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Analysis of the cutting and resistance of the original waveone® gold primary endodontic instrument compared to the counterfeit

Abstract

Continued technological and scientific advancement in endodontics makes it possible to develop procedures with quality, agility, reliability, greater safety and greater predictability. Among the multiple mechanized instruments, those with reciprocating kinematics and nickel titanium alloy obtained through the heating process have a more favorable impact on metallurgy, enhancing flexibility and resistance to cyclic fatigue. In fact, thanks to the ease of use of just an instrument with high cutting capacity, chosen according to the topographic characteristics and taper of the root canal, it is strongly considered. The advantages of this resource are attractive to specialist and clinical professionals, but also to counterfeiters. The purpose of this research was to analyze the cutting capacity, resistance, packaging identification, and visual characteristics of original Wave One Gold Primary endodontic instruments compared to counterfeit ones. The results show that the original Wave One Gold Primary instrument showed greater resistance and equal cutting capacity compared to the counterfeit. The original Wave One Gold Primary file fractured on the seventh use while the counterfeit fractured on the third use. The blisters have some differences in identification, however the QR Code on both packages did not produce a reading. The colored ring on the handle of the counterfeit instrument did not change the volume when subjected to sterilization processing, while the colored ring on the handle of the original instrument changed the volume when immediately subjected to the first sterilization cycle.

Keywords: endodontics, reciprocating instruments, endodontics, root canal preparation, dental instruments, cut, fracture strength.

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Introduction

Endodontics is increasingly benefiting from technological and scientific advancements, providing treatments with quality, speed, safety, and predictability. Among the arsenal of mechanized instruments, those with reciprocating kinematics and nickel-titanium alloy obtained through a heating process stand out, as they positively impact metallurgy, enhancing resistance to cyclic fatigue. Additionally, ease using a single instrument with high cutting capacity, selected according to the topographical characteristics and conicity of the root canal, is significant.

Reciprocating motion instruments aim to ensure safer progression during canal shaping, reducing the risk of locking and, consequently, torsional fractures.[1] Examples include WaveOne® and Reciproc®, both made from M-Wire alloy, which allows more conservative access and improved clinical outcomes. These instruments exhibit high resistance to torsion, flexibility, and shape memory effect.[2]

In the specialty, advancements in access, shaping, and cleaning of root canals are constantly progressing to reduce microorganisms, remove pulp remnants, and create cleaner, smoother root canal walls before obturation.[2]

To improve material quality, new systems have been developed, composed of thermally processed alloys, allowing for considerable evolution of resources that operate under reciprocating. The WaveOne® Gold system, thermally forged with a cross-sectional design, with two cutting edges at 85 degrees and kinematics starting at 170º of a rotational angle, counterclockwise (cutting angle) and a relief angle of 50º clockwise, completing a full rotation every three cycles, thus enabling a safer technique.[3]

Currently, there has been a significant increase in counterfeit products across all areas, and healthcare is no exception. In endodontics, there is a notable rise in the acquisition of endodontic instruments with unknown provenance. Instruments such as original Reciproc Blue and Wave One Gold have a market price in Brazil of approximately $17 USD per unit, while counterfeit versions average around $4 USD.

The price of an advertised item can strongly indicate its legitimacy, considering that large companies and brands is to invest in research, development, training, and quality raw material, which reflect in the final price. Conversely, significant discounts should be approached with caution.

Ertas et al.[4] confirmed recent years, advancements in counterfeiting methods, counterfeit products entered the dental market. Its compared the cyclic fatigue resistance of original and counterfeit rotary root canal instruments. The cyclic fatigue of original and counterfeit ProTaper F2 instruments was tested (n=20) in steel canals with a radius of 3 mm and a curvature angle of 60°. The original instruments exhibited better cyclic fatigue resistance than the counterfeit ones ($p < 0.001$). The average NCF was 483 ± 84 for the original files and 186 ± 86 for the counterfeit files. They concluded that the cyclic fatigue resistance of counterfeit instruments was very low. As a result, clinicians should be cautious about purchasing counterfeit products.

Proffitt[5] confirms that the price of an item can strongly indicate its legitimacy, emphasizing that significant discounts should be treated with caution. When considering the acquisition of dental products from an online supplier, it is crucial to conduct proper verifications regarding the legitimacy and provenance of the items. Trusted suppliers provide serial numbers and can be traced. Therefore, it is highly recommended to contact the manufacturer before completing the purchase to confirm the authenticity of the offer and whether they actually sell through the chosen channel.

The Medicines and Healthcare products Regulatory Agency (MHRA)[6] addressing an increasing number of counterfeit and non-compliant dental devices and instruments to dental practices in the UK. This article examines extent problem, the dangers posed by the use of counterfeit and non-compliant products, discusses initiatives the issue, and how dental teams can identify these products and mitigate associated risks.

However, the use of counterfeit instruments can not only interfere with treatment success but also endanger patient health[7].

Rodrigues et al.[8] reported the main differences observed direct visual inspection between original and counterfeit Reciproc instruments include assessment of the instruments' bending resistance, cyclic fatigue, surface finish, Vickers microhardness, and chemical composition. The visual aspects of original R25 instruments (VDW, Munich, Germany) counterfeit and original, supposedly dimensions similar to the Reciproc R25 files acquired from the website www.mercadolivre.com.br, evaluated under direct observation, stereomicroscopy, and scanning electron microscopy. The flexibility of the original and counterfeit Reciproc R25 was determined through bending tests of 450 according to ISO 3630-1 specifications. The instruments were also subjected to cyclic fatigue resistance, measuring fracture time in an artificial stainless steel canal with 60° angle and curvature radius of 5mm. The fracture surfaces of fragments were examined scanning electron microscopy. The roughness of the instruments was quantified using a profilometer, and microhardness tests were conducted using a Vickers hardness tester.

Although the packaging of the original and counterfeit instruments was similar, several differences were noted, such as ISO color coding, measurement, plugs, and morphological characteristics. The original Reciproc instruments exhibited greater cyclic fatigue lifes and bending resistance than the counterfeit Reciproc instruments (p-value < 0.05), as well as lower microhardness and roughness (p-value < 0.05). EDX results revealed differences in the chemical composition of the instruments (p-value <0.05), indicate that the instruments were manufactured from different raw materials. The authors concluded that the original Reciproc files outperformed the counterfeit instruments in all tests. Therefore, it is crucial to develop strategies to identify these counterfeit instruments to prevent inadvertent use.

