Scanning Electronic Microscopy Surface Characteristics of Six Endodontic Files Systems Available in Ukraine: Observational Study

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Abstract

Objective of the research was to assess surface characteristics of six different endodontic Ni-Ti files systems available in Ukraine before their clinical use by the scanning electronic microscopy (SEM) method. A sample of overall 30 files (5 files in each subsample) of six different brands (SANI for retreatment, SANI Blue Storm, Soco SC Plus, HyFlex CM, Profile, PreRace) was used for the SEM-based surface analysis. Assessment of obtained SE images was conducted by two independent investigators due to the adapted Troian's et al. approach for the new files, while categorization of SEM-registered imperfections and irregularities of files' surface was provided by the following categories: debris, grooves, microcavities, scrapings and cracks.

SEM-analysis revealed that none of the studied specimen was characterized with fully defect-free surface. Categorization of SEM-registered imperfections and irregularities revealed their following average prevalence among all study sample: debris – 63.33±36.67%, grooves – 46.67±15.56%, microcavities – 33.33±8.89%, scrapings – 10.0±10.0%, cracks – 10.0±10.0%. No statistically significant difference was noted regarding prevalence of microcavities among all studied subsamples ($p > 0.05$).

In most cases instruments' long axis surface demonstrated 1-3 areas of defects or deformations, but also every third analyzed instrument demonstrated presence of more than 5 areas of defects and imperfections. Sani Blue Storm, HyFlex CM and PreRace files demonstrated lesser amount of surface imperfections compare to other analyzed systems. Scrapings and cracks were noted the least frequently among all studied subsamples, while their prevalence levels also did not differ significantly among all analyzed Ni-Ti files systems ($p > 0.05$).

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Introduction

Ni-Ti rotary files became ones of the most prevalently used for the endodontic treatment purpose due to their unique mechanical characteristics and adaptivity to the different root canal configurations.[1,2,3] Recent systematic review of clinical studies reported relatively low overall incidence of Ni-Ti files fracture at the level of 2.27% irrespectively of their motion kinematics (continuous rotation or reciprocating motion).[4]

Ongoing improvement of Ni-Ti files includes not only modifications of their design, usage of optimized processing methods of wire blank, and different treatment approaches of Ni-Ti alloy, but also obligatory quality control of different manufacturing stages, including evaluation of end-product with the use of proper examination methods.[1,5]

Defects and irregularities of Ni-Ti files surface and structure originated through manufacturing process potentially may be associated with the risk of their fracture during clinical usage causing development of specific complications and thus compromising prognosis of provided endodontic treatment.[6] Meanwhile, discussion is still ongoing regarding objective clinical significance of different Ni-Ti files surface imperfections registered with specific research methods.

Due to the results of systematic review dedicated to the analysis of methods employed for the assessment of surface and structure of Ni-

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Ti files, scanning electronic microscopy (SEM) seems to be the most prevalently used among 95 selected studies.[6] SEM analysis of new Ni-Ti files just extracted from the packages may be interpret as possibility "to evaluate quality of their surface finishing and adequacy of packaging conditions".[7] Several previous SEM-based studies came to the conclusion that none of analyzed Ni-Ti files was free from surface flaws, while novel brands of Ni-Ti endodontic systems demonstrated no structural alterations.[7,8,9,10,11]

Nevertheless, high incidence of surface defects registered among different brand of Ni-Ti files with the use of SEM method argument the need for further research that potentially may add relevant information and improve approaches of Ni-Ti surface treatment and polishing to diminish the occurrence of surface defects, irregularities, and imperfections, associated directly with manufacturing process.[7]

The aim of present observational study was to assess surface characteristics of six different endodontic Ni-Ti files systems available in Ukraine before their clinical use by the scanning electronic microscopy method.

Materials and methods

Study sample was formed out of brand-new Ni-Ti files of six different manufacturers officially presented within Ukrainian dental market. 50 Ni-Ti files packs of different brands, size and taper were bought from different official representatives. Out of 50 files packs of each manufacturer 5 files of the same size and taper were randomly selected, thus forming study sample of overall 30 files of different brands for the surface analysis with the use of scanning electron microscopy method. Characteristics of Ni-Ti files specimens selected for further SEM analysis presented in Table 1.

