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Original Article

Comparison of shaping ability and cutting efficiency of a novel rotary file system (Trunatomy) versus Protaper Next and 2Shape in severely curved mandibular mesiobuccal canals (An in vitro study)

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ABSTRACT

Introduction: This study aimed to compare the shaping ability and cutting efficiency of Trunatomy, Protaper Next and 2Shape file systems in preparing severely curved canals. **Methods:** Forty-five mandibular mesiobuccal canals with 40-60 degrees of curvature were divided into three equal groups: Trunatomy, Protaper Next and 2Shape. Root canal instrumentation was done according to the manufacturers' instructions of each NiTi system. Pre- and post-instrumentation images were taken using cone beam computed tomography to measure canal transportation, centering ability, dentin thickness and canal curvature radius and volume. Pre- and post-instrumentation weights were measured using an analytical scale. **Results:** Trunatomy had significantly the lowest values of canal transportation, amount of removed dentin and percent change in canal curvature radius and volume. Protaper Next had significantly the highest buccolingual canal transportation. There was no significant difference among the three systems in canal centering. Trunatomy significantly recorded lesser percent change in root canal weight than 2Shape. **Conclusion:** The three file systems were able to prepare severely curved root canals efficiently and safely.

Keywords: Canal transportation, CBCT, dentin thickness, severely curved canals, Trunatom

I. INTRODUCTION

The endodontic treatment goal is the management of pulpal/periradicular pathosis and preservation the natural healthy dentition of the patient ([1]). The most critical step in ensuring a successful outcome of treatment is root canal preparation. For efficient root canal shaping, it's crucial to preserve the canal anatomy and dentine thickness. Procedural errors such as instrument fractures, ledges, perforations and apical blockage might result in insufficient debridement, which can cause endodontic failure ([2]). The anatomy of the root canals has a great influence on the risk of canal transportation. The radius and degree of canal curvature affect the risk of canal transportation; the risk of canal straightening increases with decreasing radius and increasing degree of canal curvature ([3]).

There are several methods and parameters used in the literature to evaluate the shaping ability and cutting efficiency. An accurate and reproducible method is important to measure the root canal before and after preparation ([4]). Cone-beam computed tomography (CBCT) is a practical and nondestructive method for evaluation of the mechanical performance of endodontic instruments and their effect on root dentin thickness during root canal preparation in three dimensions ([5]). By creating three-dimensional images, CBCT overcomes the drawbacks of conventional radiography. Anatomical noise can be eliminated. The isotropic voxels enable the production of geometrically precise images that allow image measurements to be free of distortion in any plane and can be confirmed repeatedly ([6]).

Lots of innovations in NiTi instruments have been achieved in the last decade by improvements in the design, physical properties, metallurgy, kinematics, and thermal treatment of the NiTi alloy. Continuous modifications and production of new instruments need more research on the efficiency of these instruments to enable clinicians to make proper decisions using evidence-based practice ([7]).

2Shape (MicroMega, France) is another file system manufactured of T-wire with heat treatment of NiTi alloy to be more flexible and show better negotiationith canal curvatures. The file features an asymmetrical cross-section with a triple helix which provides high cutting efficiency through its two main cutting edges. For better debris removal and decreased constraints on the instrument a secondary cutting edge is created, reducing the instrument fracture and increasing the efficacy for better selective cleaning. It has only two contact edges during preparation, similar to Trunatomy and Protaper Next ([9]).

Protaper Next (Dentsply Sirona, Ballaigues, Switzerland) is a file system made of thermally treated M-wire NiTi alloy to increase its flexibility and improve cutting performance. The file features a variable taper which minimizes the contact between the file and dentin and increases the torsional resistance. It also features an off-centered rectangular cross-section with 2 cutting edges that create a snake-like "swaggering" movement to be more flexible, allow safe preparation of severely curved narrow canals and enhance debris removal ([10]).