Carvalho et al.[2] investigated effectiveness of XP-Endo Finisher (XPF) compared XP-Endo Shaper (XPS) or Reciproc Blue (RB) in reducing bacterial load during chemical-mechanical preparation with 0.9% sodium chloride or 2.5% sodium hypochlorite solutions 80 mandibular incisors a single oval root canal contaminated with Enterococcus faecalis. The teeth were randomly assigned to 8 experimental groups (n = 10) according to surgical-chemical preparation as follows: G1: XPS, G2: XPS + XPF, G3: RB, and G4: RB + XPF. The reduction of bacterial load was evaluated by counting colony-forming units before (S1) and after (S2) canal preparation. Cultivable bacteria were present all S1 samples. All instrumentation techniques were effective reducing bacterial load, regardless of the irrigation solution. With sodium chloride, Reciproc Blue was more effective than XP-Endo Shaper. With sodium hypochlorite, Reciproc Blue and XPS showed similar efficacy. The XP-Endo Finisher enhanced bacterial reduction for both tested systems. The use of sodium hypochlorite improved canal preparation, regardless of the instrumentation technique used. The concluded that XPS and RB files are effective in reducing bacterial levels in oval-shaped root canals. The use of XPF as an irrigation solution agitation method improved the cleaning efficiency of both tested file systems. Mechanical preparation with saline reduced cultivable bacteria in root canal, but antimicrobial substances such as sodium hypochlorite should be used for better disinfection of root canal.

Van der Vyver et al.[3] evaluated effect of root canal shaping using instruments nickel-titanium, M-Wire, and gold wire with different preparation techniques on 135 mesiobuccal canals of extracted human maxillary molars. The specimens were randomly divided into 3 equal groups (n=45) with K-files (KF) (Dentsply Sirona, Ballaigues, Switzerland), One G files (OG) (Micro-Mega, Besançon, France), and ProGlider files (PG) (Dentsply Sirona). Specimens from each group were further divided equally into 3 subgroups for instrumentation with ProTaper Next (PTN, Dentsply Sirona), One Shape (OS, Micro-Mega), and WaveOne Gold (WOG, Dentsply Sirona) (n=15). Micro-computed tomographic images were used to scan the teeth before instrumentation and after shaping, difference the centering ratio and canal transport values at the apical, middle, and coronal levels, as well as the overall changes in canal volume.

The centering ratios for all groups were statistically similar all levels. Apical transport was significantly high for K/OS and K/PTN. Medium root canal transport was significantly high for K/PTN, K/OS, and OG/OS. Coronal canal transport was significantly high for K/PTN and K/OS. The change in canal volume was observed with all PTN groups, while the least change was noted with PG/WOG. The WaveOne Gold file, made with gold wire and combined with ProGlider, showed better root canal shaping ability, and remove less dentin from the canal walls. The nickel-titanium files One Shape and M-Wire (PTN), when used in combination with KF, transported more canals. The PTN removed the most dentin the canal walls, regardless of the GPP technique used. The thermally forged WaveOne® Gold system features a cross-sectional design with two cutting edges at 85 degrees and kinematics starting at 170º of a rotational angle, counterclockwise (cutting angle) and a relief angle of 50º clockwise, completing a full rotation every three cycles, thus enabling a safer technique.

Tavanafar et al.[9] compared the shaping capacity 3 Ni-Ti motor-driven files in severely curved simulated resin canal blocks prepared an apical size of 25 using the systems (n=16 per group): ProTaper Universal (PTU), ProTaper NEXT (PTN), and WaveOne Primary (WO), all from Dentsply Maillefer, Ballaigues, Switzerland. Composite images were created from the overlay of pre- and post-instrumentation images. The amount of resin removed by each system was measured using a digital model and image analysis software. The shaping capacity of each system was compared using different parameters: total resin removal, centering ability, canal transport in the apical, middle, and coronal thirds of the canal. Preparation times were also recorded.

Canals prepared with PTN were better centered in the apical part than those prepared with WO and PTU. WO removed significantly more resin from external aspect at the maximum curvature point. WO

and PTU caused similar canal transport at 7 out of 11 measurement points. At measurement points 3, 4, and 5, WO caused more canal straightening than PTU. Instrumentation with PTU required more time than with other two instruments. No preparation errors or instrument fractures occurred. The authors concluded that in the apical third of the canals, PTN achieved the best results concerning canal transport.

Kim et al.[10] compared the shaping ability of ProTaper GOLD, WaveOne GOLD, and the newly developed TruNatomy in 60 simulated S-shaped resin canal blocks, which were stained red and photographed. The blocks were randomly divided into 3 groups: ProTaper GOLD (n = 20), WaveOne GOLD (n = 20), and TruNatomy (n = 20). The simulated canals were instrumented according to the NiTi file systems and re-photographed. Pre- and post-preparation images were overlapped, and the amount of resin removed from the mesial and distal sides of the canal was measured up to 9 mm from the apical terminus, in 1 mm increments. The preparation time was also calculated. TruNatomy showed a significant deviation between the mesial and distal sides of the canal only in the coronal area at 6, 7, 8, and 9 mm levels ($p<0.05$). When comparing canal transport across the 3 groups at 9 different levels, TruNatomy exhibited significantly less canal transport than the other groups at 3 and 5 mm levels ($p<0.05$), while ProTaper GOLD showed the greatest transport in the apical curve at 2 and 3 mm levels ($p<0.05$). TruNatomy removed less resin than the other groups in all sections ($p<0.05$), while ProTaper GOLD removed slightly more resin than WaveOne GOLD, although this difference was not significant ($p=0.043$). Shaping time was the small for TruNatomy, followed by WaveOne GOLD and ProTaper GOLD ($p<0.05$). The concluded that TruNatomy maintained the original curvature of the apical canal in S-shaped curved canals better than ProTaper GOLD and WaveOne GOLD.

Shi et al.[11] compared the performance of ProTaper Gold (PTG) multiple-file system and WaveOne Gold (WOG) single-file system in simulated S-shaped root canals. Forty S-shaped canals (n = 20 canals/group) in resin blocks were instrumented to an apical size of 0.25 mm using PTG and WOG Primary, respectively. The WOG group removed significantly less resin at 0, 3, 6, 7, and 9 mm from the apex. The WOG group remained more centered in canals at 0 mm from the apex. The PTG group demonstrated better centering ability and less canal transport at 4, 5, and 6 mm from the apex. In the coronal curvature section, the use of WOG Primary significantly decreased the curvature angle and increased the radius compared to PTG files. There was no significant difference between the two groups regarding the apical curvature angle and radius alteration. They concluded that the WaveOne Gold Primary file has less aggressive dentin cutting action and provides a centralized apical preparation, while the ProTaper Gold system is more advantageous shaping the coronal curvature of S-shaped canals.