Each file from the study sample was gently removed from the original packaging without altering file's working part with any kind of instrument, and attached to the holder within scanning electron microscope (Tescan Mira3 LMU, TESCAN, Brno, Czech Republic) with no specific treatment or preparation. Following exposure parameters of scanning electron microscope were used during present research: SEM HV (acceleration voltage) – 10.0 kV, SEM MAG (magnification) ranging from 23× to 379×, view field ranging from 300 μm to 5.0 mm, with use of SE (secondary electrons) and BSE (backscattered electrons) detectors.

№	Endodontic file system (Manufacturer)	Anonymized set	Cross-section	Diameter	Taper	Quantity
1	SANI for retreatment (Chengdu Sani Medical Equipment Co.)	A1-A5	Triangular cross-section	25	/.02	5
2	SANI Blue Storm (Chengdu Sani Medical Equipment Co.)	B1-B5	Rectangular cross-section followed by square cross-section	25	/.04	5
3	Soco SC Plus (Chengdu Sani Medical Equipment Co.)	C1-C5	Triangular cross-section	20	/.04	5
4	HyFlex CM (Coltene)	D1-D5	Double fluted Hedstroöm design with positive rake angle	20	/.04	5
5	Profile (Dentsply Sirona)	E1-E5	Radial-landed U file flutes, multiple taper design	20	/.04	5
6	PreRace (FKG Dentaire)	F1-F5	Triangular cross-section with sharp edges	30	/.06	5

Table 1. Characteristics of Ni-Ti files specimens selected for the surface analysis by the SEM method.

Obtained SE images of files' surface were anonymized by the engineer, who has provided scanning electron microscopy procedure in the manner of using alphabet order for each different file system (A, B, C, D, E, F), and numerical order to mark each specimen of each analyzed file system, thus forming six sub-samples (A1-A5, B1-B5, C1-C5, D1-D5, E1-E5, F1-F5). Obtained anonymized images obtained under different magnifications and various view fields were grouped by the correspondence to specific file system, and sent to the e-mails of authors (investigators) of present manuscript, who analyzed them independently.

Assessment of obtained SE images of Ni-Ti files surface by two independent investigators was provided due to the adapted Troian's et al. approach for the non-used files with following scoring and interpretation: 1 – instrument's long axis surface is free of defects and deformations; 2 – instrument's long axis surface demonstrates 1-3 areas of defects or deformations; 3 – file's long axis surface demonstrated 4-5 areas of defects or deformations; 4 – file's long axis surface demonstrated more than 5 areas of defects or deformations.[12] Also two independent investigators were asked to categorized SEM-registered imperfections and irregularities of files' surface by the manner previously described in

AbuMostafa A. et al. study: 1) debris (loosely connected/not firmly attached fragments or remnants on the file's surface); 2) grooves (line-like marks and/or scratches on the file's surface); 3) microcavities (pit-like defects or holes on the file's surface); 4) scrapings (peeled of but still attached part of file's surface); 5) cracks (split-like defect/separation/fissure on the file's surface).[8] Prevalence of different imperfections and irregularities was quantified among each analyzed subsample separately considering its adherence to the specific file system.

Local element content analysis of one randomly selected file from each Ni-Ti file system was provided selectively among chosen areas of file's surface with the signs of present impurities using EDS (Energy Dispersive Spectrometry) detector (Oxford X-max 80 mm, Oxford Instruments, Abingdon, UK), installed within scanning electron microscope. Obtained results of local element content analysis represent content of chemical elements at the selected areas with detected signs of surface impurities in means of weight percent (wt%), normalized to 100%.

Results registered by the observers were tabulated within Microsoft Excel software (Microsoft Office 2019, Microsoft) and submitted for calculation of interclass correlation coefficient using Kappa criterion. As per reference provided in Chianello G. et al. study, a standard error of mean at the level of 0.066 was considered for intra-examiner and inter-examiner calibration.[7] Statistical analysis of results obtained after SEM-analysis was provided with the use of Fisher's criterion ($p < 0.05$).[13]

Results

Percentage prevalence distribution of Troian's scores within each analyzed subsample presented in Figure 1.