Hussien et al. evaluated the shaping abilities of 2Shape, protaper Next and neolix in curved canals. Fifty-seven mesiobuccal mandibular canals were prepared. Before and after preparation images were taken by CBCT. 2Shape and PTN showed lower canal transportation than neolix group. They concluded the three systems had a similar shaping ability([11]).

Almeida et al. compared the cutting efficiency of ProTaper Next and ProTaper Universal using a bench testing machine, torque and apical forces were measured as the cutting parameters. PTN required more apical forces and torque and less effective at cutting than PTU instruments([12]).

Faisal et al. compared 2Shape and NeoNiTi's cutting efficiency and shaping ability. Forty curved mandibular teeth with canal curvatures of 25 and 35 degrees were divided and prepared. Pre- and post-Preparation images were taken by Micro-CT. All results were comparable, except that the NeoNiTi group significantly increased the amount of dentin removed at canal curvatures of 35°. They concluded that the 2Shape and NeoNiTi systems could safely prepare severely curved canals([13]).

A recently introduced rotary file system called the Trunatomy system (Dentsply Sirona, Ballaigues, Switzerland) is manufactured from a slim NiTi wire, 0.8 mm in diameter instead of 1.2 mm of which most generic NiTi instruments are manufactured. It is also manufactured with a new post-manufacture heat-treatment alloy to provide greater flexibility with improved fatigue resistance. The file features an off-centered parallelogram cross-section design with 2 cutting edges, a regressive taper and short file handles to enhance the file flexibility, ability to be pre-curved and have less resistance which requires less applied pressure to be more conservative during canal preparation ([8]). There are no enough studies about the shaping ability and cutting efficiency of Trunatomy system.

The aim of the present study was to compare the 3 file systems; Trunatomy, Protaper next and 2Shape in preparing severely curved mesiobuccal canals (40º-60º) of mandibular molars regarding shaping ability and cutting efficiency by using cone beam computed tomography (CBCT) and an analytical scale.

II. MATERIALS AND METHODS

The sample size was determined via the PS software (version 3.1.2) (Vanderbilt University, Nashville, Tennessee, USA) according to a previous study ([14]). With a total sample size of 45 teeth for the three groups and a power of 80% with an alpha error probability of 0.05, it was determined that 15 teeth per group was the appropriate sample size for the study's primary outcome (canal transportation). The magnitude of the effect to be detected was estimated as the mean and standard deviation of the variable of interest.

Forty-five mesial mandibular roots were used. Each root had Weine’s type III canal configuration, mesiobuccal canal curvature range was 40°-60° measured according to Schneider’s method with mature apices, non-calcified and canals without resorptive lesions, previous root canal treatment or root caries ([15]). A size 10 K-file was used to locate the mesiobuccal canal and check its patency. After that, the working length of all samples was standardized at 15 mm. The forty-five roots were randomly assigned to three equal groups (n=15) according to the NiTi instrument used for root canal instrumentation; Trunatomy, 2Shape and Protaper Next. Samples were embedded in impression material and mounted in plastic blocks filled with acrylic resin.

Before preparation, all roots were allowed to air dry for twenty-four hours to obtain them moisture-free. Each root was then weighed using a five-digit gram analytical scale. Each sample was then identified and stored in saline in a separate coded vial. After the canal preparation, the difference between the pre-and post-weight would be calculated ([16]). A cone beam computed tomography (CBCT) image was taken for each embedded sample prior to canal preparation.

A. Root canal instrumentation:

In all groups, irrigation was performed throughout the preparation procedure between every two successive file sizes with 5 mL of 2.5% sodium hypochlorite solution. Glide path was created using size 15 K-file for each canal. Each root canal was instrumented according to the manufacturer's recommendations of each NiTi system. In Trunatomy group, Orifice modifier (#20/0.08) was first used for preparation of the coronal two thirds then Glider file (#17/ 0.02), Small file (#20/ 0.04) and Prime file (#26/ 0.04) were used to the full working length. Files were used in 2-3 gentle amplitudes approximately 2-5 mm in and out of the canal. In 2Shape group, one flare file (#25/ 0.09) was first used for preparation of the coronal two thirds then TS1 file (#25/ 0.04) and TS2 file (#25/ 0.06) were used to the full working length. Files were used in the progressive movement in three up-and-down movements with an upward circumferential filing motion until feeling the resistance to eliminate the primary constraints. In Protaper Next group, XA file (#19/ 0.035) was first used for preparation of the coronal two thirds then X1 file (#17/ 0.04) and X2 file (#25/ 0.06) were used at to the full working length. Files were used in a brushing motion, away from external root concavities and not advancing more than 1 mm per second into the canal. In all samples, MD-ChelCream was used for instrument lubrication.

