INITIAL®: The beginning of a new era for endodontic instrumentation?

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_Abstract

In the past three decades, numerous endodontic instruments have been developed to replace traditional steel manual instruments (pulp broaches, K- and H-files), yet sometimes these developments have not offered the clinical benefits expected. The eighties saw the appearance of more sophisticated instruments, still steel, such as the Unifile (DENTSPLY), Canal Master U (BRASSELER), Rispi Sonic and Shaper Sonic (MICRO-MEGA). The nineties and the new century saw an explosion of NiTi instruments; endodontic instrument shapes and methods multiplied to the point that it was sometimes difficult to keep up. Some developments were quickly forgotten, others were widely adopted and remain standards.

Fig. 1

Fig. 1_The INITIAL endodontic file.

The recently launched Initial (NEOLIX), while on the surface just another new instrument for enlarging canals, deserves close attention because of its innovative manufacturing process, its shape, its functionality and its compatibility with the techniques currently in use. It is an instrument that approaches endodontics differently, perhaps introducing a new era for mechanical endodontic instrumentation.

_Introduction

During endodontic treatment, after preparation of the access cavity and first shaping of the canals using a #8, 10 or 15/100 manual file, the practitioner seeks to widen the canal entrance. This amounts to preparing the coronal third, which in turn allows instruments to penetrate to the approximate level of the cemento-enamel junction. This facilitates root filling.[1,2]

Enlarging the canal entrance is performed either with conventional manual or mechanical instruments or with instruments designed for this purpose, such as the ProTaper Universal SX (DENTSPLY Maillefer) or ENDOFLARE (MICRO-MEGA), or with Gates-Glidden or other drills.[3,4] Numerous studies have shown the importance of this step prior to root-canal preparation.[5–11]

INITIAL is a novel instrument for flaring the coronal third of the canal. The instrument is original in its manufacturing process, its geometry and its motion. This universal opener is used prior to specific instruments for canal preparation (Fig. 1). It is made of NiTi and it allows continuous rotation or variable-speed reciprocating motion, acts like an enlarger to a maximum of 10 mm and can be used with a circumferential motion, owing to its blade design.

_Indications

INITIAL is intended to shape the coronal third of a canal, on average a length of 5 mm up to a maximum of 10 mm, depending on the tooth's anatomy. This preliminary preparation using INITIAL facilitates the subsequent passage of any sort of canal preparation instrument down to the apex (Fig. 2). It also allows the elimination of dentinal irregularities at the level of the access cavity and facilitates access to the canal orifice. INITIAL is not intended to reach the apical region but rather is designed to widen and flare the access.

_Characteristics

INITIAL is a Class IIa medical device according to Council Directive 93/42/EEC, with the following characteristics:

_It is an endodontic drill made of NiTi consisting of a blade mounted on a 15 mm mandrel, the active portion of which is 10 mm long.
_The active part is itself divided into two distinct areas. The first, the apical part, guides the instrument to the canal lumen and is shaped as a square K-file, 2.5 mm long with an apical diameter of 25/100 mm. The second area, the medio-coronal, with a median diameter of 7.5 mm, has a double orientation at the cutting edges of a spiral, one radial (as traditionally found on endodontic instruments) that works tangentially[12] and the other axial, working concomitantly on the canal walls directly. The combined action of these two orientations limits the screwing action and allows the canal entrance to be enlarged safely.
_The taper is 12%, as for other enlarging instrument. The inactive portion of the blade has an octagonal cross-section with a diagonal (equivalent to diameter) reduced to 0.90 mm. This increases the flexibility of the upper part of the instrument, provides better visibility, allows access to the cavity and should a file break facilitates grasping the piece with endodontic pliers.
_The chuck is 12 mm and a standard diameter of 2.35 mm allows the instrument to be used with all endodontic contra-angle handpieces (Fig. 3).
_The combination of the dual orientation of the cutting edge requires either continuous mechanised rotation or reciprocating motion. This is a characteristic of INITIAL, which can be driven by a rotary engine, either Marathon Endo-a-class or Marathon Endo-e-class (NEOLIX), but any other continuous rotation motor with electronic control of speed and torque will suffice (Fig. 4).

