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Evaluating in-Vitro Performance of Novel Nickel-Titanium Rotary System (TruNatomy) based on debris extrusion and preparation time from Severely Curved Canals

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The authors deny any conflicts of interest related to this study.

Evaluating in-Vitro Performance of Novel Nickel-Titanium Rotary System (TruNatomy) based on debris extrusion and preparation time from Severely Curved Canals

Short title: Apically debris extrusion from curved canals

Abstract

Introduction: This laboratory-based study aimed to investigate the quantitative amount of apically extruded debris from severely curved root canals and preparation time for the novel rotary system, **TruNatomy (TN)**, compared to Reciproc Blue (RCB), HyFlex (HCM, HEDM) and ProTaper Next (PTN) rotary systems.

Methods: One hundred mandibular molar human teeth with severe curvature of the mesiobuccal canal (25°- 45°) were included in the present study. The specimens were randomly distributed in balanced five groups (n=20): TN, RCB, HCM, PTN, and HEDM. The amount of extruded debris **for each group** during instrumentation at body temperature was collected in an Eppendorf tube. After desiccation, the mean debris weights **for each group** were calculated. The total preparation time for each group was also recorded. Data were statistically analysed using the Kruskal–Wallis test at a significance level of **$P < 0.05$** .

Results: HCM and HEDM groups extruded a **significantly higher** amount of debris than **the** other tested groups ($P < 0.001$). TN extruded the least amount of debris, but it was not significantly different compared to **the RCB and PTN groups** ($P > 0.05$). **In terms of preparation time, the TN group did not show any significant difference compared to the other groups.**

Conclusions: All instrumentation systems extruded debris. The TN was among the groups that produced the lowest amount of apically extruded debris that is probable clinically acceptable, since it is equitable to two popular systems and statistically significantly less than two other popular systems studied.

Keywords

Debris extrusion; Nickel-Titanium rotary system; Reciproc Blue; Pro Taper Next; TruNatomy, **HCM; HEDM**

Introduction

Debris of pulpal tissue remnants, irrigants, microorganisms, and dentinal chips can be pumped through the apex to periapical tissue during the chemo-mechanical preparation step in root canal treatment^{1,2}. This inevitable extruded debris may lead to undesirable postoperative pain, apical inflammation, and even delayed healing^{1,2}. A number of influencing factors determine the amount of extruded debris: physical factors associated with tooth anatomy² such as canal curvature, working length etc., and mechanical factors such as instrumentation techniques, motion kinematics, number and design of instruments etc.³.

In multi-rooted posterior teeth, clinicians are challenged with severely curved canals in one or more planes, causing the endodontic treatment highly complicated. To preserve the canal geometry with less iatrogenic error, continuous innovation in NiTi rotary instrument manufacturing process results in new design concepts⁴.

HyFlex Controlled Memory (HCM) (Coltene/Whaledent, Altstatten, Switzerland) has a symmetrical cross-section with three cutting edges, and it is manufactured from CM wire. The deformed HCM instrument would regain its original shape after a sterilization procedure⁵. HyFlex EDM (HEDM) "one file" (Coltene/Whaledent, Altstatten, Switzerland) is also manufactured from CM wire by an electrical discharge machining (EDM) process that improves the cutting efficiency and fracture resistance of the HEDM. It has variable taper and cross-section along its shaft with 0.25 mm apical diameter⁵. ProTaper Next (PTN) (Dentsply Maillefer, Ballaigues, Switzerland) is a heat-treated M wire NiTi alloy with an off-centered rectangular cross-section. Five different sizes (X1 to X5) are provided in this file system^{6,7}. Reciproc Blue (RCB) is a single-file system and developed as a successor of the M-Wire Reciproc (VDW Dental, Munich, Germany) system with improved cyclic fatigue resistance properties. It undergoes a unique heat treatment that results in the blue titanium oxide layer on the instrument surface⁸.

Recently, a novel heat-treated NiTi instrument, TruNatomy (TN) (Dentsply Sirona, USA) was introduced and manufactured from a unique thin NiTi wire with 0.8 mm of maximum flute diameter instead of 1.2 mm that commonly specified in other various files. Also, it has an off-centered parallelogram cross-section, which provides space for additional debris removal. It consists of 5 specific instruments^{9,10}.

