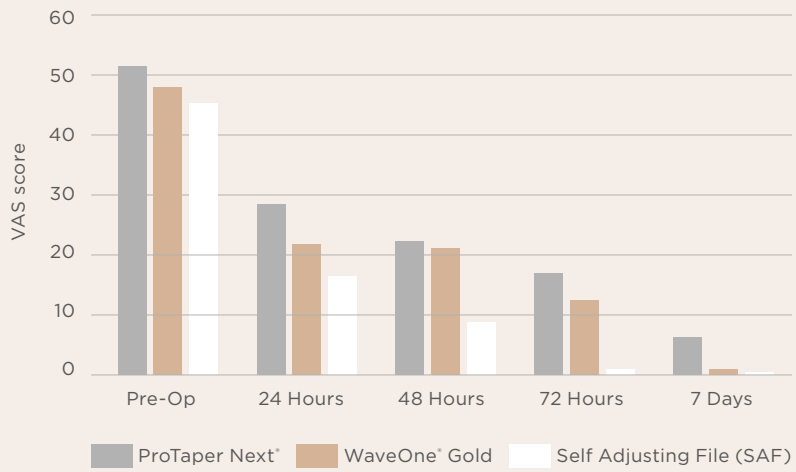

Figure 10:
Composition of mean VAS Scores among ProTaper® Next, WaveOne® Gold & SAF systems at different time intervals. "mild" (25-49 in VAS score range), "no pain"(0-24 range in VAS score pain).

214 patients with irreversible pulpitis, aged between 18 and 55 years old, were randomly assigned to 6 trained post-graduate students for a root canal treatment with either ProTaper Next, WaveOne Gold® or Self Adjusting File (SAF). All participants noted the score of pain (Visual Analog Scale (VAS) sheet; 0 - 24 = No pain; 25 - 49 = Mild; 50 - 74 = Moderate; 75 -100 = Severe), pre-operative and post operative after 24h, 48h, 72h and 7 days.

There was a significant reduction in post-operative pain compared to pre-operative pain with all studied instrument systems, without any severe pain or flare up observations (see ***Figure 10***). Focusing on post-operative pain, its classification decreased from "mild" (25-49 in VAS score range) to "no pain"(0-24 range in VAS score pain) with all systems over the 7 days period. SAF system showed lower post-op pain ratings compared to WaveOne® Gold after 24, 48, and 72h, but similar results after 7 days. On the other hand, treatments with WaveOne® Gold instruments were globally associated with lower post-operative pain ratings compared to those performed with ProTaper® Next. This lower incidence of pain is attributed to the reciprocating motion, expected to extrude less debris apically than rotary motion.

Postoperative Pain after Use of the WaveOne® Gold and XP-Endo® Shaper Systems: A Randomized Clinical Trial[33].

Authors: Xavier F, Zuolo M, Nevares G, Kherlakian D, Velozo C, de Albuquerque D.

Published in: J Endod. 2021 Oct;47(10):1550-1556.

In this prospective clinical trial, 148 patients aged between 24 and 86 years old randomly received an endodontic treatment with either WaveOne® Gold or XP-Endo® Shaper (FKG Dentaire, La Chaux-de-Fonds, Switzerland) instrument systems by five experienced endo-specialists. Only asymptomatic teeth, premolars or molars with vital pulp requiring endodontic treatment for prosthetic reasons were included, in order to study only the factors related to the root canal preparation, avoiding any bias of a preoperative pathology. The post-operative perceived pain was rated using the Visual Analog Scale (VAS) 24, 48, 72 hours and 7 days after the treatment.

Both canal preparations were irrigated with 2.5% NaOCl and 17% EDTA. Single cone technique with gutta-Percha points matching the instrument's preparation was performed, using AH Plus sealer (Dentsply Sirona).

THE OUTCOMES ARE:

WaveOne® Gold caused less postoperative pain, short-term (significant differences) and long-term (non-significant differences), compared to XP-Endo® Shaper. The average pain was in the mild range for both systems. (see ***Table 12***) The higher incidence of pain of the XP-Endo® Shaper might be attributed to the difference in the instrument design and also to the type of movement, i.e. rotary at 800 rpm, which may lead to more debris generations and extrusion.

