Scientific Manual

TruNatomy®

1. Outline

2. Preface by Prof. O. Peters and Dr. G. Bruder

TruNatomy®: From Concept to Clinical Solution

There cannot be any doubt that root canal treatment with Nickel-titanium instruments has revolutionized the practice of endodontics over the last 2 decades. The most decisive improvement is the ability to shape even severely curved canals, for example in molars, effectively and without major canal preparation errors. It is clear from clinical evidence that this goes a long way in improving immediately observed outcomes. Or said differently, post-operative radiographs of cases treated with rotary or reciprocating files demonstrate superb shapes and great root canal fillings. This approach is often associated with rather large tapers for the files and the need to remove a sizeable amount of dentin ("straight-line access"). It is evident that for many roots canal-treated teeth, root fractures and other problems were limiting factors and these can be associated with lack of dentin structure.

Consequently, the development of the TruNatomy® system started with a careful and focused evaluation of what was missing and what could be improved on. A main question was, what are the true and relevant outcomes from a patients' viewpoint? Unsurprisingly, patients are most interested in teeth that are in function, not painful and last a long time after root canal treatment. It became further evident that these so-called patient-reported outcomes are directly related to the restoration after root canal treatment. Restorative outcomes, the selection of restoration type and the time the restored teeth last appear to be directly connected to the amount and distribution of available hard tissue (dentin), the type of restoration and the forces that occur during function [1].

Therefore, retaining as much dentin as reasonably possible at the level of the restoration margin became a main goal of development. What this meant, essentially, was to achieve the important goal of antimicrobial efficacy with less tooth destruction. We needed a rotary file that could work with less coronal enlargement, go around tight curves safely and still provide enough space apically for irrigation solution to be delivered. Due to a clever combination of new materials, design features and adjunct devices this concept has been delivered. It is now possible, with smaller access cavities and without large coronal flaring, to creates canal shapes that bring a very flexible optimized irrigation needle to an appropriate depth.

The second important piece in the development of TruNatomy® was the finding that root canal treatment is seen by many clinicians as complex, even as a daunting process [2]. Therefore, the design requirements included a high safety factor and the need to provide good feel and feedback. The inclusion of a stringent pathway from locating the orifice to providing a secure glide path allows clinicians to treat even more complex canals with confidence.

The development from the first drawing to the final marketed file took more than 3 years and was supported by clinical and laboratory studies, many of which are included in this scientific manual. We are confident that with TruNatomy®, the ability to treat teeth with various degrees of canal curvature and retain structurally important dentin will help clinicians and patients.

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Co-designers, Clinical expert advisors during TruNatomy® development

3. TruNatomy® system description, with a focus on instruments

The TruNatomy® system includes a dedicated Orifice Modifier, a Glide Path instrument, and four shaping instruments (Prime, Small, Medium, Large), as well as a special irrigation needle, conforming gutta-percha points and absorbent paper points (see ***Figure 1***). All the TruNatomy® instruments are operated at 500 rpm with a torque of 1.5 Ncm and with gentle stroking motion. The instruments are based on a series of new patent-protected instruments geometry (see ***Figure 2*** illustrating the parallelogram cross-section of the instruments), a Maximum File Diameter (MFD) of 0.8 mm in the operative part and a dedicated newly developed heat-treatment. All TruNatomy® have a short shank of 9.5 mm simplifying molar access.

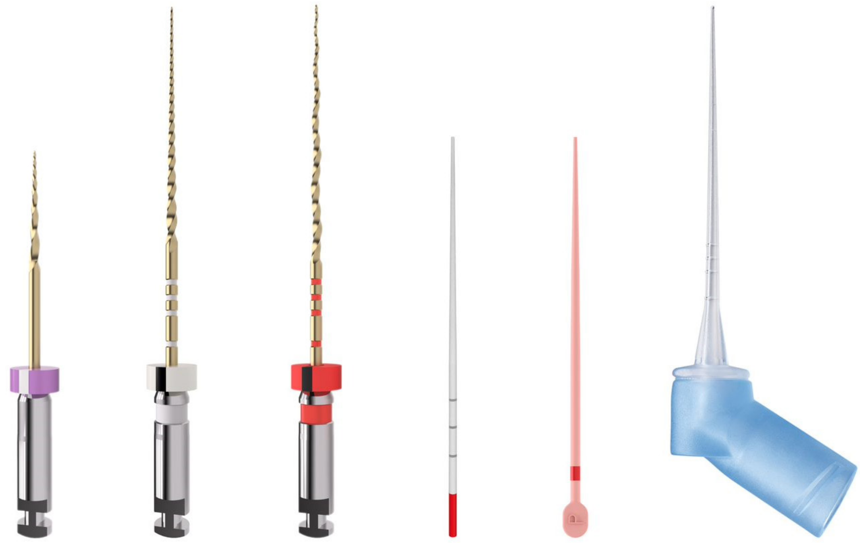

Figure 1: *TruNatomy® basic solution (from left to right: Orifice Modifier, Glide Path, Prime instrument, Prime paper points, Prime Conform® fit Gutta Percha and irrigation needle)*

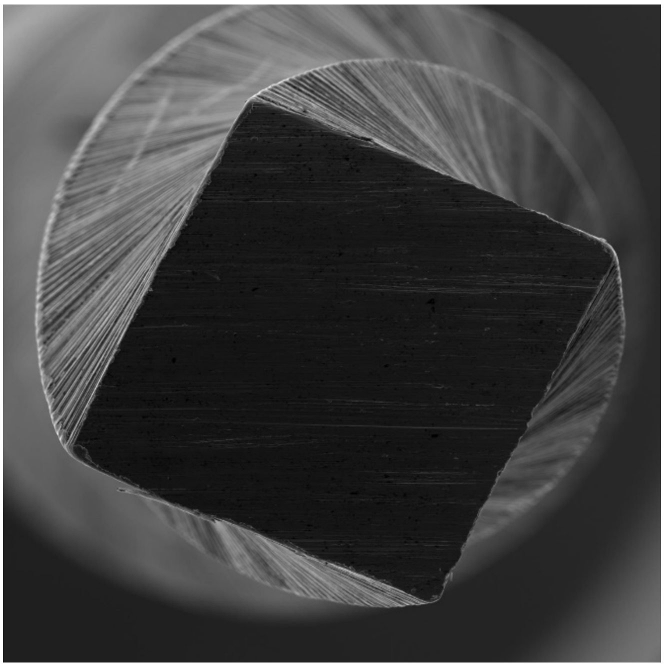

Figure 2: *SEM image of the cross section of the small size (TruNatomy® shaping file).*

Figure 3: *Orifice modifier, Glider, PRIME as a basic sequence. The assortment is completed by three optional sizes, SMALL, MEDIUM and LARGE. Numbers on the left of the instruments provide the size and the average taper.*

More into details (***Figure 3***), the orifice modifier (size 20.08), with a fixed taper and an active part of 7 mm, shapes the orifice to create the entry point without the need for a straight-line access. The Glider (size 17.02v) ("v" is for variable taper), with a progressive taper and a centered parallelogram cross section design as shown in Figure 2, is used to create a pathway to the canal terminus. TruNatomy® shaping files, available in four sizes (Prime 26.04v, Small 20.04v, Medium 36.03v, Large 46.02v (being launched in 2022)) and three lengths (21, 25 and 31 mm), have an off-centered parallelogram cross section with a regressive taper.

By using specific off-set machining manufacturing process, the shaping files possess a geometry in which the center of mass of the instrument is not aligned with the center of rotation. This reduces the stress level during cutting and increases the available space for debris removal.

As illustrated in ***Figure 4***, TruNatomy® shaping files all have the same diameter at the coronal third, preserving peri-cervical dentin, compared to traditional constant taper preparation. On the other hand, at the apical third, the diameter of the files increases (Small < Prime < Medium < Large) in order to ensure proper debridement and disinfection.

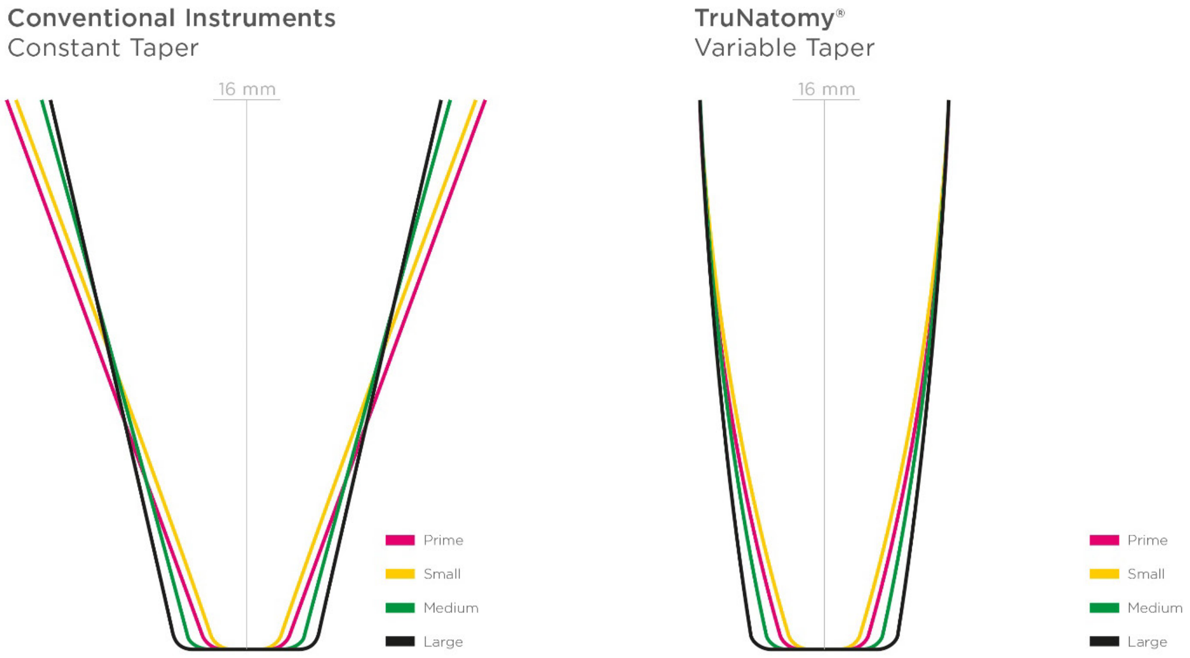

Figure 4: *Dentin removal where needed - comparison of the preparation of a constant taper sequence (on the left) vs. TruNatomy® sequence (on the right), showing the conservative coronal shape with an appropriate apical preparation.*

