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Comparative evaluation of four different rotary nickel titanium files on apical geometry of root canal assessed by micro-computed tomography – An In Vitro cross-sectional study

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Abstract

Aim: Going through the evidence, there have been no previous studies performed to evaluate the apical geometry of mesio-buccal root canal of mandibular first molar using Micro-CT by these files. Hence, this study was intended with an aim to assess the effect of different rotary nickel titanium files on apical geometry of root canals and to evaluate the apical geometry of root canals using four (Hyflex CM, Endostar Azure, Hero Shaper, N.I.C H.S. Flex) rotary nickel titanium files and their efficacy was assessed by micro-computed tomography

Method: 40 Extracted human mandibular molar teeth were collected. All collected samples were mounted on modelling wax & sent for Cone beam computed tomography (CBCT) to verify the presence of a single canal & a single apex at the apical third (Vertucci type

1). The following materials were used for sample preparation: 40 Extracted human mandibular first molars, round bur- BR 45 (Mani, Japan), Safe Ended Bur - ex -24 (Mani, Japan) and DG-16 (GDC India). For biomechanical preparations, the following materials were used: One flare Rotary Files (Micromega, France), One G Rotary Files (Micromega, France), Hyflex Rotary Files. (Coltene, Switzerland), Endo Star Azure Rotary Files. (Poland, Warsaw), Hero Shaper Rotary Files. (Micromega, France), NIC H.S. Flex Rotary File System (China), 5.25% Sodium Hypochlorite, 0.9% Normal Saline, 17% Ethylenediamine Tetra Acetic Acid (EDTA) Solution (Smear Clear; Sybron Endo, Orange CA), Stainless Steel K-Files (#10-#15) (Mani Inc, Japan), 30 Gauge Side Vented Needle (Prime, INDIA) and Endoscale (Dentsply Mallifier, Switzerland. After instrumentation the samples were stored in 0.9% Normal Saline until use. After the pre- operative Micro-CT scans all samples were divided randomly into four groups each of 10 (n = 10) on the basis of rotary files used. From these, the following groups were formed: Hyflex Cm Rotary Files, Endo star azure rotary files, Hero Shaper Rotary Files, NIC H.S. Flex Rotary File System. The continuous data was presented as mean and standard deviation (SD) across all the groups. ANOVA test was performed for comparing the mean difference between all the 4 groups, followed by post hoc. All p values <0.05 will be considered statistically significant.

Results: although all the four file systems i.e. Hyflex CM, Endostar Azure, Heroshaper and HS Flex had a statistically significant difference in the cutting efficiency at baseline when compared to post operative, Group 2 (Endostar Azure) had the highest cutting efficiency followed by group 4 (N.I.C HS Flex) which signifies that although all the file systems are effective and efficient in cutting, 2 groups are more superior in the same.

Conclusion: That there was a significant difference in the cutting efficiency of Hyflex CM, Endostar Azure, Hero shaper & NIC HS flex rotary file systems in the apical 3mm of the mesio-buccal root canal. All the files had a better cutting efficiency when pre & post - operative micro -CT scans were compared

Keyword: apical geometry, micro -CT, nickel-titanium files, root canals

Introduction

The clinical success of root canal treatment, as judged by the post-operative radiograph after the root filling, is based on optimized root canal instrumentation. Although interest in the effects of instrumentation on intracanal infection is not new, it is obvious that during the last few years a renewed focus of interest has appeared on the relationship between instrumentation and infection control in the root canal [1].

While various chemical and physical irritants can cause irritation and even necrosis of the pulp, the most common causes for pulpal inflammation (pulpitis) are bacteria and/ or their products entering the pulp through a deep carious lesion or a leaking filling. Bacterial infection may remain relatively superficial leaving most of the pulp tissue vital or the bacteria may invade further and colonize the entire root canal system leading to apical periodontitis, hence to promote healing, microorganisms within the root canal system must be eliminated[1].

Cleaning and shaping of root canals successfully require high volumes of irrigation solutions that can be applied to the apical third of the root canal after enlargement with instruments, hence Nickel-titanium rotary instruments have become an important adjunct for root

canal shaping and the outcomes observed with these instruments are fairly predictable[2].