Table 12:
Post operative pain after instrumentation with the two evaluated systems. No pain (0), mild pain (1–3), moderate pain (4–6), and severe pain (7–10).

	Score (%)			
System	0	1-3	4-6	7-10
Pain after 24h				
XPES	52.7	40.5	6.8	0.0
WOG	73.0	21.6	2.7	2.7
Pain after 48h				
XPES	32.4	51.4	16.2	0.0
WOG	89.2	8.1	2.7	0.0
Pain after 72h				
XPES	60.8	36.5	2.7	0.0
WOG	97.3	2.7	0.0	0.0
Pain after 7 d				
XPES	0.0	0.0	0.0	0.0
WOG	0.0	0.0	0.0	0.0

Table 13:
Mean postoperative pain values (mean ± standard deviation) at each time point.

	24h	48h	72h	p*
ProTaper Universal Retreatment	3.7 ± 2.2	1.4 ± 1.7	0.5 ± 0.8	< .001
Hyflex EDM	2.9 ± 2.4	1.2 ± 1.4	0.8 ± 1.7	< .001
Reciproc Blue	3.2 ± 2.1	1.9 ± 2.0	0.8 + 1.2	< .001
WaveOne Gold	3.2 ± 2.2	1.4 ± 1.8	0.6 + 1.0	< .001
p**	.419	.210	.728	

Table 14:
Number of analgesics pills (mean ± standard deviation) consumed at each time point.

	24h	48h	72h	p*
ProTaper Universal Retreatment	0.36 ± 0.68	0.11 ± 0.44	0.00 ± 0.00	.000*
Hyflex EDM	0.18 ± 0.49	0.04 ± 0.21	0.04 ± 0.21	.022*
Reciproc Blue	0.31 ± 0.73	0.20 ± 0.59	0.09 + 0.28	.095
WaveOne Gold	0.33 ± 0.71	0.16 ± 0.56	0.02 + 0.15	.000*
p**	> .05	> .05	> .05	

**Friedman test **Kruskal-Wallis test*

The effect of two rotary and two reciprocating NiTi systems on postoperative pain after root canal retreatment on single-rooted incisor teeth: A randomized controlled trial[34].

Authors: Çanakçi BC, Er Ö, Genç Şen Ö, Süt N.

Published in: Int Endod J. 2021 Nov;54(11):2016-2024.

In this randomized prospective clinical study, 180 patients received a root canal retreatment on a single-rooted incisor teeth, initially treated more than 4 years ago, and showing an initial root filling 2 to 4 mm short of the radiographic apex. Either rotary instruments (ProTaper® Universal Retreatment instruments or HyFlex EDM (Coltene-Whaledent)), or reciprocating instruments (Reciproc® Blue instruments (VDW, Germany) or WaveOne® Gold instruments) were used.

No solvent was used to remove the filling materials, 2.5% NaOCl and 17% EDTA were used for irrigation purposes and a lateral condensation technique was used for all treated canals, using the compatible gutta-percha cones and AH Plus® sealer (Dentsply Sirona). The post-operative perceived pain was rated with the Visual Analog Scale (VAS) 24, 48, 72 hours and 7 days after the retreatment. The number of analgesics intake by patients was also registered.

THE OUTCOMES ARE:

- **There was a significant reduction in post-operative pain day by day with all studied instrument systems**, without any swelling observations but some flare-ups, without any significant differences between the groups (see ***Table 13***).
- There were no significant differences in the number of analgesics taken by patients amongst groups (see ***Table 14***)

No significant differences in terms of post-operative pain or analgesic intake were observed with these 4 rotary or reciprocating NiTi systems.

Instrumentation kinematics does not affect bacterial reduction, post-operative pain, and flare-ups: A randomized clinical trial[35].

Authors: S. M. Saber, A. M. A. Alfadag, N. N. Nawar, G.