TruNatomy® instruments are manufactured from standard NiTi wires, which are worked by micro milling and finally submitted to a proprietary post machining heat-treatment. Typically, such heat-treated instruments reach the martensitic phase during clinical treatment, offering the following clinical advantages:

- Pre-bendable instruments, which can be useful when bypassing ledges (see ***Figure 5*** showing the pre-curving ability of TruNatomy® files),
- Instruments with enhanced fatigue resistance and flexibility for optimized performance in complex curvatures and root canal anatomies...

… when compared to other NiTi instruments which are mostly in a more rigid austenitic phase [3]. For more information on thermomechanically treated NiTi alloys, Zupanc et al. [3] have published a review, emphasizing their properties, the differences between the austenite and the martensitic phase, and the advantages of both phases from a clinical perspective.

Figure 5: *Pre-bending of the TruNatomy® Prime instrument thanks to its dedicated heat-treatment.*

4. Mechanical properties and *in vitro/ex vivo* studies

TruNatomy® system was launched worldwide in 2019. So far, fifteen peer-reviewed scientific papers have been published on this endodontic system, mainly comparing fatigue resistance, debris extrusion and respect of the canal anatomy. Three of these scientific studies, not following the manufacturer's recommendations (speed or reciprocating motions), where excluded from this scientific manual ([4-6]). Nonetheless, it's important to emphasis that conclusions drawn from these three studies revealed no early breakages or any safety issues using TruNatomy®.

1. Fatigue resistance

In general, instruments used in rotary motion break in two distinct modes—torsional and flexural. Torsional fracture occurs when an instrument tip is locked in a canal while the shank continues to rotate, thereby exerting enough torque to fracture the tip. In contrast, flexural fracture occurs when the cyclic loading leads to metal fatigue [7]. NiTi instruments can withstand several hundred flexural cycles before they fracture. Repeated loading and cyclic fatigue tests for endodontic instruments are not described in pertinent ISO norms. Nonetheless, several *in vitro* studies on the fatigue behavior of TruNatomy® instruments, performed at 37 °C due to the presence of martensitic phase (see section 3 above for more details), have been published in peer-reviewed journals and are summarized below.

In vitro comparison of cyclic fatigue resistance of TruNatomy in single and double curvature canals compared with different nickel-titanium rotary instruments. Elnaghy AM, Elsaka SE, Mandorah AO.BMC Oral Health. 2020 [8]

The aim of this study was to compare the cyclic fatigue resistance of TruNatomy® small and prime files (Dentsply Maillefer) with HyFlex™ CM (Coltène-Whaledent, Altstätten, Switzerland), RaCe (FKG Dentaire, La Chaux-de-Fonds, Switzerland) and Vortex Blue® (Dentsply Sirona, Ballaigues, Switzerland) NiTi files.
The cyclic fatigue of TruNatomy® Prime files (26/0.04), TruNatomy® Small files (20/0.04), and sizes 20/0.04 and 25/0.04 of Hyflex™ CM, Vortex Blue® and RaCe were tested in artificial stainless-steel canals with a single curvature (60° curvature with 5 mm radius) and a double curvature (60° curvature with 5 mm radius and apical 70° curvature and 2 mm radius). A X-Smart endodontic motor (Dentsply Sirona, Ballaigues, Switzerland) was used at the file manufacturer's specified speed and torque. The instruments were immersed in saline solution at 37 °C during the testing. A set of 30 instruments per size per canal curvature were used.

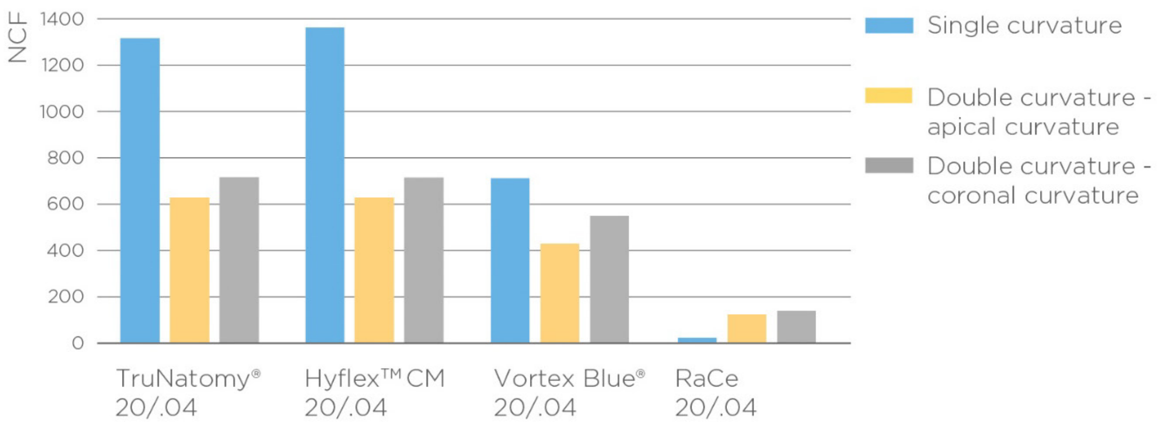

Figure 6: *Median number of cycles to failure (NCF)*

The outcomes are the following (***Figure 6***):

- TruNatomy® and HyFlex™ CM files showed the highest fatigue resistance (both above 1300 cycles to failure (NCF) in single curvature, and above 600 NCF in double curvature, with the size 20/.04) compared to Vortex Blue® and RaCe (both below 712 NCF in single curvature, and below 550 in double curvature, with the size 20/.04).
- All instruments showed higher fatigue resistance for size 20/.04 than size 25 or 26/.04.
- The instruments fractured first in the apical curvature and then in the coronal curvature in the double canal.

Mechanical Properties of a Novel Nickel-titanium Root Canal Instrument: Stationary and Dynamic Tests. Peters OA, Arias A, Choi A. J Endod. 2020 [9]

The aim of this study was to describe the mechanical properties both in stationary and dynamic conditions in vitro of TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland) shaping files and compare them with ProTaper Next® (Dentsply Sirona, Ballaigues, Switzerland) NiTi files.
80 rotary instruments (n = 20 each for ProTaper Next® sizes X2 and X3, and TN sizes Prime and Medium) were tested for stationary cyclic fatigue. 36 rotary instruments (n = 6 each for ProTaper Next® file sizes X1, X2, and X3 and TruNatomy® Small, Prime, and Medium) were tested for Torsional resistance according to ISO 3630-1. 36 rotary instruments (n = 6 each for ProTaper Next® file sizes X1, X2, and X3 and TruNatomy® Small, Prime, and Medium, respectively) were used for dynamic tests, where the shaping was simulated in J-shaped curved plastic blocks in a computer-controlled device to register real-time torque and force. Fracture patterns after both fatigue and torsional tests were assessed using Scanning Electron Microscopy.

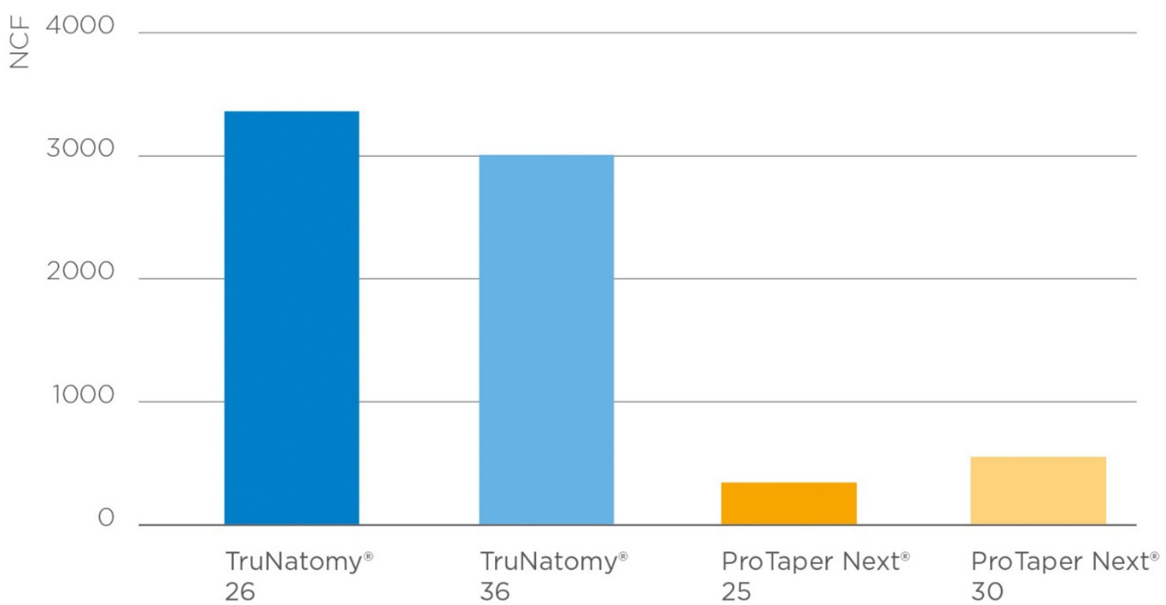

Figure 7: *Fatigue limits, mean values of cycles to fractures (NCF), for both TruNatomy® and ProTaper Next®.*

