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ORIGINAL RESEARCH

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Clinical comparison of the obturation quality of primary posterior maxillary teeth treated with pulpectomy using single rotary file, sequential rotary file, and manual file system: an observational study

Nandini D Madiajagane[1], Ganesh Jeevanandan[1,*], Marco Di Blasio[2,*], Diana Russo[3], Marco Cicciù[4], Maria Maddalena Marrapodi[5], Giuseppe Minervini[6,7]

[1]Department of Pedodontics and Preventive Dentistry, Saveetha Dental College and Hospitals, Saveetha Institute of Medical and Technical Sciences, Saveetha University, 600077 Chennai, India
[2]Department of Biomedical, Surgical and Dental Sciences, University of Milan, 20122 Milan, Italy
[3]Multidisciplinary Department of Medical-Surgical and Odontostomatological Specialties, Oral Surgery Unit, University of Campania "Luigi Vanvitelli", 80138 Naples, Italy
[4]Department of General Surgery and Surgical-Medical Specialties, School of Dentistry, University of Catania, 95124 Catania, Italy
[5]Department of Woman, Child and General and Specialist Surgery, University of Campania "Luigi Vanvitelli", 80138 Naples, Italy
[6]Department of Biochemistry, Saveetha Dental College and Hospitals, Saveetha Institute of Medical and Technical Sciences (SIMATS), Saveetha University, 600077 Chennai, India
[7]Multidisciplinary Department of Medical-Surgical and Odontostomatological Specialties, University of Campania "Luigi Vanvitelli", 80138 Naples, Italy

***Correspondence**
ganesh.sdc@saveetha.com (Ganesh Jeevanandan);
marco.diblasio@unimi.it (Marco Di Blasio)

Abstract

Background: Pulpal involvement resulting from dental caries is a frequent occurrence and poses a formidable challenge for pediatric dentists. The success of endodontic treatment relies heavily on the quality of obturation. Previously, evaluation was based on the Coll and Sadrian criteria. However, with the introduction of the Kids Endodontic Obturation Quality (KEDOO) classification, a more detailed assessment is now possible. This classification considers various parameters including arch, segment and canal-specific factors, thus addressing previous limitations. The aim of this paper is to evaluate and compare the quality of obturation achieved by the Kedo S Plus, Pro AF Baby Gold and K-file systems in primary maxillary molars using the KEDOO classification system. **Methods**: In this observational study, thirty intraoral periapical (IOPA) radiographs were obtained for each group of primary maxillary molars treated with pulpectomy: Group A (Kedo S Plus), Group B (Pro AF Baby) and Group C (K-file), resulting in a total of ninety radiographs. The exclusive assessment of obturation quality was conducted utilizing the KEDOO classification system. **Results**: Statistical analysis was performed employing Kruskal Wallis and Analysis of Variance (ANOVA) tests. Kedo S Plus file system showed more number of optimal obturations (73.3%) in comparison with other groups. There was significant difference between the groups on comparison of quality of obturation. **Conclusions**: KEDOO classification system assesses outcomes based on the presence and location of voids as well as the extent of material fill. Kedo S Plus, Pro AF Baby file, and Hand K File systems each achieved varying levels of obturation quality. The single rotary file system (Kedo S Plus) is a promising alternative to sequential and manual instrumentation in achieving optimal obturation in primary maxillary molars. **Clinical Trial Registration**: The study was registered under the Clinical Trials Registry of India (CTRI) with the registration number CTRI/2024/06/069200.

Keywords

Deciduous teeth; Rotary hand file; Pediatric endodontics; Pulpectomy

1. Introduction

Despite significant advancements in dental care, dental caries remains widespread, impacting a substantial portion of the pediatric population globally [1]. Early childhood caries (ECC), defined by the American Academy of Pediatric Dentistry as the presence of multiple decayed teeth in children under 6 years old, presents significant clinical challenges, ranging from compromised mastication to pain and abscesses, often necessitating consideration for extraction rather than retention [1, 2]. Contemporary pediatric dentistry emphasizes the importance of preserving deciduous teeth through pulpectomy procedures, aimed at alleviating issues associated with premature loss and facilitating behavior management through rotary instrumentation [3]. The preservation of dental pulp vitality emerges as a critical aspect of pediatric endodontic therapy, devoted to upholding tooth integrity and supporting structures [4]. Pulpectomy entails meticulous removal of pulpal tissue and dentin, addressing both biomechanical and chemomechanical aspects [5]. Subsequently, root canals of primary teeth are packed with resorbable material to prevent reinfection and microleakage [6].

Success in root canal treatment relies on precise techniques, including thorough sealing and three-dimensional filling

to prevent bacterial penetration into periapical tissues [7]. However, pediatric endodontics, particularly in deciduous teeth, presents challenges such as root curvature and intricate anatomy, as well as the risk of affecting permanent successors [8].

