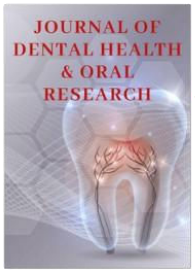

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Research Article

A Study of Adverse Events Associated with Endodontic Files Utilizing the Manufacturer and User Facility Device Experience (MAUDE) Database

Luaibi S[1], Timban SA[1], Boopalan K[1], Nalliah RP[2,3*]

[1]Research Assistant, University of Michigan School of Dentistry, 1011 N, University Avenue, Ann Arbor, MI, 48109, USA

[2]Associate Dean for Patient Services, University of Michigan School of Dentistry, 1011 N, University Avenue, Ann Arbor, MI, 48109, USA

[3]Clinical Professor, University of Michigan School of Public Health, 1415 Washington Heights, Ann Arbor, MI, USA

***Correspondence author:** Romesh P Nalliah DDS MHCM FRSPH FACD, Associate Dean for Patient Services, University of Michigan School of Dentistry 1011 N, University Avenue, Ann Arbor, MI, USA; E-mail: romeshn@umich.edu

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Abstract

Background: Endodontic treatment relies on instrumentation to effectively disinfect and seal the root canal system. Nickel-Titanium (NiTi) rotary files have improved efficiency and precision but remain susceptible to unexpected fractures, raising concerns regarding patient safety and treatment prognosis. Understanding the nature and frequency of adverse events associated with these files is essential for improving clinical practice. The objective of our study is to investigate and characterize adverse events linked to endodontic rotary files, utilizing the US Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database for the years 2023 and 2024.

Methods: A retrospective study was performed using the MAUDE database. Reports from 2023 and 2024 were identified using the keywords "endodontic file" and "breakage." Relevant reports were categorized by device- and patient-related issues, including device malfunctions, injuries, embedded files and other harms. Data extraction and categorization were conducted by two independent reviewers. Descriptive statistics were used for quantitative analysis and qualitative methods for identifying recurring risk factors. Study limitations due to underreporting and incomplete records in the MAUDE database were acknowledged.

Results: Device malfunctions were the predominant adverse event, with file breakage accounting for 313 reports in 2024, an increase from 260 in 2023. Patient complications primarily involved files becoming embedded in tissue (237 reports in 2024; 197 in 2023). Total reported incidents were 595 in 2023 and 656 in 2024, with a nearly equal distribution between device- and patient-related issues. Retrieval rates of broken files were low (29 in 2023; 22 in 2024) and device evaluation by manufacturers occurred in 264 cases, while only 91 devices were available for assessment. Incomplete or inconclusive clinical information was noted in a subset of reports.

Conclusion: File breakage remains the most common and clinically significant adverse event associated with endodontic files, with device durability and retrieval challenges affecting patient outcomes. Both device characteristics and patient-specific factors contribute substantially to the occurrence of adverse events. The study underscores the need for improved manufacturing processes, refined clinical techniques and enhanced reporting systems to minimize risks. Future research should target innovations in file design, technique and incident reporting to ensure safer and more reliable endodontic practice.

Keywords: Endodontic; Nickel-Titanium (NiTi); Endodontic Treatment

Introduction

Endodontic treatment is vital for conserving the natural teeth, as it effectively reduces infection and seals the root canal system [1]. Stainless steel hand files have been the traditional instrument used for endodontic treatment such that its manufacture is standardized under ISO regulation [2]. However, the introduction of Nickel Titanium (NiTi) rotary files in the late 1980s became an advantageous choice for many as it offered greater instrumentation efficiency, precision and durability over the former [3]. Yet it's important to note that even NiTi rotary files are still prone to unexpected fractures, which can complicate treatment and affect clinical outcomes [4,5].

The primary causes of file fractures result from torsional stress and flexural fatigue. Torsional stress occurs when the tip of the file gets trapped in the canal while its shaft continues to rotate, leading to failure. Flexural fatigue causes instrument breakage due to repeated bending in curved canals [4]. The prognosis of the treatment after instrument separation is highly determined by the location of the fractured file. While some files can be bypassed or retained without compromising the treatment outcome, fractures in the apical region require greater consideration of retrieval or bypass [5]. Fractures in the apical region that are accompanied by apical disease may weaken the structure of the tooth and reduce the prognosis if left untreated [5].