Today, thermal treatment of NiTi alloys helps us to optimize the mechanical properties and increase the flexibility of thisinstruments.[2] The goal of instrumentation and irrigation is to remove all necrotic and vital organic tissue as well as some hard tissue from the root canal system, and give the canal system a shape that allows easy debridement and predictable placement of medicaments and a permanent root filling. Microbiologically the goal of instrumentation and irrigation is to remove and/or kill all microorganisms in the root canal system, and neutralize any antigenic/ biological potential of the microbial components remaining in the canal [3].

Hyflex CM rotary instruments (Coltene-Whaledent, Allstetten, Switzerland) are made from a new type of NiTi wire, namely CM wire (controlled memory), that has been subjected to proprietary thermo-mechanical processing. It is manufactured by a unique process that controls the material‘s memory, making the files extremely flexible[3].

Hero Shaper (Micro Mega, Becacon, France) is designed, with a variable helical angle and unadapted pitch that increases with the taper of the instrument. This design has been made with this particular feature with the purpose of avoiding the screwing effect of the instrument inside the root canal[4].

Endostar Azure Rotary System is a set of modernised files, used for effective and efficient root canal preparation. They are manufactured from the highest quality of nickel-titanium alloy which provide durability and flexibility to this file system[5]. These files can easily fit in even severly curved canals, thus minimizing the risk of canal perforation. The modified shape of NiTi S file is with two 90-degree cutting edges that ensures efficient cutting. Micro-CT has been used to compare the performance of different rotary instruments in preparing root canals and to assist with characterization of morphological changes associated with each technique [6].

Going through the evidence, there have been no previous studies performed to evaluate the apical geometry of mesio-buccal root canal of Mandibular first molar using Micro-CT by these files. Hence, this study was intended with an aim to assess the effect of different rotary nickel titanium files on apical geometry of root canals and to evaluate the apical geometry of root canals using four (Hyflex CM, Endostar Azure, Hero Shaper, N.I.C H.S. Flex) rotary nickel titanium files and their efficacy was assessed by micro-computed tomography.

Methodology

Sample Size : Sample size was calculated using G* Power 3.0.10. The error was set at 5% (0.5) and power of the study (1- β) was set at 80% (0.8). The sample size was determined to be 10 per group. Study was conducted on 40 human extracted teeth.

Sample collection: 40 Extracted human Mandibular molar teeth were collected from the Department of Oral and Maxillofacial surgery of the same institute after informed signed consent from the patients undergoing extraction. All collected samples were mounted on modelling wax & sent for Cone beam computed tomography (CBCT) to verify the presence of a single canal & a single apex at the apical third (Vertucci type 1).

Sample Preparation: The following materials were used for sample preparation: 40 Extracted human mandibular first molars, round bur- BR 45 (Mani,Japan), Safe Ended Bur - ex -24 (Mani,Japan) and DG-16 (GDC India). For biomechanical preparations, the following materials were used: One flare Rotary Files (Micromega,

France), One G Rotary Files (Micromega, France), HyflexRotary Files. (Coltene, Switzerland), Endo Star Azure Rotary Files. (Poland, Warsaw), Hero Shaper Rotary Files. (Micromega, France), NIC H.S. Flex Rotary File System (China), 5.25% Sodium Hypochlorite, 0.9% Normal Saline, 17% Ethylenediamine Tetra Acetic Acid (EDTA) Solution (Smear Clear; Sybron Endo, Orange CA), Stainless Steel K-Files (#10-#15) (Mani Inc, Japan), 30 Gauge Side Vented Needle (Prime, INDIA) and Endoscale (Dentsply Mallifier, Switzerland.

Study Protocol: Samples were sent to National Chemical Laboratory, PUNE for Pre - operative Micro-CT scan at resolution of 18 µm to check the pre-operative volume, measurement of canal mesio-distally and bucco- lingually **as shown in figure 1** to compare the cutting efficiency & to check the surface of the canal for any present irregularities.