A post-instrumentation CBCT scan was acquired using the same settings as the pre-instrumentation scan after root canal preparation. Preoperative and postoperative scans were superimposed using OnDemand 3d App software (Cybermed, South Korea), which ensured accurate measurement of dentin thickness at the exact level. Dentin thickness at all aspects of the canal lumen was simultaneously measured at both scans for each axial view. For each sample, the procedures were repeated, and dentin thickness was measured every 1 mm along the axial axis.

The shaping ability of the studied file systems was evaluated using the parameters of canal transportation, centering ability ratio and percent change in root canal curvature. Canal transportation and centering ability ratio were measured at each pre-determined levels; 2, 3, 5 and 8 mm in mesial, distal, buccal and lingual directions, according to the method established by **Gambill et al., 1996** ([17]) (Figure 1)**.**

Using the following equations for canal transportation:

- Mesio-distal transportation:
  (M1-M2) - (D1-D2)
- Bucco-lingual transportation:
  (B1-B2) - (L1-L2)

If the result of the formula was zero, this meant no transportation, while the positive results indicated mesial or buccal transportation and negative results indicated distal or lingual transportation.

Using the following equations for centering ability:

- Mesio-distally
  (M1-M2) / (D1-D2) or (D1-D2) / (M1-M2)
- Bucco-lingually
  (B1-B2) / (L1-L2) or (L1-L2) / (B1-B2)

The lower value is considered as the numerator of the ratio where:

- M1 is the measured distance from the mesial edge of the root to the mesial edge of the un-instrumented canal.
- M2 is the measured distance from the mesial edge of the root to the mesial edge of the instrumented canal.
- D1 is the measured distance from the distal edge of the root to the distal edge of the un-instrumented canal.
- D2 is the measured distance from the distal edge of the root to the distal edge of the instrumented canal.
- B1 is the measured distance from the buccal edge of the root to the buccal edge of the un-instrumented canal.
- B2 is the measured distance from the buccal edge of the root to the buccal edge of the instrumented canal.
- L1 is the measured distance from the lingual edge of the root to the lingual edge of the un-instrumented canal.
- L2 is the measured distance from the lingual edge of the root to the lingual edge of the instrumented canal.

If the result of the formula was equal one, this indicated that the rotary file remained centered in the canal. If the result was less than one, this indicated less ability of the instrument to keep centralized inside the canal. Using the technique created by **Estrela et al., 2008**, the canal curvature radius was assessed. Sagittal cuts were taken and the canal lumen was located. At each canal lumen, two lines were drawn representing the segments of the canal curvatures, upon which two perpendicular lines were drawn from their centers and extended until they intersect at a central point, which is named circumcenter. The center of the canal's curvature was indicated by the intersection of these parallel lines. Both lines were equal in length and represented the radii of canal curvature. Then the percent change in radius of curvature was calculated ([18]) (Figure 2):

$$\frac{(\text{post}-\text{instrumentation radius}-\text{pre}-\text{instrumentation radius})}{pre-instrumentation\ radius}\ \chi\ 100$$

The cutting efficiency of the studied file systems were evaluated by the measurement of the amount of removed dentin through calculating the difference in dentin thickness, percent change in root canal volume and percent change in root weight**.** For difference of dentin thickness measurements, the average thickness of each four successive cut planes from the apex was calculated to represent the apical, middle, and coronal thirds for each direction separately using the method by Hartmann et al., 2007 ([19]).