Various retrieval techniques such as the ultrasonic file removal system, have recently been developed to resolve complications in fractured file retrieval [6]. Still, they carry certain risks like perforation of the canal and weakening of the root structure [7]. There is also evidence of serious cases where fractured instruments have been accidentally ingested or inhaled, indicating the need for improving safety measures in endodontics practice [8]. Currently, there is a paucity of knowledge surrounding adverse events associated with endodontic rotary files. To address this gap, this study investigates the adverse events documented in the Manufacturer and User Facility Device Experience (MAUDE) database. The US Food and Drug Administration (FDA) maintain the MAUDE database for analyzing all medical device-related complications, including those associated with Endodontic instruments [9]. In the event of an adverse event or product issues involving medical devices, the FDA mandates that importers, device user facilities and manufacturers submit specific reports [10]. Many studies in dentistry have successfully utilized the MAUDE database to report adverse events.

In the current study, we aim to address the adverse events associated with Endodontic rotary files using the MAUDE database, analyzing the patterns of failure for better clinical implications and to improve the safety of patients in endodontic practice.

Materials and Methods

The U.S. Food and Drug Administration is responsible for maintaining the MAUDE database, which is a publicly accessible resource that collects all Medical Device Reports (MDRs) [9]. This database collects reports of adverse events with medical devices, including endodontic files, from manufacturers, healthcare providers and patients [9]. It serves as a valuable tool for its standardized reporting system that helps to identify potential safety concerns associated with endodontic files.

In this retrospective study, we used the MAUDE database to identify and analyze adverse events associated with endodontic files that have been reported within 2023 and 2024. A comprehensive search using the keywords, "endodontic file" and "breakage" showed relevant reports that cited complications ranging from device problems and patient problems causing the device to get embedded in tissue to allergic reactions, abrasions and any associated patient harms. Patient problem reports with insufficient information were also included in this study.

The extracted data was then systematically organized based on the types of files and their adverse events. It was then analyzed using Descriptive Statistics to understand the frequency and distribution of adverse events over time. Qualitative analysis was performed to find the recurring factors leading to these adverse events. To ensure the accuracy of the findings, two independent reviewers analyzed the data extraction and categorization. While the MAUDE database provides valuable information, its own limitations due to potential underreporting and incomplete entries were acknowledged. Yet, this study offers insights into the safety of endodontic files, which can help improve practices that reduce risks during root canal procedures.

Results

Fig. 1 shows the types of adverse events in 2023 and 2024. They were categorized as either Malfunction or Injury.