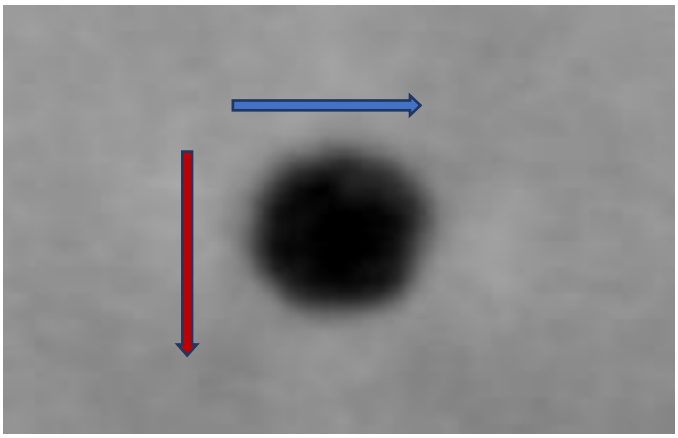


Figure 1: Pre-Operative Mesio-Distal & Bucco-Lingual Width

After initial scans, the root canals were instrumented by one operator. Access opening was performed using a Round bur- BR 45. A size 10 K-file were placed into the mesio-buccal canal until it was visible at the apical foramen to measure the working length and ensure that the canal was patent. The biomechanical preparation of the mesio-buccal canals was done using Hyflex CM, Endostar Azure, Heroshaper and N.I.C H.S flex rotary files. Canals were irrigated during the preparation using sodium hypochlorite (5.25%), 17% EDTA and 0.9% normal saline. After the biomechanical preparation of the mesio-buccal canals the samples were stored in normal saline (0.9%) and sent to National Chemical Laboratory for the analysis of change in volume, cutting efficiency and surface roughness of mesio-buccal

Protocol for Cleaning and Shaping of the Samples

After the Pre -Operative Micro-CT scans access opening was performed by the same operator for all the samples. Round bur (MANI EX 45) & Safe ended bur (MANI EX 24) was used for access cavity preparation. A size 10 K-file was placed into the canal until it was visible at the apical foramen to measure the working length and ensure that the canal was patent. Orifice opener rotary files ONE -FLARE was used to create a coronal flare. ONE -G rotary files were then used to prepare a glide path. 2ml of 5.25% sodium hypochlorite was used for irrigation after every Instrumentation. Biomechanical preparation was done till #30 0.04% for all the samples with HyflexCiM, Endostar Azure, Hero Shaper and NIC HS Flex Rotary Files. 5 mL of 17% ethylenediamine tetra acetic acid (EDTA) was used for 1 minute for each sample to remove the residual debris. Final irrigation was done with 5 ml saline to remove the residual irrigants. After instrumentation the samples were stored in 0.9% Normal Saline until use. The samples were sent to the National Chemical Laboratory, Pune for post-operative Micro-CT evaluation. Series of tomographic images (at approximately 935 x 1001 x1437 voxels, effective resolution 11.41 x 12.21 x 17.53 mm) were obtained for each specimen. CT Pro software (Nikon Metrology, Leuven, Belgium) was used to reconstruct a 3-dimensional image of each tooth. G Studio MAX 2.1 software (Volume Graphics GmbH, Heidelberg,

Germany) was then used to view the reconstructed images and make measurements. The parameters (Volume of apical 3mm of mesio-buccal root canals, Cutting Efficiency and Surface Roughness) were made by 1 observer **as shown in figure 2 and 3 below**.

Figure 2 - Pre-Operative Volume Analysis of Apical 3mm of mesio-buccal root canal in mm

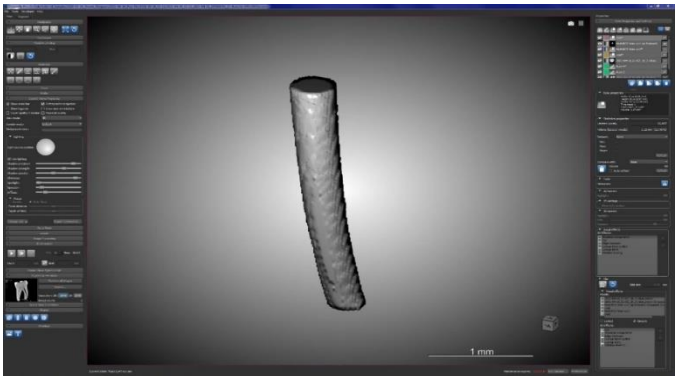


Figure 3 - Pre-Operative Volume Analysis of Apical 3mm of mesio-buccal root canal in mm

From these, the following groups were formed: After the pre- operative Micro-CT scans all samples were divided randomly into four groups each of 10 (n = 10) on the basis of rotary files used.

