#### Title

# **ENDOPENER:** the beginning of a new era in endodontic instrumentation?

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#### Abstract

In the past three decades, numerous endodontic instruments have succeeded to traditional manual steel instruments (pulp broaches, K and H files), sometimes to the extent of not achieving the clinical benefit that should accompany these developments. The eighties saw the apprearance of more sophisticated instruments, still steel, such as Unifile, Master U, RISPI, and Sonic Shaper. The nineties and the new century saw an outburst of NiTi instrumentation; 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. Today, "ENDOPENER", "yet another" new instrument for opening canals, is being launched. It deserves close attention because of its innovative manufacturing process, its shape, its functionality and the fact that it is compatible with the techniques currently in use. It is an instrument that approaches endodontics differently, perhaps introducing a new era of mechanical endodontic instrumentation?

#### Key words

Endodontics ; canal preparation ; mechanical instrumentation.

#### Text

### Introduction

During endodontic treatment, after preparation of the access cavity and opening the canals using a manual file size 8, 10 or 15/100, the practitioner seeks to widen the canal entrance. Indeed, 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].

Opening the canal is done either with conventional manual or mechanical instrumentation or with instruments designed for this purpose, such as the Universal Protaper Sx (Maillefer®) or Endoflare® (Micro-Mega®),or other drills [3-4]. Numerous studies have shown the importance of this step prior to root canal preparation [5-11].

Today, a completely original instrument is proposed for opening the coronal third of the canal. The instrument is original in its manufacturing process, its geometry and its motion. It is a "Universal Opener" called ENDOPENER and will be a precursor to specific instruments for canal preparation (Fig. 1). It is made of NiTi (nickel titanium) and it allows continuous rotation or variable speed alternating rotation, acts like an opener for a maximum of 10 mm and can be used with a circumferencial brushing action, thanks to its blade design.

#### Indications

ENDOPENER 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 by ENDOPENER facilitates the later 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. <u>ENDOPENER is not intended to reach the apical region but rather is designed to widen and "flare"</u> the access.

## **Characteristics of ENDOPENER**

ENDOPENER is a class IIa medical device according to 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 is10 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 millimeters long with an apical diameter of 25/100 mm. The second area, the medio-coronal, median diameter 7.5 mm has, at the cutting edges of a spiral, a double orientation, one radial as traditionally found on endodontic instruments which works tangentially [12] and the other axial, working concomitantly directly on the canal walls. The combined action of these two orientations limits the screwing in effect and allows the canal to be opened safely.

The taper is 12%, as for other openers. 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, in case a file breaks, facilitates grasping the piece with endodontic pliers.

The chuck is 12 mm and a standard diameter of 2.35 mm allows the instrument to adapt to all endodontic contra-angle handpieces (Fig. 3).

The combination of the dual orientations of the cutting edge requires either continuous mechanised rotation or alternating rotation. This is a characteristic of ENDOPENER which can be driven either by a rotary engine of the type Marathon<sup>®</sup> Endo-a-class or Marathon Endo-e-class but any other continuous rotation motor with electronic control of speed and torque will suffice (Fig.4).

To exploit the properties of ENDOPENER optimally, the Endo<sup>®</sup> Dual (Satelec/Acteon) motor is recommended because it is programmable and it matches the characteristics of ENDOPENER (Fig.5). For smoothing coronal canal walls, it is possible to program, if the operator so wishes, a routine of 360° continuous clockwise rotation followed by counterclockwise rotation limited to 180° or 60° 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, ENDOPENER should have a rotary motion suitable for the clinical situation. It is wise to commence with a limited speed when entering a canal channel, which can be increased as and when the instrument has freed itself from constraints. [13]

In cases where penetration is difficult due to obliteration by secondary dentine (calcification) or in the presence of high curvature, a reciprocating motion can be established [14]. This consists of a 360° rotation and a clearance movement of 180° to 60° performed by the 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.

