Original Research

https://doi.org/10.36377/ET-0203

Clinical evaluation of the capabilities and manipulative characteristics of a modified tungsten alloy endodontic finishing file

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Abstract

AIM. To conduct a clinical assessment of the capabilities and manipulation characteristics of a modified tungsten alloy endodontic finishing file.

MATERIALS AND METHODS. The study design involved the participation of 7 dentists with at least 10 years of experience performing endodontic treatment at 7 different medical clinics. Each of the specialists performed endodontic treatment of 15 teeth, both primary and repeated, in accordance with established diagnoses for diseases of the pulp and periodontium with optic magnification. The irrigation stage of the root canal system was complemented by the use of a finishing file made by twisting wire from a modified tungsten alloy with a bundle of microbristles on the end part. The study used 105 instruments in 105 clinical cases. To standardize the assessment of capabilities and manipulation characteristics, a specially designed questionnaire was used to comprehensively evaluate the work with the instrument. Clinical photo documentation of the work stages, data collection and archiving, statistical processing and subsequent analysis were carried out. The consistency of expert opinions was studied by calculating the Kendall concordance coefficient (W).

RESULTS. The clinical capabilities and manipulative characteristics of a finishing endodontic file made of a modified tungsten alloy based on a standardized profile questionnaire have been determined. The moderate consistency of expert opinions ($W = 0.54$) is statistically significant at a very high level ($p < 0.001$), which allows us to consider the expert assessments to be objective. The advantages and limitations of using these files are outlined. Clinical recommendations for the use of this instrument have been formulated.

CONCLUSIONS. The use of a twisted-type endodontic finishing file made of a modified tungsten alloy in the root canal irrigation algorithm forms a new approach in endodontics aimed at improving root canal treatment and increasing the success of treatment in clinical dentistry. The results obtained will form the basis for the development of methodological approaches to conducting both laboratory and clinical research in this area.

Keywords: endodontic treatment, root canal system, irrigation, activation of irrigation solution, finishing file, endodontic instrument, EndoKey

Article information: received – 26.02.2026; revised – 29.03.2026; accepted – 08.04.2026

Conflict of interests: The authors declare no conflict of interests.

Acknowledgments: The study was supported by NizhStomPlus LLC, Nizhny Novgorod, Russian Federation.

For citation: Goryacheva T.P., Zaplutanova D.A., Aleshina O.A., Abramova E.E., Shurova N.N., Dobrovolskaya E.V., Sidyagina T.V., Eremeeva E.A., Sadekova D.R., Dmitrieva D.V., Malanev G.A. Clinical evaluation of the capabilities and manipulative characteristics of a modified tungsten alloy endodontic finishing file. *Endodontics Today.* 2026;24(2):388–401. https://doi.org/10.36377/ET-0203

© Goryacheva T.P., Zaplutanova D.A., Aleshina O.A., Abramova E.E., Shurova N.N., Dobrovolskaya E.V., Sidyagina T.V., Eremeeva E.A., Sadekova D.R., Dmitrieva D.V., Malanev G.A., 2026

Клиническая оценка возможностей и манипуляционных характеристик финишного эндодонтического файла из модифицированного сплава вольфрама

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Резюме
ЦЕЛЬ. Провести клиническую оценку возможностей и манипуляционных характеристик финишного эндодонтического файла из модифицированного сплава вольфрама.
МАТЕРИАЛЫ И МЕТОДЫ. Дизайн исследования предполагал участие 7 врачей с опытом работы не менее 10 лет, выполняющих эндодонтическое лечение на базе 7 различных медицинских учреждений. Каждым из специалистов выполнялось эндодонтическое лечение 15 зубов, как первичное, так и повторное, в соответствии с установленными диагнозами при заболеваниях пульпы и периодонта с оптическим увеличением. Этап ирригации системы корневых каналов дополнялся применением финишного файла, изготовленного из модифицированного сплава вольфрама с пучком микрощетинок на торцевой части. В исследовании применено 105 инструментов в 105 клинических случаях. Для стандартизации оценки возможностей и манипуляционных характеристик инструмента использован специально разработанный опросник, позволяющий всесторонне оценить работу с инструментом. Производилось клиническое фото-документирование, сбор и архивирование данных, статистическая обработка с последующим анализом.
РЕЗУЛЬТАТЫ. Определены клинические возможности и манипуляционные характеристики финишного эндодонтического файла из модифицированного сплава вольфрама на основе стандартизированного профильного опросника. Показана умеренная согласованность мнений экспертов (W = 0,54) статистически значимая на очень высоком уровне $p < 0{,}001$), что позволяет признать экспертные оценки объективными. Обозначены преимущества и ограничения использования данных файлов. Сформулированы клинические рекомендации по применению инструмента.
ВЫВОДЫ. Применение финишного эндодонтического файла из модифицированного сплава вольфрама в алгоритме ирригации корневых каналов формирует новый подход в эндодонтии, направленный повышение успеха лечения в клинической стоматологии. Полученные результаты станут основой для разработки методологических подходов к проведению как лабораторных, так и клинических исследований в этой области.

Ключевые слова: эндодонтическое лечение, система корневых каналов, ирригация, активация ирригационного раствора, финишный файл, эндодонтический инструмент, EndoKey

Информация о статье: поступила – 26.02.2026; исправлена – 29.03.2026; принята – 08.04.2026

Конфликт интересов: Авторы сообщают об отсутствии конфликта интересов.

Благодарности: Исследование было поддержано ООО «НижСтомПлюс», г. Нижний Новгород.

Для цитирования: Горячева Т.П., Заплутанова Д.А., Алешина О.А., Абрамова Е.Е., Шурова Н.Н., Добровольская Е.В., Сидягина Т.В., Еремеева Е.А., Садекова Д.Р., Дмитриева Д.В., Маланьев Г.А. Клиническая оценка возможностей и манипуляционных характеристик финишного эндодонтического файла из модифицированного сплава вольфрама. *Эндодонтия Today.* 2026;24(2):388–401. https://doi.org/10.36377/ET-0203

INTRODUCTION

Endodontic treatment occupies a pivotal position within the structure of contemporary dental care. The wide spectrum of pulpal and periapical diseases justifies the existence of numerous approaches to both mechanical and chemical intervention within the endodontic system, as well as a variety of post-endodontic restorative protocols [1]. This, in turn, serves as a strong driver for the continuous and dynamic advancement of endodontics, establishing it as a leading field in dental science and clinical practice.