In order to exploit the properties of INITIAL optimally, the I-Endo dual (SATELEC ACTEON) motor is recommended because it is programmable and compatible with the characteristics of INITIAL (Fig. 5).

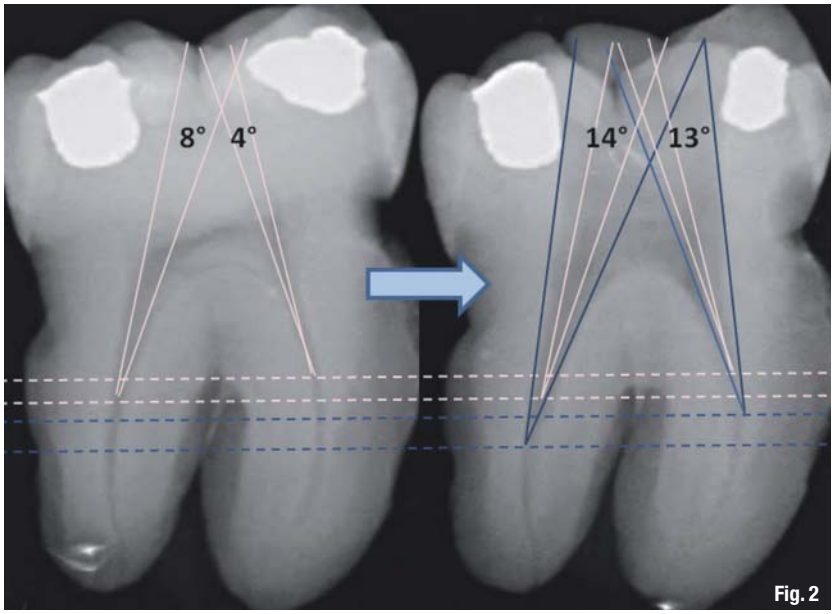

Fig. 2

Fig. 2_Radiograph before and after use of INITIAL (laboratory study): observe the angles of the canal-access passages, which increase significantly after the use of INITIAL.

For smoothing coronal canal walls, it is possible to program, if the operator so wishes, a routine of 360-degree continuous clockwise rotation followed by counter-clockwise rotation limited to 180 or 60 degrees, as helped to define extra-oral trials (Fig. 6).

Recommended speeds vary from 300 to 500 rpm according to the anatomical context. Like any endodontic instrument, INITIAL should have a rotary motion suitable for the clinical situation. It is wise to commence with a slow speed when entering a canal channel, which can be increased once the instrument has freed itself from constraints.[13]

In cases in which penetration is difficult owing to obstruction by secondary dentine (calcification) or in the presence of high curvature, a reciprocating motion can be established.[14] This entails a 360-degree rotation and a clearance movement of 180 to 60 degrees performed by the I-Endo dual engine; during this disengagement movement, tangential force diminishes in favour of the direct motion. This is therefore a period of enlargement without of the instrument progressing into the canal.