The mean values of number of cycles to fracture (NCF), reflecting the cyclic fatigue resistance for the tested instruments are (***Figure 7***):

- TruNatomy® Prime: 3364 NCF (significantly more fatigue resistant than ProTaper Next®)
- TruNatomy® Medium: 3007 NCF (significantly more fatigue resistant than ProTaper Next®)
- ProTaper Next® X2: 346 NCF
- ProTaper Next® X3: 555 NCF

Torsional limits were similar, but twist angles at failure were significantly larger for TruNatomy®. No instruments fractured during simulated shaping. In dynamic conditions, TruNatomy® showed significantly more predicable working torque (lower than 0.5 Ncm for Small, Prime and Medium) compared with ProTaper Next® (between 1 and 1.6 Ncm for X1, X2, X3), suggesting a more comfortable shaping action. The obtained data indicates that settings defined for both instruments are suitable (as fatigue and torque limits are far above the actual working rotation and torque values) and that the ones of TruNatomy® allowed higher revolutions per minute and a lower torque limit.

Comparison of the cyclic fatigue resistance of VDW.ROTATE, TruNatomy, 2Shape, and HyFlex CM nickel-titanium rotary files at body temperature. Gündoğar M, Uslu G, Özyürek T, Plotino G. Restor Dent Endod. 2020 [10]

The aim was to compare the cyclic fatigue resistance of VDW.ROTATE™ (VDW, Munich, Germany), TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland), 2Shape (Micro-Mega, Besançon, France), and HyFlex™ CM (Coltène-Whaledent, Altstätten, Switzerland) nickel-titanium (NiTi) rotary files at body temperature. 20 instruments per brand were tested in a stainless-steel artificial canal with 60 ° angle of curvature and a 5 mm radius of curvature, using an X-Smart Plus motor at the respective recommended speed and torque for each instrument. All instruments show number of cycles to fracture above 1100 (between 1110 TruNatomy® and 1840 VDW.ROTATE™), without any significant differences (P>0.05).

➪ Take home message on TruNatomy® and fatigue resistance

The three studies above highlight that TruNatomy® instruments show very high fatigue resistance, even in complex canal anatomy (e.g. double curvature, etc.). Even though fatigue resistance is a major parameter governing NiTi rotary instrument fracture, clinicians must fully understand that motor-driven rotary instruments should not be forced in an apical direction. The recommended technique has to be followed when using TruNatomy®: 2-3 gentle amplitudes approximately 2-5 mm in-and-out of the canal until working length has been reached. Upon reaching working length, gently remove the instrument to avoid over-enlarging the apical foramen.

The incidence of instrument fracture can be reduced to an absolute minimum if clinicians use the recommended motor settings (500 rpm speed and 1.5 Nm torque for TruNatomy®).

2. Canal transportation and centering ability

Canal transportation is one the most frequent adverse outcomes during canal shaping. As files tend to straighten in the canal, this typically occurs toward the inner (or convex) radicular wall at midroot as well as toward the outer curvature apically. Any canal preparation will shift the canal axis to some degree, which is often determined as the center of gravity in cross sections. It has been held that a transportation of about 100 to 150 µm may be clinically acceptable [7]. Three *in vitro* and *ex vivo* studies on the canal transportation and centering ability of TruNatomy® have been published so far in peer-reviewed journals and are summarized below.

Micro-computed Evaluation of Canal Transportation and Centering Ability of 5 Rotary and Reciprocating Systems with Different Metallurgical Properties and Surface Treatments in Curved Root Canals. Kabil E, Katić M, Anić I, Bago I. J Endod. 2021 [11]

The aim was to evaluate the transportation and canal centering ability of five rotary and reciprocating NiTi file systems ProTaper Next® (Dentsply Sirona, Ballaigues, Switzerland), Reciproc® Blue (VDW, Munich, Germany), Reciproc® (VDW, Munich, Germany), TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland), and XP-Endo® Shaper (FKG, La Chaux-de-Fonds, Switzerland), using 50 curved mesiobuccal round canals of extracted human maxillary first and second molars, via microCT scanning, overlapping scans before and after instrumentation.
TruNatomy® preparation show the smallest overall canal transportation, with XP-Endo® shaper, but without significant differences to the other evaluated rotary instrument systems

(p > 0.05)(***Figure 8***). Regarding centering ability, there was no significant differences between the tested instrument systems (P > 0.05) (***Figure 9***).

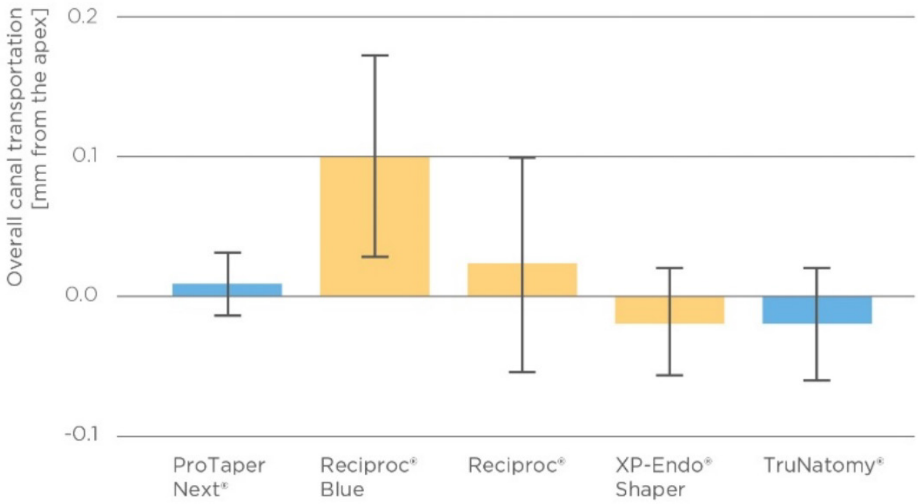

Figure 8: *The overall mean transportation of curved canals after preparation with 5 instrumentation systems. For canal transportation, a result of zero indicates no canal transportation, a positive result indicates transportation towards the mesial edge, and a negative result indicates transportation towards the distal edge (so towards the furcal aspect of the root).*

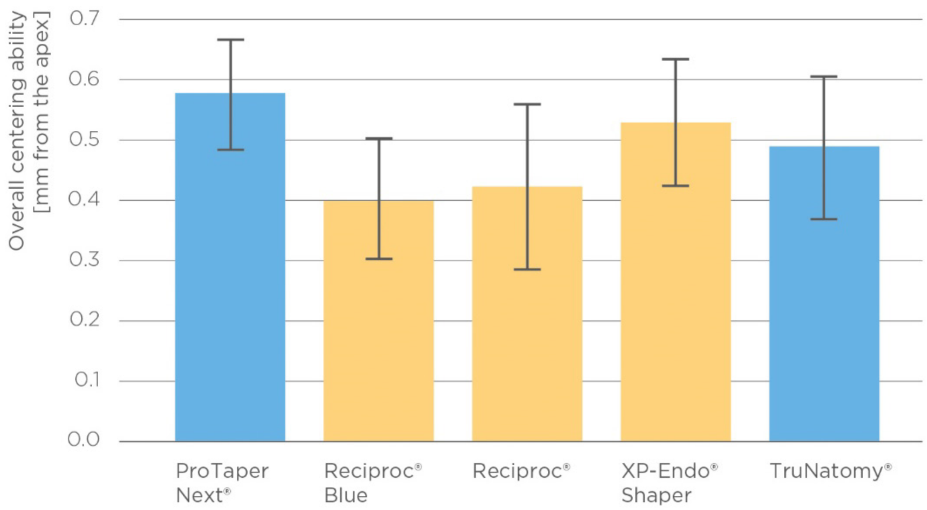

Figure 9: *The overall mean centering ability of 5 different instruments in curved root canals. For the centering ratio, a result of one would indicate a good centering ability.*

Comparison of Canal Transportation in TruNatomy, ProTaper Gold, and Hyflex Electric Discharge Machining File Using Cone-beam Computed Tomography. Kumar M, Paliwal A, Manish K, Ganapathy SK, Kumari N, Singh AR.J Contemp Dent Pract. 2021 [12]

The canal transportation of TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland), ProTaper Gold® (Dentsply Sirona, Ballaigues, Switzerland) and Hyflex® EDM (Coltène-Whaledent, Altstätten, Switzerland) was compared via Cone-Beam Computed Tomography (CBCT) imaging on 105 extracted teeth (mandibular first molar and second premolars). All the canal preparations were performed by one clinician and the analysis of the images was performed by another investigator, blinded.
TruNatomy® shows the least canal transportation compared to the other evaluated file sequences, with significant differences at the middle third and at the coronal third, but not at the apical level (***Figure 10***). This is attributed to the small maximum file diameter (MFD) of 0.8

mm, the cross section, and off-centered design but also to the heat treated NiTi wire, increasing the flexibility of the TruNatomy® instruments and all together preserving the tooth integrity.