Published in: International Endodontic Journal, [s. l.], v. 55, n. 5, p. 405–415, 2022

This prospective clinical study aims at comparing the effect of the instrument motions, rotary vs. reciprocating, on several aspects such as post-operative pain, bacterial reduction and flare-ups incidence. In total, 66 patients were randomly treated with either One Shape 37/0.06 (Micro-Mega, France) used in rotary motion or WaveOne® Gold Medium 35/0.06 for the treatment of asymptomatic single rooted mandibular premolars. The canals were irrigated with 2.5% NaOCl and 17% EDTA. The post-operative perceived pain was rated via the Visual Analog Scale (VAS) 24, 48, 72 hours and 7 days after the retreatment. Bacterial samples before and after treatment (shaping and irrigation) were analysed via quantitative real-time polymerase chain reaction (qPCR). Flare-ups were also registered.

THE OUTCOMES ARE:

- No early breakage or iatrogenic incidents were reported. Only three patients reported flare-ups, two with WaveOne® Gold and one with One Shape (Micro-Mega, France), which is statistically non-significant.
- **The bacterial reduction was significant, more than 94% after instrumentation (shaping and irrigation) with either One Shape or WaveOne® Gold, based on CFU counting. It was more than 98% with WaveOne® Gold and around 96% with One Shape, based on qPCR results.** However, no significant differences between rotary and reciprocating were observed (see ***Table 15***), emphasising the importance of the mechanical shaping combined with NaOCl irrigation, also called chemo-mechanical cleaning, for an appropriated canal disinfection.

There was a significant reduction in post-operative pain day by day with both studied instruments (again without any significant differences between the groups) without any analgesic intakes reported. This can be attributed to a working length control via Xrays and electronic apex locator verification but also to the use of a side-vented irrigation needle expected to safely deliver irrigants.

Table 15:
Inter- and intra-group comparisons of bacterial count evaluated by culture and molecular detection techniques. Means with different superscript letters within the same vertical column are statistically different (p ≤ .05); significant (p ≤ .05)*

		Log bacterial count (mean ± SD)		
Measurement	Sample	WaveOne Gold	One-shape	p-value
CFU	S1	5.13 + 0.13A	5.03 ± 0.36A	0.16
	S2	2.76 ± 0.68B	2.75 ± 0.70B	0.92
	Percentage reduction (%)	94.24 ± 14.05	95.67 ± 11.25	0.65
	p-value	**< 0.001***	**< 0.001***	
qPCR	S1	5.49 ± 0.80A	5.62 ± 0.79A	0.52
	S2	2.70 ± 0.30B	2.46 ± 0.79B	0.11
	Percentage reduction (%)	98.98 ± 1.76	96.23 ± 17.33	0.37
	p-value	**< 0.001***	**< 0.001***	

WaveOne® Gold reciprocating instruments: clinical application in the private practice: Part 1[36] and Part 2[37]

Authors: P. Van der Vyver and M. Vorster

Published in: International Dentistry South Africa 2017 Vol. 7 Issue 4.

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P. Van der Vyver and M. Vorster have published several clinical case reports illustrating the clinical benefits of the full WaveOne® Gold solution[36, 37]. A selection of some of them is presented in this section:

CASE REPORT 2[37]

The patient, a 26-year-old male presented with a non-vital mandibular right first molar. A pre-operative periapical radiograph revealed a very deep, previously placed Class II composite restoration (***Figure 11***). After access cavity preparation three root canal systems were detected (two mesial and one distal) and length determination was done (***Figure 12***). Initial glide path preparation with sizes 08 and 10 K-Files was difficult and challenging due to the S-Shaped canal configuration in the apical 5 mm of the two mesial root canals. The glide paths were expanded using a WaveOne® Gold Glider instrument. Root canal preparation was initiated by taking the WaveOne® Gold Small 20/07 file, up to working length in all three root canals. The root canal preparation was enlarged in the distal root canal with a WaveOne® Primary Small 25/07 file to create more deep shape. ***Figure 13*** depicts the post-operative result after obturation with the Calamus® Dual Obturation System (Dentsply Sirona) using two Small and one Primary WaveOne® Gutta Percha points (Dentsply Sirona) and AH Plus® Root canal sealer (Dentsply Sirona). One year follow-up radiograph is shown in ***Figure 14***.