Orel et al.[12] evaluated the shaping ability of endodontic systems made different nickel-titanium alloys in 36 simulated curved root canal blocks divided into 3 groups. Group 1-ProTaper Gold (PTG) (Dentsply Maillefer, Ballaigues, Switzerland) F2 25/08; Group 2-Reciproc Blue (RB), RB 25/08 (VDW, Munich, Germany); Group 3-WaveOne Gold (WOG) (Dentsply Maillefer), WOG 25/07. Each block was standardized and photographed before and after shaping the same position, with the foramen oriented to the left. Post-shaping images were overlapped with initial images. Thirteen measurement points were used for evaluation, spaced 1 mm apart from level 0 (apical foramen) to level 12 (coronal orifice). The amount of resin removed from the internal (X1) and external (X2) walls, the direction of transport (X1 − X2), and the centering ability ((X1 − X2)/Y) were measured, calculated, and analyzed comparatively. PTG demonstrated better centering ability than WOG and RB in the coronal third, while RB was more centralized in the middle third compared to WOG and PTG. In the apical third, the centering ability of WOG was higher, without statistical significance. WOG 25/07 and PTG 25/08 tended to cut more on the internal wall of the root canals, while RB 25/08 cut more on the external wall.

Sharanpriya et al.[13] analyzed in vitro the amount of debris extruded by 2 file systems at different working lengths 40 human mesiobuccal first molar canals, which equally divided into 4 groups: Reciproc (full length), Reciproc (short by 1 mm), WaveOne Gold (full length), and WaveOne Gold (short by 1 mm), using a crown-to-apex technique during canal preparation with intermittent irrigation. The extruded debris was weighed and compared; the amount of extruded debris was similar all four groups, with no significant variations. Reciproc extruded less material than WaveOne Gold. Its Concluded that the file systems do not appear to affect debris extrusion, regardless the physical properties of the files.

Jamleh et al.[14] used reciprocating rotary system WaveOne Gold for the deobturation filled with two types de materials. Results showed with approximately 89.89% and 86.98% of the filling materials in TFBC and AHP, respectively. Total Fill sealer presented lower apical loads and faster retreatment compared to AH Plus sealer.

Abboud et al.[15] avaliaram o tempo de preparo do canal usando 3 diferentes cinemáticas de movimento durante o retratamento: rotatório contínuo, reciprocante e movimento de torque reverso ótimo (OTR) em pré-molares inferiores de canal único valendo-se do sistema mecânico AF Gold (25/06) e, após isso, e as raízes obturadas. O tempo de preparo do canal durante o retratamento com limas WaveOne Gold usando movimento reciprocante foi significativamente maior do que tempo necessário com limas ProTaper Universal Retreatment usando movimento contínuo ou movimento OTR.

When considering the purchase of dental products from an online supplier, it is crucial to conduct proper checks regarding legitimacy and provenance. Items from reliable suppliers have serial numbers and can be traced. Therefore, it is highly recommended to contact the manufacturer before finalizing the purchase to confirm the authenticity of the offer and whether they actually sell through the chosen channel.[5] However, the use of counterfeit instruments can not only interfere with treatment success but also jeopardize patient health.[7] Counterfeit reciprocating instruments may have altered flexibility, increasing the risk of fractures, hindering canal decontamination, and causing other issues such as apicals deviations and perforations.[4,8]

The purpose of this investigation was to analyze the cutting ability, resistance, packaging identification, and visual characteristics of the original Wave One Gold Primary® endodontic instruments compared to the counterfeit versions.

Material and methods

Original WaveOne® Gold Primary file blisters were used (Figures 1A and B, and 2A and B), as well as counterfeit WaveOne® Gold Primary files, both measuring 25 millimeters in length (Figure 3), along with their cursors (Figure 4).

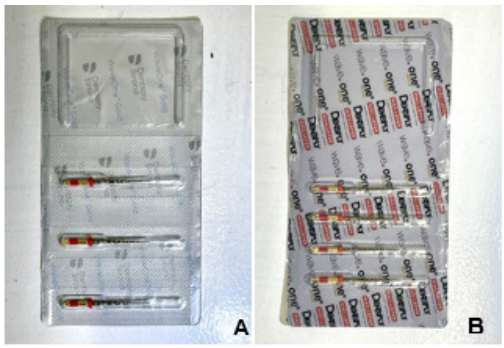

Figure 1 Front of the blisters - Original WaveOne® Gold Primary (A) (contains 3 files) and counterfeit WaveOne Gold Primary (B) (contains 4 files).

Figure 2 Back of the blisters - Original WaveOne® Gold Primary (A) and counterfeit WaveOne Gold Primary (B).

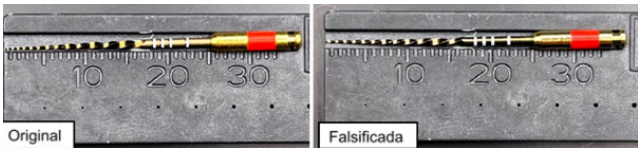

Figure 3 Length of the original WaveOne® Gold Primary files and the counterfeit WaveOne Gold Primary files.

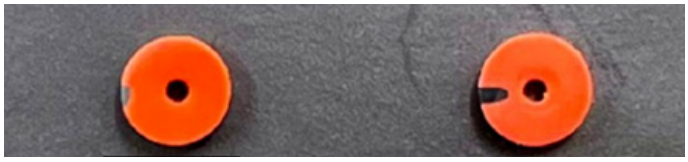

Figure 4 Cursors of the original WaveOne® Gold Primary files and the counterfeit WaveOne Gold Primary files.

It was established that both groups would use clear acrylic resin 12 blocks, all with the same morphology, 45 degrees of curvature, cross-section, taper, and length, with simulated canals divided into two groups (Figure 5), with aim of using the files until the instrument fractured.

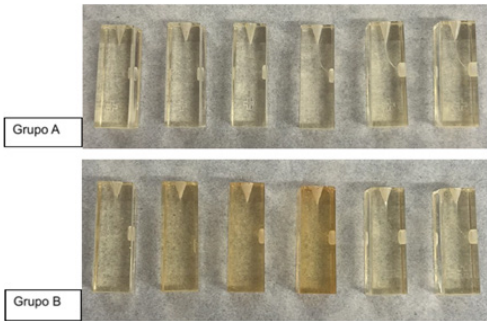

Figure 5 Blocks separated into two groups, A and B.