Hyflex Cm Rotary Files: The mesio-buccal root canals were prepared by using Hyflex CM rotary files at Speed of 500 rpm ad Torque of 2.5 NCM, up to apical preparation size of #30 0.04% to standardize the taper and apical preparation size diameter. Endo star azure rotary files: The mesio-buccal root canals were prepared by using the Endostar Azure rotary files at Speed of 300 rpm and Torque of 2.5 Ncmupto apical preparation size of #30 0.04% to standardize the taper and apical preparation size diameter. Hero Shaper Rotary Files: The mesio-buccal root canals were prepared using HeroShaper rotary files at Speed of 300 rpm and Torque of 2.5 Ncmupto apical preparation size of #30 0.04% to standardize the taper and apical preparation size diameter. NIC H.S. Flex Rotary File System: The mesio-buccal root canals were prepared using N.I.C H.S Flex rotary files at Speed of 300 rpm and Torque of 2.5 N-cm files upto apical preparation size of #30 0.04% to standardize the taper and apical preparation size diameter. Canal patency was maintained with the size #10 K file. During instrumentation, intermittent irrigation was performed using 5.25% sodium hypochlorite followed by 17% EDTA. Final wash was performed using normal saline.

Statistical Analysis

The continuous data was presented as mean and standard deviation (SD) across all the groups. ANOVA test was performed for comparing the mean difference between all the 4 groups, followed by post hoc and Kruskal wallis test followed by post hoc were applied. All p values <0.05 will be considered statistically significant. The data on categorical variables is shown as n (% of cases) and the data continuous variables are presented as mean and standard deviation (SD). The inter-group statistical comparison of distribution of categorical variables is tested using Chi-Square test or Fisher‘s exact probability test if more than 20% cells have expected frequency less than 5. The inter-group statistical comparison of means of normally distributed continuous variables is done using analysis of variance (ANOVA) with Post-Hoc Bonferroni‘s test for multiple group comparisons. The intra- group statistical comparison of means of

continuous variables is done using paired t test. The underlying normality assumption was tested before subjecting the study variables to ANOVA and t test. All results are shown in tabular as well as graphical format to visualize the statistically significant difference more clearly.

Results

In the entire study, the p-values less than 0.05 are considered to be statistically significant. All hypotheses were formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference). The entire data is statistically analyzed using Statistical Package for Social Sciences (SPSS ver 24.0, IBM Corporation, USA) for MS Windows.

Inter-group statistical comparison of mean of mesio-distal width:

Group 1 - Hyflex CM

Group 2 -Edostar Azure

Group 3- Heroshaper

Group 4 -N.I.C

H.S flex Distribution of mean post-op mesio-distal width is significantly higher in Group 2 compared to groups 1, 3 and 4 (P-value<0.05 for all).

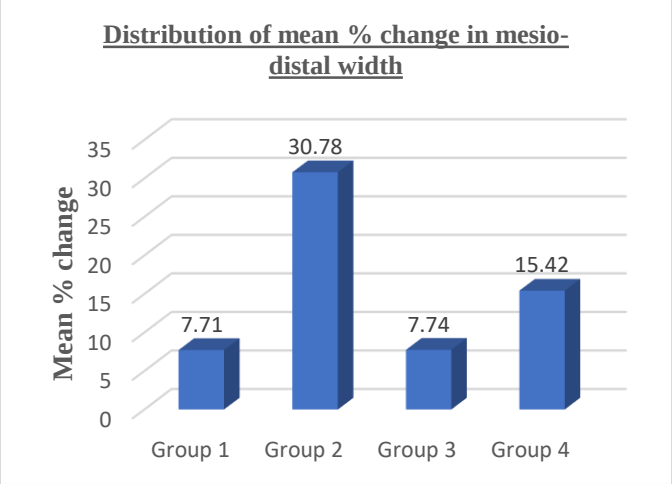
Distribution of mean post-op mesio-distal width is significantly higher in Group 4 compared to groups 1 and 3 (P-value<0.05 for all). Distribution of mean post-op mesio-distal width did not differ significantly between groups 1 and 3 (P-value>0.05).