From the equation:

(M1-M2) + (D1-D2) + (B1-B2) + (L1-L2)

For volumetric measurement, Mimics software (Materialise NV, Leuven, Belgium) was employed. A fixed density threshold (0- -1024 HU) was assigned to segment the canal lumen according to difference in density. Minimum manual clean-up was needed to confine the created segments to the canal lumen. The volume of the segmented anatomy was automatically calculated for each canal lumen solely at each scan. Then the percent change in

$$\frac{(\text{post}-\text{instrumentation volume}-\text{pre}-\text{instrumentation volume})}{pre-instrumentation\ volume}\ \chi\ 100$$

root canal volume was calculated from the equation ([20]) (Figure 3):

After canal instrumentation, each root was re-dried using the previously mentioned method and weighed. Measurements were recorded in a schematic chart to be used for subtractive analysis. Percent change in root weight was calculated according to the method developed by **Miserendino et al.,1988** using the equation([16]):

$$\frac{(\text{pre}-\text{instrumentation weight}-\text{post}-\text{instrumentation weight})}{pre-instrumentation\ weight}\ \chi\ 100$$

B. Statistical analysis:

Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows. Using the Kolmogorov-Smirnov and Shapiro-Wilk tests to determine whether the data were normal, the transportation and centering data revealed a non-parametric distribution, whereas the remaining data revealed a parametric distribution. Kruskal Wallis was used for non-parametric data to compare between more than two groups in unrelated samples. The Mann Whitney test was developed to compare two groups in samples from unrelated populations. In linked samples, the Friedman test was employed to compare between more than two groups. In related samples, the Wilcoxon test was employed to compare two groups. Correlation analysis was tested using the Spearman test. One-way ANOVA and the Tukey post hoc test were employed for parametric data to compare more than two groups in unrelated samples. In linked samples, comparisons between more than two groups were made using the repeated measure ANOVA test. In linked samples, a paired sample t-test was employed to compare two groups. The significance level was set at $P \leq 0.05$.

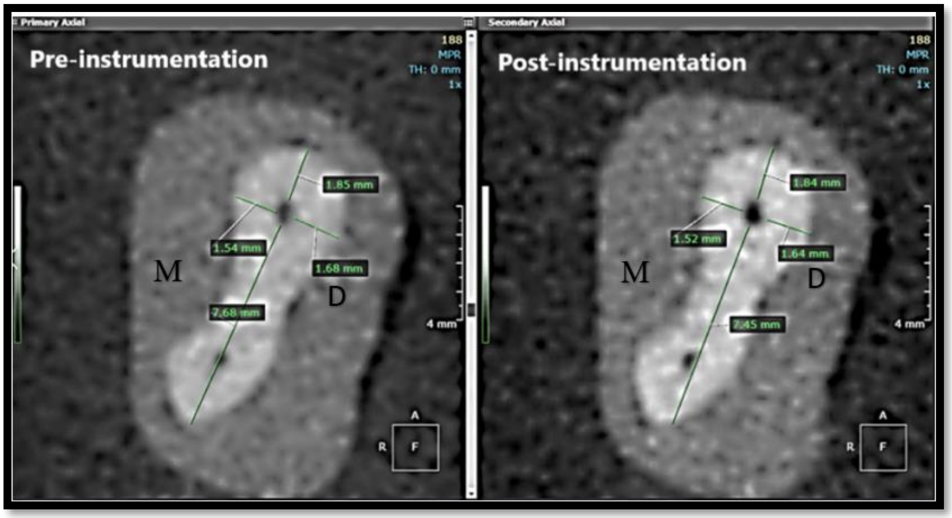

Figure (1): A CBCT image showing measurement of the dentin thicknesses on the axial view of a selected specimen at 3mm level in the present study (pre- and post- instrumentation)