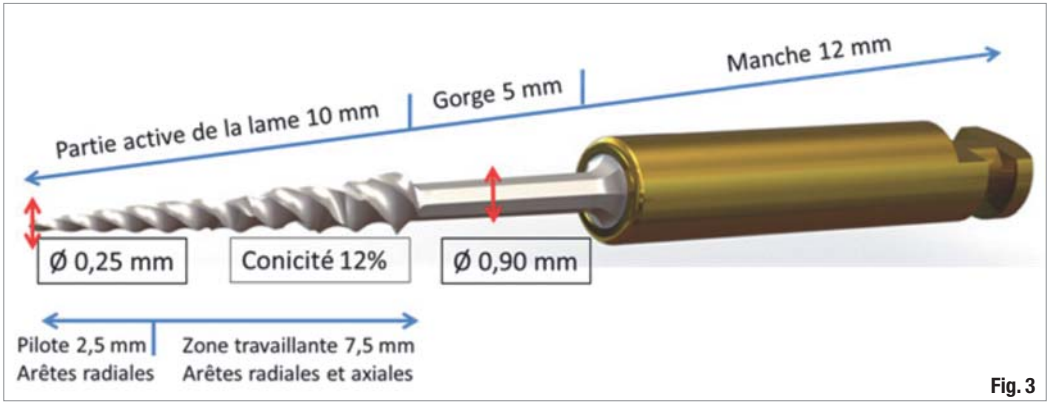

Fig. 3

Fig. 3_Dimensional characteristics of INITIAL.

Characteristics	INITIAL (Neolix)	ENDOFLARE (Micro-Mega)	ProTaper Universal SX (DENTSPLY-Maillefer)
Manufacturing process	WEDM	Micro-grinding	Micro-grinding
Surface treatment	Electro-scouring	Electro-polishing	Electro-polishing
Aspect	Matt	Shiny	Shiny
Penetration capacity (mm)	15	15	20
Active zone (mm)	10	10	14
Apical diameter (mm)	25/100	25/100	19/100
Taper (%)	12	12	Progressive, 3.5 to 8.5
Number of cutting edges	4	3	3
Cross-section active zone	Quadrangular	Triangular	Triangular
Cross-section inactive zone	Octahedral	Circular	Circular
Flutes	Concave	Concave	Reinforced by a convex bar
Cutting edges	Tangential and direct	Tangential	Tangential
Motion type	Continuous rotation or reciprocating	Continuous rotation	Continuous rotation
Speed (rpm)	300 to 500	300 to 600	300
Maximum torque (N cm)	3	3	2
Mandrel standard diameter (mm)	2.35	2.35, or InGet shaft	2.35

Table 1

Table 1_Characteristics of enodontic instruments used to prepare the coronal part ofthe canal.

_Comparative characteristics of INITIAL and two currently used enlarging instruments

The usual reason for using Gates-Glidden, Largo and other enlarging drills, and NiTi enlarging instruments (DENTSPLY Maillefer; MICRO-MEGA) is to prepare the coronal part of the canal while respecting the original anatomy.[15] Every enlarging instruments has different characteristics, as shown in Table 1.

_The place of initial in a classical endodontic protocol

1. Take an essential preoperative radiograph to assess the initial root-canal anatomy and the complexity of the canals and to estimate the working length.
2. After placing the rubber dam, open the pulp chamber of the tooth for extirpation.
3. Debride the pulp chamber with ultrasounds and irrigate with an antiseptic.
4. Locate the canal entrances with a DG 16 probe (Hu-Friedy) and evaluate the glide path of the different canals using #8, 10 or 15 K-files. These preliminary procedures allow the directions of the canals to be determined and the difficulty of the preparation to be assessed.
5. Use INITIAL mounted on an endodontic contra-angle handpiece (16:1 reduction) on a motor with programmable speed (initially 300 rpm) and torque limited to a maximum of 3 Ncm. Prepare to a depth of 5 mm, with a circumferential motion, then irrigate thoroughly; the maximum depth should not go beyond the beginning of the first curvature. A depth of 10 mm should be considered the maximum (Fig. 7a).
6. Determine the working length electronically or by preoperative intra-oral radiograph.
7. Continue mechanical preparation, using your preferred instruments. All systems using continuous rotation or reciprocating motion are compatible with INITIAL. Do not neglect irrigation.
8. INITIAL can also be used during preparation to reposition the root-canal entrances (Fig. 7b), possibly using reciprocating motion (Fig. 8).
9. Continue the preparation to the apical cemento-dentinal junction using the technology of your choice.
10. Seal and control.

Fig. 4_Marathon Endo-a-class and Endo-e-class, continuous rotation endodontic motors.