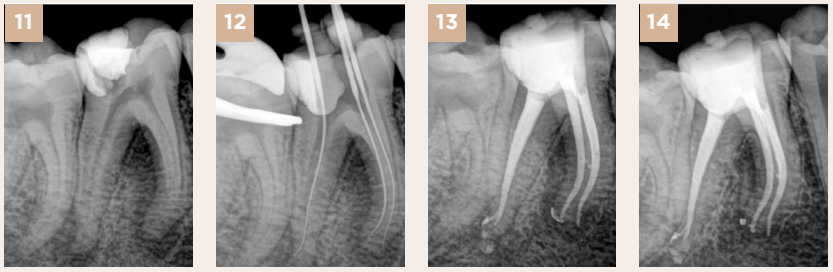


Figure 11:
Preoperative periapical radiograph.

Figure 12:
Length determination radiograph. Note the "S"-shaped canal configuration in the apical part of the mesio-lingual root canal system and apical curvature in the mesio-buccal root canal system.

Figure 13:
Postoperative periapical radiograph directly after obturation.

Figure 14:
One year follow-up radiograph. Note the partial resorption of the sealer puff on mesial root.

CASE REPORT 4[37]

The patient, a 19-year-old male presented with a non-vital mandibular left molar probably caused by a previously placed leaking occlusal restoration (***Figure 15***). A CBCT scan revealed large periapical areas around the mesial and distal roots (***Figure 16***). After access cavity preparation, four root canal systems were located (two mesial and two distal). It was noted that the canals were large in diameter and a size 20 K-file could be taken easily to full working length. Root canal preparation was done with a single WaveOne® Gold Medium size 35/06 instrument. The canals were irrigated and obturated before the tooth was restored with SDR® (Dentsply Sirona), a posterior bulk fill flowable base material and capped with a 2 mm layer of Ceram. x® SphereTEC™ one composite resin (Dentsply Sirona). ***Figure 17*** depicts the postoperative result after 6 months. A follow up CBCT scan also revealed good healing of the periapical pathology (***Figure 18***). The 3 years follow-up is shown in ***Figures 19 and 20***.

Figure 15:
Preoperative periapical radiograph.

Figure 16:
Preoperative CBCT scan images: **(a)** *Sagittal view;* **(b)** *Axial view. Note the large periapical pathology around the mesial and distal roots.*

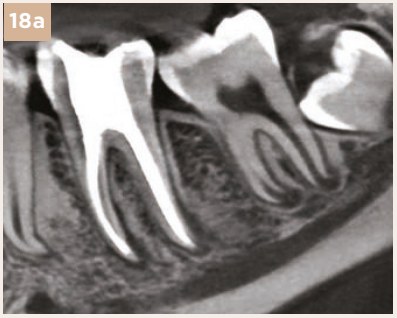
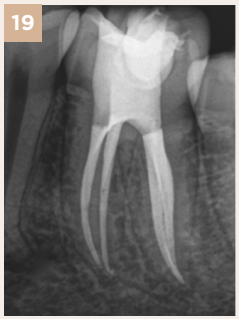
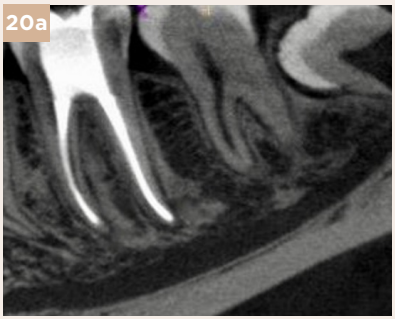


Figure 17:
Postoperative periapical radiograph after 6 months.

Figure 18:
Postoperative CBCT scan images after 6 months: **(a)** *Sagittal view;* **(b)** *Axial view. Note the healing of the periapical pathology.*





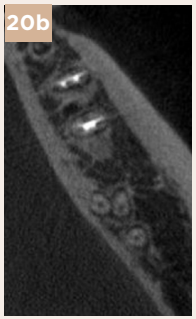


Figure 19:
Postoperative periapical radiograph after 3 years.