- Group A: prepared with original WaveOne® Gold Primary instruments.
- Group B: prepared with counterfeit WaveOne Gold Primary instruments.

The blocks were cleaned with gauze soaked in alcohol and then dried with gauze (Figure 6). The operator wore gloves during the cleaning process to prevent interference from hand oils on the weight of the blocks. Weighing was conducted on a high-precision scale, with the lid closed, while recording the measurements of each block (Figure 7). When removed from the scale, the blocks were placed in their respective plastic packaging, taking care to note the initial letter of each group and the corresponding number from 1 to 6 (Figure 8). After weighing the blocks, each file was weighed on the high-precision scale, also with the lid closed, and measurements were recorded. The weight of the original file was 0.3847g, while the counterfeit weighed 0.4004g (Figure 9).

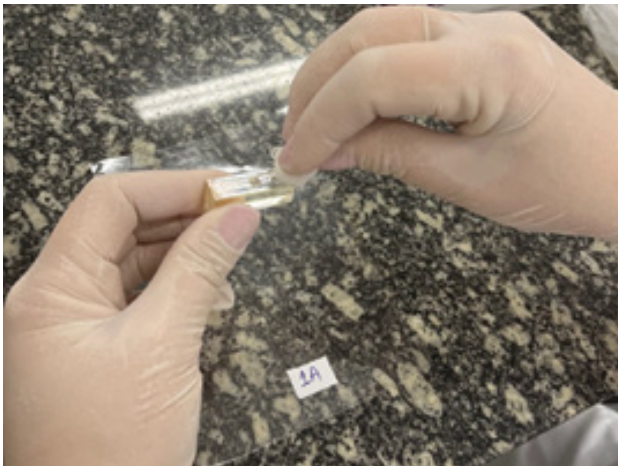

Figure 6 The blocks with simulated canals being cleaned with alcohol and gauze.

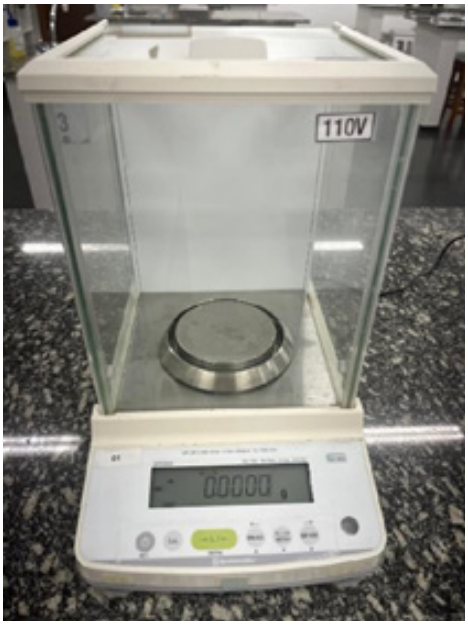

Figure 7 High-precision digital analytical balance with BEL® glass container.

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Figure 8 Identification of blocks from 01 to 06, along with the initial letter of group names A and B respectively.

Figure 9 Weighing of the files.

Initially, a K10 manual file was introduced into the block to ensure access to the canal, and it was irrigated with saline solution. The preparation was performed an electric motor (X-Smart®, Dentsply-Maillefer) set to WAVEONE GOLD program, and the blocks were properly irrigated after every three pecking movements to reduce friction on the acrylic resin (Figure 10).

Figure 10 Instrumentation of the blocks.

The instruments, after cleaning, were placed in individual packaging and underwent a moist sterilization process with cycle 2. After the first sterilization cycle, it was necessary to remove the ABS ring from the original file, as it had altered and, due to its expansion, reuse was avoided, while the counterfeit file showed no modifications.

The washing and sterilization process was repeated after each use of the file, necessitating the use of an additional block that underwent the same weighing and preparation process until the fracture of both the original and counterfeit files. A final weighing of the blocks was performed to check for mass loss after instrumentation with the original WaveOne® Gold Primary and the counterfeit WaveOne Gold Primary, ensuring that the cleaning and weighing protocol was repeated after the instrument fracture.

Subsequently, the resistance of the instruments was evaluated, determining how much each file could withstand after this process. It was repeated multiple times until fracture on the seventh use (Figure 11), thus analyzing which file group yielded better results in preparing the simulated canal blocks. After the second instrumentation, the counterfeit file exhibited significant deformation at its active tip, losing its shape (Figure 12), leading to the file's fracture during the third use.

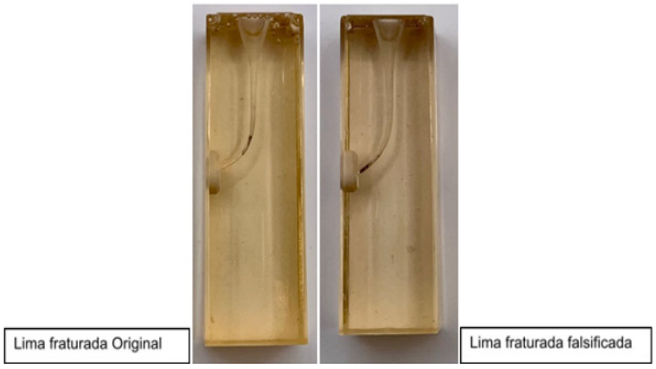

Figure 11 Blocks with fractured files inside the canal.

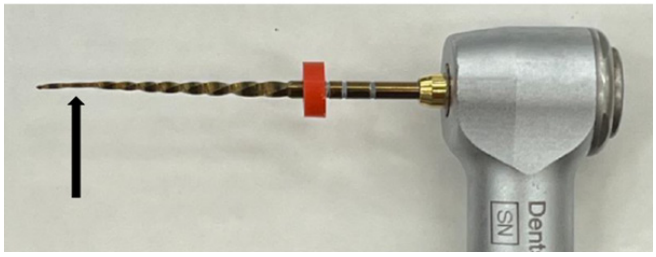

Figure 12 Counterfeit file with deformation at its active tip.

Subsequently, after resuming the flow until the moment of fracture, the instruments were subjected scanning electron microscopy (SEM) analysis at the Institute of Energetic and Nuclear Research (IPEN), University of São Paulo, to gather more information regarding the metallurgy of the instruments used and elements for discussion (Figures 13–18).