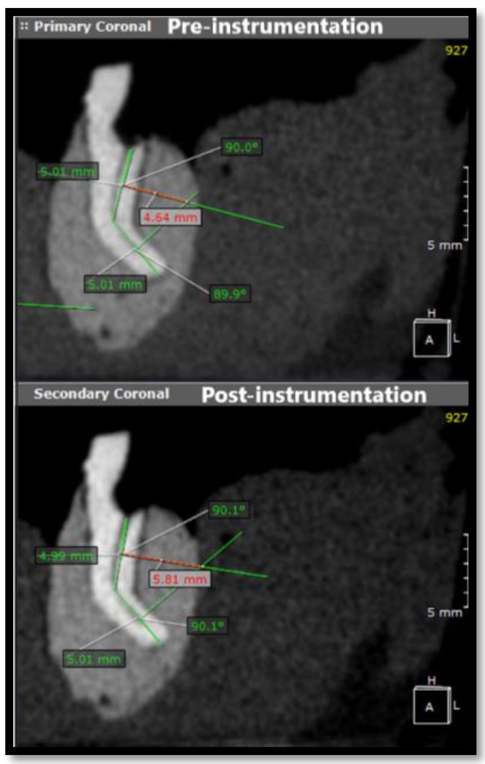

Figure (2): A CBCT image showing measurement of the radii of curvature on the mesiodistal view of a selected specimen in the present study