The relevance of clinical research in endodontics is due to the complexity and still insufficient effectiveness of treatment in patients with pulpal and periapical pathology. To a considerable extent, this is associated with the persistence of residual multispecies biofilms

and the smear layer on the root canal walls. These factors hinder effective disinfection, compromise the adhesion of filling materials, reduce the sealing ability of root canal obturation, and ultimately negatively affect long-term treatment outcomes [2–4].

Available evidence indicates that mechanical preparation leaves approximately 35% of the root canal walls untouched; consequently, bacterial biofilms may persist in areas that remain uninstrumented [5]. The retention of microbial agents is further facilitated by the complex morphology of the root canal system (RCS). Existing classifications, particularly the widely recognized Vertucci classification [6], do not always accurately reflect the anatomical reality revealed by micro-computed tomography (micro-CT). For instance, the study by Dalili Kajan et al. demonstrated significant anatomical variability of the RCS based on Vertucci's terminology [7]. These findings emphasize that the structure of the RCS is substantially more complex than represented in conventional classifications. Moreover, due to its lower resolution, cone-beam computed tomography (CBCT) does not allow detailed visualization of the fine anatomical structures that can be detected using micro-CT, considered the diagnostic "gold standard", thereby limiting the feasibility of targeted mechanical instrumentation throughout the entire RCS [8]. Consequently, the Vertucci classification and similar systems should, in certain contexts, be regarded as simplified representations of the actual clinical scenario. In this regard, Pokrovsky et al. proposed the use of the term "root canal" not as a descriptor of the entire anatomical structure of the RCS, but rather as the portion subjected to mechanical preparation aimed at "simplifying" the canal system and creating optimal conditions for irrigation of inaccessible areas [9].

Most root canals exhibit irregular shapes, with varying diameters in the buccolingual and mesiodistal directions, and frequently contain numerous lateral canals, ramifications, anastomoses, and isthmuses. Apical ramifications, multiple apical foramina, and other anatomical complexities are also commonly observed [10]. Therefore, it becomes evident that managing such a complex system using purely mechanical methods is highly challenging. Particular difficulties arise in the preparation of isthmus regions. Isthmuses may present as fin-shaped, web-like, or ribbon-like structures connecting the main canals. They can be classified as distinct, mixed, plate-like, or canal-type connections, with some exhibiting closed configurations. These areas are inaccessible to cutting manual or rotary instruments, and smear layer as well as dentinal debris may accumulate and compact within these anatomical structures.

Chemical action during irrigation of the RCS significantly reduces the bacterial load, as irrigants interact directly with canal walls, enabling antimicrobial agents to penetrate dentinal tubules, which serve as reservoirs for microorganisms. Nevertheless, even after such preparation, microorganisms may persist both in the main canal and in other compartments of the RCS. Various methods of irrigant activation have been developed to enhance irrigation efficacy by improving the distribution and movement of chemical agents within the RCS, thereby increasing their interaction with canal surfaces [3; 11–14].

A promising direction in this field is the development of novel endodontic instruments capable not only of activating irrigation solutions but also of exerting mechanical action on the surfaces of root canals with complex configurations. Over the past decade, endodontic files designed for the final finishing of the RCS following mechanical preparation with Ni–Ti systems have been actively introduced. This category of instruments features a flexible working part that generates turbulence and hydrodynamic agitation of the irrigant, thereby enhancing its activation. As a result, improved disinfection of anatomically complex root canals is achieved, along with more effective removal of dentinal debris, smear layer, and remnants of filling materials (such as calcium hydroxide, gutta-percha fragments, sealers, etc.), without inducing additional dentin cutting [15–17].

This group of instruments includes the NiTi file XP-endo Finisher (FKG Dentaire SA, Switzerland) with a monolithic working part; the NiTi file Gentlefile Brush (MedicNRG, Israel), the terminal segment of which consists of seven stainless steel filaments; and the EndoKey instrument (Nova Brush, Russian Federation), manufactured from a modified tungsten alloy and featuring three micro-bristles at the tip of its working part [15–17].

To date, the available literature provides only fragmented data regarding the application of these instruments. A number of aspects remain insufficiently investigated. In particular, there is a need for well-designed clinical studies aimed at evaluating the functional capabilities and handling characteristics of finishing files in clinical practice. Such research would facilitate a clearer understanding among practitioners of the principles underlying their use, allow for a more comprehensive assessment of their potential, and ultimately contribute to improving the quality of endodontic treatment.

AIM

To conduct a clinical evaluation of the performance capabilities and handling characteristics of a finishing endodontic file manufactured from a modified tungsten alloy.

MATERIALS AND METHODS

The study was designed as a prospective observational clinical investigation with expert assessment and involved seven dentists with no less than 10 years of professional experience in dentistry. All participants held valid certification or accreditation in Therapeutic Dentistry within the Russian Federation and routinely performed endodontic procedures across seven different privately owned medical institutions in Nizhny Novgorod and the surrounding region, thereby minimizing the risk of consensus-based decision-making. The study protocol was approved by the Local Ethics Committee of the Institute of Postgraduate Medical Education "Prioritet".

Each clinician performed endodontic treatment on 15 teeth (both primary and secondary cases) in accordance with established diagnoses of pulpal and periapi-

cal diseases. The irrigation stage of the RCS was supplemented by the use of a finishing file manufactured by twisting tungsten wire. The clinical performance and handling characteristics of the single-use finishing endodontic instrument EndoKey (Nova Brush, Russian Federation; registration certificate No. RZN 2024/23430) were evaluated.

The instrument featured a working part diameter corresponding to ISO size 25 with a 0 taper. It was fabricated from a modified tungsten alloy to ensure enhanced flexibility and mechanical strength. The apical segment of the working part consisted of three microbristles approximately 5 mm in length, with a circular cross-section and a diameter of 0.1 mm. During rotation, these bristles expand and adapt to the canal walls, exerting a polishing effect on the dentinal surface.