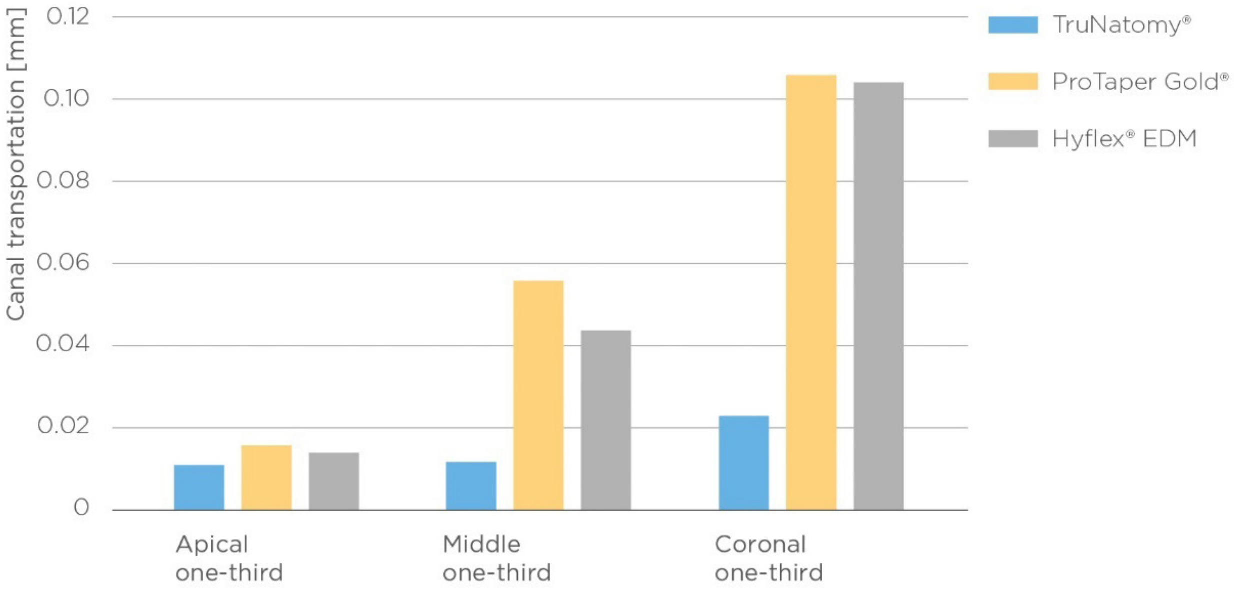

Figure 10: *Canal transportation by three file systems at three regions of canals.*

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 [13]

This study compared the canal transportation and shaping time, of TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland), ProTaper Gold® (Dentsply Sirona, Ballaigues, Switzerland) and WaveOne® Gold (Dentsply Sirona, Ballaigues, Switzerland) instrument sequences, in 60 S-Shaped plastic blocks. TruNatomy® showed less canal transportation than the other sequences (***Figure 11***) and the quickest shaping time in double-curved simulated blocks (***Table 1***), emphasizing again the ability of TruNatomy® sequence to maintain the original canal anatomy.

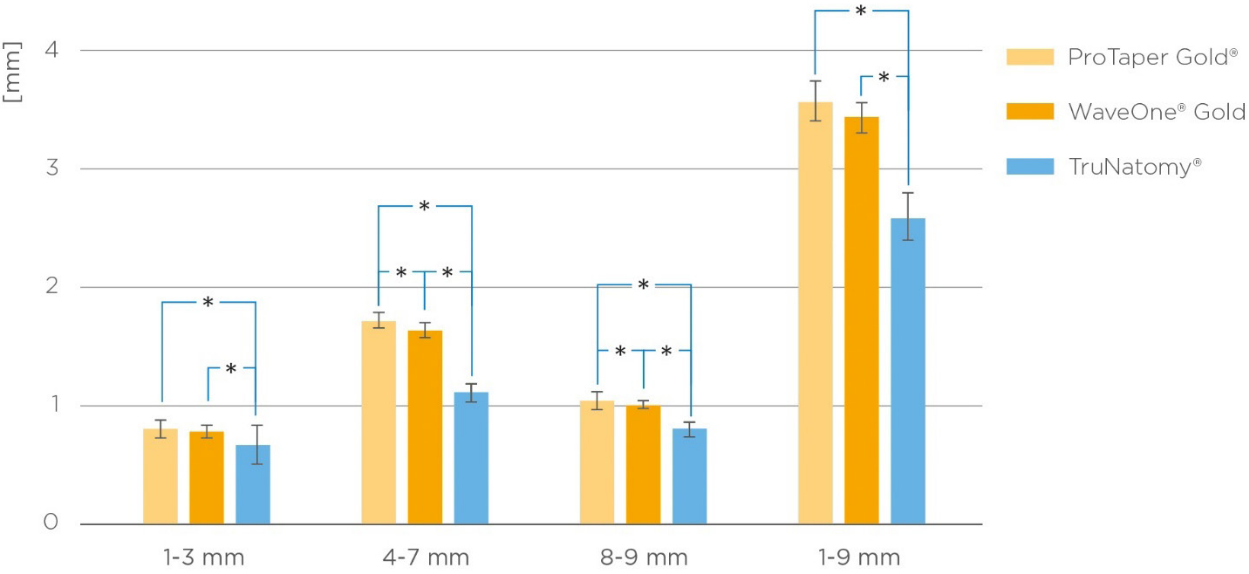

Figure 11: *Mean and standardization of the total amount of removed resin for each range. 1 mm from the apical terminus to 9 mm from the apical terminus*

Table 1: Means and standard deviations of canal preparation time (s)

Parameter	ProTaper Gold® Mean ±SD	WaveOne Gold® Mean ±SD	TruNatomy® Mean ±SD
Time a, b, c	245.75 ±22.03	170.75 ±24.72	139.10 ±24.54

Statistically significant differences for total preparation time: a between Protaper Gold® and WaveOne Gold®, b between WaveOne Gold® and TruNatomy®, c between Protaper Gold® and TruNatomy® ($p<0.05$)

Take home message on TruNatomy® and canal transportation

With its dedicated heat-treatment, thinner Maximum File Diameter (MFD) of 0.8 mm, and design developed to preserve structural dentin and tooth integrity, TruNatomy® instruments show very low canal transportation, as confirmed by the three peer-reviewed *in vitro* and *ex vivo* articles summarized above. In two of the studies, the comparison to other instruments already on the market even reached statistical significance.

3. Shaping ability

The impact of TruNatomy and ProTaper Gold instruments on the preservation of the periradicular dentin and on the enlargement of the apical canal of mandibular molars. Silva EJNL, de Lima CO, Barbosa AFA, Lopes RT, Sassone LM, Versiani MA, Journal of Endodontics. 2022 [14]

The canal preparations of TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland) up to the medium size (36/.03v) and of ProTaper Gold® (Dentsply Sirona, Ballaigues, Switzerland) up to the F3 (30/.09v) were compared in mandibular molars via micro-computed tomography. 20 molars (n=10) were scanned before and after preparation, and untouched area, transportation, dentin removal, dentin thickness parameters were quantified.
Both sequences of instruments were similar in terms of global untouched area and reduction of dentin thickness, i.e. both showing efficient preparations. More into details, TruNatomy® removed less dentin than Protaper Gold® at the coronal level of mesial roots (1.0 +/- 0.4 % and 1.8 +/- 0.7 %, respectively) and produced less transportation at the apical third of the mesiobuccally canal (0.03 +/- 0.01 mm and 0.05 +/- 0.02 mm, respectively).

Micro-computed Tomographic Assessment and Comparative Study of the Shaping Ability of 6 Nickel-Titanium Files: An In Vitro Study. Pérez Morales MLN, González Sánchez JA, Olivieri JG, Elmsmari F, Salmon P, Jaramillo DE, Terol FD. J Endod. 2021 [15]

The shaping ability of WaveOne Gold® (Dentsply Sirona, Ballaigues, Switzerland), the Reciproc® Blue (VDW, Munich, Germany), TRuShape™ (Dentsply Sirona, Tulsa, USA), XP-Endo® Shaper (FKG, La Chaux-de-Fonds, Switzerland), iRace (FKG, La Chaux-de-Fonds, Switzerland), and TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland) NiTi files was compared in moderately curves canals via micro-computed tomography. 10 extracted lower molars (20 canals in mesial roots) per group were scanned before and after preparation, and the images were analyzed in order to quantify the shaping ability in terms of changes in canal geometry (structure thickness, volume of root canal, percentage of surface touched/untouched, centroids, etc.).
TruNatomy® and XP-Endo® Shaper respected the canal anatomy better than the other evaluated systems, touching 50 and 58 % respectively of the canal walls. At the same time, TruNatomy® was shown, as all evaluated files system, to be able to clean and shape the canal, with a minimal apical transportation (no significant differences).