SEM-analysis revealed that none of the studied specimen was characterized with fully defect-free surface, due to which prevalence of Troian's score "1" was equaled to 0% in each studied subsample. Average prevalence of score "2" associated with presence of 1-3 areas of defects or deformations on the instrument's surface was at the level of 40.0±20.0% among all 30 files, while prevalence of this score was the highest one compared to others. Average prevalence of Troian's score "3" and "4" among all study sample were 26.67±8.89% and 33.33±13.33% correspondingly. The highest prevalence of 1-3 areas of defects or deformations on the instruments' surface was noted among subsample B1-B5, subsample D1-D5 and subsample F1-F5, while the highest prevalence of 4-5 areas of defects and deformations were noted among subsample C1-C5 and subsample E1-E5. More than 5 areas of defects and deformations were note among 1 file (20%) in subsamples B1-B5, D1-D5 and F1-F5, while among 2 files (40%) in subsamples C1-C5 and E1-E5, and among 3 files in subsample A1-A5.

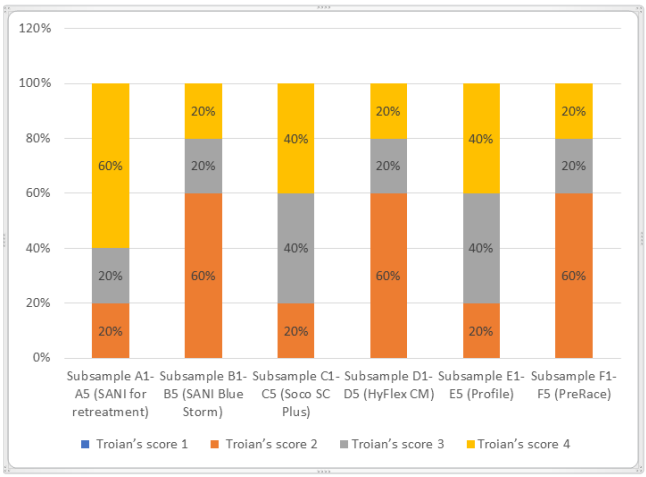

Figure 1. Distribution of percentage prevalence of Troian's scores among studied subsamples.

Percentage prevalence of SEM-identified surface defects and imperfections within each analyzed subsample presented in Table 2.

	Debris	Grooves	Microcavities	Scrapings	Cracks
Subsample A1-A5 (SANI for retreatment)	100%	80%	40%	20%	20%
Subsample B1-B5 (SANI Blue Storm)	20%	40%	20%	0%	0%
Subsample C1-C5 (Soco SC Plus)	100%	60%	40%	20%	20%
Subsample D1-D5 (HyFlex CM)	40%	40%	40%	0%	0%
Subsample E1-E5 (Profile)	100%	40%	20%	20%	20%
Subsample F1-F5 (PreRace)	20%	20%	40%	0%	0%

Table 2. Percentage prevalence of SEM-identified surface defects and imperfections within each analyzed subsample.

SEM-registered imperfections and irregularities of files' surface categorized by the manner previously described by AbuMostafa A.

et al. were distributed with following average prevalence parameters among all study sample: debris – 63.33±36.67%, grooves – 46.67±15.56%, microcavities – 33.33±8.89%, scrapings – 10.0±10.0%, cracks – 10.0±10.0%.

Prevalence of SEM-identified debris in subsamples A1-A5, C1-C5 and E1-E5 was statistically greater than in subsamples B1-B5 ($p < 0.05$), D1-D5 ($p < 0.05$) and F1-F5 ($p < 0.05$). Prevalence of grooves among studied specimens in subsamples B1-B5, D1-D5 and E1-E5 was analogical, while also not statistically different from prevalence of grooves noted in subsample C1-C5 ($p > 0.05$). No statistically significant difference was also noted regarding prevalence of microcavities among all studied subsamples ($p > 0.05$). Scrapings and cracks were noted the least frequently among all studied subsamples, while their prevalence levels did not differ significantly among all analyzed Ni-Ti files systems ($p > 0.05$).