A total of 105 instruments (15 per operator) were used across 105 clinical cases, including both primary (n = 29) and secondary endodontic treatments (n = 76), the latter associated with the removal of existing filling materials and their remnants from the canal walls. Prior to participation in the study, each clinician underwent both theoretical and hands-on training in the use of the instrument.

Prior to treatment, in each individual clinical case, the clinicians performed the necessary diagnostic procedures and established the indication for endodontic therapy. Before initiation of treatment, the teeth were cleaned of both hard and soft dental deposits. The operative field was isolated using a rubber dam, combined with preliminary pre-endodontic restoration of the hard dental tissues, which prevented the ingress of biological fluids into the tooth cavity and protected the oral mucosa from the chemical effects of irrigants.

The standard stages of endodontic treatment included necrosectomy, access cavity preparation with opening and expansion of the pulp chamber, and mechanical preparation of the RCS using Ni–Ti rotary systems selected at the clinician's discretion. All endodontic procedures were performed under magnification, utilizing dental operating microscopes and binocular loupes, with photographic documentation and data archiving.

Irrigation of the RCS was carried out using endodontic syringes with smooth plunger movement and flexible needles featuring a rounded, non-cutting tip. The irrigants included 3% sodium hypochlorite, 17% EDTA, and distilled water in sufficient volume. Ultrasonic activation of the irrigant was also employed. The final irrigant portion, visually assessed as clear and free of any suspended debris, was subsequently activated using the finishing file.

Prior to use, all finishing files were sterilized. A visual inspection of each instrument was performed before clinical application. The shank of the finishing file was connected directly to a micromotor with a contra-angle handpiece or an endomotor without the need for an additional adapter. A rubber stop was set according to the working length, reduced by 2 mm. The RCS was filled with 3% sodium hypochlorite, and the instrument was then introduced into the canal.

Instrumentation was performed using smooth reciprocating (in-and-out) motions in cycles of 3–5 seconds with sufficient amplitude, at a rotational speed ranging from 3500 to 6000 rpm, without applying pressure in the apical third of the canal. The instrument was withdrawn only after complete cessation of rotation. The canal was then thoroughly irrigated with 3% sodium hypochlorite, followed by aspiration of the irrigant together with dentinal debris and organic remnants.

A total of three to five such cycles were performed, with visual assessment of irrigation efficacy after each cycle. The primary evaluation criteria included the transparency of the irrigant and the absence of dentinal debris, organic residues, and, in retreatment cases, remnants of filling materials within the solution. After use, each instrument was visually inspected for defects, disinfected, and subsequently disposed of as Class B medical waste.

To standardize the assessment of the performance and handling characteristics of the twisted-type tungsten finishing endodontic file, a dedicated questionnaire was specifically developed and completed by all study participants upon completion of clinical procedures.

The questionnaire comprised several sections designed to provide a comprehensive evaluation of instrument use, including: baseline knowledge of instruments of this type; identification of clinical application features influencing the quality of root canal preparation; assessment of handling comfort; advantages, limitations, and disadvantages of the finishing file identified during the study, including comparison with instruments previously integrated into routine practice; evaluation of the instrument's potential; and recommendations for its further use in specific clinical scenarios.

The core set of questions required dichotomous (*yes* / *no*) responses. In addition, several items allowed for free-text descriptions of clinical experience with the instrument. Thirteen questions employed a numerical rating scale ranging from 0 to 10, where 0 represented the lowest value of the evaluated parameter and 10 the highest.

The data obtained during the study were systematized and compiled into a unified database, followed by statistical processing using Microsoft Office® 365 (Microsoft Corporation, Seattle, USA), Microsoft Excel, and the STADIA 6.0 statistical software package.

Inter-rater agreement among the group of seven experts was assessed for 13 parameters of the finishing endodontic file made from a modified tungsten alloy, evaluated using the 10-point scale. For statistical analysis, Kendall's coefficient of concordance (W) [18] was applied. The calculations were performed in Microsoft Excel. The original dataset, containing numerical scores, was transformed into a rank matrix. The concordance coefficient was then calculated using a formula that accounts for tied ranks.

$$W = \frac{12 \cdot \sum_{i=1}^{n} d_i^2}{m^2(n^3 - 1) - m \cdot \sum_{j=1}^{m} T_j}.$$

All input parameters were predefined (number of experts $m = 7$; number of evaluated factors $n = 13$). The degrees of freedom were calculated as $df = n - 1$ ($df = 12$). The statistical significance of the obtained results was assessed using the Pearson chi-square test.

For the obtained scores, descriptive statistical measures were calculated, including the arithmetic mean (*M*), standard error of the mean (*m*), standard deviation (σ), and median (Me). The distributions of the studied samples were analyzed for normality, i.e., their approximation to a Gaussian distribution.

In cases where the distributions were normal (or approximately normal), comparisons between groups were performed using Student's *t*-test (based on mean values). When the distributions deviated from normality, nonparametric statistical methods were applied (based on median comparisons): the Wilcoxon test and the Van der Waerden test were used for independent samples.

The level of statistical significance was determined for testing the null hypothesis (H_0: no difference between the compared samples).

RESULTS

In the initial section of the questionnaire, the baseline awareness of dentists regarding the type of instrument, its manufacturing material, and knowledge of possible analogues was assessed. This group of questions was structured in a dichotomous format (*yes* / *no*).

More than half of the specialists (57.2%) reported encountering information in the scientific literature on finishing endodontic instruments with functional characteristics similar to the investigated device. None of the participants had previously used the instrument under study in clinical practice. A total of 28.6% of specialists were aware of the use of tungsten-based instruments in dentistry. However, all participants reported no prior clinical experience with endodontic instruments manufactured specifically from tungsten. Prior to clinical application, it was confirmed that all specialists (100% *yes* responses) fully understood the operating principles and workflow associated with the instrument.