Distribution of mean post-op % change in mesio-distal width is significantly higher in Group 2 compared to groups 1, 3 and 4 (P-value<0.05 for all). Distribution of mean post-op % change in mesio-distal width is significantly higher in Group 4 compared to groups 1 and 3 (P- value<0.05 for all). Distribution of mean post-op % change in mesio-distal width did not differ significantly between groups 1 and 3 (P-value>0.05) as shown below in **table 1 and figure 4**

Table 1: showing Inter-group distribution of mean of mesio-distal width.

	Width (mm)							
	Group 1 (n=10)		Group 2 (n=10)		Group 3 (n=10)		Group 4 (n=10)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Pre-op	0.260	0.013	0.264	0.014	0.259	0.014	0.260	0.013
Post-op	0.280	0.013	0.345	0.014	0.279	0.014	0.300	0.013
% change	7.71%	--	30.78%	--	7.74%	--	15.42%	--

Figure 4: Inter-group distribution of mean % change in mesio-distal width



Intra-group statistical comparison of mean of mesio-distal width

In all the four groups distribution of mean post-op mesio-distal width is significantly higher compared to mean pre-op mesio-distal width (P-value<0.05) as shown below

Table 2: showing Intra-group statistical comparison of mean of mesio-distal width

	P-values [Intra-Group]			
	Group 1	Group 2	Group 3	Group 4
Pre-op vs Post-op	0.001***	0.001***	0.001***	0.002**

P-value by paired t test. P-value<0.05 is considered to be statistically significant.
**P-value<0.01, ***P-value<0.001.

Inter-group statistical comparison of mean of bucco-lingual width

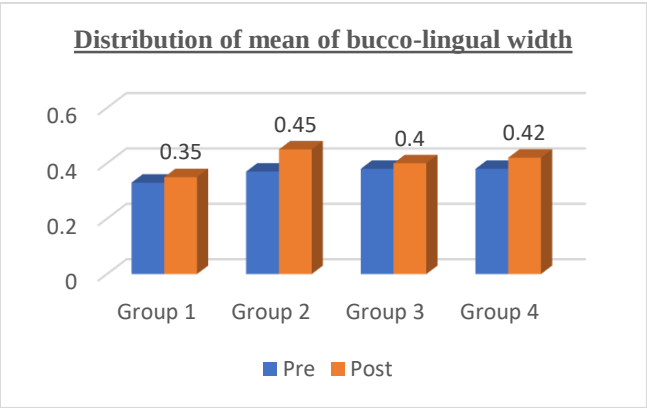
Distribution of mean pre-op bucco-lingual width did not differ significantly across four study groups (P-value>0.05 for all).

Distribution of mean post-op bucco-lingual width is significantly higher in Group 2 compared to groups 1 and 3 (P-value<0.05 for all). Distribution of mean post-op bucco-lingual width is significantly higher in Group 4 compared to group 1 (P- value<0.05). Distribution of mean post-op % change in bucco-lingual width is significantly higher in Group 2 compared to groups 1, 3 and 4 (P-value<0.05 for all). Distribution of mean post-op % change in bucco-lingual width is significantly higher in Group 4 compared to groups 1 and 3 (P-value<0.05 for all). Distribution of mean post-op % change in bucco-lingual width did not differ significantly between groups 1 and 3 (P- value>0.05) as shown below in table 3 and figure 5

Table 3: showing Inter-group distribution of mean of bucco-lingual width.

	Width (mm)							
	Group 1 (n=10)		Group 2 (n=10)		Group 3 (n=10)		Group 4 (n=10)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Pre-op	0.337	0.053	0.374	0.041	0.383	0.035	0.381	0.035
Post-op	0.356	0.054	0.459	0.043	0.403	0.035	0.421	0.035
% change	5.74%	--	23.02%	--	5.26%	--	10.58%	--

Figure 5: Inter-group distribution of mean % change in bucco-lingual width



Intra-group statistical comparison of mean of bucco-lingual width

In all the four groups distribution of mean post-op bucco-lingual width is significantly higher compared to mean pre-op bucco-lingual width(P-value<0.05) as shown below

Table 4: showing Intra-group statistical comparison of mean of bucco-lingual width.

	P-values [Intra-Group]			
	Group 1	Group 2	Group 3	Group 4
Pre-op vs Post-op	0.001***	0.001***	0.001***	0.001***
P-value by paired t test. P-value<0.05 is considered to be statistically significant. NS – Statistically non-significant.				