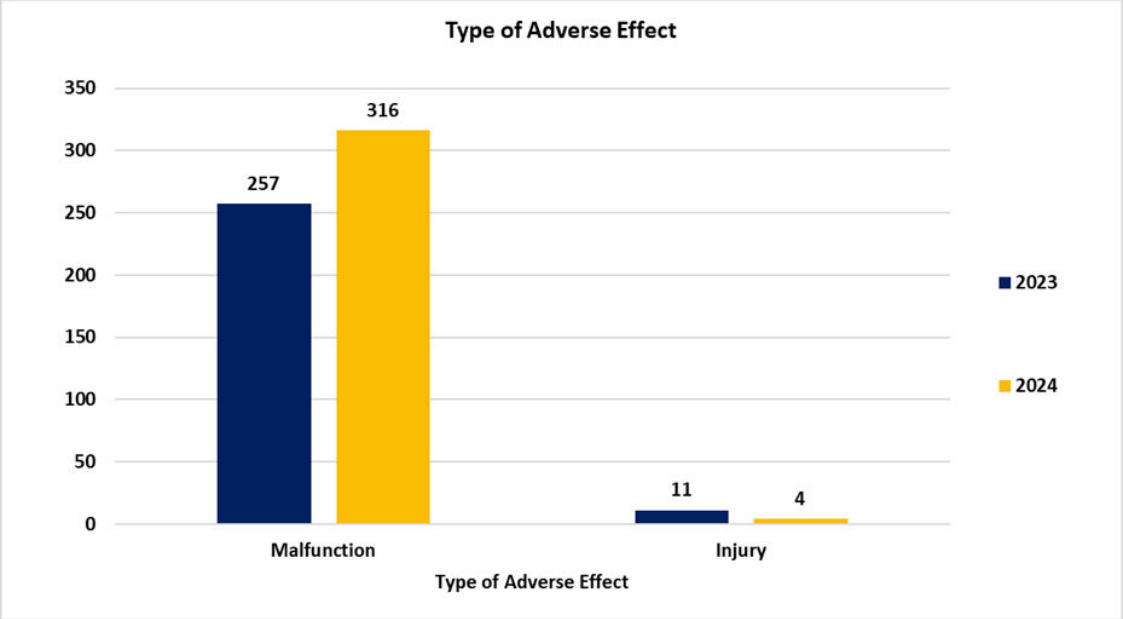

Figure 1: The types of adverse events in 2023 and 2024.

Fig. 2 provides information regarding categories of adverse events that have occurred due to problems in the device.

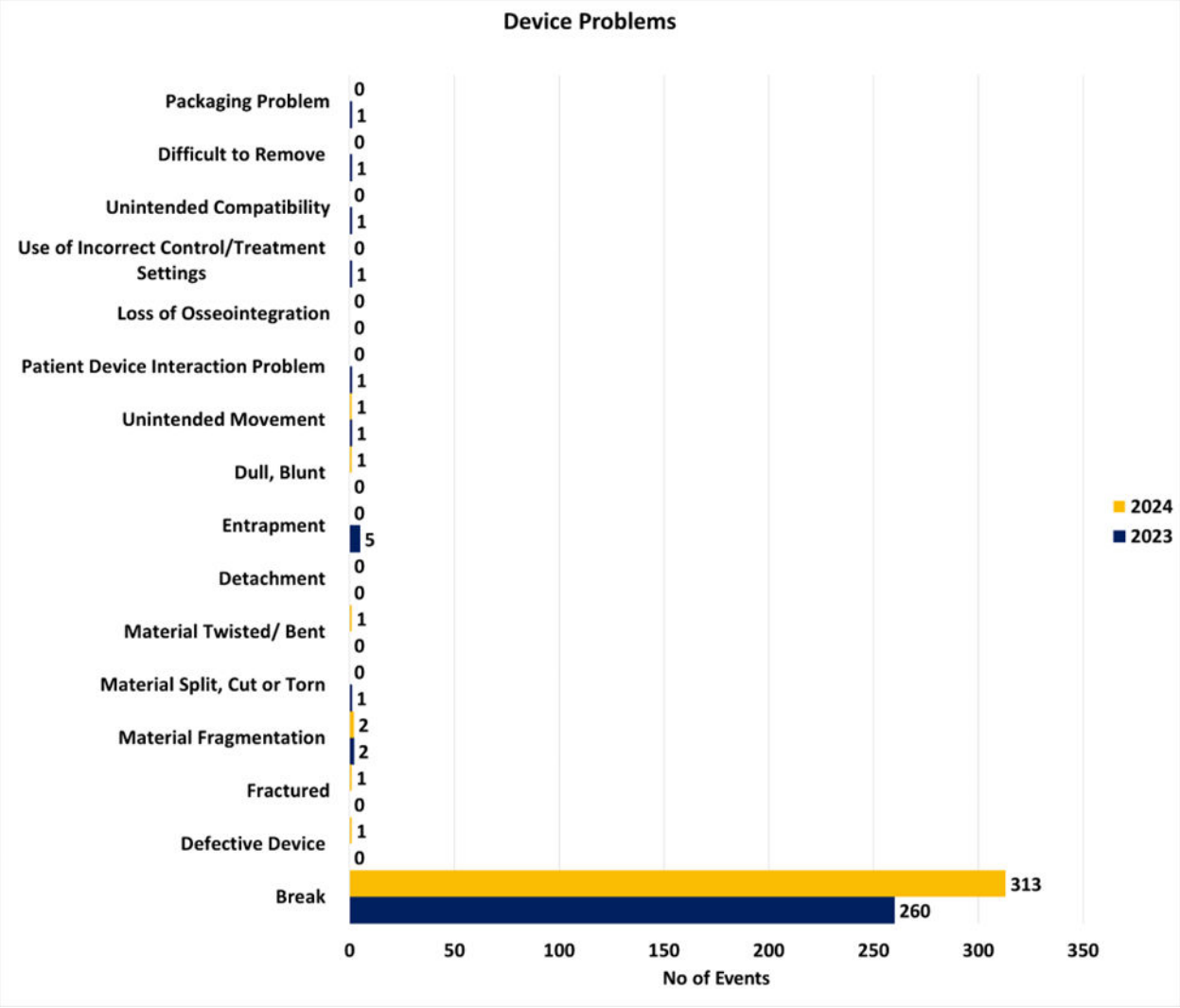

Figure 2: Categories of device-related adverse events.