Fig. 4

_Discussion

Why focus on this new instrument? Firstly, because the machining technology is entirely innovative; secondly, for its new, variable changing profile; and, finally, for its clinical functionality, safety, comfort in use and universality that make this new approach to endodontics something not to be ignored.

Machining

Most endodontic instruments are machined by micro-grinding.[16] This manufacturing method, in use for many years, is still limited in its ability to produce complex shapes. Indeed, with the micro-grinding method, the cutting tool is the grinding wheel, which has a fixed shape, and it imposes on the object a 3-D inverse profile. Thus, the geometry of the object after micro-grinding is predetermined by the shape of the grinding wheel. This is why almost all endodontic instruments have tangential cutting edges.[12] Furthermore, wear of the micro-grinding wheel requires constant adjustment to maintain the geometrical and dimensional characteristics of the instrument.

Fig. 5

Initial is the first instrument to be machined differently. Its geometry is obtained by wire-cut electrical discharge machining (WEDM).[17] This technique was developed initially in 1943 in the former USSR by Lazarenko[18] and has been improved since then. It entails melting, vaporisation and removal of material within a complex dielectric field.[19,20] The energy required for the machining is generated by electrical discharges passing between two electrodes and creating an electric arc between the workpiece and the tool (Fig. 9).[17] The advantages of this technology are numerous. Firstly, the precision of the cut can be measured in microns;[21] secondly, machining by localised microfusion then suppresses any mechanical stress during manufacture, thus avoiding micro-defects and changes in surface properties of the metal by atomic dislocations (defects in the alignment of atoms); thirdly, the metal remains intact, as if it had not been machined; and, finally, machining parameters remain stable because the cathode wire that conducts electricity is the only piece that suffers wear. This technology can provide an almost total freedom for the production of various geometric designs because there are no constraints due to a grinding tool. In addition, compared with grinding, EDM is more environmentally friendly because it does not require cutting oil, organic solvents or harsh detergents, all of which are toxic to varying degrees.

WEDM is traditionally used in industrial sectors such as aerospace, nuclear, medical, general engineering, automotive, and machine tools to create complex shapes and articles on a small scale because the technology is difficult to implement.[22]

This process has recently been modified for the large-scale production of endodontic instruments; it involves a dual-wire electrode, consisting of the instrument being manufactured and a mobile EDM wire, yielding very high machining accuracy, step by step and without physical contact with the workpiece. With this method, the instrument shape is determined by the relative position in space of the EDM wire and the workpiece. The spatial positions of the EDM wire and that of the workpiece can potentially vary independently at any moment, thus allowing variation in the geometry of the part, which is not achievable by conventional machining techniques. Linked to a repetitive mechanism, this technology, innovative in the field of endodontics, differs from the other industrial grinding processes that are conventionally available.

Fig. 5_I-Endo dual, multifunction endodontic motor that provides a choice of continuous rotation or reciprocating motion.

Fig. 6_Reciprocating-motion sequences of INITIAL.
Fig. 7a_Illustration of access-cavity flaring.
Fig. 7b_Illustration of canal-access repositioning.