During evaluation of the finishing file's performance, 71.5% of specialists confirmed the presence of visually detectable turbulent mixing of the irrigant within the root canal during its use. All specialists (100%) reported a change in the color of the irrigant (turbidity) following activation with the finishing file in cases of retreatment endodontic therapy.

In routine practice, 71.5% of clinicians had experience with root canal preparation for fiberglass posts or core build-ups (cast metal or zirconia-based). In all such clinical cases (100%), clinicians observed increased turbidity of the irrigating solution. The perceived potential of the finishing file for root canal preparation prior to post placement was rated at 5.7 ± 1.1 points (Me: 6).

In the clinical practice of three specialists, four cases of formation of an intracanal "dentin plug" or a borderline condition were recorded. In these cases, the finishing file was used for its disruption. It was determined that the micro-bristle bundle separates compacted dentinal debris, which tends to aggregate, dispersing it into suspension within the irrigant volume (Fig. 1). The assessed potential of the instrument for disruption of intracanal dentinal "plugs" was 6.6 ± 2.0 points (Me: 7).

The potential of using the finishing file for irrigant activation in retreatment endodontic cases (M ± SD: 6.6 ± 1.9; Me: 7) was comparable to the corresponding parameter assessed in primary endodontic treatment (M ± SD: 6.7 ± 2.1; Me: 7).

The effectiveness of the instrument in removing various filling materials from the root canal surface was evaluated by specialists on a 1–10 scale, where 10 indicated maximal effectiveness. For calcium hydroxide, the mean score was 6.9 ± 2.3 (Me: 7); for gutta-percha, 6.3 ± 2.1 (Me: 7); for resorcinol-formaldehyde paste, 5.7 ± 2.6 (Me: 7); and for endodontic cements (phosphate cement and analogues), 2.6 ± 1.7 (Me: 2).

The degree of instrument adaptation to anatomical variations in root canal curvature (including C-shaped, S-shaped, and oval canals) was rated at 6.6 ± 2.7 (Me: 8).

The flexibility of the instrument, according to expert assessment, approached the maximum possible level, with a score of 9.1 ± 1.0 (Me: 9.5) (Fig. 2).

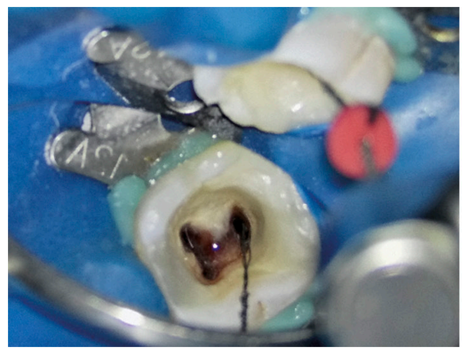
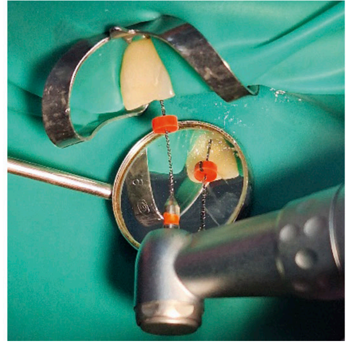
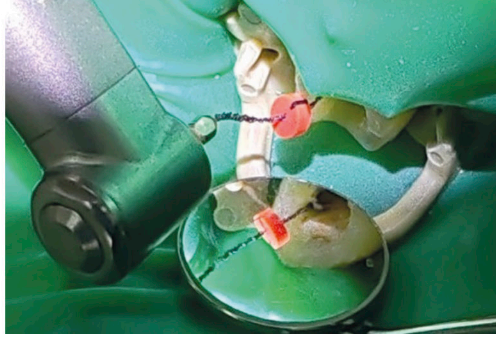


Fig. 1. A bundle of microbristles in the projection of the root canal orifice of 2.6 tooth

Рис. 1. Пучок микрощетинок в проекции устья корневого канала зуба 2.6



A



B

Fig. 2. Integration of the finishing file into the working field: *A* – 1.1 tooth; *B* – 1.6 tooth

Рис. 2. Интеграция финишного файла в рабочее поле: *A* –зуб 1.1; *B* – зуб 1.6

The degree of usability of the instrument (comfort and ease of handling), assessed on a 1–10 scale where 10 represented maximal convenience, was rated by specialists above average at 7.5 ± 2.6 points (Me: 8). Two participants reported that the working length of the instrument (25 mm) was excessive when performing endodontic treatment in posterior teeth due to limited access. However, the high flexibility of the instrument allowed this limitation to be compensated without compromising the structural integrity of the finishing file. Moreover, the curved deformation of the instrument within the operative field did not affect its functional performance inside the root canal.

According to all specialists, the use of the instrument within the endodontic treatment workflow did not require additional energy expenditure. The perceived reduction in operator fatigue during root canal procedures was rated at 6.1 ± 3.5 points (Me: 6). The potential for repeated use of the instrument after sterilization was evaluated at 4.4 ± 3.7 points (Me: 3).

Analysis of inter-expert agreement among the seven specialists across 13 parameters assessed using a 10-point scale revealed a moderate level of concordance according to conventional interpretation of Kendall's *W*. The Kendall coefficient of concordance was $W = 0.54$. This value indicates that the expert assessments can be considered objective and suitable for interpretation.

At the same time, Kendall's *W* was evaluated for statistical significance. For this purpose, the null hypothesis was formulated (H_0: Kendall's coefficient of concordance *W* is approximately equal to zero), and the test statistic was calculated as $\chi^2 fact = m \times W \times df$, where m is the number of experts, *W* is Kendall's coefficient, and df is the degrees of freedom ($n - 1$). The resulting value was $\chi^2 fact = 45.36$. This value was compared with $\chi^2 crit\ 0.001 = 32.91$. The comparison demonstrated that *W* is statistically significantly different from zero at $\alpha = 0.001$, as $\chi^2 fact = 45.36$ falls within the region of the alternative hypothesis H_1 (H_1: Kendall's coefficient of concordance *W* is statistically significantly different from zero).