Figures 2 to 7 represent SEM-obtained images of studied files with SEM-identified surface defects and irregularities

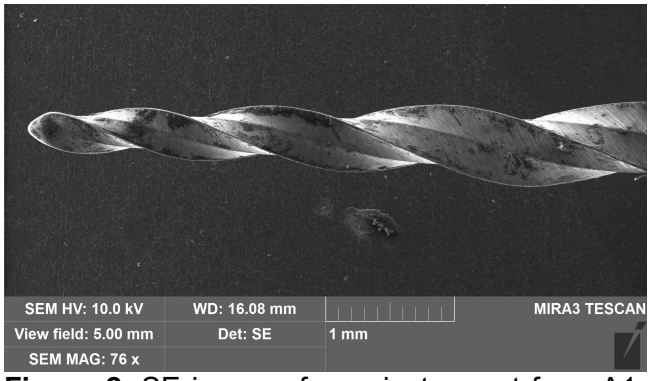

Figure 2. SE image of new instrument from A1-A5 anonymized subsample (SANI for retreatment, Chengdu Sani Medical Equipment Co.).

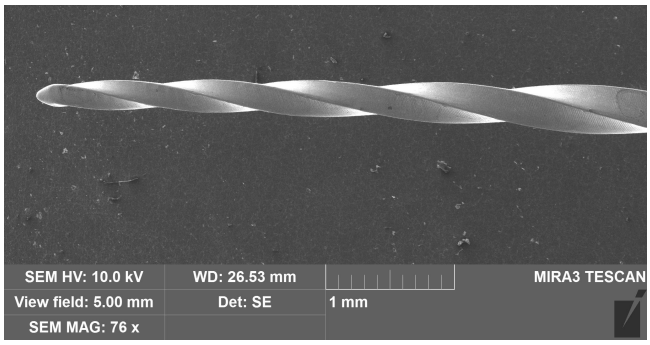

Figure 3. SE image of new instrument from B1-B5 anonymized subsample (SANI Blue Storm, Chengdu Sani Medical Equipment Co.).

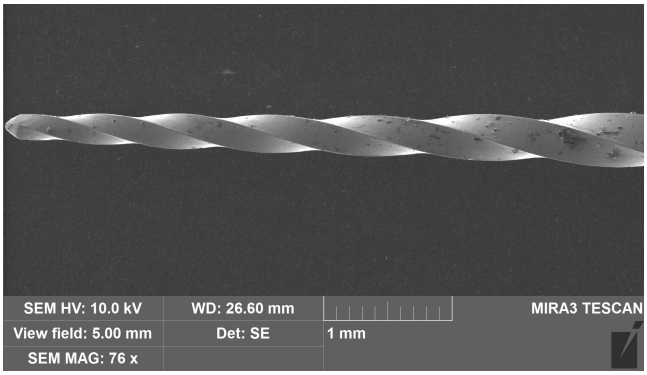

Figure 4. SE image of new instrument from C1-C5 anonymized subsample (Soco SC Plus, Chengdu Sani Medical Equipment Co.).

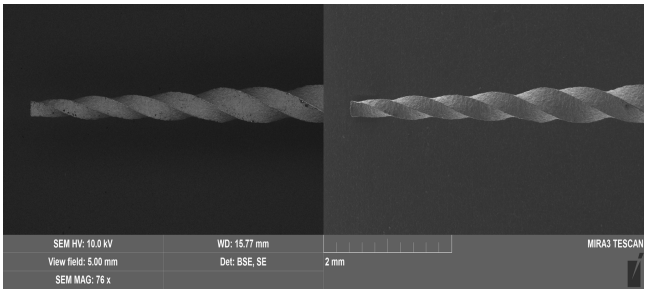

Figure 5. SE image of new instrument from D1-D5 anonymized subsample (HyFlex CM, Coltene).

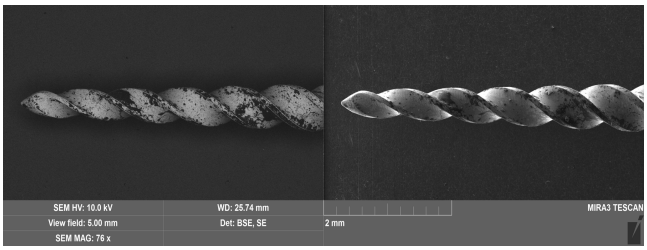

Figure 6. SE image of new instrument from E1-E5 anonymized subsample (Profile, Dentsply Sirona).

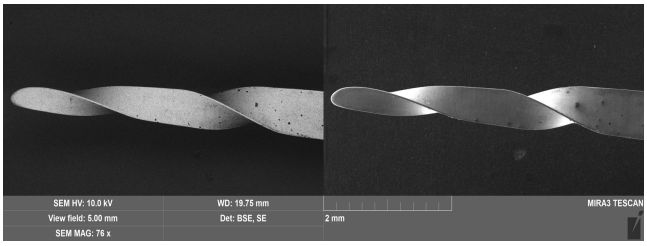

Figure 7. SE image of new instrument from F1-F5 anonymized subsample (PreRace, FKG Dentaire).