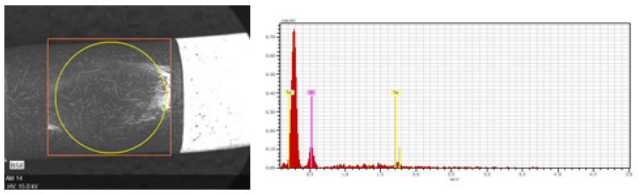

Figure 13 Image of the colored ring on the handle of the counterfeit instrument and reading of the components.

Element AN Series Net unn. C norm. C Atom. C Error

[wt.%] [wt.%] [at.%] [%]

Oxygen 8 K-series 256 10.14 79.96 97.83 2.3

Tantalum 73 M-series 67 2.54 20.04 2.17 0.1

Total: 12.68 100.00 100.00

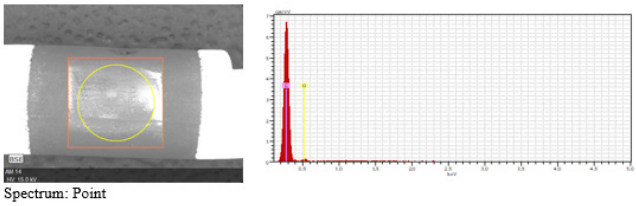

Figure 14 Image of the colored ring on the handle of the original instrument and reading of the components.

Element AN Series Net unn. C norm. C Atom. C Error

[wt.%] [wt.%] [at.%] [%]

Carbon 6 K-series 12708 92.43 92.43 94.21 10.9

Oxygen 8 K-series 259 7.57 7.57 5.79 1.7

Total: 100.00 100.00 100.00

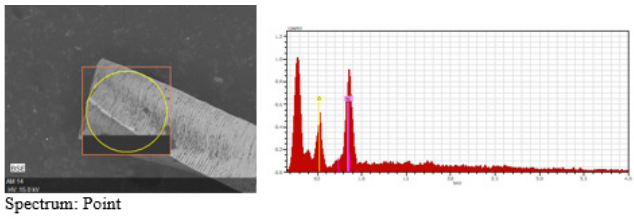

Figure 15 Area of the counterfeit instrument and reading of the components.

Element AN Series Net unn. C norm. C Atom. C Error

[wt.%] [wt.%] [at.%] [%]

Nickel 28 L-series 2127 73.09 73.09 42.54 10.5

Oxygen 8 K-series 771 26.91 26.91 57.46 4.7

Total: 100.00 100.00 100.00

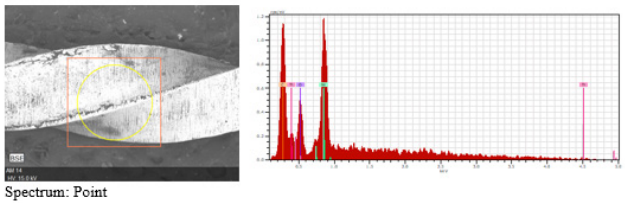

Figure 16 Area of the original instrument and composition reading.

Element AN Series Net unn. C norm. C Atom. C Error

[wt.%] [wt.%] [at.%] [%]

Titanium 22 L-series 561 34.78 34.78 16.83 6.4

Carbon 6 K-series 2102 27.03 27.03 52.16 3.9

Nickel 28 L-series 2724 23.07 23.07 9.11 3.2

Oxygen 8 K-series 789 15.12 15.12 21.90 2.6

Total: 100.00 100.00 100.00

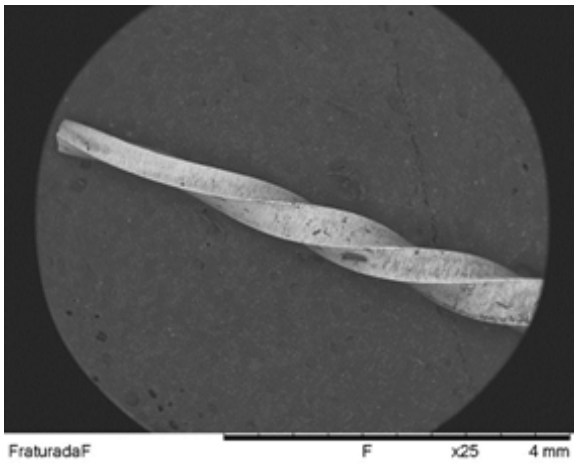

Figure 17 Image of the falsified instrument near the fracture area showing stretching.

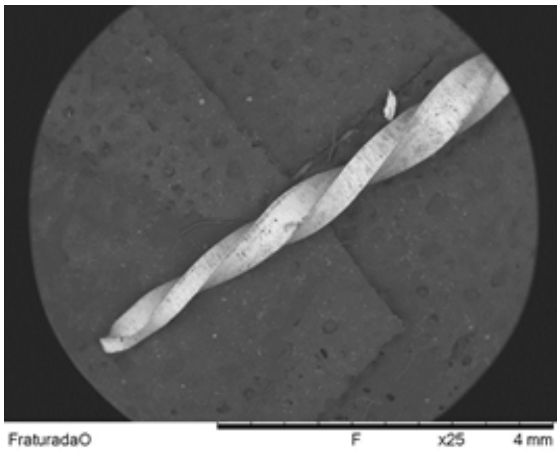

Figure 18 Image of the original instrument near the fracture area showing no stretching.

Results

The results of this investigation are presented in Tables 1, 2, 3, 4, and 5.

Table 1 Data obtained from the initial and final weights of the blocks using original and counterfeit instruments, along with the weight difference in milligrams

Group A – original file				Group B – counterfeit file			
Block	**Initial weight**	**Final weight**	**Mass loss**	**Block**	**Initial weight**	**Final weight**	**Mass loss**
A1	3.4281	3.4206	0.0075	B1	3.4994	3.4923	0.0071
A2	3.423	3.4167	0.0063	B2	3.4482	3.4421	0.0061
A3	3.4817	3.4759	0.0058	B3	3.4703	Fracture moment	
A4	3.4291	3.4238	0.0053	B4			
A5	3.5078	3.503	0.0048	B5			
A6	3.4232	3.4185	0.0047	B6			
A7	3.4085	Fracture moment					

Table 2 Statistical analysis of the difference between the mean initial weight of the blocks using the original file before fracture versus the mean initial weight of the blocks using the counterfeit file before fracture

Blocks	Average initial weight of the blocks	Average initial weight of the blocks
	original file	34,726
	"t" de Student = -1,2495 Pvalor = 0,1234	
Mean (X)	34,431	falsified file

Table 3 Statistical analysis of the difference between the average final weight of the blocks using the original file before fracture versus the average final weight of the blocks using the falsified file before fracture