In terms of root count, research suggests that primary upper molars may exhibit two to four roots. It is common for upper first molars to present two roots due to the fusion of the distobuccal and palatal roots, while upper second molars often showcase three roots [9, 10]. The complexity of root canals requires adjustments in protocols and advancements in rotary instruments, yet careful technique and instrument choice are crucial to avoid overextension and debris extrusion, which are associated with increased postoperative discomfort [11]. The choice of metal alloy, particularly nickel-titanium (Ni-Ti) and its heat treatment, plays a crucial role in optimizing performance. Recent research by Seracchiani *et al.* [12] emphasizes that Ni-Ti files with equiatomic composition enhance their mechanical properties, such as flexibility and cyclic fatigue resistance, making them well-suited for the challenges of pediatric endodontics due to their martensitic behaviour. Achieving successful root canal treatment in deciduous teeth necessitates meticulous biomechanical preparation and careful selection of obturating materials, ultimately resulting in a tight seal with minimal voids [13].

While traditional hand instruments like reamers, files and ultrasonic tools have been conventionally used for pulpectomy, they tend to be time-consuming and can result in procedural errors such as ledge formation and canal transportation [14]. Consequently, rotary Ni-Ti instruments have gained popularity, particularly in pediatric dentistry, where minimizing chair time is crucial for managing young patients [15]. With attention to children's limited attention spans, innovative instrumentation is sought to streamline procedures in pediatric dentistry. The adoption of rotary instrumentation over conventional hand techniques has been a gradual shift in pediatric endodontic procedures over recent years [16]. However, the use of rotary instruments demands technical skill and experience to prevent complications such as instrument separation during canal preparation. Rotary Ni-Ti systems, prevalent in adult endodontics, offer controlled memory that adapts to canal curvatures with minimal transportation [17]. Over the past two decades, numerous rotary file systems have been introduced for pediatric dentistry, functioning through reciprocating or rotary motions. Research has shown that rotary file systems can be effective for primary teeth when they are correctly sized and used with minimal procedural complications. The success of any treatment depends on multiple factors, including the appropriate selection of instrumentation, the quality of the obturation material, and the precision of the procedural technique. Quality of obturation plays a crucial role in ensuring the long-term success of the treatment. The efficacy of obturation predominantly relies on its quality, which is evaluated through diverse methods such as radiographs, dye penetration, radioisotopes, and clearing techniques subsequent to tooth sectioning [18]. In pediatric endodontics, several classification systems have been developed to assess the quality of obturation, each with its own criteria and applicability to different clinical situations. The Coll and Sadrian classification, for example, evaluates obturation quality based on the extent of filling relative to the root apex. However, these systems often focus on general endodontic principles and may not account for the specific anatomical and procedural challenges posed by primary teeth, particularly in molars. Recognizing this gap, the KEDOO classification was developed, offering a more detailed, canal-specific assessment. This system is tailored to pediatric cases, particularly for the posterior maxillary and mandibular teeth, with distinctions between individual canals such as mesial, distal and palatal. The KEDOO classification also incorporates the presence of voids, enhancing its utility in evaluating obturation quality in primary teeth. The conventional approach of assessing obturation quality through radiographs, as per the Coll and Sadrian criteria, lacked precision and void assessment criteria, shortcomings rectified by the innovative KEDOO classification employed in this investigation [18]. Against this context, our study endeavors to primarily evaluate obturation quality in primary maxillary second molars. The aim of this study is to assess and compare the quality of obturation in primary maxillary molars achieved with the Kedo S Plus, Pro AF Baby Gold and K-file systems, using the KEDOO classification system. The null hypothesis for this study is that there is no significant difference in the quality of obturation among the primary maxillary molars treated with pulpectomy using the Kedo S Plus single-file rotary system, the Pro AF Baby sequential rotary system, and the manual K-file system, as evaluated by the KEDOO classification system.

2. Materials and methods

An observational study, conducted at the Department of Pediatric and Preventive Dentistry in a dental institute, employed a single-blinded approach. The study was registered under the Clinical Trials Registry of India (CTRI) with the registration number CTRI/2024/06/069200. Ethical clearance for the trial was obtained from the Scientific Review Board of Saveetha Dental College and Hospitals, Chennai, India (IHEC/SDC/PEDO-2102/23/048). The study was performed between 27 April 2023 and 20 June 2024.

Before commencing the trial, parental or guardian consent was secured from recruited participants, aligning with STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for observational studies.

2.1 Inclusion criteria

A total sample of ninety post-operative radiographs of children aged 4–7 years, for whom pulpectomy was performed in the primary maxillary second molars, were included in the study. Only those with complete pre-operative and post-operative radiographs of the treated teeth were included.

2.2 Exclusion criteria

Exclusion criteria comprised teeth that had congenital anomalies affecting radiographic evaluation of obturation quality, and cases where pre-operative or post-operative radiographic records were incomplete or inadequate. Radiographs of teeth with mesiobuccal or distobuccal canal obturations were ex-

cluded. Teeth with extensive structural damage that would impair the assessment of obturation quality were also grounds for exclusion.

Quality of obturation was assessed according to the KEDOO classification. The instrumentation used to biomechanically prepare the canals before obturation were as follows: Group A: Kedo-S Plus (n = 30), Group B: Pro AF Baby (n = 30), and Group C: Hand K-files (n = 30).