Scanning electron images of apical parts of different brands' instruments taken from different subsamples represented in the Figure 8.

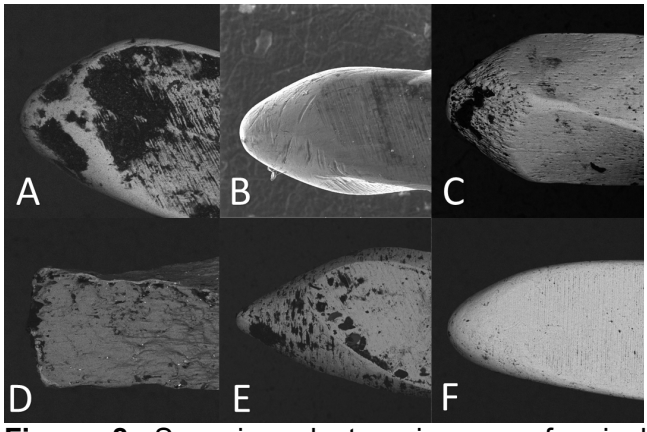

Figure 8. Scanning electron images of apical parts of instruments from different subsamples (A - SANI for retreatment, B - SANI Blue Storm, C - Soco SC Plus, D - HyFlex CM, E - Profile, F - PreRace).

Local element content analysis of randomly selected files from each subsample was provided selectively among chosen areas of files' surface with the signs of present impurities and revealed specifics of impurities element content among different instruments.

Areas of impurities on surface of SANI for retreatment file characterized with the presence of C, O, Al, Si, S, Ca, Ti, Ni, W; on surface of SANI Blue Storm file – with the presence of O, Na, Al, Si, S, Cl, K, Ca, Ti, Ni, Au; on the surface of Soco SC plus file – with the presence of C, N, O, F, Na, Mg, Si, Cl, Ca, Ti, Ni; on the surface of HyFlex CM file – by the presence of C, O, Na, Mg, Al, Si, S, Cl, K, Ca, Ti, Ni, Au; on the surface of ProFile file – by the presence of C, O, Na, Mg, Al, Si, S, Ti, Ni; on the surface of PreRace file – by the presence of C, N, O, Na, Mg, Al, Si, S, Cl, Cr, Fe, Ni.

Ranges of each element content at the files' surface areas with signs of impurities presented in Table 3.

Discussion

Manufacturing process of Ni-Ti rotary endodontic files is complex and difficult in realization, nevertheless adherence to the standardization principles and to proper quality level of manufacturing should be interpreted as ongoing issue of concern for the production companies.[1,2,3] Previously it was hypothesized that surface irregularities at new Ni-Ti files further may contribute to the present defect progression and instrument distortion in general due to the stress concentration effect at imperfections aeras during clinical use.[14] On the other hand endodontic instrument fractures seem to be associated also with operator skills, instrumentation technique, root canal configurations, quantity of overall instrument usage and cycles of sterilization, and specifics of file's design.[8,15] Based on that it appears to be reasonable to establish strict limits of clinical significance regarding SEM-identified files' surface imperfections impact on the prognosis of their potential breakage during primary or repetitive usage.

Results obtained in our study are similar to those previously described by AbuMostafa A. et al.: irregularities and imperfections of files' surfaces has been identified with the use of SEM method on each analyzed specimen irrespectively of its association with specific brand and manufacturer, while the prevalence distribution of diverse types of defects was different among various file systems.[8] In Chianello G. et al. study all analyzed systems of Ni-Ti files demonstrated the presence of surface scrapings, while prevalence of surface debris and grooves ranged in 45.5-100% among all SEM-studied instruments.[7] Researches also calculated that number of surface alterations ranged from minimum of 2 to maximum of 7 per one analyzed Ni-Ti file.[7] Such outcomes comply with results registered in our research, since prevalence of debris and grooves verified in our sample ranged from 20% to 100% and from 20% to 80% respectively, while also presence of 1-3 and more than 5 defects along surface of instrument long axis was the most prevalent.