Blocks	Average final weight of the blocks using the original file	Average final weight of the blocks using the counterfeit file
Mean (X)	34,431	34,672
	"t" de Student = -0,8037	Pvalor=0,2261

Table 4 Statistical analysis of the difference between the average mass loss of the blocks using the original file before fracture versus the average mass loss of the blocks using the falsified file before fracture

Blocks	Average mass loss of the blocks using the original file	Average mass loss of the blocks using the falsified file
Mean (X)	0,0057	0,0066
"t" de Student = -1,0550		
Pvalor= 0,1660		

Table 5 Statistical analysis of the difference in the number of blocks instrumented with the original file before fracture versus those instrumented with the falsified file before fracture

Blocks	Original file	Fake file
Instrumented	7	3
Not instrumented	0	4
Total	7	7
Pvalor = 0,0350		

Table 1 presents a comparison between initial and final weights blocks after instrumentation, along with the respective weight difference calculated using the equation (Mass Loss = Initial Weight - Final Weight) for both the original and counterfeit WaveOne® Gold Primary instruments.

The Student's t-test was used to analyze the statistical difference between two independent samples of unequal sizes, where the score of each sample should be equal to or less than 30, with a significance level of 5%.

The results in Tables 2, 3 and 4 show in all cases, without statistical significance at the 5% level, that is, the average weight of the blocks using the original and falsified files, as well as the average mass loss were not different.

Due to the results above (Tables 2, 3, and 4), Fisher's Exact Test was used 5% level to verify the independence of the two small sample sizes, classified under two mutually exclusive criteria and arranged in a 2x2 contingency table. The variables in question are: the number of blocks instrumented with the original file before fracture versus the number of blocks instrumented with the falsified file before fracture.

The Fisher's Exact Test in Table 5 shows a significant difference between the number of blocks instrumented by the original file before fracture and the counterfeit file before fracture. This allows us to conclude that, at a 5% significance level, the counterfeit files have inferior quality compared to the original files, resulting in greater resistance of the original files.

Discussion

Endodontics is increasingly benefiting from technological and scientific advancements, enabling treatments that are high-quality, quick, safe, and predictable. Among the array of mechanized instruments, those featuring reciprocating kinematics and nickel-titanium alloy, produced through a heating process that positively impacts metallurgy, stand out flexibility and resistance to cyclic fatigue. Additionally, ease using a single instrument with high cutting capacity, selected based on the topographic characteristics and taper of the root canal, is significant.

In this regard, Yared[1] employs a single Ni-Ti rotary instrument canal preparation alongside a manual file size 08, completing the canal preparation with an F2 ProTaper instrument. This ensures a safer progression during canal preparation, reducing the risk of locking and consequently, torsional fractures. Moreover, the benefits of this technique include reduced number of files, low cost, decreased file fatigue, and the elimination of potential cross-contamination due to the use of single files.

Regarding the identification of packaging, it can be noted that the original blisters provide detailed information, such as importer data, ANVISA registration, and details about the file, whereas the counterfeit blister presents fewer details. Both have a QR code; however, scanning the counterfeit did not yield any information, and it was also impossible to scan the QR code on the original packaging. This raises a question to Dentsply about the functionality of this verification method.

In reality, feedback was obtained from the manufacturer indicating that the code on the blister is an internal verification code similar to a barcode, called Datamatrix, and therefore scanning it is not possible. Regarding the inquiry about ways to verify an original product, it is expected that possible methods will emerge to provide students and professionals with assurance that they are acquiring reliable materials.

Proffitt[5] confirms the importance of the legitimacy of products sold, as it is strongly recommended due to their authenticity. Major companies and brands invest in research, development, training, and quality raw materials, which reflects final price with significant discounts. For instance, when purchasing dental products from online suppliers, it is crucial to conduct inspections regarding legitimacy and provenance. Safe products have serial numbers and can be traced.

It is advisable to communicate with the producer before obtaining a product to verify the authenticity of the offer and whether they are genuinely selling it. According to the Medicines and Healthcare Products Regulatory Agency (MHRA) (2015/2016),[6] there is increasing number of counterfeit and non-compliant dental devices and instruments sold to dental practices in the UK. This research examines the extent of the problem, the dangers posed the use of counterfeit and non-compliant products, and discusses initiatives to address the issue, as well as how dental teams can identify these products and mitigate associated risks.

Regarding the visual characteristics of the original Wave One Gold Primary® endodontic instruments compared to counterfeit versions, both have the same dimensions- 25mm in length and 2mm in cursor size—but the most noticeable difference is in the coloration of the files. The original file features a more vibrant gold color and a cursor with a more circular marker on its edge, whereas the counterfeit file displays a less intense, duller color with an elliptical cursor marker.

Conversely, counterfeit files may be made with other materials that visually mimic the original but lack the rigorous quality control that legitimate manufacturers enforce. This can result in differences such as flaws in heat treatment, the use of more brittle alloys, and wider manufacturing tolerances, which increase the risk of fracture or deformation during use.[7]

This issue is evident in the packaging, which contains fewer usage instructions for professionals compared to the original versions that adhere to stricter and more detailed standards.[4]

The purpose of this investigation was to analyze cutting ability and resistance of the two files, in relation to the number of uses and the resistance of both files until fracture.

In terms of analyzing cutting ability, Table 1 presents a comparison between initial and final weights endodontic files after instrumenting each simulated block and the respective weight difference calculated using the equation (Initial Weight - Final Weight = Mass Loss) for the files used in this study, including the original WaveOne® Gold Primary and the counterfeit version.

According to Table 1, there was a loss of cutting ability of the instrument based on the number of uses for both tested files, with no statistical significance between the average initial weights of blocks prepared with the original file compared to those prepared with the counterfeit file (Table 2). This lack of significance was also observed in the average final weights of the blocks with the original file compared to the counterfeit file (Table 3). The same was true for the mass loss of the blocks with both files, showing no statistical significance. This indicates that the cutting ability according to the use of both versions is equivalent. However, the original file fractured after the seventh use, while the counterfeit file fractured after the third use, demonstrating that the latter is less resistant compared to the original file (Table 5).

The data presented show that the original WaveOne® Gold Primary system was tested in six complete instrumentation cycles before fracturing in the seventh cycle, indicating significantly greater durability compared to the counterfeit version, which fractured after the third use, making it less resistant and durable when subjected to instrumentation cycles.