It was claimed that TN could preserve tooth structure and canal geometry, especially in the severely curved canal due to its regressive slim taper, less shape memory, and special heat treatment of the NiTi alloy^{9,10}. Although several studies were carried out on cyclic fatigue and torsional resistance of the TN rotary system^{9,11}, no data was available in the literature on debris extrusion performance of this new instrument compared to the other systems. Regardless of the treatment system used, most of studies have shown that some extrusion will occur^{3, 6, 12}. Consequently, this in-vitro study aimed to quantitatively measure the amount of debris extruded from severely curved canals and preparation time for five different NiTi rotary systems (RCB, HEDM, HCM, TN, PTN). The null hypothesis to be tested was that there would be no significant difference in the amount of debris extrusion between the tested rotary systems.

Material and methods

Sample selection and preparation

The Ethical approval was obtained from the institutional research board (IRB) at the corresponding author's institution (Ref. No.: IRB/23/2017). A total of one hundred mesial roots with mesiobuccal canals were selected for this study with curvature angles ranging between 25° to 45° (Schneider 1971) and curvature radius less than 6 mm (Schafer et al., 2002), which were identified using an image analysis software (AxioVision 4.5; Carl Zeiss Vision, Hallbergmoos, Germany). Periapical digital radiographs in both mesiodistal and buccolingual were taken in order to exclude teeth with calcification, Vertocci type II, external roots defects, and other anatomic irregularities. The teeth were grouped according to the canal curvature angle and radius to ensure the homogeneity between the experimental groups. After that, the teeth were randomly distributed to the five tested groups (n=20) using a computer algorithm ([http:// www.random.org](http://www.random.org)). The mean value of the curvature angles was $33.6056 \pm 6.02165^\circ$ and the radius was 4.07010 ± 0.95214 mm. The analysis of variance (ANOVA) was performed for the curvatures and radii ($P = 1$ and $P = 0.978$ respectively) to assess the homogeneity.

Using a high-speed hand bur (Diatech, Coltene Whaledent, Altstätten, Switzerland) with refrigerated water, molar teeth were sectioned buccolingually in the furcation area to separate the mesial roots. Calculus and superficial tissues on the roots were removed mechanically. Occlusal reduction for mesial buccal cusp was made to obtain a standardized working length (WL) of 17 mm and stable reference points for all included teeth. After the access cavity procedure, the patency was checked under a dental operating microscope (Zeiss OPMI; Carl

Zeiss, Jena, Germany) with a magnification of $\times 20$. The WL was calculated by subtracting 1 mm from the initial length for each canal when the file tip was visible from the apical foramen under the microscope. Narrow canals, in which size 10 K-files (Dentsply Maillefer) or smaller could be inserted passively to **the** WL, were only selected for the study, and stored in thymol solution.

Instrumentation

Conventional straight-line access and smooth glide path were performed for all mesial buccal canals. Subsequently the instrumentation for all the tested groups were carried out using a Silver Reciproc electric motor (VDW, Munich, Germany) as follows:

The RCB group (n=20): A Reciproc R25 file (25/.08) was driven in the "Reciproc All" mode. The file was operated in a slow in-and-out pecking motion. After every three pecks, the instrument's flutes were cleaned with gauze, and the canal was irrigated.

The PTN group (n=20): Files were operated to full WL with outstroke brushing motion at 300 rpm **and** a torque of 2.4 N-cm. The file sequence consisted of employing two file sizes X1 (17/.04) and X2 (25/.06) during the instrumentation.

The TN group (n=20): TN files were operated at a speed of 500 rpm and a torque of 1.5 N-cm. The file sequence consisted of an orifice modifier to half WL then glider, small (20/.04) and prime (26/.04) to full WL.

HCM group (n=20): Files were operated in gentle apical pecking motions to full WL at a speed and a torque of 500 rpm and 2.5 N-cm respectively. The files sequence after orifice opener (25/.08) consisted of two files: (20/.04) and (25/.04).