Verification of statistical significance using Pearson's chi-square test ($\chi^2 fact = 45.36$, $df = 12$) confirmed the non-random nature of agreement among evaluations ($p < 0.001$). The high level of statistical significance ($p < 0.001$) supports the reliability of the obtained expert assessments as a robust component of the clinical study.

A summary table of rank sums for each evaluated parameter with corresponding identifiers is presented in Table 1.

To visualize the structure of expert opinions, an "Expert Assessment Profile" graph was constructed, enabling a clear representation of cases in which specialist opinions coincided and those in which discrepancies occurred (Fig. 3). The x-axis represents the indices of the evaluated parameters, while the y-axis shows the score values assigned by each of the seven experts (ranging from 1 to 10). The interpretation of parameter numbering is provided in the "Summary Table of Rank Sums" (Table 1).

Analysis of the graphical data demonstrates the presence of convergence zones corresponding to parameters with the highest level of agreement. For example, in the evaluation of instrument flexibility (parameter No. 10, Table 1), minimal variability between expert ratings was observed.

The intersections and divergences of the plotted lines clearly illustrate a moderate degree of concordance ($W = 0.54$) as well as variability in expert judgments regarding parameters with more debatable characteristics.

Table 1. Summary table of rank sums

Таблица 1. Сводная таблица сумм рангов

No.	Investigated parameter	Sum of ranks	Deviation from mean rank sum
1	Potential use in retreatment endodontic procedures	55.5	6.5
2	Potential use in primary endodontic procedures	58.5	9.5
3	Effectiveness during root canal preparation for post-and-core restorations	41.5	–7.5
4	Effectiveness in disintegration of dentinal plugs	56.5	7.5
5	Effectiveness in removal of gutta-percha fragment	53.5	4.5
6	Effectiveness in removal of resorcinol-formaldehyde paste remnants	48.5	0.5
7	Effectiveness in removal of cement-based materials (phosphate cement and others)	12.0	–37.9
8	Effectiveness in removal of calcium hydroxide	57.5	8.5
9	Degree of adaptation to anatomical features (curvature) of the root canal	52.0	3.0
10	Instrument flexibility level	82.3	33.3
11	Ease of use (handling comfort)	67.5	18.5
12	Reduction of operator fatigue	36.0	–13.0
13	Potential for repeated use after sterilization	16.0	–33.0
Total		**637.3**	

The moderate, statistically significant inter-expert agreement ($p < 0.001$) allowed further analysis of the instrument's effectiveness under different clinical conditions. It was determined that the performance of the finishing file was comparable in primary and retreatment endodontic procedures ($p > 0.05$).

At the same time, comparison of the instrument's effectiveness in removing different filling materials from the root canal surface revealed statistically significant differences between the removal of endodontic cements and other materials, including gutta-percha, calcium hydroxide, and resorcinol-formaldehyde paste ($p < 0.05$ in all cases).

According to expert conclusions, the instrument not only facilitates activation of sodium hypochlorite but also contributes to the removal of both temporary and permanent filling material remnants from canal walls. It was observed that in 34.2% of retreatment cases, the use of the finishing file enabled the retrieval of gutta-percha fragments that had not been previously removed by other techniques. Additionally, calcium hydroxide was observed to be dispersed into the irrigant volume despite prior ultrasonic activation alone, which was visually identified as pronounced turbidity of the solution in 27.6% of cases. The effectiveness of the finishing file in the re-suspension and evacuation of dentinal debris from the root canal system was also emphasized.

Experts further noted the potential applicability of the finishing file for the retrieval of separated endodontic instrument fragments, given its structural characteristics. However, due to the absence of such clinical cases in the present study, this assumption requires further validation under experimental simulation conditions. Clinicians expressed particular interest in investigating this aspect in ex vivo experimental settings.

During the evaluation of the instrument's capabilities, it was established that the twisted-type tungsten finishing file is capable of removing filling materials and their remnants in the area of the root canal orifices without excessive dentin removal using conventional cutting instruments. This approach enables endodontic procedures in this region to be aligned with the principle of "biological rationale" (Fig. 4).

Clinicians identified several advantages of the finishing file observed during the study, including effective removal of calcium-containing medicaments and gutta-percha from the root canal during retreatment procedures; adjunctive enhancement of ultrasonic irrigant activation within the RCS; ease of use without dependence on specific equipment platforms; compatibility with both micromotor-driven and endodontic handpiece systems; simplicity and ease of manipulation; and absence of significant operator hand fatigue during clinical use.

During clinical evaluation of the instrument, the following limitations were identified. The working length of the instrument is adequate for use in anterior teeth; however, it may be excessive in posterior regions, particularly in cases with limited mouth opening.

While 57.1% of specialists reported no difficulties during use, 42.9% noted that the fan-like expansion of the micro-bristles at the working end may complicate insertion into the root canal in anatomically challenging areas, such as maxillary molars.

At the same time, practical experience allowed formulation of clinical recommendations to mitigate this limitation. According to these guidelines, the endodontic workflow should involve positioning the tip of the instrument at the level of the canal orifice without initial contact with dentinal walls, followed by activation. Under these conditions, centrifugal forces cause spontaneous bundling of the micro-bristles, enabling atraumatic and unobstructed entry of the finishing file into the root canal space.

It was noted that in cases where the availability of dental equipment or instruments is limited (e.g., absence of ultrasonic devices, magnification systems, etc.) in the clinical setting, the use of the finishing file may represent a viable option of choice for clinicians to achieve the aforementioned procedural objectives.

No cases of instrument binding within the root canal, fracture, irreversible deformation of the working part of the finishing file, or breakage during use were recorded. In addition, no compromise of the integrity of the rubber dam was observed.