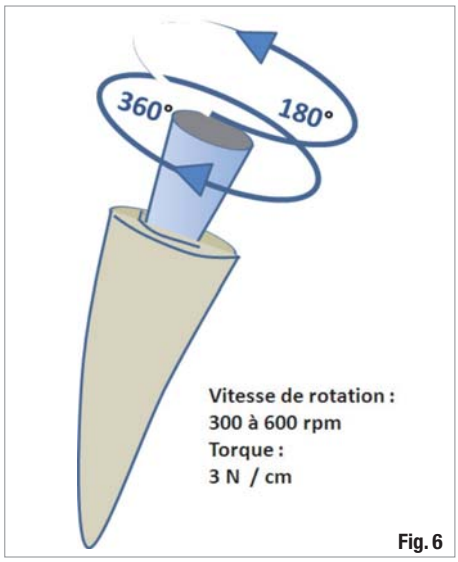

Fig. 6

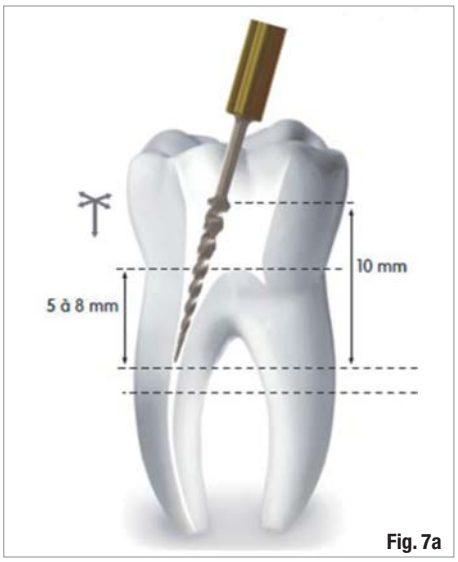

Fig. 7a

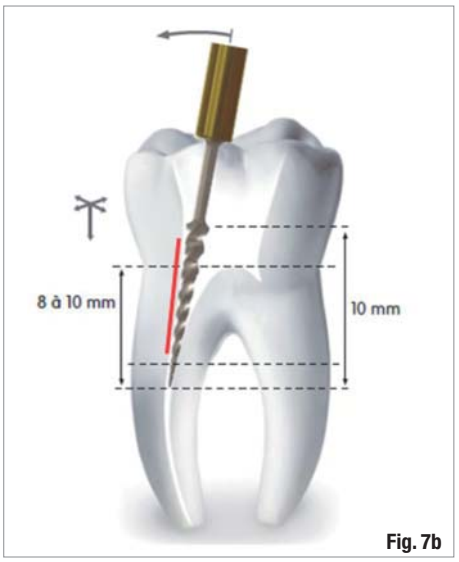

Fig. 7b

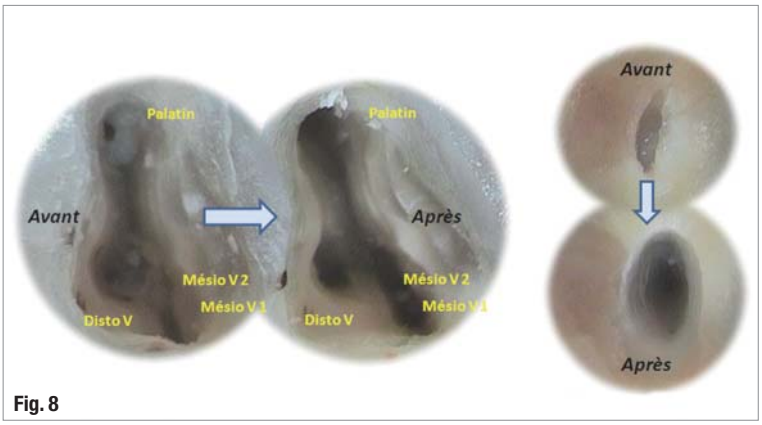

Fig. 8

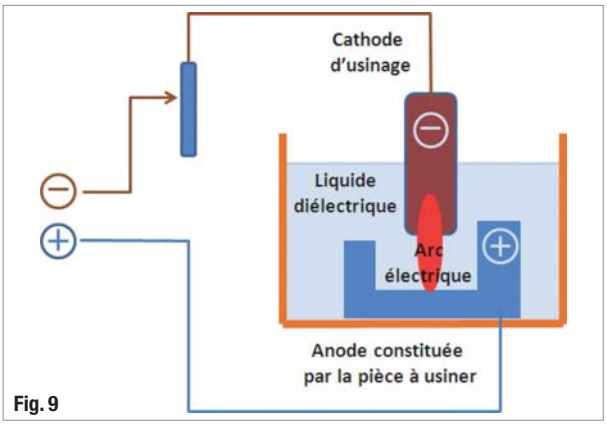

Fig. 9

Fig. 8_Intracoronal photographs of preparation before and after INITIAL showing access cavities and canal entrances in teeth 26 and 33 as an example.
Fig. 9_Principle of EDM without contact between the machining tool and the workpiece.

