Counterfeit Endodontic Files Features Objectified with Scanning Electronic Microscopy: Comparative Study of SOCO SC Pro Original and Falsified Rotary Instruments

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Abstract

Objective of the research was to compare SEM characteristics of original and counterfeit SOCO SC Plus endodontic files and systematize features, which potentially may be used as markers for the falsified rotary instruments identification. 45 original SOCO SC Pro endodontic files (SCor group) and 45 SOCO SC Pro counterfeit files (SCcf group) were used for the scanning electronic microscopy analysis. Each group of files was analyzed with obtaining following set of scanning electron microscopy images: the general view of the working part, the view of the instrument's working tip, the view of the surface and the side face, the view of the fixation area in the projection of the shank.

Group of SOCO SC Plus counterfeit files demonstrated statistically higher prevalence of scrapings (p < 0.05) and cracks (p < 0.05) compared to the group of SOCO SC Plus original instruments. Counterfeit SOCO SC Plus files demonstrated greater diameter of the working tip's base, sharper tip's design and presence of compound's residuals at the fixation area in the projection of the shank, which potentially was used for connection of rotary instrument's parts by pasting technique.

Considering obtained results it may be resumed that SEM analysis may be successfully used for identification and approval of counterfeit origin of rotary instruments, if such by the any signs of visual inspection, packaging or labeling features or macroscopic analysis demonstrate nonconformities, doubtful signs or suspicion of being counterfeit, but for effective realization of such approach SEM reference data of original items should be available.

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Introduction

As per information provided by the World Health Organization nearly every 1 out of 10 medical products at low- and middle-income countries may be categorized as being substandard or falsified.¹ Due to the FDI policy statement counterfeit dental product represents "fake replica of a real product that has value", while non-compliant product refers to the device originated from black market or grey market that does not correspond with the established

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regulations.²

FDI policy statement regarding greymarket originated dental products includes recommendation for dental specialists to refuse buying non-compliant devices, but the question remains how to identify such if in some cases counterfeit products may looks and behave similar to original ones.² Several notes were systematized, which dentist may use in case of suspecting buying or using counterfeit dental product: drastic difference in pricing; purchasing online from the unknown supplier; visual difference from the original device that has been successfully used before; divergences in company and product names and logos; nonconformity with previous design and color of packaging: absence of corresponding certification mark; inability to track the product by the batch and/or serial number.^{2, 3}

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However, a lack of targeted researches regarding analysis of counterfeit dental devices and objectification of their characteristics have been noted in dental literature.⁴ Moreover, only few studies have been aimed at establishing some unprejudiced criteria for counterfeit product identification before its clinical usage.^{4, 5, 6, 7}

Endodontic files seem to be ones of the most prevalently seized counterfeit and substandard dental devices.³ Medicines and Healthcare products Regulatory Agency in 2014 reported that out of 12122 seized poor-quality dental equipment 27.57% was represented by endodontic instruments.³

Limited number of researches was dedicated to the evaluation of counterfeit endodontic rotary instruments with the usage of different examination techniques, including visual inspection, batch number tracking, scanning electronic microscopy, stereomicroscopic analysis, chemical content analysis and chemical elements detection.^{4, 5, 6, 7}

Available studies reported lower performance of counterfeit endodontic instruments compare to the original rotary files, which in turn was associated with the greater risk of file separation, endodontic complications and harm to the patients.^{4, 7} Considering above mentioned facts it was pointed out that there is a need to develop practically-oriented strategies that may be easily used by dental specialists in real clinical conditions for the identification of counterfeit endodontics instruments and thus for the prevention of their usage.^{4, 7, 8}

Objective

The aim of present research was to compare SEM characteristics of original and counterfeit SOCO SC Plus endodontic files and systematize features, which potentially may be used as markers for the falsified rotary instruments identification.