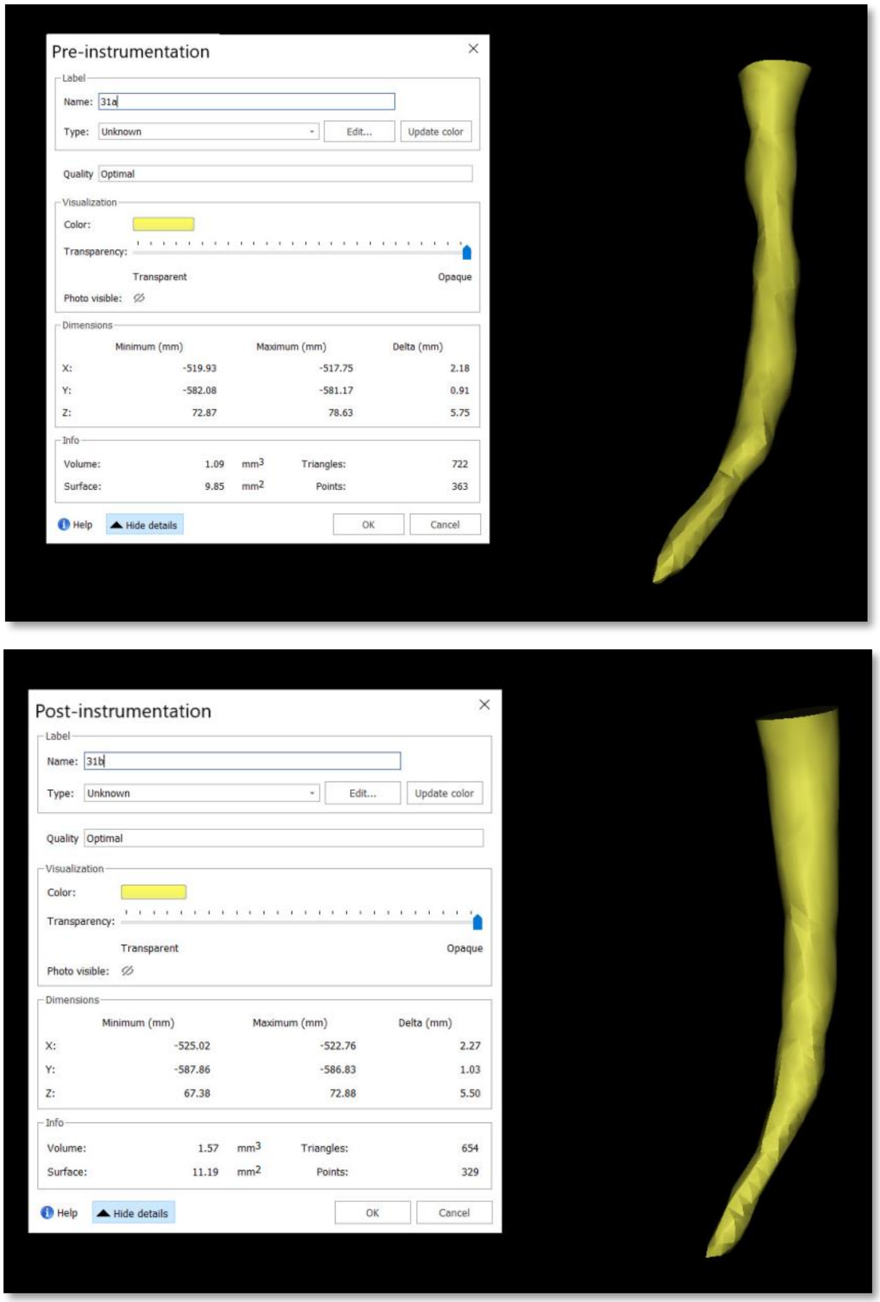

Figure (3): A CBCT image with Mimics software showing measurement of pre- and post-instrumented root canal volume in the present study

III. RESULTS

Canal transportation results showed, Trunatomy group significantly exhibited the lowest MD canal transportation when compared to 2Shape and Protaper-Next groups ($p< 0.001$). There was a statistically significant difference in the overall BL canal transportation where Trunatomy group reported the lowest BL canal transportation followed by 2Shape group then Protaper Next group at p value < 0.001.

Trunatomy group significantly exhibited the lowest percent change in canal curvature radius and the lowest amount of removed dentin when compared to 2Shape and Protaper-Next groups at p<0.001. On the other hand, there was no statistically significant difference between 2Shape and Protaper-Next groups. Centering ability results showed no statistically significant difference among the three studied groups in mesiodistal and buccolingual directions.

Trunatomy group significantly recorded the lowest percent change in root canal volume followed by Protaper-Next group then 2Shape group and the lowest percent change in root weight when compared to 2Shape group at p value= 0.011.

Table (1): Mean, standard deviation (SD) values of MD and BL Canal transportation in different studied groups.

Variables	**Canal transportation**						**p-value**
	Trunatomy		**2Shape**		**Protaper-Next**		
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
2mm							
MD	0.030 Cb	0.025	0.061 dA	0.022	0.069 dA	0.021	**0.001***
BL	0.041 cB	0.031	0.102 aA	0.038	0.114 aA	0.044	**<0.001***
3mm							
MD	0.029 cB	0.021	0.075 cA	0.020	0.084 cA	0.025	**<0.001***
BL	0.057 bB	0.028	0.107 aA	0.042	0.122 aA	0.047	**0.001***
5mm							
MD	0.123 aA	0.035	0.169 aA	0.056	0.159 aA	0.042	**0.050ns**
BL	0.090 aB	0.034	0.117 aB	0.037	0.155 aA	0.035	**<0.001***
8mm							
MD	0.081 bA	0.051	0.113 bA	0.042	0.118 bA	0.037	**0.075ns**
BL	0.110 aA	0.034	0.111 aA	0.039	0.126 aA	0.032	**0.495ns**
p-value							
MD	**<0.001***		**<0.001***		**<0.001***		
BL	**<0.001***		**0.439ns**		**0.098ns**		

Means with different small letters indicate significant difference in the same column for the same variable. Means with different capital letters indicates significate difference in the same row for the same variable.
*; significant (p<0.05) ns; non-significant (p>0.05)

Table (2): Mean, standard deviation (SD) values of MD and BL Centering ability in different studied groups.