Most reported issues were due to breakage of files when compared to other reasons, contributing to 313 reports in 2024 when compared to 260 reports in 2023.

Fig. 3 shows the causes of adverse events affecting patients. A total of 321 reports were received in 2023 and 336 reports in 2024.

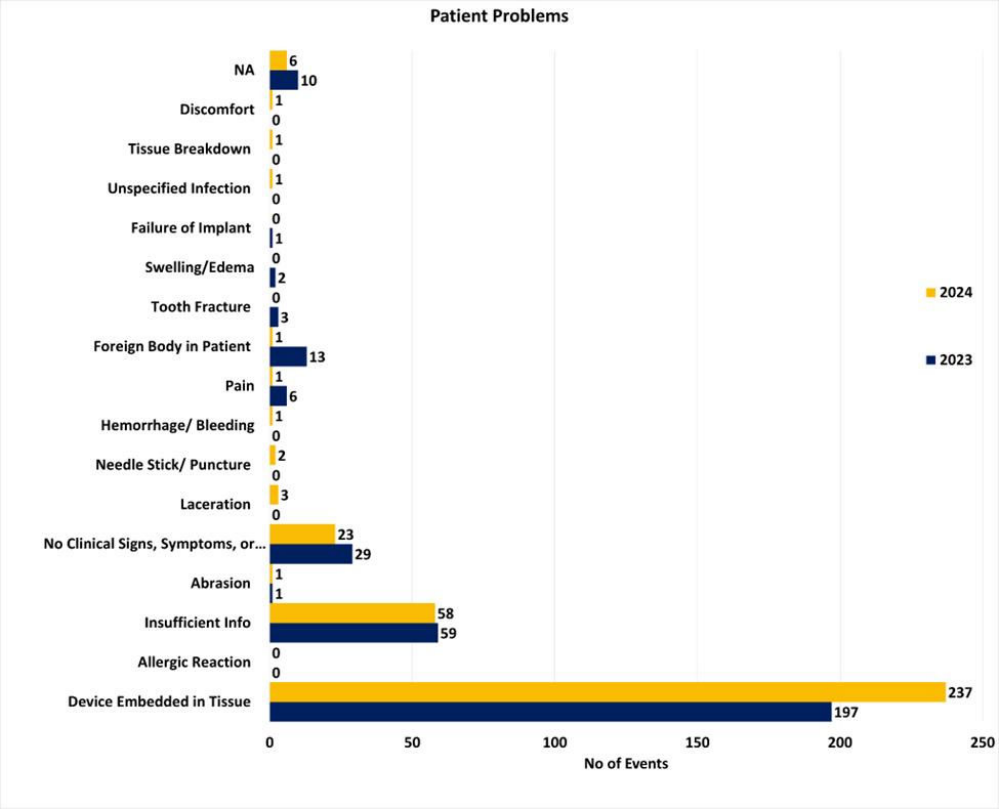

Figure 3: The causes of adverse events affecting patients.

Out of all, device getting embedded in tissue was the most reported cause of adverse events with around 237 in 2024 and 197 reports in 2023.

Fig. 4 shows the comparison between device and patient problems reported in the year 2023 and 2024.