This process, which is applicable only to electrically conductive materials, can change the appearance of machined metal surfaces.[17] In particular, the formation of irregular layers of metal oxides, 20 to 30 µ thick, has been demonstrated (Fig. 10). This condition requires that surfaces be chemically treated following EDM to remove the oxide layers (study of multi-materials and interfaces undertaken by the Laboratoire des Multimatériaux et Interfaces, a research unit of the National Centre for Scientific Research and Université Claude Bernard Lyon 1), while deeper in the material there is an increase in hardness and increased resistance to corrosion and wear.[17] The surface of the instrument remains uneven, and it requires a specific chemical treatment to rid the instrument of these oxide layers while preserving the quality of cut. This treatment helps to strengthen the resistance of the instrument's surface and limits the risk of crack initiation.[17] In order to reduce fatigue to the base value of the material, it is necessary to remove the altered layer entirely (Fig. 11).[17] In the case of INITIAL, measurement of the torsional resistance, 3 mm from the tip in accordance with standardised ISO tests (ref. 3630-1) with a SOMFY-TAC (Metil Industrie) torsion meter, gives values comparable to those obtained for the similar NiTi orifice drills such as the ENDOFLARE (335 cN.cm for INITIAL with a standard deviation of 16.3, compared with 322 cN.cm for the ENDOFLARE with a standard deviation of 38.5). Values were almost the same when measuring at 45 degrees of flexion, 3 mm from the tip (126 cN.cm for INITIAL with a standard deviation of 8.3, compared with 134 cN.cm for the ENDOFLARE with a standard deviation of 3.2). Comparison with the SX is more difficult, given the dimensional configuration of the latter, which is more flexible than other enlarging instruments (15 cN.cm with a standard deviation of 2.5), but it has significantly less torsional strength (43 cN.cm with a standard deviation of 2.3). The higher the torque, the more resistant is the instrument, whereas the higher the bending moment, the less flexible is the instrument.

Variable profile

The shape of INITIAL is original because it develops a dual geometry. The active blade has four tangential cutting edges, a pitch of 3.6 mm in the apical portion (0 to 2 mm), 4.5 mm in the median portion (2 to 6 mm) and 6 mm in the coronal portion (6 to 10 mm). The blade

Fig. 10_The layers of metal oxides after WEDM (Laboratoire des Multimatériaux et Interfaces).