## Comparative characteristics of ENDOPENER and two currently used openers

The usual reason for using NiTi openers (Maillefer, Micro-Mega) is to prepare the coronal part of the canal with maximum respect for the original anatomy [15]. Nevertheless, every opener has different characteristics, as shown in the following table.

Characteristics	ENDOPENER – THOMAS	Endoflare®	Protaper Universal Sx®
	Neolix patent	Micro-Mega	Dentsply-Maillefer
Manufacturing process	Wire-cut electro-erosion	Micro grinding	Micro grinding
Surface treatment	Electo scouring	Electro polishing	Electro polishing
Aspect	Matt	Shiny	Shiny
Penetration capacity	15 mm 10 mm	15 mm	20 mm 14 mm
Apical diameter (mm)	25/100	25/100	19/100
Taper	12%	12%	Progressive 3.5 to 8.5 %
Cutting edges (no.)	4	3	3

Cross-section active zone	Quadrangular	Triangular	Triangular
Cross-section inactive zone	Octahedric	Circular	Circular
Flutes	Concave	Concave	Reinforced by a convex bar
Cutting edges	Tangential and direct	Tangential	Tangential
Movements	Continuous rotation or reciprocating	Continuous rotation	Continuous rotation
Speed	300 to 500 rpm	300 to 600 rpm	300 rpm
Maximum torque	3 N.cm	3 N.cm	2 N.cm
Mandrel	Standard diameter: 2.35 mm	Standard diameter : 2.35 mm or InGet	Standard diameter : 2.35 mm

## The place of ENDOPENER in a classical endodontic protocol

**1** - Take an essential preoperative radiograph to assess the ENDOPENER root canal anatomy, the complexity of the canals and to estimate the working length (WL).

**2** - After establishing the rubber dam, open the pulp chamber of the tooth for extirpation.

**3** - Debride the pulp chamber with Ultrasons (US) and irrigate with an antiseptic.

**4** - Locate the canal entrances with a DG 16 probe and evaluate the glide path of the different canals using K files # 8, 10 or 15. These preliminary procedures allow the directions of the canals to be determined and the difficulty of the preparation to be assessed.

**5** - Use ENDOPENER mounted on an endodontic contra-angle handpiece (16:1 reduction) on a motor with programmable speed (initially 300 rpm) and torque limited to maximum 3 N.cm. Prepare to a depth of 5 mm, with a circumferential brushing action, then thoroughly irrigate; 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 intraoral radiograph.

**7** - Continue mechanical preparation, using the practitioner's preferred instruments. All systems using continuous rotation or alternating rotation are compatible with ENDOPENER. Do not neglect irrigation.

**8** - ENDOPENER can also be used during preparation to reposition the root canal entrances (Fig.7b), possibly using alternating rotation motion (Fig. 8).

**9** - Continue the preparation to the apical cement-dentine junction using the technology the practitioner chooses.

10 - Seal and control.

#### **Discussion about ENDOPENER**

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

#### 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 reproduce 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 three-dimensional inverse profile. Thus the geometry of the object after micro-grinding is predetermined by the shape of the grindwheel.

This is why almost all endodontic instruments have tangential cutting edges [12]. Furthermore, wear of the micro-grindwheel requires constant adjustment to maintain the geometrical and dimensional characteristics of the instrument.

ENDOPENER is the first instrument to be machined differently. Its geometry is obtained by wire-cut electric discharge machining (WEDM) [17]. This technique was developed initialy in 1943 in the former USSR by Lazarenko [18] and has been improved since then. It consists of melting, evaporation and ejection of material within a complex dielectric field [20]. The energy required for the machining is made by electrical discharges passing between two electrodes and creating an electric arc between the workpiece and the tool [17] (Fig. 9). The advantages of this technology are numerous. Firstly, the precision of the cut can be measured in microns [21]; machining by localized 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); 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, nor 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, machine tools, etc., to create complex shapes and items in small series, because the technology is difficult to implement [22].

This process has recently been modified to be suitable for the large scale production of endodontic instruments; it involves a dual wire electrode, consisting of the instrument being manufactured and a mobile wire EDM giving 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 conventionally available.