Materials and methods

Study sample

45 original SOCO SC Pro endodontic files (SCor group) and 45 SOCO SC Pro counterfeit files (SCcf group) were used for the scanning electronic microscopy (SEM) analysis. Original SOCO SC Pro endodontic files were bought from the original distributor of SOCO endodontic files instruments in Ukraine (https://soco.com.ua/), while SOCO SC Pro counterfeit files were bought

through Internet-market, which had no connection to the original distributor. Counterfeit origin of the files was established by the tracking of batch and serial numbers, which were not approved bv the original manufacturer Medical Equipment (Chengdu Sani Co.. Chengdu, China). Out of 45 original SOCO SC Pro endodontic files 15 items were represented by size 20 (0.2 mm), taper 4% (/.04), length 25 mm; 15 items – by size 15 (0.15 mm), taper 3% (/.03), length 25 mm; and 15 - by size 17 (0.17 mm), taper 8% (/.08), length 25 mm. The same distribution of counterfeit files was formed within SCcf group (Table 1).

Group	Endodontic file system (Manufacturer)	Anonymized set	Cross- section	Diameter	Taper	Quantity
SCor group (SOCO SC Plus original)	SOCO SC Plus (Chengdu Sani Medical Equipment Co., Chengdu, China)	A1-A15	Triangular cross- section	20	/.04	15
		B1-B15	Triangular cross- section	15	/.03	15
		C1-C15	Triangular cross- section	17	/.08	15
SCcf group (SOCO SC Plus counterfeit)	SOCO SC Plus counterfeit	D1-D15	Triangular cross- section	20	/.04	15
		E1-E15	Triangular cross- section	15	/.03	15
		F1-F15	Triangular cross-	17	/.08	15

Table 1. Distribution of rotary instruments within SOCO SC Pro original endodontic files group and SOCO SC Pro counterfeit endodontic files group.

Scanning electron microscopy of the endodontic files was provided within Laboratory of Electron Microscopy "Nano Technologies in Medicine" Ukraine). Endodontic (Kviv. instruments included either in SCor or SCcf group were gently removed from their original packages and transferred into the holder of scanning electron microscope (Tescan Mira3 LMU, TESCAN, Brno, Czech Republic) equipped with EDS (Energy Dispersive Spectrometry) detector (Oxford X-max 80 mm. Oxford Instruments, Abingdon, UK). During unpacking and transferring manipulations working parts of the rotary files were not altered with any kind of instruments, while also endodontic files did not undergo any peculiar treatment or preparation before SEM-analysis.⁹

Each group of files was analyzed with obtaining following set of SE images: the general view of the working part, the view of the instrument's working tip, the view of the surface and the side face, the view of the fixation area in the projection of the shank.

Following exposure parameters of scanning electron microscope were used during present research: SEM HV (acceleration voltage) - 20.0 kV; SEM MAG (magnification) - 21× (for the general view of the working part), 76× (for the view of the fixation area in the projection of the shank), 271× (for the view of the surface and the side face), 474× (for the view of the instrument's working tip); view field $-400 \ \mu m$ (for the view of the instrument's working tip), 700 µm (for the view of the surface and the side face), 2.5 mm (for the view of the fixation area in the projection of the shank), 18.0 mm (for the general view of the working part); with use of SE (secondary electrons) and BSE (backscattered electrons) detectors.

Analyzed view of SEM	SEM HV (acceleration voltage)	SEM MAG (magnification)	View field
General view of the working part	20.0 kV	21×	18.0 mm
View of the instrument's working tip	20.0 kV	474×	400 µm
View of the surface and the side face	20.0 kV	271×	700 µm
View of the fixation area in the projection of the shank	20.0 kV	76×	2.5 mm

Table 2. Parameters of SEM used duringresearch.

All the images obtained after scanning electronic microscopy were anonymized and grouped within specific sets of SE-images by laboratory technician, who marked those sets with capital letters for corresponding files' parameters (including its adherence to the original or counterfeit group) and number for the sequence number of the analyzed item (rotary file) within the set by the following manner: A1-A15 for the original SOCO SC plus files of size 20 and 4% taper, B1-B15 for the original SOCO SC plus files of size 15 and 3% taper, C1-C15 for the original SOCO SC plus files of size 17 and 8% taper, D1-D15 for the counterfeit SOCO SC plus files of size 20 and 4% taper, E1-E15 for the counterfeit SOCO SC plus files of size 15 and 3% taper, F1-F15 for the counterfeit SOCO SC plus files of size 17 and 8% taper (Table 1).