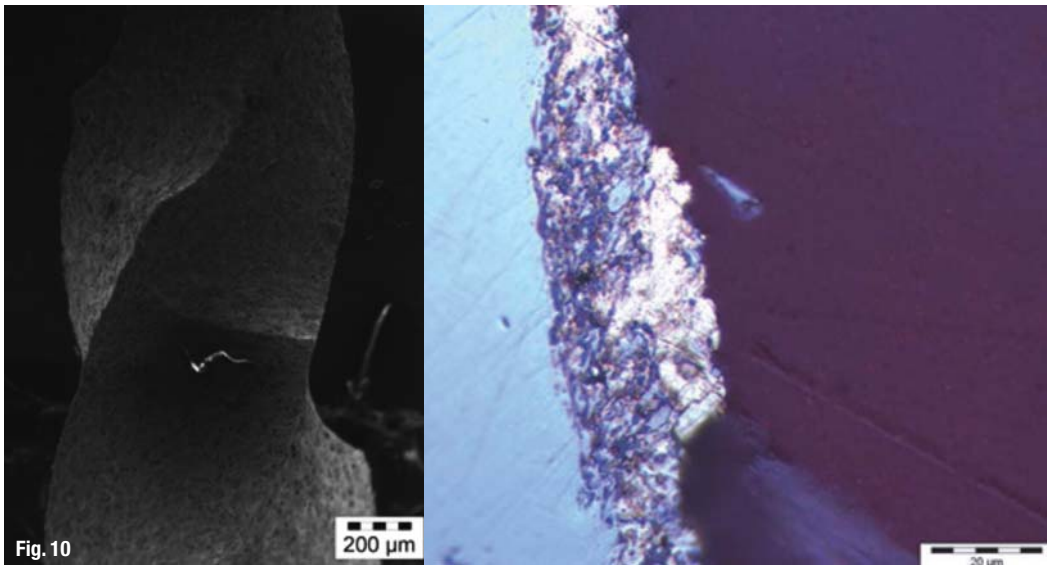

Fig. 10

also has frontal edges spaced 1.4 to 1.6 mm apart, depending on the portion but only on the 7.5 mm above the apical portion. These characteristics make INITIAL a very complex instrument with a variable changing profile along the blade's working length. The cutting edges have the ability to work tangentially like any other flaring instrument, but also frontally. This last function, in addition to removing dentine from the canal walls, completes and limits the tangential engagement of the first and allows action restricted to the coronal portion. This also explains why INITIAL behaves and acts differently depending on the working motion.

Furthermore, the inactive blade is octagonal in cross-section, instead of the usual circular cross-section. This characteristic, in itself not important, could be an advantage in case of high fracture of the instrument; in such an event, it would be sufficient to twist the enlarging instrument counter-clockwise with endodontic pliers to remove the instrument from the canal.

If the dimensional characteristics and indications for use are at first glance similar to those of other orifice drills in the market, INITIAL can in no way be compared with them and the instrument performs very differently in clinical use.

Clinical functionality and general usefulness

Continuous rotation allows the instrument to develop a dynamic action, tangential to the canal walls, and to work like a conventional enlarging instrument, that is, to advance towards the apical region while widening the canal, owing to the instrument's 12% taper. All orifice drills have this property. This is why it is recommended that periodical checks be performed for blockage of the cutting edges, frequently observed on all the enlarging instruments, especially on the first few millimetres of the instrument, which serve to guide the penetration into root canals. For this reason, the use of a motor with torque control is recommended. Beyond the first 2.5 mm, INITIAL will naturally be restrained in its progress by a direct force that is much more static and therefore opposes the screwing effect.

Using reciprocating motion with the I-Endo dual motor, particularly 360 degrees clockwise and 180 to 60 degrees counter-clockwise, potentiates the forward force and limits tangential dynamic cutting. This allows the canal enlargement to be enhanced and/or monitored without loss of direction.

These two actions, one tangential and dynamic, the other static and forward, make this instrument an all-in-one tool. Its use is indicated regardless of the technique, system or endodontic philosophy preferred by the clinician.

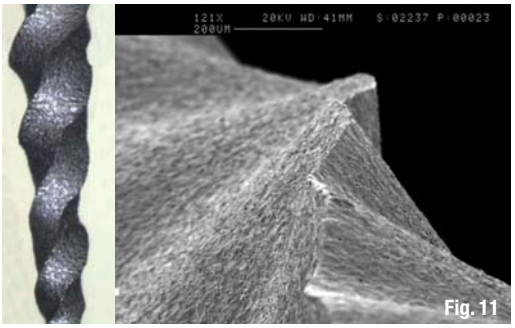

Fig. 11_Aspect of the surface after electro-scouring and electro-polishing under an optical and scanning electron microscope. *(Image courtesy of University of Rennes 1.)*

_Conclusion

INITIAL is the first root-canal instrument to be machined by WEDM. Its geometry is more complex than other orifice drills. It has cutting edges that work tangentially like other endodontic drills and other edges for surface smoothing, with less torsional stress, allowing a more anatomical enlargement of the canal entrance. These simultaneous actions complement each other to limit blockage by debris and help prevent spontaneous instrument fracture, which facilitates the subsequent preparation of access to the apical part of the canal.

It is likely that these advantages of INITIAL will be incorporated into other root-canal instruments, which will thus more easily meet the operative, mechanical and biological requirements of endodontists. In this manner, initial may introduce a new era for endodontic instrumentation._

Editorial note: A complete list of references is available from the publisher.

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