Take home message on TruNatomy® and shaping ability

The studies summarized above confirmed that engine-driven NiTi instrumentation systems are unable to contact 100% of the root canal wall [15]. Such results are nevertheless expected, and in alignment with another peer-reviewed publication indicating that 35 % or more of canal surface remains untouched after mechanical instruments, mainly due to the anatomical complexity of the root canal system [16]. Thus, biofilms remain on these inaccessible root canal walls and may recolonize the root canal system, which adversely affects treatment outcome. Irrigation is therefore an essential part of root canal debridement to achieve intracanal disinfection, to dissolve and to remove pulp tissue, dentinal debris, smear layer, microorganisms and their by-products [17]. In this framework, the TruNatomy® needle (4% taper, 30 gauge closed end tip, 27 mm working length) can be of great support (see ***Figure 1***). It is made in soft polypropylene, allowing the needle to curve and flex easily to follow the root canal anatomy. Moreover, the back-to-back 2-sided vent design maintains a balanced irrigation solution volume for greater control throughout the canal.

4. Apical debris extrusion

Postoperative pain and also prolonged extraradicular infection can develop as a sequel to apical extrusion of debris during root canal instrumentation (particularly after over-instrumentation). Bacteria embedded in dentinal chips can be physically protected from the host defense cells and therefore can persist in the periradicular tissues and sustain periradicular inflammation, which can lead to undesirable post-operative pain or even failure of the endodontic treatment [7] . Thus, several publications have focused on apically extruded debris after root canal preparation, using TruNatomy® system, as shown below.

Apically extruded debris associated with ProTaper Next, ProTaper Gold and TruNatomy systems: An in vitro study. Yılmaz Çırakoglu N, Özbay Y. J Dent Res Dent Clin Dent Prospects. 2021 [18]

In this study, the amount of apically extruded debris after root canal preparation using ProTaper Next® (Dentsply Sirona, Ballaigues, Switzerland), ProTaper Gold® (Dentsply Sirona, Ballaigues, Switzerland), and TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland) NiTi systems was investigated, using 45 extracted human mandibular premolars. All the canal preparations were performed by the same operator. The apically extruded debris, after canal preparation, was weighted in Eppendorf tubes after five days in a incubator at 70°C in order to evaporate the distilled water. It was shown that TruNatomy® produced significantly less debris extrusion (see following graph).

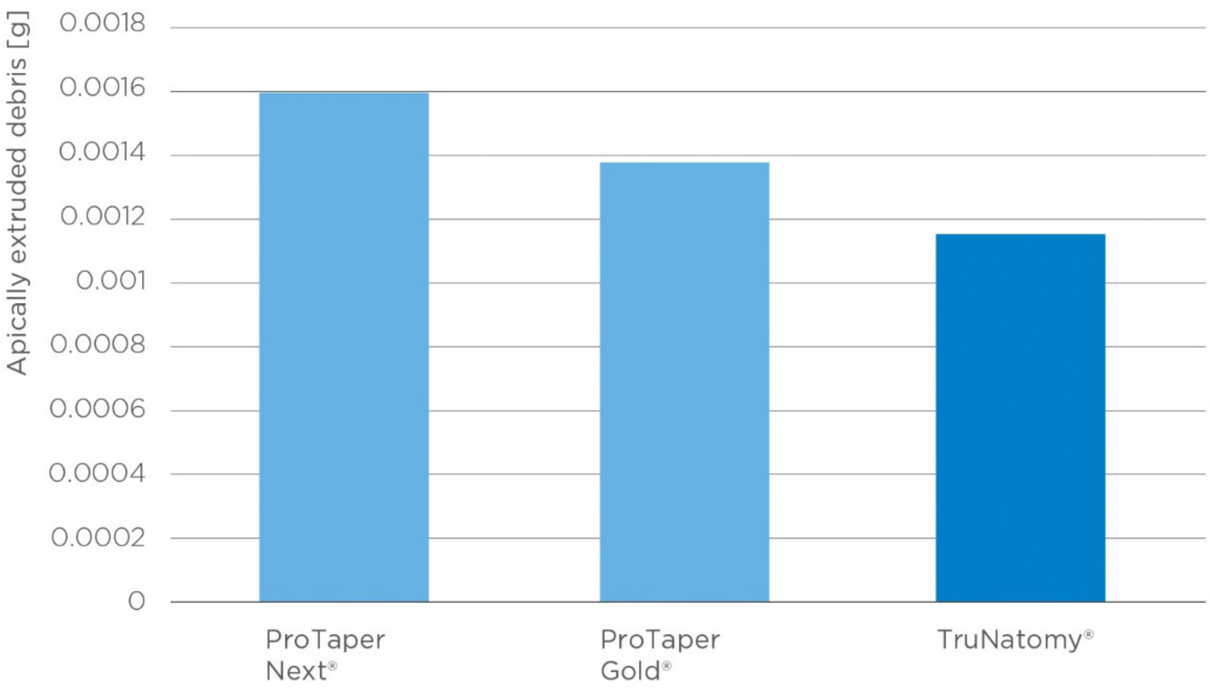

Figure 12: *The amount of apically extruded debris after canal preparation with different instrumentation systems.*

Evaluating In Vitro Performance of Novel Nickel-Titanium Rotary System (TruNatomy) Based on Debris Extrusion and Preparation Time from Severely Curved Canals. Mustafa R, Al Omari T, Al-Nasrawi S, Al Fodeh R, Dkmak A, Haider J.J Endod. 2021 [19]

Debris extrusion of the following NiTi instruments was compared *in vitro*, using 1000 human mandibular molars with severe curvature (25-45°) (see the set-up of the study below): TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland) compared with Reciproc® Blue (VDW Dental, Munich, Germany), Hyflex® CM (Coltène-Whaledent, Altstätten, Switzerland) and Hyflex® EDM (Coltène-Whaledent, Altstätten, Switzerland) and ProTaper Next® (Dentsply Sirona, Ballaigues, Switzerland) rotary systems. One single operator performed the canal preparations, while another blinded operator analyzed the extruded debris.

It was shown that TruNatomy® group extruded the lowest amount compared to the other evaluated systems (P > 0.001) (see the figure below), together with ProTaper Next® and Reciproc® Blue.

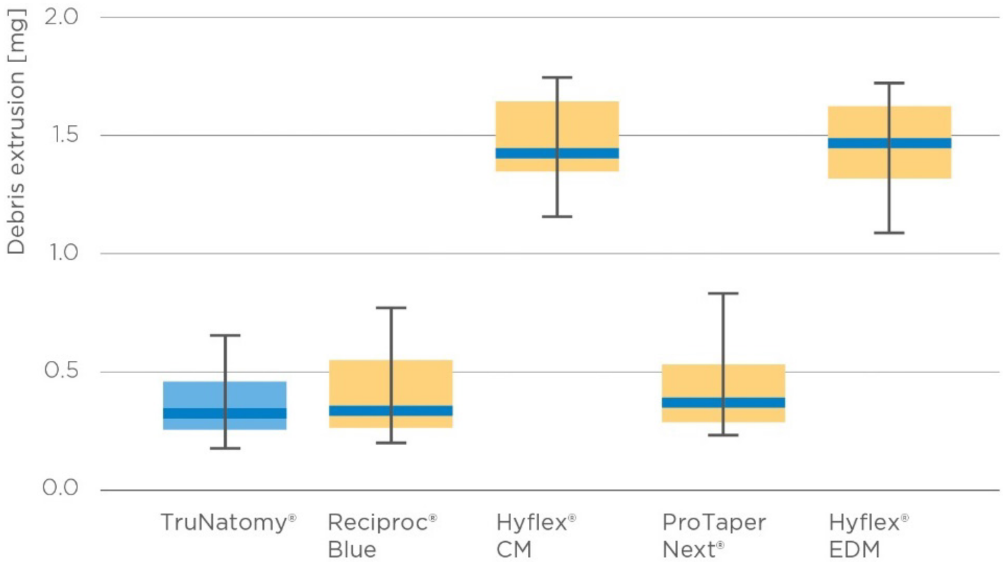

Figure 13: *A box plot showing the median, minimal and maximal values as well as the standard deviation data related to the amount of extruded debris for all tested groups.*

Apical debris extrusion of full-sequenced rotary systems in narrow ribbon-shaped canals. Al Omari, T., et al., Aust Endod J, 2021 [20]

Debris extrusion of the TruNatomy® (Dentsply Sirona, Ballaigues, Switzerland) (up to the Prime 26/.04), RACE® EVO system (up the size 25/.06) and VDW.ROTATE™ (VDW, Munich, Germany) (up to 25/.06 size) NiTi instruments was compared *in vitro*, using 60 single-root mandibular anterior teeth. One single operator performed the canal preparations, using sodium hypochlorite 2.5 %.

It was shown that TruNatomy® group extruded 105.15 +/- 17.17 mg of debris, RACE® EVO (FKG, La Chaux-de-Fonds, Switzerland) 110.25 +/- 24.30 mg and VDW.ROTATE™ 73.31 +/- 32.59 mg, without significant differences between TruNatomy® and RACE® EVO, but VDW.ROTATE™ show significantly less extrusion than the two other systems.

Regarding preparation time (shaping and irrigation), VDW.ROTATE™ was the fastest (95.17 +/- 15.73 s) following by RACE® EVO (100.98 +/- 17.77 s) and TruNatomy® (109.88 +/- 14.33 s).

Take home message on TruNatomy® and apical debris extrusion

Two studies shows that TruNatomy® produces less debris extrusion [18, 19] compared to other systems which is not aligned with the findings of the third study from Al Omari *et al* [20]. These discrepancies can be explained by several factors such as the teeth selection (pre-molar, molars with severe curvature vs anterior teeth), type of irrigant (distilled water vs. NaOCl, respectively), and can be also highly operator dependent.