Further analysis of obtained images and their pair-wise comparison was provided by the two independent investigators only between anonymized sets in the following manner: images of A1-A15 anonymized set were compared with images of D1-D15 anonymized set, images of B1-B15 – with images of F1-F15, images of C1-C15 – with images D1-D15. Analysis of SE-images obtained for Ni-Ti files' surface was provided due to the previously described adapted Troian's et al. approach.^{9, 10} Categorization of SEM-registered irregularities of files' surface was provided based on criteria proposed in AbuMostafa A. et al. study.^{9, 11} All the SE-images were analyzed and categorized due to the Troian's and AbuMostafa criteria by the two investigators independently, who have been previously calibrated during involvement in the research dedicated to the SEM-analysis of surface characteristics of six endodontic files systems available in Ukraine.⁹

Design of present research and its correspondence with all ethical norms was approved Institutional Review by Board of Faculty of Dentistry at Uzhhorod National present University (Ukraine), while study represent part of complex scientific research work of the Department of Restorative Dentistry Uzhhorod National University (Ukraine) at dedicated to the implementation of modern materials and technologies in dental practice.

Statistical Analysis

Results registered by the investigators were structured, grouped and systematized within Microsoft Excel software version 16.0 (Microsoft Office 2019, Microsoft Corporation India Pvt. Ltd., New Delhi, India). Shapiro-Wilk testing approach was provided to assess the correspondence of obtained datasets to the distribution. Datasets with normal normal distribution pattern was compared trough ANOVA analysis, while data with distribution different from normal was analyzed considering Kruskal-Wallis test. Statistical analysis of results obtained after SEM-analysis was provided with the use of Fisher's criterion (p <0.05).9,12 Inter- and intrarater agreements levels have been assessed by Cohen's kappa coefficient. Standard error of mean equaled to 0.066 (previously proposed in the Chianello G. et al. study)¹³ was used as a reference for intra-examiner and inter-examiner calibration during analysis and interpretation of obtained SEM-images.

Results

No statistically significant differences were found between any compared pair of image sets (A1-A15 vs. D1-D15 – p > 0.05, B1-B15 vs. F1-F15 – p > 0.05, C1-C15 vs. D1-D15 – p > 0.05) regarding mean Troian's score associated

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with quantity of defects and deformations along the surface of studied files. The most prevalently scores "3" and "4" were registered both among SCor group and among SCcf group (31.11% vs 37.78% respectively, p > 0.05 considering score's "3" prevalence; and 33.33% vs. 40.0% respectively, p > 0.05 considering score's "4" prevalence).

Due to the AbuMostafa A. et al. criteria 100% of original and counterfeit files of demonstrated presence debris. while prevalence of grooves (51.11% vs. 57.78%) and microcavities (40% vs. 48.89%) between original and counterfeit rotary instruments was comparatively similar, even though in SCcf group such irregularities were observed more frequently, but statistical difference of such could not be approved (p > 0.05).

Group of SOCO SC Plus counterfeit files demonstrated statistically higher prevalence of scrapings (p < 0.05) and cracks (p < 0.05) compared to the group of SOCO SC Plus original instruments.

Intra-rater agreement of SEM-images analysis and interpretation outcomes based on correspondence of Troian's score and AbuMostafa A. criteria during repeated check reached 0.91, while inter-rater agreement was represented by Cohen's kappa value of 0.87.

Comparison of A1-A15 and D1-D15 SEMimages sets obtained for SOCO SC Plus original and counterfeit files (size 20 taper 4%) respectively revealed following principal outcomes:

- original and counterfeit files characterized with analogical characteristics within general view of the working part;
- original and counterfeit files characterized with similar characteristics within view of the surface and the side face, except that prevalence of scrapings and cracks among the counterfeit files was higher;
- counterfeit files demonstrated wider diameter at the base of the working tip, which didn't correspond with ISO standard size for these files (Figure 1);
- counterfeit files demonstrated sharper design of the working tip (Figure 1);
- counterfeit files demonstrated the presence of some compound at the fixation area in the projection of the shank, due to which it may be presumed that connection between those parts was provided by pasting technique

(Figure 2);

- original files did not demonstrated presence of any compound at the fixation area in the projection of the shank, due to which it may be presumed that connection between those parts was provided by pressing method (Figure 2).



Figure 1. Comparison of instruments' working tip between original (A1-A15) and counterfeit (D1-D15) SOCO SC Plus files (size 20 taper 4%). Note wider diameter of working tip's base among counterfeit files.