Another SEM-based study reported the greatest prevalence of debris, grooves and microcavities among five different new Ni-Ti files systems, while scrapings and cracks were the least frequently registered among all studied specimens.[8] Such distribution outcomes are in full correspondence with results obtained in our research, even though absolute prevalence reported in AbuMostafa et al. study and in our research are different. Compliance of results presented in two abovementioned studies may be also argumented by the fact that they are similar by the design and application of the same categorization criteria for the files surface irregularities identified with the SEM method.

Medojevic M.J. et al. found that higher

prevalence of surface defects and identified impurities was registered at the apical part of studied specimen among five different Ni-Ti file systems, while also metal strips were verified on the working surface of all tested instruments.[9] Also, in the same study researches verified that the most prevalent type of defect among analyzed sample was fretting.[9] In our study we use another categorization criteria for SEM identified surface imperfections and irregularities, but there were no principal differences regarding prevalence of surface defects among new Ni-Ti rotary files while comparing results obtained in our study and in number of studies provided by Medojevic M.J. et al.[9,10]

Considering registered 100% SEM-identified surface imperfections prevalence among non-used files of studied sample, and potential interrelations between SEM-identified surface's irregularities and further patterns of crack formation-propagation previously reported in literature,[16] it seems to be clinically relevant to objectify the role of verified manufacturing defects on the prognosis of possible file fracture during endodontic treatment. Safety quotient (SQ) was developed for the clinical use of Ni-Ti files system which is defined as ratio of quantity of files demonstrating plastic deformation to the quantity of fractures registered among instruments of different brand, design etc.[17] Analog of SQ may also be developed based on SEM analysis results of Ni-Ti files surface. Our proposal for the future is to introduce SEM-based SQ (SEM-SQ) as ratio of quantity of file's surface defects and their various types registered by SEM method to the quantity of recorded fractures among instruments with such defects, while also considering brand, design, and structural characteristics of each instrument. This way it could be possible not to overestimate role of SEM-registered surface irregularities regarding their clinical relevance, and to revise criteria for the SEM-analysis of endodontic files regarding their significance separately for research purpose and for clinics.

Repetitive use of Ni-Ti files instruments in in-vitro conditions or within clinical conditions caused SEM-approved changes within their surface and cutting blades.[12] Recent systematic reviews also reported increase of Ni-Ti surface roughness and irregularities correspondingly to the number of undergone autoclave cycles that instruments were exposed to, evidenced both by SEM and atomic force microscopy (AFM) methods.[15,18]

Bonaccorso A. et al stated that typical surface analysis of Ni-Ti instruments reveals presence of carbon (62%), oxygen (30%), nickel (2%) and titanium (5%), while content of nickel and titanium increases from surface to core of the file.[19] Author also highlighted potential presence of such microelements as Si, Ca, Mg on the Ni-Ti files surface caused by environmental contamination.[19] Deposits of carbon and sulfur also may be found on Ni-Ti files surface because of lubricating oil usage during manufacturing process.[19] Traces of such elements as C, O, Na, Mg, Al, Si, S, Cl, K, Ca on the surface of new Ni-Ti files were also reported in SEM-based study of Medojevic M.J. et al, who has also provided EDS analysis of endodontic instruments, and reported presence of impurities among all studied specimens.[9] Such outcomes correspond with data registered in our study, even though EDS analysis provided in our study was selective and realized among areas of surface with previously detected signs of impurities. It was also revealed that present impurities content on the surface of analyzed endodontic files significantly varies among all specimens included in our study.

Chianello G. et al. resumed that high prevalence of surface defects among Ni-Ti files verified by the SEM method and reported at several previous studies, as also in our research, highlighting significance of next two aspects: 1) endodontic files should be thoroughly cleaned before sterilization; 2) additional studies focused on the improvement of Ni-Ti surface treatment and polishing are needed to minimize the risk of surface defect occurrence during manufacturing processes.[7] Thorough cleaning of endodontic files before sterilization should be provided since areas of identified before-use surface imperfections represents critical zones, where further clinically significant structural disturbances may occur and progress, if such will be succumbed by debris or stress during clinical application.[7] Second aspect highlighted by Chianello G. et al. is still the matter of relevant studies, but it is worth to mention that SEM analysis of novel three brands of Ni-Ti files revealed that such were characterized with no structural alterations.[11]