Moreover, the natural periapical back pressure, reducing the apical extrusion, cannot be simulated in *in vitro* conditions and is a common limitation to all the studies summarized above. It should also be noted that the design of TruNatomy®, i.e. off-set centers of mass with regressive taper and 0.8 MFD, may be a benefit for curved canals in terms of apical debris extrusion [18, 19], enlarging the apical portion of the canal while limiting the file stress and the compression of debris in the upper portion.

5. Angulated access cavities study

TruNatomy® is the first file system that can withstand canal curvatures at root canal entry. This allows a smaller access preparation with less invasive, i.e. more conservative, access cavities. Thus, most risks of traditional root canal treatment via a so called "straight line access" could be minimized (e.g. massive loss of hard tissue with increased late facture risk for the tooth, less residual tooth structure making later revision treatment more difficult, longer treatment time). Conservative therapeutic approaches in endodontics could be classified between three modified types of access: occlusal via a smaller opening (15 ° entrance angle), mesial (via the cavitated caries defect) for premolars and molars (30 ° entrance angle) and cervical with wedge-shaped defects or root caries on anterior teeth and single-rooted premolars (45 ° access angle)(see ***Figure 14***).

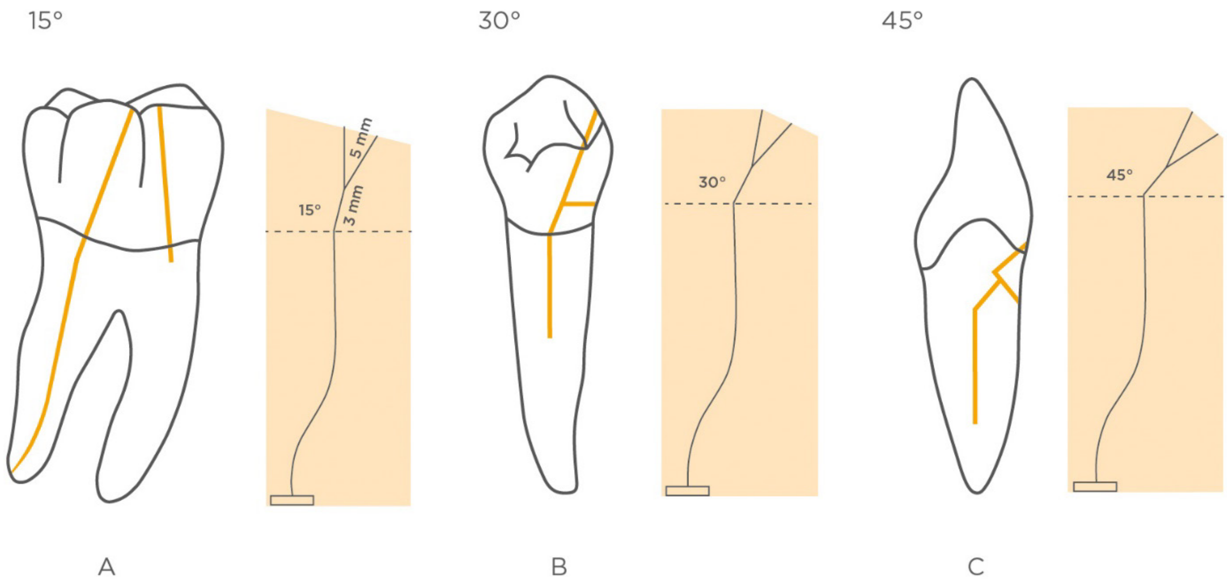

Figure 14: *Clinically simulated root canals and canal access angles of 15 ° (A), 30 ° (B) and 45 ° (C).*

Volumetric Bio-Mechanics of Instrumentation via Angulated Access Cavities – A Randomized, Blinded and Clinically Simulated in vitro Study. T. Lang , D.Q. Nguyen, I. Steiner, A. Ditz, K.W. Weich,P. Gaengler. unpublished data [21]

The aim of this work was (i) to create an in-vitro model for the clinical simulation of these three different modified access types (***Figure 14***), (ii) to assess the volumetric loss of substance between four different preparation systems.

Simulated s-shaped root canals with medium degree of obliteration in acrylic polymer bodies with canal entrance angles 15°, 30° and 45° were wet shaped with NaOCl (3%), at body temperature in randomized blinded sequences (n = 7) according to manufacturer's instructions:

1. Conventional geometry, up to 35/.04 (F360, Komet)
2. Conventional geometry, up to 40/.04 (Hyflex® EDM, (Coltène-Whaledent, Altstätten, Switzerland))
3. Off-centered geometry, up to 36/.03 (TruNatomy®, (Dentsply Sirona, Ballaigues, Switzerland))
4. Off-centered geometry, up to 30/.04 (XP-Endo® Shaper, (FKG, La Chaux-de-Fonds, Switzerland))

Vectorization (AutoCAD) of whole root canal was performed before and after preparation, summarized in apical, middle and coronal thirds. Volumetric shaping and dentin loss was recorded and statistically evaluated using independent two-sided t-test.

Total volume-loss at 15° access was significantly lowest with TruNatomy® and XP-Endo® Shaper. At 30°, total loss remained low and increased with F360 and Hyflex. At 45° the group differences remained: TruNatomy® (6.5 mm) and XP-Endo® Shaper (6.4 mm) versus F360 (8.3 mm) and Hyflex® EDM (8.4 mm)(see ***Figure 15*** and ***Figure 16***). This difference was highly significant.
Conventional instruments achieve optimal shape of apical third of root canal via all entrance angles only with high simulated dentin loss along coronal and middle thirds. In contrast, off-centered instrument geometry contributes to dentin protection and supports the concept of conservative endodontics for lifelong tooth preservation.

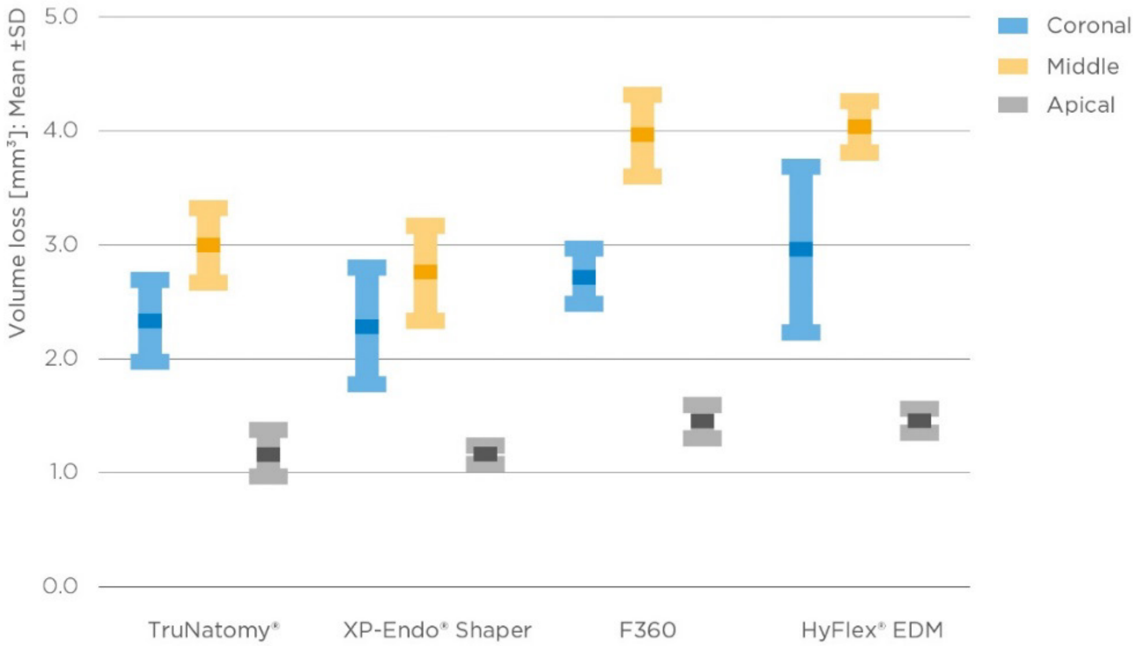

Figure 15: *Error bars of volume loss for the four test groups (TN: TruNatomy; XP: XP-Endo Shaper; F360: Komet F360 and HF: HyFlex EDM) coronal, middle and apical for the four tested files with an access cavity of 45°.*