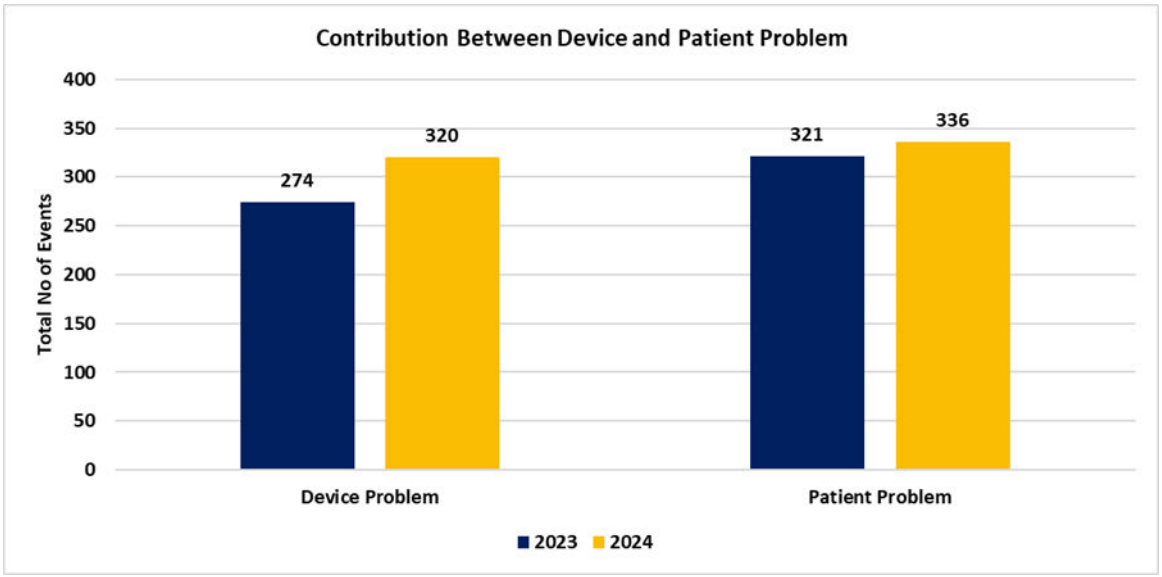

Figure 4: Ccomparison between device and patient problems reported in the year 2023 and 2024.

Fig. 5-7 provide the information related to the outcomes of the adverse events. Reports regarding whether the device was retrieved, whether the device was evaluated by the manufacturer and if the devices were available to evaluate are provided in the graphs below for the years 2023 and 2024.

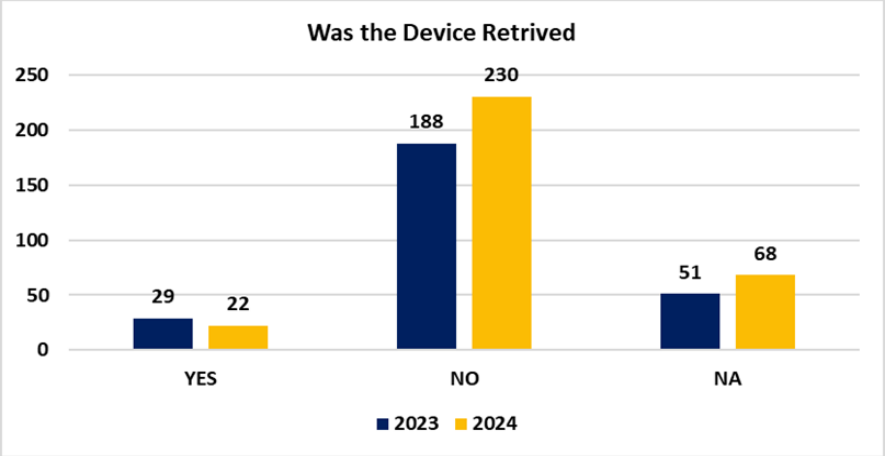

Figure 5: Reports regarding whether the device was retrieved.