Variables	**Centering ability**						p-value
	Trunatomy		2Shape		Protaper-Next		
	Mean	SD	Mean	SD	Mean	SD	
2mm							
MD	0.684 aA	0.180	0.717 aA	0.085	0.729 aA	0.103	0.570ns
BL	0.767 aA	0.166	0.730 aA	0.079	0.715 aA	0.100	0.702ns
3mm							
MD	0.628 aB	0.094	0.725 aA	0.077	0.730 aA	0.109	0.024*
BL	0.702 aA	0.097	0.713 aA	0.079	0.731 aA	0.085	0.462ns
5mm							
MD	0.700 aA	0.106	0.654 abA	0.098	0.635 aA	0.059	0.613ns
BL	0.650 abA	0.081	0.590 bB	0.039	0.542 bC	0.064	0.001*
8mm							
MD	0.725 aA	0.056	0.647 bB	0.072	0.651 aB	0.111	0.013*
BL	0.492 bA	0.067	0.458 cA	0.125	0.444 cA	0.067	0.235ns
p-value							
MD	0.499ns		0.022*		0.056ns		
BL	<0.001*		<0.001*		<0.001*		

Means with different small letters indicate significant difference in the same column for the same variable. Means with different capital letters indicates significate difference in the same row for the same variable.
*; significant (p<0.05) ns; non-significant (p>0.05)

Table (3): Mean, standard deviation (SD) values of percent change in canal curvature radius in different studied groups.

Variables	Total change of radius in canal curvature Percentage of change	
	Mean	SD
Trunatomy	5.791 [b]	2.095
2Shape	12.393 [a]	1.932
Protaper-Next	12.251 [a]	2.752
p-value	<0.001*	

Means with different small letters indicate significant difference.
*; significant (p<0.05) ns; non-significant (p>0.05)

Table (4): Mean, standard deviation (SD) values of cutting efficiency in different studied groups.

Variables	Overall Dentin thickness	
	Mean	SD
Trunatomy		
Difference in dentin thickness	0.158 [b]	0.075
percent change in canal volume	32.991 [c]	8.265
percent change in root weight	0.817 [b]	0.249
2Shape		
Difference in dentin thickness	0.268 [a]	0.080
percent change in canal volume	84.648 [a]	24.228
percent change in root weight	1.323 [a]	0.446
Protaper-Next		
Difference in dentin thickness	0.263 [a]	0.083
percent change in canal volume	59.508 [b]	22.275
percent change in root weight	1.102 [ab]	0.528
p-value		
Difference in dentin thickness	<0.001*	
percent change in canal volume	<0.001*	
percent change in root weight	0.015*	

Means with different small letters indicate significant difference.
*; significant (p<0.05) ns; non-significant (p>0.05)

IV. DISCUSSION

Lots of innovations in NiTi instruments have been achieved in the last decade by improvements in the design, physical properties, metallurgy, kinematics and thermal treatment of the NiTi alloy **([7])**. The aim of the present study was to compare the shaping ability and cutting efficiency of three file systems: Trunatomy, Protaper next and 2Shape in preparing severely curved (40º-60º) mesiobuccal canals of mandibular molars. Multirooted teeth with a complex anatomy provide more challenges during root canal preparation. The mandibular molars are the most that require endodontic treatment and have the lowest success rate. Mesial root canals possess variable curvatures in the mesiodistal and buccolingual directions. These curvatures could not appear on periapical radiographs, making them vulnerable to procedural errors. Those canals are particularly prone to strip perforation because their distal surfaces are concave ([21]). Hence, mesio-buccal mandibular canals that are usually narrow, curved and challenging were selected for this study.

There are several methods used in the literature to evaluate the shaping ability and cutting efficiency. In the present study, shaping ability and cutting efficiency were analyzed using Cone Beam Computed Tomography (CBCT) and analytical scale respectively.

The present study used the parameters of canal transportation, centering ability, and percent change in canal radius curvature to examine the shaping ability of experimental instruments during root canal preparation. The parameters used to analyze the cutting efficiency of the studied file systems were the measurement of the amount of removed dentin through calculating the difference in dentin thickness, percent change in root canal volume and percent change in root weight**.**

The results of the present study showed that all tested file systems produced canal transportation. Apical transportation should be less than 0.3 mm so as not to compromise the apical seal of root canal filling. All canal transportation values recorded for the experimental instruments in this study were less than 0.3 mm in all directions. This finding could indicate that the three systems were able to prepare the root canal without jeopardizing the apical seal ([22]).