Similar to the WaveOne® and Reciproc® files, both made from M-Wire alloy, which allows for more conservative access and quality clinical outcomes, these instruments exhibit high resistance to torsion, flexibility, and a memory effect. In the specialty, advancements in access, shaping, and cleaning of root canals are continually progressing to combat the reduction of microorganisms and the removal of pulp remnants, enabling cleaner and smoother canal walls before obturation.[2]

To enhance material quality, new systems have been developed using thermally processed alloys, allowing for considerable evolution in resources that operate under reciprocating motion. Currently, there is a significant increase in counterfeit products across all sectors, including healthcare. In endodontics, the acquisition of endodontic instruments with unknown provenance has become notably significant. For instance, original instruments like Reciproc Blue and Wave One Gold have a market price of approximately 17 USD each in Brazil, while counterfeit versions average around 4 USD.

Additionally, it was observed during the second use of the counterfeit file that the active tip of the file underwent deformation

(Figure 12), suggesting a clear difference in quality between this counterfeit instrument and the original file after just two uses.

Clearly, the fracture resistance and durability of counterfeit materials can be significantly lower, which poses considerable risks in clinical procedures.[7] The original WaveOne® Gold Primary endodontic files are made from high-quality NiTi alloy, providing enhanced resistance, flexibility, and durability, consisting of approximately 56% nickel and 44% titanium.[16,17] Moreover, the GOLD technology ensures greater flexibility, as the file is manufactured from NiTi Gold alloy, with a heat treatment process exclusive to Dentsply. Furthermore, the WAVEONE® GOLD Primary file is 50% more resistant to cyclic fatigue than the WAVEONE® Primary (DENTSPLY SIRONA).[18,19] In this regard, according to Ertas et al.,[4] the M-Wire alloy is thermally processed to offer resistance to torsion and cyclic fatigue, which, according Van der Vyver et al.,[3] allows for safer techniques when using files made NiTi M-Wire and gold wire in various preparation techniques in the mesio-buccal canals of extracted human molars. WaveOne® Gold system features a thermally forged design with a parallelogram cross-section with two cutting edges at 850 degrees and kinematics starting at 170 degrees of counterclockwise rotation (cutting angle) and a 50-degree relief angle in the clockwise direction, completing one full rotation on its axis every three cycles.

Another advantage of WaveOne® Primary Gold, according to Tavanafar et al.,[9] is that this file significantly removes more resin from the external aspect at the maximum curvature point when comparing the shaping capabilities of three motor-driven Ni-Ti files in severely curved resin canal blocks prepared an apical size 25.

In turn, Kim et al.,[10] when comparing the shaping capabilities of ProTaper GOLD, WaveOne GOLD, and newly developed TruNatomy in 60 resin simulated canal blocks shaped like an S, found that the TruNatomy file removed less resin, while ProTaper GOLD removed slightly more resin than WaveOne GOLD, without statistical significance. The shaping time was low for TruNatomy, followed by WaveOne GOLD and ProTaper GOLD.

When preparation of root canal systems is performed with single WaveOne Gold (WOG) Primary files in 40 simulated S-shaped root canals, according research by Shi et al.,[11] that represents one of the most challenging root canal morphologies compared the performance ProTaper Gold (PTG) multiple file system in resin blocks. None files fractured during instrumentation. The WOG Primary group remained more centralized canals at 0 mm from the apex. In the coronal curvature portion, WOG Primary file significantly reduced the curvature angle and increased the radius compared to PTG files. The WaveOne Gold Primary file has less aggressive dentin cutting design and achieves more centralized apical preparation.

On other hand, preparation of canals using rotary systems can result in postoperative pain. Sivas Yilmaz et al. investigated postoperative pain intensity and incidence after using different nickel-titanium (NiTi) file systems 150 patients treated by two experienced endodontists following a standardized protocol. The file systems used were ProTaper Next, Reciproc Blue, and WaveOne Gold in teeth undergoing single-session root canal treatment. Data were collected on pain incidence and intensity at 6, 12, 18, 24, 48, and 72 hours postoperatively. No statistical significance was found several the groups regarding postoperative pain intensity, with similar outcomes observed for both reciprocating and continuous rotary systems.

Similarly, Bhojwani et al.[20] clinically compared incidence of postoperative pain after endodontic treatment of 32 posterior teeth with irreversible pulpitis using WaveOne Gold and TruNatomy file systems in patients selected to have a similar diagnosis before treatment. They aimed to understand whether postoperative pain is dependent the file system used in single-session treatments. Using a visual analog scale, classified postoperative pain intensity as: no pain, mild pain, moderate pain, and severe pain after 24 hours, 72 hours, and 7 days. The occurrence of postoperative pain was lower WaveOne Gold group after 24 and 72 hours compared to TruNatomy group, with no postoperative pain detected in either group after 7 days.

Regarding shaping capability, Orel et al.[12] evaluated capacity in three endodontic systems from different nickel-titanium alloys in 36 simulated curved root canal blocks divided into three groups: Group 1 - ProTaper Gold (PTG), Group 2 - Reciproc Blue (RB), and Group 3 - WaveOne Gold (WOG). The amount of resin removed from the internal walls (X1) and external walls (X2), direction of transport (X1−X2), and centralization capacity ((X1−X2)/Y) were measured, calculated, and analyzed comparatively. Statistical differences were observed in the shaping capability of the systems the middle and coronal thirds. In the apical third, the centralization capacity of WaveOne Gold (WOG) was greater, although without statistical significance, showing tendency to cut more on the internal wall of root canals.

Concerning of debris removal, Sharanpriya et al.[13] analyzed the amount of debris produced two systems in 40 extracted human mesio-buccal canals. They examined four groups: Reciproc (full length), Reciproc (shortened by 1 millimeter), WaveOne Gold (full length), and WaveOne Gold (shortened by 1 millimeter), using a crown-to-apex technique with intermittent irrigation. Dbris was weighed and compared, showing similar weights across all four groups without significant differences. However, less debris was produced with Reciproc compared to WaveOne Gold, indicating that the file systems did not significantly affect debris expulsion.

As to endodontic retreatment, Jamleh et al.[14] investigated canals obturated with gutta-percha and bioceramic sealers AH Plus (AHP) or TotalFill (TFBC). The reciprocating rotary system WaveOne Gold was able to remove 89.89% of the filling materials in TFBC and 86.98% in AHP. TotalFill cement showed lower apical loads and faster retreatment compared to AH Plus.