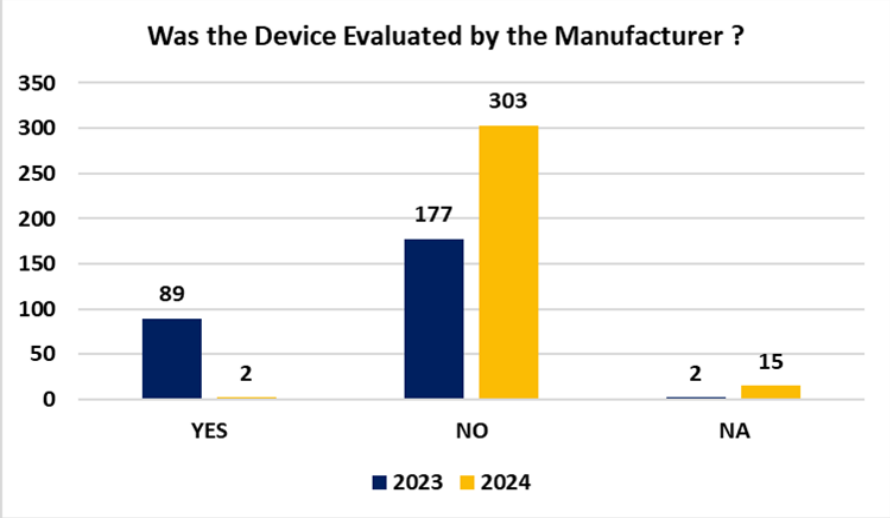

Figure 6: Reports regarding device was evaluated by the manufacturer.

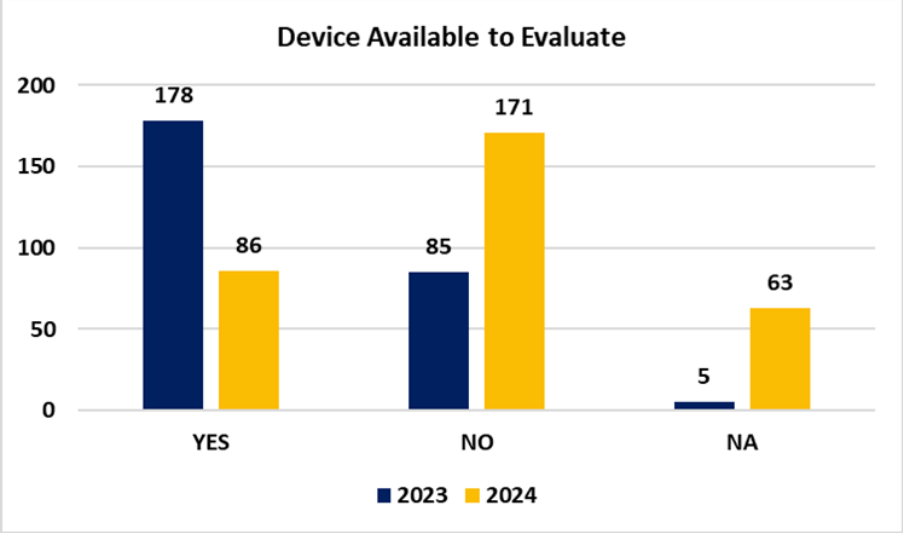

Figure 7: Reports regarding devices were available to evaluate.

Discussion

The introduction of root canal instrumentation has significantly improved the efficiency and outcomes of endodontic treatment over the years [11]. In this study, the extensive nature of the MAUDE database was utilized to investigate adverse events associated with particular endodontic files, specifically those related to product codes "EKS", "EKP" and "EKW". The data that was available from the MAUDE database for the years 2023 and 2024 were meticulously analyzed and focused on factors that contributed to these adverse events and their subsequent effects on patient care. This study revealed several important findings about complications associated with the device and different patient-specific factors that could affect the safety and effectiveness of treatment.

The most prominent observation was the highest prevalence of device malfunctions being specifically related to file breakage, with around 260 reported cases in 2023 and a notable increase to 313 in 2024. The high prevalence of file breakage is consistent with previous research that highlights a main disadvantage of files such as NiTi files being its susceptibility to fractures is consistent with previous research highlighting NiTi files' susceptibility to fractures [2]. These specialized endodontic files are subjected to harsh mechanical stresses during the meticulous process of root canal preparation, such as cyclic loading and torsional forces, which significantly increases the risk of crack initiation and fracture [12]. This issue is exacerbated by the phenomenon of "material fragmentation," in which files disintegrate into multiple fragments, complicating retrieval and increasing the likelihood of procedural complications for dental practitioners [13]. The alarming frequency of file breakage highlights the importance of research that aims to enrich our understanding of the challenges of endodontic treatment. Investigating current trends in root canal instrumentation can provide better judgement in- devising effective strategies to reduce file failures in endodontic treatment.

In contrast, reported cases of direct patient injury remain relatively low, suggesting that while malfunctions are common, significant harm is less frequently documented [5]. Nonetheless, each injury must be thoroughly examined in order to understand its consequences and develop prevention strategies.