Trunatomy group significantly showed the least deviation at all levels when compared to 2Shape and Protaper Next groups, especially at the apical level. This could be attributed to Trunatomy file design which is characterized by a smaller diameter and special heat treatment that provides greater flexibility, allowing the file to follow the original canal curvature, particularly in severely curved canals without cutting too much dentin. On the other hand, all three studied groups significantly showed the highest mesiodistal canal transportation at the middle level. This could be attributed to the presence of the canal curvature at this critical level ([8, 23, 24]).

Protaper Next group had significantly the highest buccolingual canal transportation when compared to Trunatomy and 2Shape groups at the middle level. Protaper Next has a file design that is characterized by progressive taper along the cutting surface with an increase in file diameter which produces more transportation, especially when preparing severely curved canals ([25, 26, 27]).

None of the instruments could remain perfectly centered in the canal. Trunatomy group significantly showed the highest mesiodistal deviation at 3 mm level and the lowest mesiodistal deviation at 8 mm level when compared to 2Shape and Protaper Next groups. This difference might be explained by the fact that Trunatomy files are slim and touched the least amount of canal surface area at the apical part that might have affected its centering ability at this level ([28]). At the buccolingual direction, Trunatomy group significantly showed the lowest deviation followed by 2Shape group then Protaper Next group at the middle level. This could be explained by the finding of the present study where Protaper Next showed the significantly highest buccolingual canal transportation at the middle level compared to the other two groups.

There was no significant difference between 2Shape and Protaper Next groups with better centering ability at the apical level. This could be due to the 2Shape file design with its constant taper that provides better centering ability in the apical part of the root canal while Protaper Next file moves in a swaggering motion that would allow more canal centralization during preparation ([25, 27])**.** It could be also explained by the finding of the present study where 2Shape and Protaper Next removed a comparable amount of dentin removal.

Trunatomy group significantly reported the lowest percent change in canal curvature radius. This result could be attributed to the ability of Trunatomy file to significantly remove the least amount of dentin at the canal curvature level at 5 mm that is supported by the results of the present study as well as the other studies ([26, 27]). There was no statistically significant difference between 2Shape and Protaper Next. These results could be attributed to the fact that both systems produced a comparable amount of mesiodistal canal transportation as well as a comparable amount of dentin removal.

Trunatomy group had significantly the lowest amount of removed dentin when compared to 2Shape and Protaper Next groups. This could be attributed to Trunatomy file was designed on the bases of minimally invasive endodontics in which the small regressive taper file is manufactured from slim NiTi alloys ([24, 29]). The in and out motion of Trunatomy file removes less amount of dentin removal during canal preparation when compared to the brushing motion of 2Shape and Protaper Next ([30]). On the other hand, 2Shape and Protaper Next files have a larger taper than Trunatomy file. 2Shape files have a constant taper that increases in diameter along its working length and Protaper Next files have a variable taper with Schilder's envelope of motion that makes the final taper of the preparation greater than the original file taper leading to more dentin cutting ([23]). Trunatomy group significantly recorded the lowest percent change in root canal volume followed by Protaper Next group then 2Shape group. This could be explained by the in and out motion of the Trunatomy file with a slim taper removing less dentin during canal preparation than the brushing motion and larger taper of 2Shape and Protaper Next ([30]**).**

Trunatomy group had significantly less percent change in root weight than 2Shape group. Although no relevant studies were found in the review of literature, this could be explained by the significant less amount of dentin removal reported by Trunatomy in this study and previous studies ([24, 29]).

From the results of the present study, it was shown that the three studied rotary systems were able to safely shape and efficiently prepare the severely curved MB root canals

V. CONCLUSION

Within the limitations of this study, it can be concluded that: The three studied file systems were able to achieve efficient and safe preparation of severely curved MB root canals. The three methods used for evaluation of cutting efficiency showed resulted in similar conclusions. Trunatomy files were significantly able to produce less apical canal transportation, less change in canal curvature radius and less amount of removed dentin than the other two file systems in the study.

Conflict of interest:
No conflict of interest.

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Ethics:
This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo university on: 27/10/2020 approval number: 15-10-20.

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