Discussion

This study evaluated the apical geometry of apical third of mesio-buccal root canal of mandibular first molar after instrumentation with hyflex cm, endostar azure; heroshaper and N.I.C H.S flex rotary files. The apical one third of the root canal is challenging area to prepare, anatomically this area is curved and also ramifications are present hence it is important to shape this area to facilitate cleaning by irrigants. Many authors have concluded that proper shaping and cleaning of this area leads to increase longetivity of the root canal treatment[7-9]. This study evaluated the cutting efficiency of these files by checking the change in volume, surface roughness and change in mesio-distal and bucco-lingual width of mesio-buccal canal of mandibular first molar.

The mesio-buccal canal in mandibular first molar is the most difficult canal to treat because of its tortuous path[10-15].It leaves the pulp chamber in a mesial direction, which alters to a distal direction in the middle of the root.[57,58,59] From the proximal perspective, the mesio-buccal canal curves to the buccal first and then lingually, hence the mesiobuccal canal were selected for this study. Mesio-buccal root canal of Mandibular first molar with completely form edapices & Vertucci‘ type I

configuration were selected using cone beam computed tomography for the study for standardization of the samples.

Mico-Ct was used to conduct this study as it is non-invasive & useful to evaluate the apical diameter of mandibular molars in which 2 canals are present, because the sections can be non-destructively reoriented in several ways to gain a perpendicular section for each canal in both planes. In addition, the apical volume of the root canals including fins and isthmuses can be properly quantified by using dedicated software [16]

Prior to instrumentation pre operative micro-CT images were obtained to check for any irregularities or cracks in the cross-sectional view of the apical third of the root canal. Any samples with surface irregularities or cracks were excluded from the study. Following instrumentation post operative scans were taken and evaluated, no surface roughness was observed with the use of any of the four file systems [13].

When the four file systems, Group 1: Hyflex CM, Group 2: Endostar Azure, Group 3: Heroshaper, Group 4: N.I.C H.S Flex ; were compared to each other byMicro CT, the cutting efficiency of all the four systems was statistically significant when compared to baseline; but it was observed that group 2 which was the Endo Star Azure files had the highest cutting efficiency statistically as compared to the other 3 systems, followed by the N.I.C HS FLEX system. Group 1 and 3 had a relatively similar cutting efficiency on comparison with no statistically significant differences[15].

Jiang W et al. 2010 [15] conducted in a study to evaluate the shaping ability of a new heat-treated NiTi system-Endostar Azure in continuous rotation or reciprocation in artificial curved canals of 40 resin blocks. This was the first study to evaluate the shaping ability of this file system, the Endostar Azure. According to the parameters and limitations of the study, reciprocating motion demonstrated less canal transportation at all levels and less preparation time than continuous rotation.[65] This study concluded that the Endostar Azure system, operated in either continuous rotation or reciprocation, can be safely used to the full WL, showing satisfactory preservation of the original canal shape, and further studies on natural teeth with different anatomical conditions are required to validate the results obtained in this study.

Therefore it can be stated that within the limitations of our study, that although all the four file systems i.e. Hyflex CM, Endostar Azure, Hero shaper and HS Flex had a statistically significant difference in the cutting efficiency at baseline when compared to post operative, Group 2 (Endostar Azure) had thehighest cutting efficiency followed by group 4 (N.I.C HS Flex) which signifies that although all the file systems are effective and efficient in cutting , 2 groups are more superior in thesame.

Further research on this topic with more sample size and comparison with reciprocation files and single file systems can be done to assess the changes in apical geometry.

Conclusion

Within the limitations of this study, it can be concluded that there was a significant difference in the cutting efficiency of Hyflex CM, Endostar Azure, Hero shaper & NIC HS flex rotary file systems in the apical 3mm of the mesio-buccal root canal of mandibular first molar when apical geometry was assessed by Micro-CT. All the files had a better cutting efficiency when pre & post - operative micro CT scans were compared in which Group 2 – Endostar Azure showed significantly better results followed by Group 4 – N.I.CHS flex rotary files. Also, there was a statistical difference in pre operative

and post operative volumes in all the four groups & no surface roughness was observed in post-operative Micro-CT scans of all the four groups. Thus the null hypothesis is rejected.

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