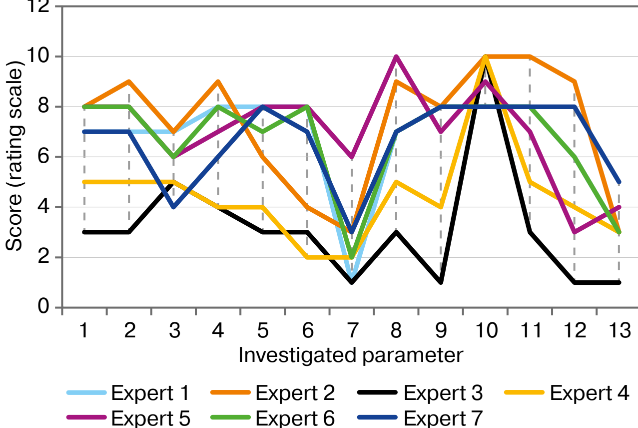


Fig. 3. Expert assessment profile

Рис. 3. Профиль экспертных оценок

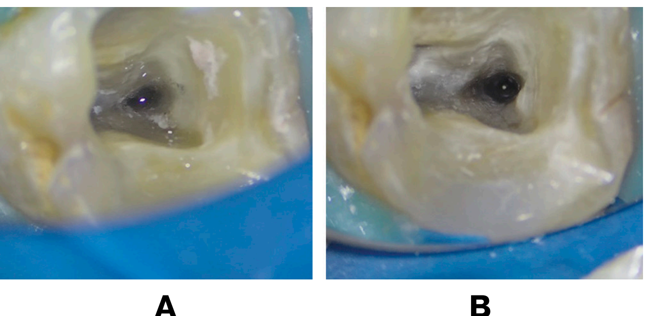


Fig. 4. The root canal orifices of 2.6 tooth (K04.5):
A – before using the finishing file;
B – after using the finishing file

Рис. 4. Устье корневого канала зуба 2.6 (K04.5):
A – до использования финишного файла;
B – после использования финишного файла

DISCUSSION

The RCS represents a highly complex anatomical structure defined by the branching pattern of the vascular bundle connecting the periodontal region with the dental pulp. The main root canal, while maintaining a central position, forms an extensive network of ramifications both in the apical region and in other segments of the canal system. Several classifications of root canal morphology have been proposed, including straight, radial, bay-like, oval, and delta-shaped configurations. These branches may present as closed canals terminating within dentin or as through canals giving rise to additional ramifications along their entire length, which may occur at any level, including the furcation area of molars.

As early as the beginning of the 20th century, Hess and Fischer described delta-like ramifications in the apical third of root canals. These anatomical structures form a network through which pulpal vessels anastomose with periodontal vasculature, bypassing the main apical foramen, and play an important role in maintaining pulpal blood supply. It is generally assumed that accessory foramina tend to undergo gradual obliteration over time; however, this process is highly individual. In cross-section, the canal may appear tubular or plate-like, whereas in longitudinal section it may be straight or curved. Curvatures may be single or double, forming the so-called bayonet-shaped canal [19].

These anatomical characteristics of the RCS justify the need for both mechanical and chemical approaches in eliminating the microbial load within its internal structure.

The goal of endodontic intervention is not limited to the elimination of freely suspended cocci, spirochetes, and their toxins within the RCS, but also includes the eradication of biofilm adherent to dentinal surfaces [19; 20]. Biofilm is defined as a structured consortium of microorganisms embedded in an extracellular matrix and adherent to the hydrated surface of the root canal wall [10]. Pathogenic bacteria are also found within the so-called smear layer. The smear layer is an amorphous and heterogeneous substrate formed during mechanical instrumentation of the canal [1]. In addition to microorganisms, it contains odontoblastic processes, dentinal debris, remnants of vital or necrotic pulp tissue, and blood components. This layer promotes bacterial survival and proliferation, which is a critical consideration during subsequent root canal obturation [20].

Removal of the smear layer is essential, as it serves both as a nutrient reservoir for microorganisms and as a protective barrier against the action of antiseptic agents [1]. Its polysaccharide matrix significantly impedes the penetration of antimicrobial substances into the biofilm structure. Therefore, its elimination requires a combined approach involving mechanical disruption of the biofilm architecture and the application of disinfecting agents capable of destroying the constituent microorganisms [10].

Despite the fact that the objective of chemomechanical root canal preparation is the achievement of disinfection across all areas of the RCS, this goal is difficult to attain in anatomically restricted spaces [21]. Consequently, a rational direction for improving the effectiveness of endodontic treatment is the management of regions that are inaccessible to conventional techniques and instruments. Accordingly, the search for and development of novel methods and devices for the effective removal of biofilms from root canals with complex morphology represents a key challenge in contemporary endodontics. This trend is reflected in the development of flexible finishing files equipped with micro-bristle bundles.

A persistent clinical limitation encountered by practitioners, which may compromise the hermetic obturation of the RCS during retreatment procedures, is the retention of filling material remnants on the intracanal dentinal surface. In undercuts, isthmuses, and slit-like spaces of the canal, residual fragments of gutta-percha, sealers, calcium hydroxide, cements, and other materials may persist [15]. Several studies have demonstrated the difficulty of completely removing calcium hydroxide from canal walls prior to obturation, which is necessary to ensure adequate adhesion of filling materials to dentinal surfaces [21–25]. It has been shown that the presence of calcium hydroxide interferes with sealer penetration into dentinal tubules, leading to potential apical microleakage. Furthermore, it may alter the physical properties of sealers and reduce the strength of their bond with gutta-percha [20; 26; 27]. Therefore, the development and implementation of additional strategies are required to improve the success rate of endodontic retreatment [28].

Irrigation is a critical determinant of endodontic treatment success [29]. The conventional technique for RCS irrigation is based on the use of an endodontic syringe; however, its isolated application does not ensure complete debridement or optimal chemical action [30]. For example, in the study by Ahn & Jorge [31], conducted in vitro, the effects of 5.25% sodium hypochlorite, 2% chlorhexidine, 17% EDTA, and 10% povidone-iodine on dentinal disinfection of the RCS were evaluated [31; 32]. Similarly, in the study by Bhasin et al., the effects of 5.25% sodium hypochlorite, 2% chlorhexidine, and N-acetylcysteine on intracanal Enterococcus faecalis and Streptococcus mutans were assessed [33]. In none of these studies did the tested solutions achieve complete sterilization, and viable bacteria were still detected within the RCS.