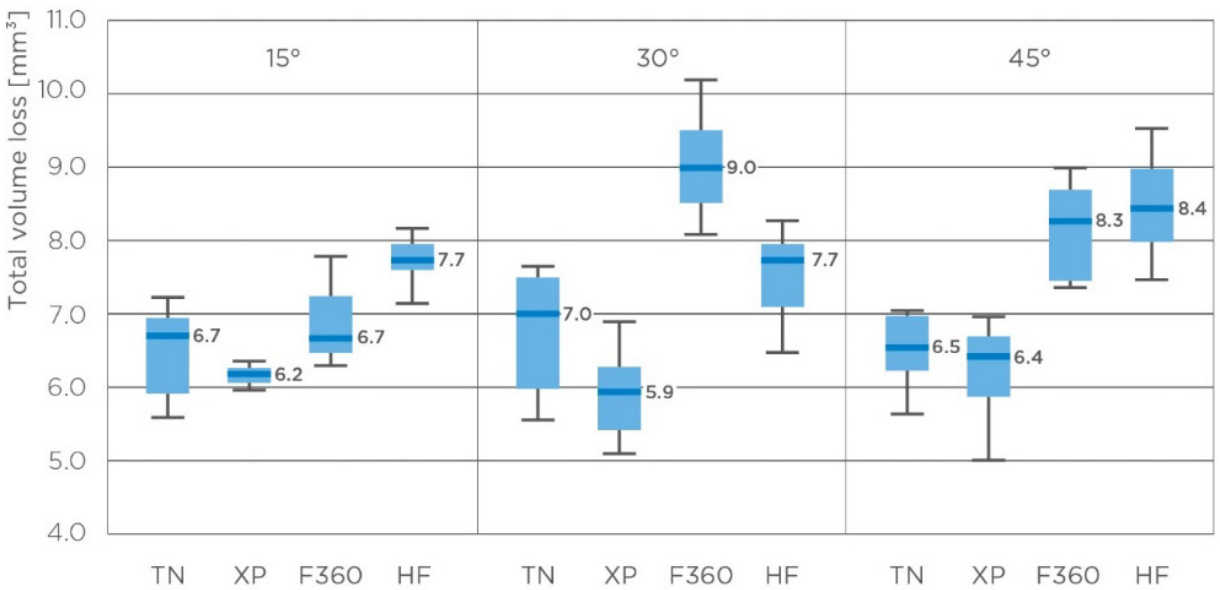

Figure 16: *Box plots of total volume loss (mm3) for the four test groups (TN: TruNatomy; XP: XP-Endo Shaper; F360: Komet F360 and HF: HyFlex EDM) compared to the canal entrance angles of 15°, 30° and 45°.*

Take home message on TruNatomy® and no straight-line access

In conservative access cavities (angulated up to 45°), simulated dentin volume loss in the coronal and middle third was lower with Trunatomy® compared to other conventional instruments, while the apical volume loss was similar. This shows the ability of TruNatomy® to preserve the peri-cervical region while ensuring sufficient apical debridement.

5. Clinical data

P. Van der Vyver, M. Vorster and O. Peters have published several clinical case reports illustrating the clinical benefits of the full TruNatomy® solution [22]. After an introduction including the definition of the peri-cervical dentine (i.e. area 4 mm coronal to the crestal bone and 6 mm apical to the crestal bone, see ***Figure 17*** below), the design features of TruNatomy® file sequences, and a clinical guidelines for the use of TruNatomy® instruments, six clinical case reports are detailed. All the case reports highlighted the conservative root canal preparation performed with TruNatomy®, in other words its ability to preserve the root structure in the peri-cervical area and to respect the full original canal anatomy.

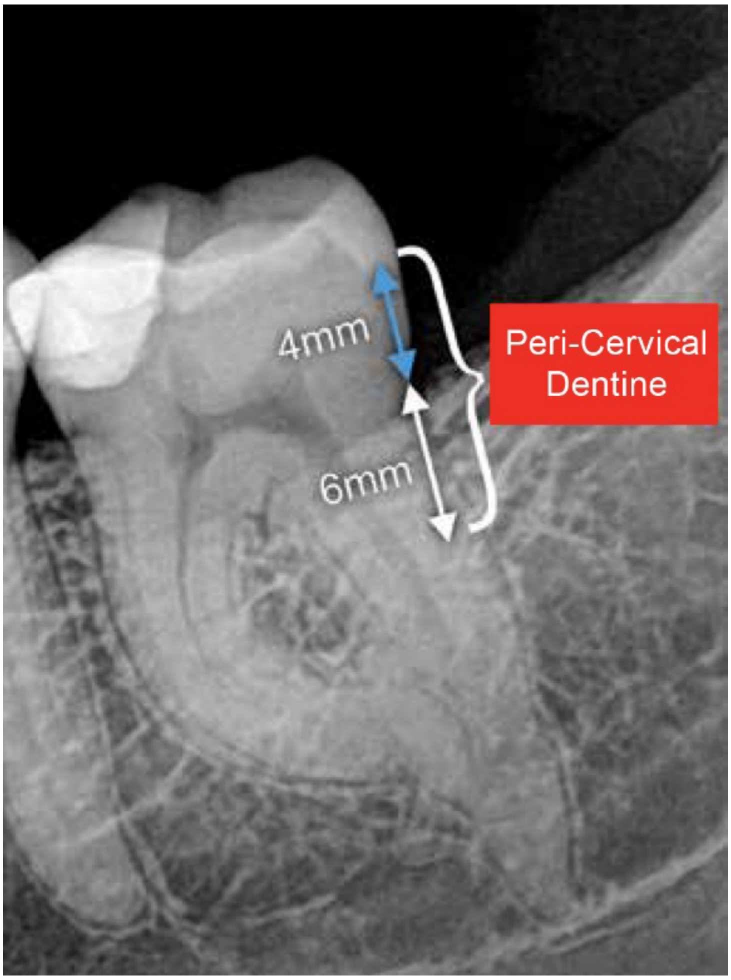

Figure 17*: X-ray image showing the peri-cervical dentine.*

See below the Case Report 6

A 45-year-old female presented with irreversible pulpitis on her mandibular right first molar (***Figure 18a***). A pre-operative CBCT scan revealed the presence of a mid-mesial root canal system in the mesial root (***Figure 18b***). After access cavity preparation, and removal of pulp calcifications in the pulp chamber, the three main root canal systems were located (mesio-lingual, mesio-buccal and distal). The groove between the mesio-lingual and mesio-buccal canals was throughed with a Start-X no 3 tip (Dentsply Sirona) to remove an overlapping dentine ledge, exposing the internal anatomy of the groove. A Micro-debrider (Dentsply Sirona) was used to locate the orifice of the mid-mesial canal. A size 08 C+ File (Dentsply Sirona) was used to negotiate the initial few millimetres of the constricted canal. Canal orifices were relocated and opened coronally with the TruNatomy® Orifice Modifier before the three mesial root canal systems were negotiated to full working length and apical patency. It was noted clinically and on CBCT that the distal root canal system was very wide in a buccal-lingual direction (***Figure 18b***) and it was possible to place a size 20 K-File to full working length Working lengths were determined by using an electronic apex locator and confirmed radiographically (***Figure 18c*** and ***Figure 18d***). It was noted that the mid-mesial canal join the mesio-lingual canal and the mesio-lingual join with the mesio-buccal canal in the apical 2mm of the root canal system. A reproducible micro glide path was established in all five root canal systems using a size 08 and 10 K-File before the glide paths were expanded with the TruNatomy® Glider. Taking into account that there was three root canal systems in the mesial root, the authors decided to use the TruNatomy® Small file for root canal preparation and maximum preservation of root structure. ***Figure 18e*** shows a magnified view of the pulp chamber floor. Note the large amount of tooth structure that was still intact after root canal preparation with the TruNatomy® Small file. The distal root canal was prepared with a TruNatomy® Medium file. Root canal irrigation was achieved by using 17% EDTA and heated 3.5 % sodium hypochlorite activated with the EDDY Endo Irrigation Tip (VDW) driven by an airscaler. Obturation of the canals were achieved by using TruNatomy® Conform Fit Gutta-Percha cones and sealer using the continuous condensation technique. ***Figure 18f*** shows a parallel view of the obturation result. Note the maximum preservation of the root structure in the peri-cervical region of the mesial and distal root canal systems. However, the mesio-angulated view (***Figure 18g***) shows that the full extent of the lateral anatomy that was cleaned and obturated. The clinical procedure of this case can be viewed on the following link or QR code: https://youtu.be/MxVKMc-E2VM