The most frequently reported issue, based on an analysis of patient concerns, was "device embedded in tissue". This issue was directly related to the high number of incidents involving file breakage, with approximately 197 reports in 2023 and 237 reports in 2024. This finding highlights the clinical challenges associated with treating endodontic file fractures, particularly when breakage occurs in the apical third of the canal [5]. Retrieving broken files from the root canal system is particularly difficult, as evident by the low retrieval rates of only 29 reports in 2023 and 22 reports in 2024. These statistics align with existing research that examines file retrieval and the impact of instrument fractures on treatment outcomes [14].

The examination of the relative contributions from patient-related factors and device-related difficulties revealed a nearly identical distribution of complications, with a total of 595 reported incidents in 2023 and 656 in 2024. This indicates that endodontic complications are significantly influenced by both patient-specific factors and device characteristics. It emphasizes the complex relationship among clinical approaches, device design, manufacturing processes and individual patient characteristics, such as anatomy and medical history. The mechanical properties of endodontic files, such as tensile strength, flexibility and resistance to fracturing, are critical in determining the frequency of device-related incidents [2].

Moreover, patient-related complications, such as accidental file ingestion or procedural errors, further highlight the necessity for a holistic approach to endodontic care. To mitigate these risks, improvements in file design and production must be supplemented by extensive clinical training, meticulous patient evaluation and the use of standardized protocols [2,8]. A comprehensive understanding of all contributing factors is required for developing effective solutions to improve patient safety and reduce adverse events during endodontic treatment.

The significance of current research on root canal instrumentation is underscored by the high frequency of malfunctions identified in this study. Notably, the frequent occurrence of file fractures emphasizes the need for research into current trends and future directions in this field [15]. Furthermore, the total number of equipment-related faults reported is consistent with previous research, emphasizing the critical knowledge that endodontists must have about the various types of rotary files and their behavior under clinical conditions [1]. This crucial information also reinforces the importance of exploring effective file retrieval methods, particularly in light of the detrimental impact that instrument fractures can have on treatment outcomes [5,8].

Research on accidental ingestion of endodontic files also emphasizes the need to consider adverse effects and equipment failures when assessing patient-related problems. Finally, understanding the high rate of file breakage necessitates knowledge of the mechanical properties of these files, as described in previous research [11].

The results of this study have significant implications for both future research and clinical practice in the field of endodontics. The findings reveal a concerningly high frequency of file breakage, underlining the critical importance of selecting, handling and maintaining endodontic files with utmost care. Clinicians must adopt thorough precautionary measures to minimize the risk of file fracture and maintain a heightened awareness of its potential occurrence during procedures. Future research should prioritize the development of more effective retrieval methods for broken files, as well as advancements in the manufacturing and design of endodontic tools to enhance their durability and performance.

Additionally, it is essential to address the limitations of the Manufacturer and User Facility Device Experience (MAUDE) database, which suffers from issues such as incomplete, inconsistent and underreported data regarding incidents associated with file breakage. Notably, manufacturers evaluated 264 devices, demonstrating a significant level of accountability. However, only 91 of these devices were available for assessment, complicating efforts to identify the underlying reasons for device malfunctions. The limitations of the MAUDE database and the need for more thorough reporting are recognized. In 2023, a total of 59 reports lacked adequate information to clearly identify the patient's condition, a figure that slightly decreased to 58 in 2024. Furthermore, a notable number of these reports classified the situation as having "no clinical signs, symptoms or conditions," with 29 such cases recorded in 2023 and 23 in 2024. Furthermore, a significant number of these reports categorized the situation as having "no clinical signs, symptoms or conditions," with 29 cases recorded in 2023 and 23 in 2024. This pattern suggests that certain device malfunctions may not result in immediate or severe harm to patients and therefore reporters may feel less inclined to report the issue.

Future research efforts should prioritize improving device design and manufacturing processes through rigorous testing and innovation. Furthermore, improvements in clinical techniques and reporting practices are critical to achieving a thorough understanding of adverse events. Beyond technical considerations, it is also crucial to acknowledge the psychological impact of these adverse events on patients. The emotional distress caused by incidents such as file ingestion or retention can be impactful, so future research should investigate the psychosocial implications for patients undergoing endodontic treatment. By addressing these various aspects, the goal of fostering a safer and more effective environment for both practitioners and patients in the realm of endodontics can make significant improvements.