Conventional endodontic syringes and needles are also limited in their ability to achieve full decontamination, as in narrow root canals the irrigant may fail to reach the apical region due to surface tension effects, resulting in the formation of an "air lock". Consequently, the apical zone remains insufficiently irrigated [10]. More effective canal debridement therefore requires activation techniques that modify the hydrodynamics of the irrigant and enhance its penetration into anatomically complex and inaccessible areas of the RCS [34].

Possible approaches for delivering irrigant to the apical region of the canal in combination with fluid agitation within the canal include: enlargement of the api-

cal third of the canal lumen; use of a greater volume of irrigating solution; direct delivery of the irrigant into the apical area; prolongation of irrigant exposure time; and application of activation techniques [35].

In this context, activation is defined as a process aimed at enhancing the effect of the irrigating solution on the RCS surface to achieve improved disinfection. This is accomplished through mechanical, ultrasonic, sonic, or thermal stimulation of the solution. Such approaches improve the penetration of chemical agents into the apical third of the root canal and its accessory ramifications; facilitate the destruction of biofilms and microorganisms; and enhance the removal of organic tissue remnants that may persist after mechanical preparation, as well as residual filling material fragments located in dentinal undercuts in cases of retreatment. In addition, activation reduces the time required for complete debridement of the RCS while maintaining irrigant concentration [34; 36–38].

The mechanism of ultrasonic activation is based on the effects of cavitation and microstreaming. Cavitation refers to the formation of voids (bubbles) and the expansion, contraction, and distortion of pre-existing bubbles within the solution, which promotes effective removal of fine debris and contributes to the disruption of chemical molecules and microbial cell envelopes [33]. It results in the formation of gas- or vapor-filled cavities within the fluid [34]. Microstreaming is defined as a localized fluid microflow characterized by a stable, unidirectional circulation occurring in the immediate vicinity of a small oscillating object [33]. This phenomenon generates vortex-like flows, with the highest velocity observed near the tip of the ultrasonic file. However, while microstreaming is a biophysical force closely associated with endodontic instruments, the clinical relevance of cavitation in vivo remains controversial [3; 30; 39–41].

Practical recommendations in the literature for ultrasonic irrigation suggest that the size of the ultrasonic file should not exceed ISO sizes 15–20; instruments used should be non-cutting to prevent canal transportation (deviation from the original canal axis); the file should be inserted no more than 1.5–2 mm short of the working length; reciprocating movements within the canal should be minimized; and pre-bending of the file is recommended when working in curved canals to prevent apical perforation and ledge formation. Irrigation should be performed in three cycles of 20 seconds, with irrigant renewal of 1.5–2 mL between cycles [30].

It is noted that the highest efficiency is achieved when the ultrasonic tip is freely positioned within the canal, which is not always clinically feasible. When instrument movement is restricted by canal walls – which is difficult to control in clinical conditions – the effectiveness of ultrasonic activation is significantly reduced [31].

The operation of sonic devices and instruments used for RCS preparation is based on hydrodynamic activation of the irrigating solution, whereby sonic systems generate lower-frequency but higher-amplitude oscillations [34]. Sound waves acting on and reflecting from the root canal walls, in combination with irrigation, promote bubble formation, removal of the smear layer, opening and cleaning of accessory canals, as well as heating and thereby activation of the irrigant within the canal. The circular motion of the file contributes to rapid canal enlargement. At the same time, oscillation frequency, tip resistance, and amplitude are automatically regulated [1]. However, as sound waves propagate, they progressively attenuate, accompanied by a reduction in intensity. This attenuation is largely due to absorption of the acoustic wave and scattering by heterogeneities within the RCS environment, whose dimensions are either smaller than or comparable to the wavelength of the sound [2; 42].

Vacuum-assisted irrigation systems (based on the creation of negative pressure within the canal to simultaneously aspirate the used irrigant and deliver a fresh solution) and thermal activation (heating of the irrigating solution) may also be used in endodontic practice.

Nevertheless, mechanical activation of the irrigant remains the simplest and most accessible method in routine clinical settings. “Manual dynamic activation” and “instrument-based activation” involve the insertion and withdrawal of a gutta-percha cone or endodontic instrument with low-amplitude vertical movements, thereby inducing fluid movement within the RCS. Each of the above-mentioned methods has both advantages and limitations [40].

Improvement of endodontic treatment outcomes is closely linked to the development and use of novel instruments. The quality, strength, structural design, and flexibility of endodontic files directly determine the efficiency of root canal preparation, the prognosis of tooth restoration, and the safety of the procedure for the patient. Historically, materials used for endodontic instruments have undergone significant evolution – from stainless steel to nickel–titanium (Ni–Ti) alloys, which became widely adopted due to their elasticity and ability to adapt to root canal curvature. Nevertheless, even modern Ni–Ti instruments have certain limitations, including fatigue-related fracture, loss of elastic properties after repeated use, and the risk of sudden separation during clinical procedures [41].

The current stage of endodontic instrument development is marked by the introduction of tungsten-based alloys. Tungsten is a metal traditionally used in high-technology industries, characterized by exceptional hardness, high density, resistance to cyclic loading, as well as corrosion, thermal, and chemical stability, making it one of the most durable metals in nature [28; 43; 44]. The strength and ductility of tungsten allow the production of unique components, including ultra-thin wire resistant to deformation while maintaining structural stability, which has become the basis for modern finishing files [35]. Tungsten is virtually insoluble in sulfuric, hydrofluoric, and hydrochloric acids. Owing to its high density and biological inertness, tungsten is even used for reinforcing nickel–titanium endodontic instruments, improving their wear resistance and fatigue durability [45].

This study is dedicated to the clinical evaluation of the performance capabilities and handling characteristics of a novel type of finishing endodontic file made

from a modified tungsten alloy – EndoKey (Nova Brush, Russian Frderation). A distinctive feature of the investigated instrument is the presence of ultra-fine microbristles with a circular cross-section at the apical end of the working part. During rotation, these micro-bristles, under the influence of centrifugal force, expand and adaptively contact the root canal walls, generating vortex fluid dynamics and effectively amplifying irrigant oscillatory activity.