HEDM group (n=20): One file (HEDM 25/.08) was used after the orifice opener in the same manner as the HCM group at a speed and torque of 500 rpm and 2.5 N-cm respectively.

Evaluation of Debris Extrusion

The debris collection methodology was modified from a previous study¹². Briefly, debris extruded during canals preparation was collected using Eppendorf tubes. Initially, each tube was individually weighed five times using a microbalance (Citizen CX 220 Analytical Lab Balance, Internal Cal. Weighing Hook, USA) with an accuracy of 0.00001 gm and the mean

value was calculated. After that, each mesial root was placed at the cemento-enamel junction level inside a pre-weighed Eppendorf tube and fixed using a rubber stopper. A 25G irrigating needle was inserted through the rubber stopper to maintain equal inner and outer air pressure. To prevent contamination of the Eppendorf tube during the shaping procedure, a glass ampoule was used as an outer container. The glass ampoule was fixed at the base of the cover of a larger glass container with a water bath at a controlled temperature of 35-37°C. This was confirmed using an electrode thermometer (MN35, Digital Mini MultiMeter, Boston, Massachusetts, USA) (Figure 1). This was advisable and desirable in previous study⁹.

During the cleaning and shaping procedure under high vacuum suction, each sample was irrigated with 5 ml of tri-distilled water using a 30-gauge needle (NaviTip, Ultradent Products) inserted up to 2 mm short to the WL. The canal patency was also checked with K-file size ten during instrumentation. Finally, after removing the root from the Eppendorf tube, 1 ml of tri-distilled water was used to flush any debris into the tube that might be attached to the external surface of the apical third of the root. The tube with an irrigation solution was stored in an incubator for two weeks at 37°C to evaporate the irrigating solution. Afterward, another five weight measurements for each tube were obtained, and the mean value was calculated. The difference between pre- and post-mean weights in mg for each tube represented the net weight of extruded debris. A digital timer was used to record the total preparation time in seconds for each sample including the total active instrumentation, file changes, cleaning of file flutes, and irrigation. A single operator completed the canal preparations for all groups, whereas a second examiner, who was blind regarding the experimental groups, assessed the extruded debris.

Statistical analysis

The SPSS software version 25 (IBM Corporation, New York, USA) was used to perform the statistical analyses. Shapiro-Wilk test ($P < 0.05$) revealed that the data for both weights of the extruded debris and preparation time were not normally distributed. Therefore, the Kruskal-Wallis test followed by the two-tailed Mann-Whitney U test was used to compare the groups at a significance level of $P < 0.05$. After that, Bonferroni correction was also performed to correct multiple comparisons.

Results

The mean, median (percentiles values), minimum and maximum weights of the extruded debris and preparation times for each group are displayed in Table 1 and Table 2 respectively. The

TN, RCB, and PTN groups recorded a lower amount of debris, while the HCM and HEDM groups extruded a significantly higher amount ($P < 0.001$). The TN group extruded the lowest amount among the groups ($P > 0.001$) (Figure 2).

The PTN group needed more preparation time than the other groups, which was significant when it was compared with the HCM and HEDM groups (Figure 3).

Discussion

In the current study, the performances of five different rotary systems were evaluated in terms of quantitative amount of apically extruded debris and the instrumentation time. A new novel system, TN, was included in the present study. It was compared with other rotary systems with different kinematics, designs, and manufacturing procedures as there was limited or even lack of evidence in the literature about the debris extrusion with the TN file system. The null hypothesis was rejected as the debris extrusion occurred in all groups with different amounts between the tested instrumentation systems.

The HCM and HEDM groups resulted in a highly significant difference compared to the other tested groups based on the amount of debris extrusion. This could be explained by the unwinding feature of the HyFlex rotary systems during instrumentation, which was noticed in most used HyFlex rotary files. An unwinding of the endodontic files can elongate the file pitches and reduce the flute volume. Hence the flute depth becomes less; the debris carried coronally will be less¹³. This finding agreed with previous studies' findings, which reported that the longer the pitch extension, the higher the amount of extruded debris¹⁴⁻¹⁶.