Figure 20:
Postoperative CBCT scan images after 3 years: **(a)** *Sagittal view;* **(b)** *Axial view. Note the complete healing of the periapical pathology.*

Take home message on WaveOne® Gold clinical data

Five clinical studies performed with WaveOne® Gold instruments on more than 1350 patients largely confirmed their performance and safety of use:

- In a total of 2691 root canals, none of the 1104 WaveOne® Gold instruments fractured. This may be attributed to the design of the instruments but also to their gold heat-treatment, enhancing fatigue resistance and flexibility for a safer experience[14] (***see also section 3*** above for more details on heat-treatment).
- All clinical studies agree that the post-operative pain significantly decreases with time following a root canal preparation with WaveOne® Gold (and other evaluated instruments). Some studies even concluded that the reciprocating motion, creating less debris extrusion into the periapical tissues vs. rotary motion, leads to less post operative pain[32, 33]. Nonetheless, it should be emphasized that there is no consensus yet on the impact of the instrument motions on the post-operative pain perceived by patients[34, 35].
- The chemo-mechanical bacterial reduction after WaveOne® Gold instrumentation combined with 2.5% NaOCl and 17% EDTA was almost 99% based on qPCR, highlighting its effectiveness for appropriate canal disinfection[35].
- Challenging clinical case reports are available, illustrating the WaveOne® Gold single-file technique[36, 37].

Conclusion

In summary, the following insights regarding WaveOne® Gold system were gained:

- Cyclic fatigue resistance is increased when using reciprocating files such as WaveOne® Gold, compared to rotary files[5, 17] and even compared to its predecessor WaveOne®[18, 19].
- WaveOne® Gold instruments show a very predictable and constant resistance to cyclic fatigue[18], emphasizing their reliability and safe use.
- WaveOne® Gold instruments are mostly in their martensitic phase during canal treatment, promoting both their flexibility and fatigue resistance[19].
- WaveOne® Gold instruments showed a faster preparation time and less breakage compared to rotary motion files in curved canals in the hand of novel users (non-experts) on a comparable level to expert users[21]; emphasizing its forgiving experience and rapid learning curve.
- Regarding shaping ability, WaveOne® Gold performed better than other file systems in terms of dentin removal from the canal walls and similarly to other files with respect to maintaining the original canal curvature[25-27].
- Obturation with Guttacore® or Thermafil®, following a canal preparation with WaveOne® Gold instruments is successful even in oval shaped canals, showing penetration into dentinal tubules and minimal voids[31].
- Challenging clinical case reports are available, illustrating the high performance of the WaveOne® Gold single-file technique[36, 37].
- Clinical studies performed on more than 1350 patients largely confirmed the performance and safety of the WaveOne® Gold solution. Moreover, it was shown that the post-operative pain significantly decreases with time following a root canal preparation with WaveOne® Gold but without significant differences when compared to other evaluated NiTi systems[32-35].

These key peer-reviewed studies, selected among more than 200 publications, illustrate that WaveOne® Gold solution is one of the most heavily researched endodontic NiTi systems. All together, they emphasize the simplicity, performance, safety, and clinical advantages of WaveOne® Gold, which should be your endodontic system of choice. The majority of cases can be treated with only a single instrument, in a simple, reliable and fast manner thanks to its forgiving reciprocating motion and dedicated gold heat-treatment.

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Notes

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		EC REP	CE
Files & gutta-percha	**Maillefer Instruments Holding Sàrl** Chemin du Verger 3, CH-1338 Ballaigues, Switzerland	**Dentsply DeTrey GmbH** De-Trey-Straße 1, D-78467, Konstanz, Germany	2797
Absorbent Points	**Dentsply Tulsa Dental Specialties** 608 Rolling Hills Drive, Johnson City, TN 37604, USA	**Dentsply DeTrey GmbH** De-Trey-Straße 1, D-78467, Konstanz, Germany	2797
Irrigation Needle	**Produits Dentaires SA** Rue des Bosquets 18, CH-1800, Vevey, Switzerland	**PD Dental EU** 74200 Thonon-les-Bains, France	1639
AH Plus® Bioceramic Sealer	**Maruchi** 2-208, Medical Industry Complex Bldg., 42-10, Taejanggongdan-gil, Wonju-si, Gangwon-do, KR-26311, South Korea	**KTR Europe GmbH** Mergenthaleralee 77, 65760, Eschborn, Germany	0197

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