Meanwhile considering available updates on mechanical characteristics, technological

advancements and in-vitro testing results we may resume that major positive shift of Ni-Ti file manufacturing improvement is already taking place and continuously ongoing.[1,3] Such conclusion is argumented also by other fact: recent systematic review revealed that earlier date of publication regarding the rate of instrument breakage associated with higher reported incidence of file separation.[17] It may be hypothesized that improvement of Ni-Ti files manufacturing and within their structure may also had impact on the reduction trend of file separation incidence highlighted in recent reports, together with such factors as implying recommendation regarding control of file condition before and after use, using crown-down technique during endo-treatment, forming straight line access, and discarding files if such demonstrate evident signs of deformation.[1,2,3,4,17]

Limitations of present study associated with its observational design and use of SEM method as targeted for Ni-Ti file surface evaluation, since due to the results of previous systematic review such method of investigation characterized with potential risk of samples damage and impossibility to provide fully quantitative analysis of Ni-Ti files surface.[6] Nevertheless, presence of different surface irregularities at Ni-Ti files before any clinical use was also approved by other methods of investigation, such as noncontact three-dimensional optical profilometry, which helps to provide quantitative evaluation of the surface topography of endodontic instruments with possibility of comparing the same areas of files before and after several uses.[14]

SANI for retreatment									
	C	O	Al	Si	S	Ca	Ti	Ni	W
Max. (weight%)	70.99	36.65	1.37	27.16	0.23	0.41	37.39	54.56	24.17
Min. (weight%)	5.33	2.20	0.38	1.87	0.23	0.41	1.51	1.52	24.17

SANI Blue Storm											
	O	Na	Al	Si	S	Cl	K	Ca	Ti	Ni	Au
Max. (weight%)	47.07	9.00	0.59	1.28	2.15	9.44	1.63	0.58	39.99	50.02	15.75
Min. (weight%)	9.40	9.00	0.29	0.31	2.15	9.44	1.63	0.58	15.24	13.07	15.75

Soco SC plus											
	C	N	O	F	Na	Mg	Si	Cl	Ca	Ti	Ni
Max. (weight%)	43.03	0.00	34.20	0.93	0.62	0.28	1.84	1.30	1.10	36.00	57.20
Min. (weight%)	5.25.	0.00	1.55	0.93	0.62	0.28	1.84	1.30	1.10	9.49	7.21

HyFlex													
	C	O	Na	Mg	Al	Si	S	Cl	K	Ca	Ti	Ni	Au
Max. (weight%)	44.82	31.18	2.02	1.13	0.50	1.80	0.60	1.39	1.59	0.33	37.36	24.88	26.67
Min. (weight%)	4.07	10.95	2.02	1.13	0.21	0.52	0.51	1.39	1.59	0.33	11.97	4.76	26.67

ProFile									
	C	O	Na	Mg	Al	Si	S	Ti	Ni
Max. (weight%)	54.69	23.99	0.65	1.56	0.23	2.14	0.57	37.93	53.42
Min. (weight%)	47331	5.00	0.65	0.56	0.23	0.63	0.36	10.29	5.89

PreRace												
	C	N	O	Na	Mg	Al	Si	S	Cl	Cr	Fe	Ni
Max. (weight%)	48.25	`12.53	20.39	0.24	10.24	3.59	7.95	0.46	0.72	16.64	66.04	8.45
Min. (weight%)	6.39	12.53	1.90	0.24	0.82	3.59	0.58	0.46	0.72	3.07	10.75	1.78

Table 3. Ranges of identified element content at the files' surface areas with verified signs of impurities.

Conclusion

SEM analysis revealed that out of specimens of six endodontic rotary Ni-Ti files systems available in Ukraine none has been characterized with fully defect-free surface before any clinical usage. Different kind of surface imperfections have been registered among all studies samples, while the most prevalent among such were presence of debris, grooves and microcavities. In most cases instruments' long axis surface demonstrated 1-3 areas of defects or deformations, but also every third analyzed instrument demonstrated presence of more than 5 areas of defects and imperfections. SANI Blue Storm, HyFlex CM and PreRace files demonstrated lesser amount of surface imperfections compare to other analyzed systems. Prevalence of scrapings and cracks did not differ statistically among all analyzed specimens.

Declaration of interest.

The author reports no conflict of interest, and the article is not funded or supported by any research grant.

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