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 microns thick, has been shown (Fig. 10). This condition requires that, after EDM, surfaces be chemically treated to remove the oxide layers (study of multi materials and interfaces, undertaken in the laboratory of LMI, UMR 5615: CNRS-UCBL.1, Lyon), 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]. 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 ENDOPENER, measurment of the torsion resistance, 3 mm from the tip in accordance with standardised ISO tests (ref. 3630-1) with a SOMFY-TEC (Metil Industrie) torsion meter, gives values as good as those obtained for the similar NiTi orifice openers such as the ENDOFLARE (335 cN·cm for ENDOPENER with standard deviation 16.3 compared with 322 cN·cm for the ENDOFLARE, standard deviation 38.5). Values were almost the same when measuring at 45° of flexion, 3 mm from the tip (126 cN·cm for ENDOPENER, standard deviation 8.3, against 134 for ENDOFLARE and standard deviation 3.2). Comparison with the SX is more difficult, given the dimensional configuration of the latter which is more flexible than other openers (15 cN·cm with a standard deviation 2.5) but it has significantly less torsional strength (43 cN·cm, standard deviation 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 changing profile:

The shape of ENDOPENER 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 6.0 mm in the coronal portion (6 to 10 mm). The blade has also "frontal edges" spaced 1.40 mm to 1.60 mm, depending on the portion but only on the 7.5 mm above the apical portion. These characteristics make ENDOPENER a very complex instrument with a variable changing profile along the blade's working length. The cutting edges, four in number, 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 ENDOPENER behaves and acts differently depending on the working motion,.

Furthermore, in cross-section the inactive blade is octagonal, 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 opener counterclockwise 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 openers in the market, ENDOPENER can in no way be compared with them and in clinical use the instrument is perceived to be very different.

#### 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 opener," that is, to advance towards the apical region while widening the canal, thanks to the instrument's 12% taper. All orifice openers

have this property. This is why it is recommended that periodical checks for blockage of the cutting edges, frequently observed on all the "openers", especially on the first few millimeters 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, ENDOPENER will naturally be restrained in its progress by a direct force that is much more static and which therefore opposes the screwing effect.

Using alternating rotation with the Endo-Dual<sup>®</sup> motor, particularly 360° clockwise and 180° to 60° anti-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, the system or whatever endodontic philosophy is preferred by the clinician.

#### Conclusion

ENDOPENER is the first root canal instrument to be machined by wire-cut EDM. Its geometry is more complex than other orifice openers. 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 ENDOPENER will be incorporated in other root canal instruments which will thus more easily meet the operative, mechanical and biological requirements of endodontists and thus introduce a new era for endodontic instruments, initiated by ENDOPENER.

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## Fig. 1 : The ENDOPENER endodontic file



Fig. 2 : Radiograph before and after use of ENDOPENER: Laboratory study. One can note the angles of the canal access passages, which increase significantly after the use of ENDOPENER.



## Fig. 3 : Dimensional chacteristics of ENDOPENER



Fig 4 : Marathon Endo-a-class<sup>®</sup> and Endo-e-class <sup>®</sup> Continuous rotation endodontic motors





## Fig 5 : Endo Dual <sup>®</sup> (Satelec – Acteon)

Multi-function endodontic motor that provides a choice of continuous rotation or reciprocating rotation



## Fig. 6: Reciprocating rotation sequences of ENDOPENER



# Fig 7a : Illustration of access cavity flaring







Fig. 8: Intra-coronal photographs of preparation before and after ENDOPENER. Example: access cavities and coronal cavity root canals on tooth 26 and tooth 33.





Single-canaltooth (33) Fig. 9: Principle of EDM without contact between the machining tool and the workpiece



Fig. 10 : Layer of metal oxides after WEDM (LMI,UMR 5615 : UCBL.1-CNRS, Lyon)



Fig. 11 : Aspect of the surface after electro-scouring and electro-polishing ; optical and scanning electron-microscope (SEM) images (University of Rennes 1)



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