It is postulated that mechanical interaction with canal walls occurs without dentin cutting, while simultaneously enabling the removal of dentinal debris, smear layer, biofilm, and residual filling material fragments. The rotating working part is also proposed to induce a cavitation effect, initiating hydrodynamic activity throughout the entire RCS, including the main canal as well as lateral branches and isthmuses. Intensive mixing of irrigating solutions during high-amplitude reciprocating movements facilitates their redistribution and renewal across the entire volume of the treated space.

To verify the claimed properties of the instrument, an expert-based evaluation was performed, and the obtained results were subjected to statistical analysis. The resulting Kendall's coefficient of concordance ($W = 0.54$, $p < 0.001$) indicates a moderate but statistically significant agreement among experts in the present study. Within the framework of a prospective observational design, this finding reflects a unified tendency in the assessment of the performance and handling characteristics of the tungsten-based finishing file.

At the same time, the absence of a "high" level of agreement ($W > 0.7$) may be attributed to several factors: the complexity and variability of clinical scenarios in individual endodontic cases, which allows for differences in expert interpretation; variability in professional experience and individual clinical perspectives, leading to different emphases in parameter assessment; and the observational nature of the study design, which reflects real-world clinical conditions where evaluation criteria are inherently less standardized than in interventional trials. Despite the moderate strength of agreement, the high level of statistical significance (χ^2fact = 45.36, df = 12) supports the reliability of the expert assessments as a robust basis for statistical interpretation and formulation of study conclusions.

The effectiveness of the investigated finishing file was found to be comparable in primary and retreatment endodontic procedures ($p > 0.05$), confirming the stability of its performance across different clinical scenarios. However, the instrument demonstrated statistically significantly higher effectiveness in the removal of gutta-percha, calcium hydroxide, and resorcinol-formaldehyde paste compared with endodontic cements ($p < 0.05$), indicating a selective cleaning capability dependent on the physicomechanical properties of the filling materials.

This finding may also be explained by the higher adhesion and hardness of cement-based materials, which may necessitate additional irrigation protocols or enhanced chemical activation strategies when managing such materials, for example, prolonged application time of the finishing file during clinical use.

The combination of clinical trials with a standardized assessment of experienced clinicians' opinions provided a comprehensive approach to evaluating the capabilities and handling characteristics of the tungsten-based finishing file within the endodontic treatment workflow. This approach enabled an analysis of the instrument's advantages and limitations under real-world clinical conditions.

One of the identified advantages of the finishing files is their direct compatibility with a micromotor equipped with a contra-angle handpiece or an endodontic motor, without the need for additional adapters. This distinguishes them from several analogues that require supplementary consumables, which may, in turn, increase operational costs and complicate the clinical workflow.

It was determined that the use of a single-use finishing file made of a modified tungsten alloy aligns with current trends in modern dentistry, as the technology is aimed at improving the quality of endodontic treatment. It is clinically user-friendly, meets the requirements of economic efficiency for healthcare institutions, and supports a high standard of infection control in dental practice.

A key factor confirming the reliability of the instrument was the absence of any recorded cases of file binding within the root canal, fracture, irreversible deformation of the working part, or other mechanical failures during use.

The instrument serves as an adjunct to ultrasonic irrigation activation within the RCS, thereby enhancing the effectiveness of the irrigation procedure. In this study, the use of finishing files demonstrated the retrieval of gutta-percha and calcium hydroxide remnants from the RCS in 34.2% and 27.6% of retreatment cases, respectively – outcomes not achieved during earlier stages of canal preparation. These findings were visualized under magnification during the procedures. This supports the potential of the instrument in addressing clinical challenges associated with retreatment and endodontic revision procedures.

Special attention was given to the ease and simplicity of manipulation and the absence of operator hand fatigue during use, as well as the potential applicability of the instrument for the removal of separated endodontic instrument fragments. However, further laboratory and clinical investigations, including ex vivo studies, are required for a more comprehensive evaluation of the instrument's capabilities.

To improve handling comfort in anatomically challenging root canals, as well as in cases of microstomia and pediatric dentistry, the development and application of instruments with a shortened working length should be considered. In addition, the assessment of long-term outcomes following the use of the instrument in various clinical scenarios represents an essential step toward a complete understanding of its long-term clinical effectiveness.

Despite the prospective design of the study, which enabled the assessment of the instrument's perfor-

mance under real clinical conditions, several limitations should be acknowledged. The absence of a control group and randomization procedures is inherent to the observational study design. The outcome evaluation was performed by a panel of seven experts, which, despite demonstrated statistical significance and inter-rater agreement, still retains a degree of subjectivity for the reasons outlined above. Although the level of agreement was moderate, it is sufficient to support a collective expert judgment in conditions of clinical uncertainty.

Furthermore, the clinical nature of the study precluded the use of laboratory validation methods (such as micro-CT or SEM analysis), which could have provided more detailed quantitative data regarding the debridement efficacy of the root canal surfaces.

Overall, the present study opens new and promising perspectives for the clinical application of this type of finishing files in dentistry.

CONCLUSION

Progress in the development of endodontic instrumentation reflects the substantial advancement of dental science. Each stage of evolution – from early stainless-steel instruments to nickel–titanium alloys and advanced tungsten-based finishing files – has been aimed at improving therapeutic efficiency and clinical outcomes.

The development and implementation of innovative materials, as well as the modification of endodontic instrument design, are intended to enhance the quality of endodontic treatment. It is important to emphasize that the effective combination of high-quality mechanical instrumentation and chemical disinfection remains a key determinant of successful endodontic therapy.

The present study opens new perspectives for the clinical application of finishing files in dentistry. The obtained results may serve as a foundation for the development of methodological frameworks for both laboratory and clinical investigations in this field.

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All the authors made equal contributions to the publication preparation in terms of the idea and design of the article; data collection; critical revision of the article in terms of significant intellectual content and final approval of the version of the article for publication.

ВКЛАД АВТОРОВ

Все авторы внесли равноценный вклад в подготовку публикации в части замысла и дизайна исследования; сбора данных; критического пересмотра статьи в части значимого интеллектуального содержания и окончательного одобрения варианта статьи для опубликования.