Conclusion

This study provides a comprehensive analysis of adverse events associated with endodontic files, highlighting the critical factors contributing to device malfunctions and patient complications. The findings confirm that file breakage remains the most prevalent issue, with implications for treatment efficacy and patient safety. While direct patient injuries were reported less frequently, the high incidence of device fragments embedding in tissue underscores the clinical challenges associated with file retrieval and the potential long-term consequences.

The results emphasize the need for improvements in both the design and manufacturing of endodontic files to enhance their durability and resistance to fracture. Additionally, the nearly equal distribution of patient- and device-related complications suggests that clinician technique, patient-specific factors and procedural protocols all play significant roles in mitigating adverse events. Strengthening clinical training, refining retrieval methods and standardizing safety protocols could collectively reduce the occurrence of these complications.

Given the limitations of the MAUDE database, including potential underreporting and incomplete records, future research should focus on more comprehensive data collection and reporting systems. Enhanced surveillance, coupled with continued advancements in material science and clinical techniques, will be essential in improving the safety and reliability of endodontic treatment. Ultimately, this study underscores the importance of a multifaceted approach to minimizing risks and optimizing patient outcomes in endodontic practice.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Acknowledgement
None.

Data Availability Statement
Not applicable.

Ethical Statement
The project did not meet the definition of human subject research under the purview of the IRB according to federal regulations and therefore, was exempt.

Informed Consent Statement
Informed consent was taken for this study.

Authors' Contributions
All authors contributed equally to this paper.

References

1. Çapar ID, Arslan H. A review of instrumentation kinematics of engine-driven nickel-titanium instruments. Int Endod J. 2016;49(2):119-35.
2. Dablanca-Blanco AB, Castelo-Baz P, Miguéns-Vila R, Álvarez-Novoa P, Martín-Biedma B. Endodontic rotary files: what should an endodontist know? Medicina (Kaunas). 2022;58(6):719.
3. Tabassum S, Zafar K, Umer F. Nickel-titanium rotary file systems: what's new? Eur Endod J. 2019;4(3):111-7.
4. Sattapan B, Nervo GJ, Palamara JE, Messer HH. Defects in rotary nickel-titanium files after clinical use. J Endod. 2000;26(3):161-5.
5. McGuigan MB, Louca C, Duncan HF. The impact of fractured endodontic instruments on treatment outcome. Br Dent J. 2013;214(6):285-9.
6. I-Taheri A, Ehsani S, Khademi A, Samiei M. Effects of ultrasonic removal of fractured files from the middle third of root canals on the vertical root fracture resistance. J Endod. 2019;45(11):1365-70.
7. Madarati AA, Qualtrough AJ, Watts DC. Vertical fracture resistance of roots after ultrasonic removal of fractured instruments. Int Endod J. 2010;43(5):424-9.
8. Kuo SC, Chen YL. Accidental swallowing of an endodontic file. Int Endod J. 2008;41(7):617-22.
9. MAUDE – Manufacturer and User Facility Device Experience. U.S. Food and Drug Administration [Internet]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/
10. U.S. Food and Drug Administration. Medical Device Reporting (MDR): how to report medical device problems [Internet]. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems
11. Srivastava S. Root canal instrumentation: current trends and future perspectives. Cureus. 2024;16(4):e58045.
12. McGuigan MB, Louca C, Duncan HF. Clinical decision-making after endodontic instrument fracture. Br Dent J. 2013;214(8):395-400.
13. Orozco-Ocampo YM, Escobar-Rincón D, Jiménez-García FN, Álvarez-Vargas CA, Jaramillo-Gil PX. Factors influencing NiTi endodontic file separation: a thematic review. Dent Med Probl. 2024;61(2):269-78.
14. Portigliatti R, Consoli Lizzi EP, Rodríguez PA. Predictive factors in the retrieval of endodontic instruments: the relationship between the fragment length and location. Restor Dent Endod. 2024;49(4):e35.
15. Haapasalo M, Shen Y. Evolution of nickel-titanium instruments: from past to future. Endod Topics. 2013;29(1):3-17.