Additionally, the HCM had an asymmetric cross-section with three cutting edges⁵ with minimal space to extrude debris in a coronal direction compared to the other investigated systems with two cutting edges. The cross-section design of the RCB was similar to an S shape with two cutting edges that reduced the core volume, thus minimising the apically extruded debris^{12, 17}. Both the TN¹⁰ and PTN⁷ systems shared the off-centered rectangular cross-section design, which might result in less engagement between the file and dentine, providing more space for coronal debris extrusion⁶. Furthermore, the swaggering motion of the PTN could lead to debris removal in a coronal direction rather than an apical one^{6, 7}.

Interestingly, there was no significant difference in debris extrusion between the HCM and HEDM even though their tapernesses in the last file were 4% and 8% respectively. The same

taperness finding was evident between the TN (4%) and the PTN (6%). Nonetheless, the TN 4% extruded significantly less debris apically than HCM 4%. These results can be supported by the findings of Aksel et al. that increasing preparation taper from 4% to 6% would not significantly increase the bacteria extruded apically regardless of the instrumentation techniques¹⁸. Moreover, the results from previous studies showed that greater taper did not necessarily mean to extrude more debris apically^{12, 19}, which was noticed in the present study. This needs further investigation.

A recent systematic review reported that the cross-section design of the rotary instrument had a more significant influence on the amount of extruded debris apically than the used kinematics during instrumentation²⁰. Again, in relation to the kinematics, some studies reported that the debris extrusion increased with the reciprocation motion^{2, 21, 22} while other studies, including the current one, indicated that reciprocation rotary system was associated with good performance in terms of reduced debris extrusion^{3, 23, 24}. This could be attributed to a better control of debris extrusion toward apical tissue as it is a form of automated balance force technique²³. Nonetheless, these contradictory findings of debris extrusion using reciprocation compared to the continuous motion might be related to the heterogeneity of materials and research methodologies employed. Thus, comparing findings between different studies is quite difficult.

The PTN system significantly consumed more time for canal preparation than **the** HCM and HEDM groups. The increasing number of instruments employed during the preparation can explain this when compared to the single file system employed in **the** HEDM and RCB groups. Furthermore, the PTN had a larger taper than the HCM and TN that might contribute to a more extended period during the canals' preparation.

Most previous studies used relatively straight canals^{14, 25} because of easy instrumentation. Nevertheless, commonly in multi-rooted posterior teeth, clinicians are challenged with severely curved canals in one or more planes making the endodontic treatment more complicated. Moreover, flare-up incidence was significantly higher in molar endodontics treated teeth²⁶. Additionally, the amount of extruded debris might be affected by the tooth type and the curvature^{6, 27}. Consequently, posterior molar teeth with curved mesial canals were used in **this** study to simulate the **actual** clinical circumstances^{28, 29}. Relatively small curvature and radius ranges were adopted, and a systematic strategy was considered during sample distribution. As the environmental temperature might affect NiTi metallurgy and its physical

properties³⁰, the mean temperature for intra-canal in-vivo condition was reported to be approximately 35°C³¹. Thus, an external hot water bath container was used to maintain the mean temperature around 35°C - 37°C during instrumentation in order to have a better simulation of the clinical condition. Furthermore, standardized initial, final apical preparation, and volume of irrigation solution and irrigation activation were applied to reduce the risk of unreliable comparisons between the tested groups. Sonic irrigation and its effect on apical debris extrusion and debris removal were reported in the literature^{31, 32, 33}. There is planned future research for further investigation of its effect on debris removal.

It is worth mentioning that the experimental model of the present study was highly adapted by many previous studies^{6, 14, 25, 34}. It, however, lacked the stimulation of periapical tissue resistance. On the other hand, such laboratory-based studies could provide controlled conditions for developing reliable comparisons between the tested groups on certain factors^{35, 36}. Furthermore, this could act as a baseline for future clinical studies²⁰. Future in-vivo studies will be needed to investigate debris extrusion on endodontic treatment success and patient satisfaction during and after the treatment.