Scan here with smartphone camera

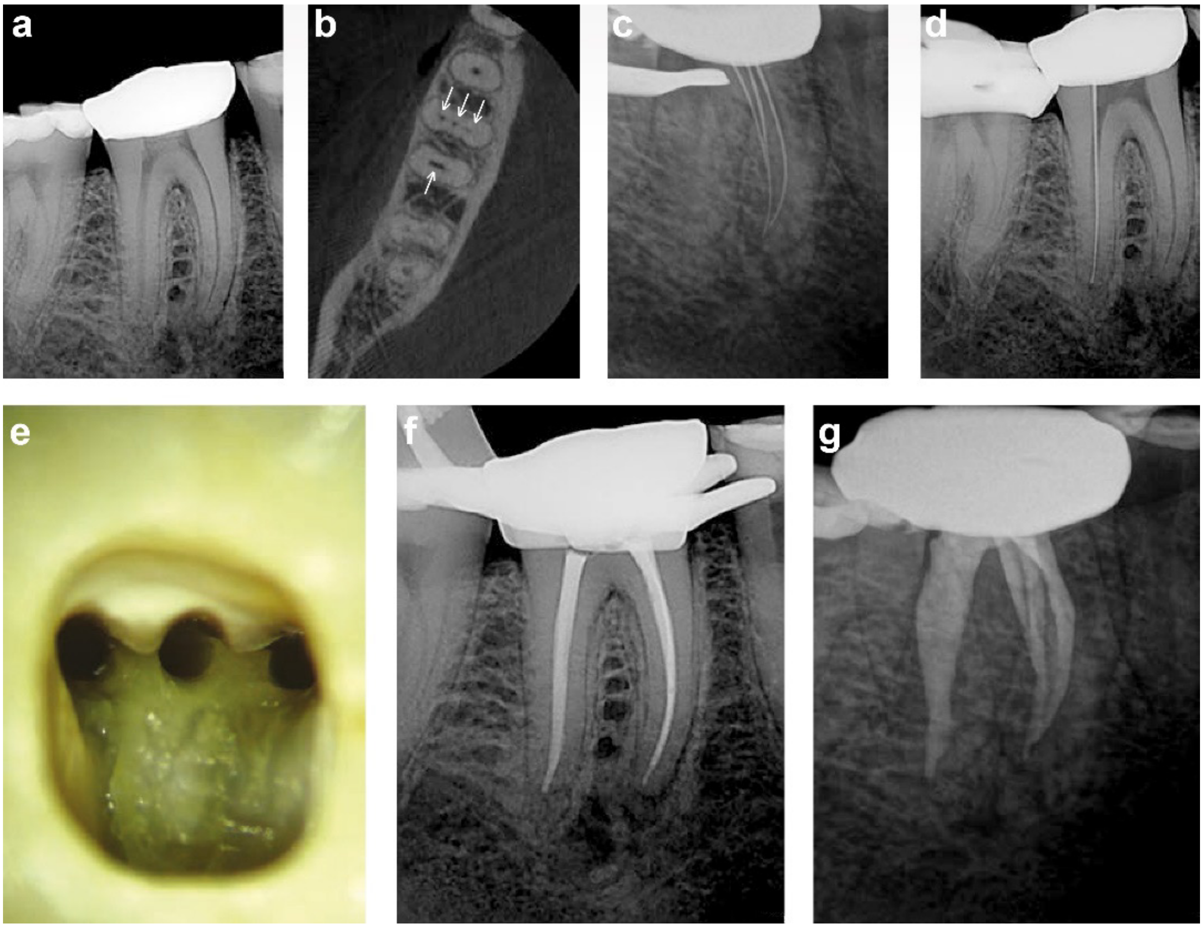

Figure 18: **(a)** Pre-operative periapical radiograph of mandibular right first molar; **(b)** An axial slice of a high resolution CBCT scan revealed four root canal systems (arrows). Three root canals in the mesial root and one large oval root canal in the distal root; **(c)** Periapical radiograph taken with a mesio-angulated view to confirm the length determination for the three mesial root canals; **(d)** Periapical radiograph to confirm the length determination for the distal root canal; **(e)** Magnified view of the pulp chamber floor. Note the large amount of tooth structure that was still intact after root canal preparation with the TruNatomy Small file; **(f)** Parallel view of the obturation result. Note the maximum preservation of the root structure in the peri-cervical region of the mesial and distal root canal systems; **(g)** Mesio-angulated view shows the full extend of the lateral anatomy that was cleaned and obturated.

6. Conclusion

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

- Studies, some of them performed at 37 °C (body temperature), confirmed the very high cyclic fatigue resistance of the TruNatomy® files compared to other files on the market [8-10].
- *In vitro* and *ex vivo* studies demonstrated that TruNatomy® produces very low canal transportation; TruNatomy® even showed the lowest canal transportation, in two studies, supporting its capacity to better preserve the dentine tissue [11-13, 15].
- TruNatomy® was shown via microCT to respect the canal anatomy (with again a minimal canal transportation) without compromising the shaping of the canal [14, 15].
- Debris extrusion in severe-curved molar and pre-molars was lower compared to other systems in two *in vitro* studies and may also lead to less post-operative pain compared to other instrumentation systems [18, 19].
- In conservative access cavities (angulated up to 45°), simulated dentin volume loss in the coronal and middle third was lower with Trunatomy® compared to other conventional instruments, while the apical volume loss was similar. This shows the ability of TruNatomy® to preserve the peri-cervical region while ensuring sufficient apical debridement [21].
- Clinical cases using TruNatomy® have demonstrated the benefits of the instruments, superior debridement whilst respecting original canal anatomy [22].

Preserving dentine, respecting original canal anatomy and therefore maintaining the structural integrity of teeth should form an integral part of root canal shaping and preparation. This is also considered as a decisive factor in the success of the restoration, for the long-term survival of natural teeth. In this framework, these studies all together illustrate the performance and clinical advantages of TruNatomy®, which should be your system of choice to treat teeth with various degrees of canal curvature while retaining structurally important dentin, without compromising the ability of canal's debridement.

7. References

1. Ng, Y.L., V. Mann, and K. Gulabivala, *Tooth survival following non-surgical root canal treatment: a systematic review of the literature.* Int Endod J, 2010. **43**(3): p. 171-89.
2. Dahlström, L., et al., *'Working in the dark': Swedish general dental practitioners on the complexity of root canal treatment.* Int Endod J, 2017. **50**(7): p. 636-645.
3. Zupanc, J., N. Vahdat-Pajouh, and E. Schäfer, *New thermomechanically treated NiTi alloys - a review.* Int Endod J, 2018. **51**(10): p. 1088-1103.
4. Elnaghy, A.M., S.E. Elsaka, and A.H. Elshazli, *Dynamic cyclic and torsional fatigue resistance of TruNatomy compared with different nickel-titanium rotary instruments.* Aust Endod J, 2020. **46**(2): p. 226-233.
5. Predin Djuric, N., et al., *Comparison of apical debris extrusion using clockwise and counter-clockwise single-file reciprocation of rotary and reciprocating systems.* Aust Endod J, 2021. **47**(3): p. 394-400.
6. Riyahi, A.M., et al., *Cyclic Fatigue Comparison of TruNatomy, Twisted File, and ProTaper Next Rotary Systems.* Int J Dent, 2020. **2020**: p. 3190938.
7. Hargreaves, L.H.B.K.M., *Cohen's Pathways of the Pulp*. 12 ed. 2020: Elsevier Health Sciences (US).
8. Elnaghy, A.M., S.E. Elsaka, and A.O. Mandorah, *In vitro comparison of cyclic fatigue resistance of TruNatomy in single and double curvature canals compared with different nickel-titanium rotary instruments.* BMC Oral Health, 2020. **20**(1): p. 38.
9. Peters, O.A., A. Arias, and A. Choi, *Mechanical Properties of a Novel Nickel-titanium Root Canal Instrument: Stationary and Dynamic Tests.* J Endod, 2020. **46**(7): p. 994-1001.
10. Gundogar, M., et al., *Comparison of the cyclic fatigue resistance of VDW.ROTATE, TruNatomy, 2Shape, and HyFlex CM nickel-titanium rotary files at body temperature.* Restor Dent Endod, 2020. **45**(3): p. e37.
11. Kabil, E., et al., *Micro-computed Evaluation of Canal Transportation and Centering Ability of 5 Rotary and Reciprocating Systems with Different Metallurgical Properties and Surface Treatments in Curved Root Canals.* J Endod, 2021. **47**(3): p. 477-484.
12. Kumar, M., et al., *Comparison of Canal Transportation in TruNatomy, ProTaper Gold, and Hyflex Electric Discharge Machining File Using Cone-beam Computed Tomography.* J Contemp Dent Pract, 2021. **22**(2): p. 117-121.
13. Kim, H., S.J. Jeon, and M.S. Seo, *Comparison of the canal transportation of ProTaper GOLD, WaveOne GOLD, and TruNatomy in simulated double-curved canals.* BMC Oral Health, 2021. **21**(1): p. 533.
14. Emmanuel J.N. L. Silva, C.O.d.L., Ana Flávia Almeida Barbosa, and L.M.S. Ricardo Tadeu Lopes, Marco Aurélio Versiani, *The impact of TruNatomy and ProTaper Gold instruments on the preservation of theperiradicular dentin and on the enlargement of the apical canal of mandibular molars.* Journal of Endodontics, 2022.
15. Perez Morales, M.L.N., et al., *Micro-computed Tomographic Assessment and Comparative Study of the Shaping Ability of 6 Nickel-Titanium Files: An In Vitro Study.* J Endod, 2021. **47**(5): p. 812-819.
16. Peters, O.A., K. Schonenberger, and A. Laib, *Effects of four Ni-Ti preparation techniques on root canal geometry assessed by micro computed tomography.* Int Endod J, 2001. **34**(3): p. 221-30.
17. Haapasalo, M., et al., *Irrigation in endodontics.* Br Dent J, 2014. **216**(6): p. 299-303.
18. Yilmaz Cirakoglu, N. and Y. Ozbay, *Apically extruded debris associated with ProTaper Next, ProTaper Gold and TruNatomy systems: An in vitro study.* J Dent Res Dent Clin Dent Prospects, 2021. **15**(1): p. 30-34.
19. Mustafa, R., et al., *Evaluating In Vitro Performance of Novel Nickel-Titanium Rotary System (TruNatomy) Based on Debris Extrusion and Preparation Time from Severely Curved Canals.* J Endod, 2021. **47**(6): p. 976-981.

20. Al Omari, T., et al., *Apical debris extrusion of full-sequenced rotary systems in narrow ribbon-shaped canals.* Aust Endod J, 2021.
21. T. Lang , D.Q.N., I. Steiner, A. Ditz, K.W. Weich,P. Gaengler,, *Volumetric Bio-Mechanics of Instrumentation via Angulated Access Cavities – A Randomized, Blinded and Clinically Simulated in vitro Study*, O.o. Witten/Herdecke, Editor. 2022: unpublished data.
22. Van der Vyver PJ, V.M., Peters OA, *Minimally invasive endodontics using a new single-file rotary system.* International Dentistry. **9**.

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ZKD / T EN TNMY SCM 000 / 00/ 2022 – created 03/2022

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