Figure 2. Comparison of instruments' fixation area in the projection of the shank between original (A1-A15) and counterfeit (D1-D15) SOCO SC Plus files (size 20 taper 4%). Note the residuals of compound at the fixation area in the projection of the shank in counterfeit files.

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Comparison of B1-B15 and E1-E15 SEMimages sets obtained for SOCO SC Plus original and counterfeit files (size 15 taper 3%) respectively revealed following significant outcomes:

- original and counterfeit files characterized with analogical characteristics within general view of the working part;
- original and counterfeit files characterized with similar characteristics within view of the surface and the side face, except that prevalence of scrapings and cracks among the counterfeit files was higher;
- counterfeit files demonstrated sharper design of the working tip (Figure 3);
- counterfeit files demonstrated wider diameter at the base of the working tip, which didn't correspond with ISO standard size for these files (Figure 3);
- counterfeit files demonstrated the presence of some compound at the fixation area in the projection of the shank, due to which it may be presumed that connection between those parts was provided by pasting technique (Figure 4);

original files did not demonstrated presence of any compound at the fixation area in the projection of the shank, due to which it may be presumed that connection between those parts was provided by pressing method.



Figure 3. Comparison of instruments' working tip between original (B1-B15) and counterfeit (E1-E15) SOCO SC Plus files (size 15 taper 3%). Note wider diameter of working tip's base, while also sharper design of the tip among counterfeit files.

Analysis of C1-C15 and F1-F15 SEMimages sets obtained for SOCO SC Plus original and counterfeit files (size 17 taper 8%) respectively revealed no significant differences between compared items. Original and counterfeit files were characterized with analogical characteristics within general view of the working part and view of the surface and the side face, except that prevalence of scrapings and cracks among the counterfeit files was higher. Design and base diameter of the working tip was similar among original and counterfeit files, while fixation area at the projection of the shank have not demonstrated presence of any compound neither among original files, nor among counterfeit files, due to which it may be presumed that connection between those parts among both groups of files was provided by pressing method. (Figure 5, 6)



Figure 4. Comparison of instruments' fixation area in the projection of the shank between original (A1-A15) and counterfeit (D1-D15) SOCO SC Plus files (size 15 taper 3%). Note the residuals of compound at the fixation area in the projection of the shank in counterfeit files.



Figure 5. Comparison of instruments' working tip between original (C1-C15) and counterfeit (F1-

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F15) SOCO SC Plus files (size 17 taper 8%). No principal differences have been noted.

Figure 6. Comparison of instruments' fixation area in the projection of the shank between original (C1-C15) and counterfeit (F1-F15) SOCO SC Plus files (size 17 taper 8%). No principal differences have been noted.

Discussion

Due to the information provided by WHO falsified medical products may not only harm individuals that have direct contact with them, but general use of falsified and substandard medical products may compromise confidence in medicine and cause reputational losses for medical care providers.¹

Previously several policies, programs and specifically developed methods were proposed as anti-counterfeit in dental practice by their primary or secondary objective.^{3, 14, 15} As an example, optimized spectrophotometric approach has been developed for dental composites assessment and their quality evaluation, which may support identification of materials with compromised physical properties and originated from "grey" market.¹⁵

In present study SEM method has been assessed as an approach for the approval of counterfeit origin of endodontic files, which helps to objectify characteristics of falsified rotary instruments in comparison to the original ones.

Counterfeit endodontic instruments characterized with relatively lower price compared to the original files. Previous study revealed that price of counterfeit ProGlider instruments bought through Internet-market was 3 times lower compared to such from official distributor.⁶ In present study price of counterfeit SOCO SC plus files was nearly 20% lower compared to such proposed by official distributor.

Quite often original and counterfeit endodontic files could be distinguished by differences of marking rings' width and denotations of measuring lines, which could be painted, or laser printed without reliefs.⁶ Rodrigues C. et al. noted the difference in ISO color coding and lines of measurements among counterfeit Reciproc files.⁷ In present research no principal visual differences were noted between SOCO SC Plus original and counterfeit rotary instruments, which was a reason to use SEM method to approve counterfeit origin of the falsified items. The latter was suspected by inability to track them through batch and serial numbers.