In relation the time required canal preparation using three different motion kinematics during retreatment, Abboud et al.[15] investigated continuous rotary motion with the universal ProTaper retreatment system (G1), reciprocating motion with WaveOne Gold system (G2), and reverse torque (OTR) using Universal ProTaper retreatment system (G3) in 45 single-rooted lower premolars. Canals were prepared with the AF Gold mechanical system (25/06) and obturated. Retreatment time was measured in seconds adding time to reach apex (T1) and time to achieve adequate cleaning (T2). The time required during retreatment with WaveOne Gold files using reciprocating motion was significantly greater than the time needed with ProTaper Universal Retreatment files using continuous motion or OTR motion.

Furthermore, the use of counterfeit instruments poses serious legal and ethical implications for healthcare professionals. By opting for inferior quality products, professionals compromise patient safety, which can lead to lawsuits and investigations by the Federal Council of Dentistry (CFO). The use of counterfeit products is illegal, violating intellectual property laws and safety standards. In Brazil, the National Health Surveillance Agency (ANVISA) prohibits the use of dental instruments purchased from uncertified sources, particularly those acquired from unregulated foreign websites.[21]

While the Penal Code and the Industrial Property Law focus more on the manufacturing and marketing of counterfeit products, buyers of these products can also be held civilly liable, especially if they are aware of the counterfeiting and still choose to use or acquire quantities that suggest an intention to resell.

According to the Code of Ethical Conduct established by the Regional Council of Dentistry of São Paulo, in Chapter V, Section I - on relationship with the patient, Art. 11, the following constitutes an ethical violation: IX - Adopting new techniques or materials that do not have effective scientific proof. This provision underscores the responsibility of dental professionals to ensure that the materials and techniques used are scientifically validated, aiming for safety and efficacy in patient treatment.[21]

It is known that the fracture of a file during instrumentation can interrupt the procedure and cause damage to the root canal, as well as increase the complexity of subsequent treatment. When a file breaks, it can become lodged in the canal, making removal difficult and increasing the risk of infections or complications. Therefore, the strength and durability of instruments are essential for safe and effective procedures for patients undergoing endodontic treatment. Counterfeit reciprocating instruments may have altered flexibility, leading to a greater risk of fractures, obstacles in canal decontamination, and other issues such as apical deviations and perforations. As noted by Rodrigues et al.,[8] it is crucial to develop strategies for recognizing counterfeit files to prevent their inadvertent use.

Conclusion

Based on the results obtained in this experiment under the conditions of this study, it seems valid to conclude that:

a) The original Wave One Gold Primary® instrument demonstrated greater resistance and equal cutting capacity compared to the counterfeit version.

b) The original Wave One Gold Primary® file fractured on the seventh use, while the counterfeit fractured on the third use.

c) The colored ring on the handle of the counterfeit instrument did not change in volume when subjected to the sterilization process, whereas the colored ring on the handle of the original instrument changed in volume after the first sterilization cycle.

d) The blisters showed some differences in identification; however, the QR code on both packaging did not yield any readable results.

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None.

Conflicts of interests

The authors declare that there are no conflicts of interest.

References

1. Yared G. Canal preparation using only one Ni-Ti rotary instrument: preliminary observations. *Int Endod J*. 2008;41(4):339–344.
2. Carvalho MC, Zuolo ML, Vasconcelos A, et al. Effectiveness of XP-endo finisher in the reduction of bacterial load in oval-shaped root canals. *Braz Oral Res.* 2019;33(1):e021.
3. Van der Vyver PJ, Paleker F, Vorster M, et al. 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. *J Endod.* 2019;45(1):62–67.
4. Ertas H, Capar ID, Arslan H, et al. Comparison of cyclic fatigue resistance of original and counterfeit rotary instruments. *Biomed Eng Online.* 2014;31;13:67.
5. Proffitt E. Counterfeit and non-compliant dental devices: the dangers and how to mitigate them. *Dent Update.* 2016;43(4):307–310, 312.
6. Medicines and healthcare products regulatory agency annual report and accounts. 2015/16.
7. Vida e Saúde. Falsificação de limas endodônticas coloca o setor odontológico em alerta. 2018.
8. Rodrigues CS, Vieira VTL, Antunes HS, et al. Mechanical characteristics of counterfeit reciproc instruments: a call for attention. *Int Endod J.* 2018;51(5):556–563.
9. Tavanafar S, Gilani PV, Saleh AM, et al. Shaping ability of protaper Universal, protaper next and WaveOne primary in severely curved resin blocks. *J Contemp Dent Pract.* 2019;20(3):363–369.
10. Kim H, Jeon SJ, Seo MS. Comparison of the canal transportation of protaper gold, WaveOne gold, and trunatomy in simulated double-curved canals. *BMC Oral Health.* 2021;21(1):533.
11. Shi L, Zhou J, Wan J, et al. Shaping ability of protaper gold and WaveOne gold nickel-titanium rotary instruments in simulated S-shaped root canals. *J Dent Sci.* 2022;17(1):430–437.
12. Orel L, Velea-Barta OA, Sinescu C, et al. Comparative assessment of the shaping ability of reciproc blue, WaveOne gold, and protaper gold in simulated root canals. *Materials (Basel).* 2022;15(9):3028.
13. Sharanpriya, Pushpa S, Karuna, et al. Asessment of various reciprocating system in the extrusion of debris from curved root canals: an original study. *J Pharm Bioallied Sci.* 2023;15(Suppl 1):S146–S150.
14. Jamleh A, Nassar M, Alfadley A, et al. Retreatment of oval-shaped root canals filled with totalfill bioceramic or AH plus sealer. *Sci Rep.* 2023;13(1):9357.
15. Abboud T, Al-Tayyan M, Achour H, et al. Time required for root canal retreatment using continuous rotation, reciprocation, and optimum torque reverse motions: an in-vitro study. *Cureus.* 2024;16(8):e67786.
16. Thompson SA. An overview of nickel-titanium alloys used in dentistry. *Int Endod J.* 2000;33(4):297–310.
17. Zanza A, Seracchiani M, Reda R, et al. Metallurgical tests in endodontics: a narrative review. *Bioengineering (Basel)*. 2022;9(1):30.
18. Dentsply Sirona. Surf the canal with confidence WaveOne gold. 2017.
19. Dentsply Sirona. Lima wave one gold. 2024.
20. Bhojwani PR, Paryani MJ, Mankar N, et al. The comparative evaluation of postoperative pain after the use of WaveOne gold and trunatomy filing systems in a tooth with irreversible pulpitis: an observational study. *Cureus.* 2022;14(10):e30707.
21. Conselho regional de odontologia de São Paulo (CROSP). Campanha de conscientização. 2024.