Conclusion

Under the limitations of this present in-vitro study, all tested rotary file systems caused debris extrusion during the apical root canal preparation. There was a significant increase in apically extruded debris for the HCM and HEDM systems compared to the other tested rotary systems. It could be stated that the novel TN system would be clinically acceptable since the debris extrusion was equitable to or significantly less than the other popular systems that had been tested in present study.

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Figures

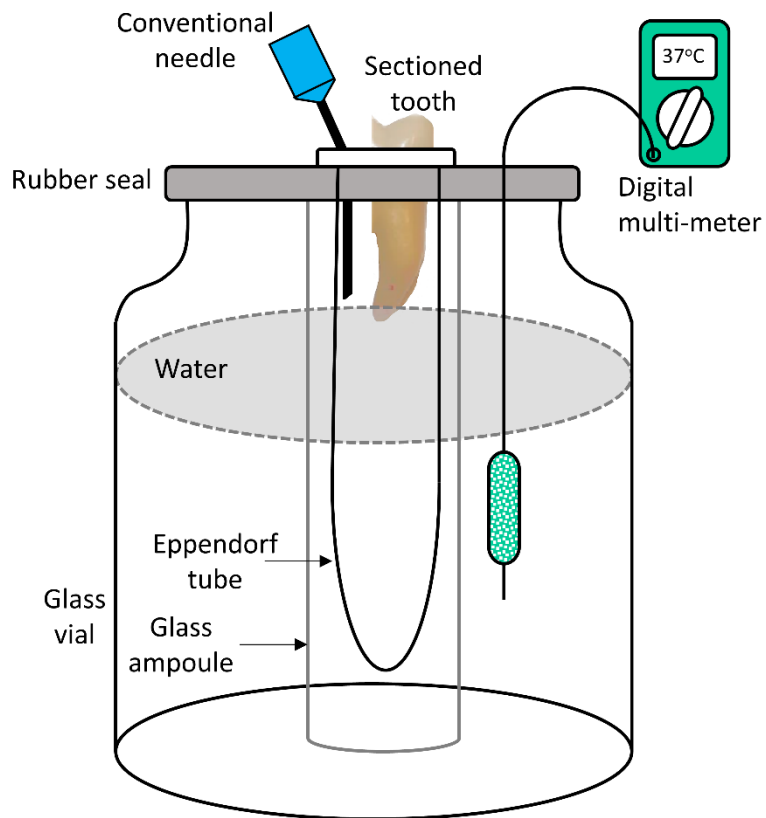


Figure 1. A representation of the set-up used for apical debris extrusion

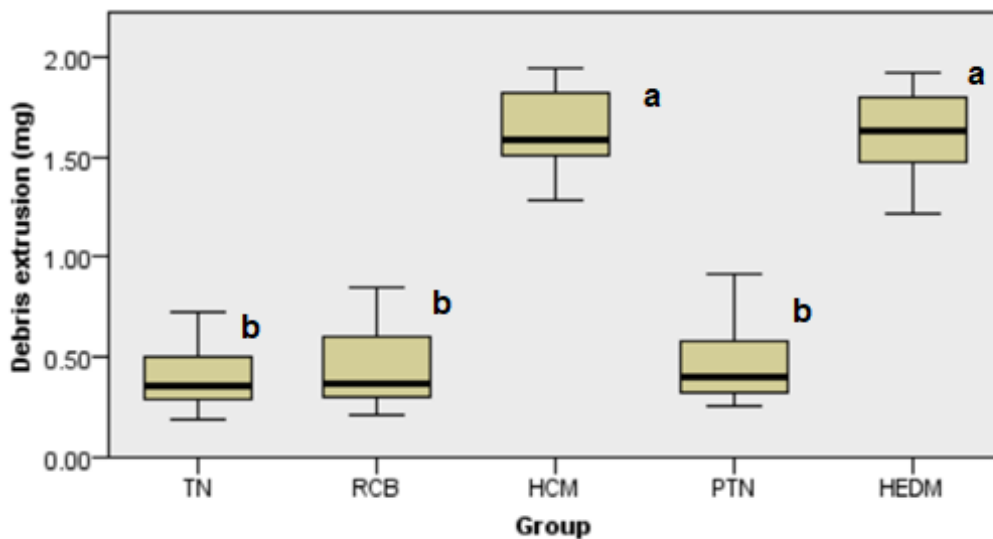


Figure 2. Box plot shows the median, minimal, and maximal values, as well as the standard deviation data related to the amount of extruded debris for all tested groups.