Most of previously provided studies resumed that because of deficient mechanical performance of counterfeit endodontic files they are more prone to early fracture due to the lowcyclic fatigue resistance, while their scarce flexibility may interfere original root canal patency, especially in roots with pronounced curvature.^{5, 6} Constant austenitic condition of counterfeit endodontic files, which was noted previously, may be one of the causes of its decreased flexibility properties.⁶ In previous research it was found that lower flexibility of counterfeit files was associated with their increased diameter, which deviated from such distinctive to specific ISO size.⁷ Increased diameter of counterfeit rotary instruments associated with increased risk of ledge formation.⁷ Present research revealed that counterfeit endodontic files of size 20 and taper 4% and of size 15 and taper 3% also were characterized with increased diameter of the tip, which potentially might be related with altered flexibility of the instruments and their potential to ledge formation.

Results of previous in-vitro study demonstrated that counterfeit ProTaper F2 rotary instruments characterized with more than 2 times lesser cyclic fatigue resistance compared to the

original files.⁴ Counterfeit instruments were prone to fracture after 186±86 working cycles, and SEM analysis revealed that fracture surface of a counterfeit file demonstrated shallower dimples, which are the indirect signs of less plastic deformation.⁴ Fractured counterfeit files also had no circular abrasion signs, which indicated about flexural fatigue failure.⁴ Considering results of invitro study it may be suggested that counterfeit instruments characterized with the higher risk of potential fracture during their clinical usage, which in turn may cause further endodonticallyrelated complications and harm to the patients. Analogical results were also registered in the study of counterfeit ProTaper Next endodontic instruments: the latter demonstrated decreased mechanical behavior compared to the original files, while only maximum torque to fracture was similar in both samples.⁵

Analysis of ProGlider counterfeit instruments revealed following findings: counterfeit and original files demonstrated similarities regarding design features (quantity of spirals, cross-section peculiarity, symmetry pattern of blade) and Ni-Ti content ratios, but during mechanical testing counterfeit presented statistically performance inferior after multimethod assessment.⁶ Tip of counterfeit file also demonstrated more rounded geometry, while original had sharper design.⁶ It is important to notice that SEM analysis revealed more irregularities on counterfeit files surface compared to the original instruments,⁶ which is in correspondence with results obtained in present study, because counterfeit SOCO SC plus demonstrated greater prevalence of scrapings and cracks.

Counterfeit Ni-Ti files may be characterized with greater electrical resistance, which in turn provoking failure in correct determination of working distance via apex locator integrated endomotors.¹⁶

Counterfeit Reciproc files demonstrated higher level of roughness, while SEM-identified surface defects may serve stress as concentration zones and region of cracks development and propagation.⁷ On the other hand previously, it was found that out of six endodontic rotary Ni-Ti files systems available in Ukraine none has been characterized with fully defect-free surface before any clinical usage.⁵ Such outcome is in correspondence with data obtained in present study: all tested samples

demonstrated presence of surface irregularities and imperfections, while counterfeit files characterized with greater registration frequency for scrapings and cracks. No other principal differences were noted for general view of the working part and view of the surface and the side face between original SOCO SC Plus files and counterfeits.

In thesis of Tsakiris G, it was noted that SEM features of counterfeit endodontic files includes following (based on the investigation of counterfeit ProTaper instruments): greater number of surface irregularities, higher amount of metal deposits and debris, deviant design of cutting tip (being sharper than in original file), deficiency of bevel tip and relief zones, noncorrespondence to the ISO standard sized of the tip.¹⁷ Counterfeit SOCO SC Plus files in present study also demonstrated higher prevalence of surface imperfections in the means of cracks and scrapings, while also altered working tip design and it's non-conformity with ISO standard size.

Taking into account provided analysis of available literature we systematize following associations between laboratory registered deviations and further potential clinical consequences of using counterfeit endodontic files:

- greater number of surface imperfections and presence of metal debris on the surface → speed-up of cyclic fatigue process → higher risk of early file fracture (separation);
- deviation of cutting tip design, including deviation of tip size → ledge formation, apex transportation, perforation, overinstrumenation;
- deviation of working part design (shortage of relief zones) \rightarrow limited flexibility \rightarrow rise of torsional loads \rightarrow higher risk of early file fracture (separation).

Previous EDS-analysis has not revealed any significant differences regarding Ni-Ti alloy content and ratio between original and counterfeit endodontic files.¹⁷ Out of all articles available for authors during targeted literature review only study of Rodrigues C.S. et al. revealed that original and counterfeit files (Reciproc) significantly differed in chemical composition based on the provided energy-dispersive X -ray microanalysis, which may be interpreted that samples were made out of different raw material.7

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Except counterfeit endodontic files replicas of different rotary instruments systems are also available at the market. Replica-like endodontic systems characterized with variations in terms of standardization (tip diameter, taper value) and design, as well as deviations of phase-transformation pattern and precision criteria compared to the original files.18, 19 Nevertheless, some replica-like representatives didn't differ from original endodontic instruments terms of cyclic fatigue or in chemical composition.¹⁸ These facts argument that even though replica-like endodontic rotary files may initially demonstrate mechanical features partially similar to the original instruments, clinical usage of such could not be reasoned under any circumstances, considering potential perturbation of treatment process.¹⁸

Recently developed multi-criteria decision-making-based assessment model for rotary Ni-Ti file selection, which may be implemented to optimize clinical dental practice, did not included analysis of any counterfeit endodontic instruments, since such characterized with "pseudo"-properties of original files and in all cases the latter outperform counterfeit items.⁸

FDI policy statement regarding nondental products compliant includes recommendations about the need to report "suspect materials, instruments and devices to the appropriate regulatory agencies and professional authorities in a timely manner", while also about the need of coordination between manufacturers and national dental association for providing education of dentists about the suspected and non-predictable risks of using counterfeit dental products or such originated from black or grey market.² Continuing dental education includes informational support of dental specialists regarding outcomes of clinical and scientific experiments and observations. recent trends and advances in dentistry. Considerina above-mentioned FDI policy statement and associated recommendations, while also main principles of continuing dental education, it may be resumed that present study complies with both of these measures, since it increases Ukrainian and international dentists' awareness regarding risk of using counterfeit endodontic files and demonstrates one of the easy-to-implement approaches for their objective verification.

Even though mechanical testing of rotary

files plays important role for in-depth analysis of endodontic files behavior, there is still a need for implementation of so-called multimethod approach, which could help to gain more clinically-valuable information about prognosis of file performance under various clinical conditions.⁶

Due to the results obtained in our study we may proposed the usage of SEM method for endodontic instruments that by the any signs of visual inspection, packaging or labeling features or macroscopic analysis demonstrate suspicion of being counterfeit. Triade of non-corresponded tip diameter, sharper design of the working tip and presence of foreign compound in the area of shank connection may be interpreted as SEMmarkers of counterfeit SOCO SC Plus endodontic files. Such approach is less expensive than detailed mechanical testing, while also helps to verify defects of endodontic instruments before their clinical usage. On the other hand, SEM analysis of endodontic files randomized sample formed out of large volume purchase with the objective to verify critical deviations from the reference (standard) may be also interpreted both as quality assurance measure and more important as preventive approach, since it will help to minimize the risk of using counterfeit products and development of potential complications related with this matter.

Conclusion. SEM analysis of original and counterfeit SOCO SC Plus endodontic files revealed that both of them characterized with similar surface characteristics, except that cracks and scraping were registered more frequently among counterfeit instruments. Counterfeit SOCO SC Plus files demonstrated greater diameter of the working tips' base, sharper tip design and presence of compound's residuals at the fixation area in the projection of the shank, which potentially was used for connection of rotary instrument's parts by pasting technique. Considering obtained results it may be resumed that SEM analysis may be successfully used for identification and approval of counterfeit origin of rotary instruments, if such by the any signs of visual inspection, packaging or labeling features macroscopic analysis demonstrate nonor conformities, doubtful signs or suspicion of being counterfeit, but for effective realization of such approach reference data of original items should be available.

Declaration of interest.

The authors report no conflict of interest, and the article is not funded or supported by any research grant. Even though clinicians, who took part in this research, are using SOCO SC Plus instruments in their dental practice no direct or indirect benefits in financial or other forms have been provided to them from the original distributor of SOCO SC Plus files or any other party. Study was held only under personal initiative of authors, strictly for scientific objective, all the costs were covered strictly by authors and with no refund provided by any other party.

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