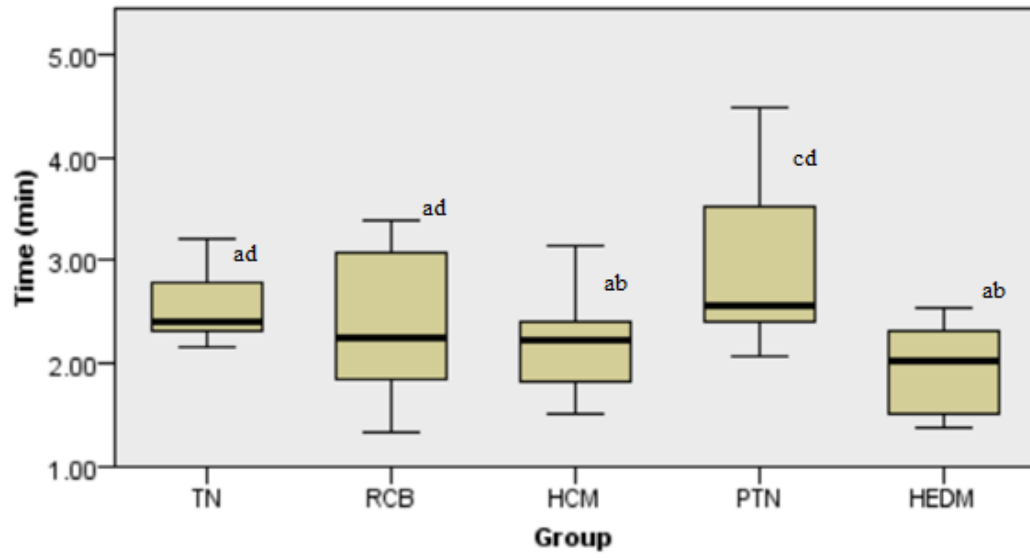


Figure 3. Box plot shows the median, minimal, and maximal values, as well as the standard deviation data associated with the preparation time for all tested groups

Tables

Table 1: Mean (SD), Median (25th- 75th) percentiles, minimum and maximum values for weight of apically extruded debris (mg) in the tested groups.

Rotary System	Debris weight (mg)			
	Mean (SD)	Median (25 th -75 th percentile)	Minimum	Maximum
TN	0.40423 (0.16500)	0.35166 ^b (0.28833-0.51083)	0.18333	0.72666
RCB	0.45016 (0.19751)	0.36333 ^b (0.29500-0.63750)	0.21000	0.85333
HCM	1.63662(0.18323)	1.59083 ^a (1.94666- 1.83250)	1.28666	1.70250
PTN	0.46083 (0.18578)	0.395833 ^b (0.31666-0.58125)	0.25500	0.92000
HEDM	1.63440(0.21005)	1.63583 ^a (1.47041-1.80666)	1.21300	1.92666

Values with different letters indicate statistically significant difference ($p < 0.001$).

Table 2: Mean (SD), Median (25th- 75th) percentiles, minimum and maximum values for preparation time (min) of the tested groups.

Rotary System	Preparation time (min)			
	Mean (SD)	Median (25 th -75 th percentile)	Minimum	Maximum
TN	2.547(0.359)	2.400 ^{ad} (2.3025-2.912)	2.160	3.210
RCB	2.394(0.694)	2.245 ^{ad} (1.705-3.090)	1.330	3.400
HCM	2.178(0.462)	2.235 ^{ab} (1.7025- 2.420)	1.500	3.150
PTN	2.986(0.781)	2.570 ^{cd} (2.397 -1.702)	2.060	4.500
HEDM	1.927(0.440)	2.020 ^{ab} (1.5-2.307)	1.370	2.550

Values with different letters indicate statistically significant difference ($p < 0.001$).