All the pulpectomies were performed by two skilled pediatric dental postgraduate students of Saveetha Dental College and Hospital. Canal preparation was done using the following instrumentation:

Group A: Root canals were instrumented using the Kedo-S Plus file system (KEDO DENTAL, India) per manufacturer instructions. The mesial, distal and palatal canals were instrumented using the P1 file (blue color-coded) in a lateral brushing motion with an X-Smart endodontic motor (Dentsply India Pvt. Ltd., Delhi, India) until reaching the working length.

Group B: Root canals were instrumented using the Pro AF Baby Gold system (Kids-e Dental, India) following manufacturer guidelines. B1 (#20/0.04) file (yellow coded) and B2 (#25/0.04) file (red coded) were used in mesial and distal canals, while the palatal canals were finished with B4 (#30/0.04) file (blue coded) with an X-Smart endodontic motor (Dentsply India Pvt. Ltd., Delhi, India) until reaching the full working length.

Group C: Instrumentation was performed using K-files (size 15 to size 30, Mani, Inc., Japan) employing the quarter pull-turn method.

Canal Filling Material and Technique: The canal filling material used in this study was Metapex (Metapex, Meta Biomed Co., Ltd., Korea), a calcium hydroxide-based paste. The material was introduced into the canals using pressure syringe technique and the canals were filled to the working length using a gentle condensation with moist cotton pellets.

2.3 Assessment of obturation quality

The KEDOO classification system was employed to evaluate obturation quality (Fig. 1) [10].

The Kids Endodontic Obturation Quality (KEDOO) classification was utilized in this study to evaluate the quality of obturation in the primary maxillary molars. This classification system is arch, segment and canal-specific, ensuring a comprehensive evaluation of the obturation quality in different sections of the tooth. For mandibular molars, the canals were divided into mesial and distal only, while in maxillary molars, the canals were divided into mesial, distal and palatal for more detailed assessment. An additional criterion included in the KEDOO classification was the presence of voids in the canals, further enhancing the thoroughness of the evaluation process. This approach provided a standardized method to assess obturation quality across various canal types, making it easier to compare different obturation techniques. The inclusion of void assessment ensured that the evaluation was not just limited to the extent of the obturating material but also its consistency and quality within the canal space. Size 1 photo-stimulated phosphor plate (PSP) (Digora Optime, Soredex, Helsinki, Finland, version 2.1) radiography was utilized for assessing the obturation quality.

Two blinded pediatric dentists conducted the assessment, achieving a moderate level of agreement (Cronbach's alpha value of 0.72).

2.4 Statistical analysis

The statistical analysis was conducted using SPSS Statistics Software version 23.0 (SPSS Inc., Chicago, IL, USA). Cohen's kappa coefficient was employed to assess the reliability of evaluating obturation quality between two examiners. The Kruskal-Wallis test was utilized to assess the quality of obturation among the groups and to perform pairwise comparisons.

3. Results

The mean total age of the children enrolled in the trial was 5.62 ± 1.24. Among them, 53.3% were boys and 46.7% were girls. No statistical significant difference ($p = 0.089$) was observed between the genders, indicating no variation in the population distribution (Table 1). Cohen's kappa coefficient was utilized to assess the reliability in evaluating the quality of obturation between the two examiners. A moderate level of reliability was found between the examiners, $\kappa = 0.72$ (95% Confidence Interval (CI)), $p = 0.05$ (Table 2). The assessment of intra-examiner reliability was performed by having each examiner re-evaluate a subset of radiographs after a two-week interval. Cohen's kappa coefficient was used to measure the consistency between the initial and repeated evaluations by the same examiner. The intra-examiner reliability demonstrated a high level of agreement, with Cohen's kappa coefficient values reflecting strong consistency in the assessment of obturation quality, $p = 0.01$ (Table 2).

The Bonferroni test conducted to evaluate the quality of obturation rejected the null hypothesis, demonstrating differences in obturation quality among the three different files used in the study. Obturations performed with Kedo S-plus P1 files exhibited a higher number of optimal obturations (Class 3.1) at 73.3%. No under obturations were observed in any of the canals when Kedo S Plus P1 files were utilized (Table 3). Upon pairwise comparison using Bonferroni test, statistical significance was observed between Kedo S Plus P1 file-Pro AF Baby file and Kedo S Plus P1 file-K file ($p < 0.05$) (Table 4).

4. Discussion

Pulpectomy is designed not only to relieve discomfort but also to uphold the integrity and functionality of the affected teeth [19]. No difference was seen between the clinical and radiographic success rates between single and multi-visit pulpectomy in primary teeth with apical periodontitis following a 6-month observation period [20]. Moreover, the single-visit pulpectomy technique not only saves time and reduces treatment expenses but also alleviates child anxiety by eliminating the necessity for a second visit involving additional anesthetic injections and rubber dam placement [20]. Consequently, the single-visit pulpectomy approach was favored in this investigation. All pulpectomy procedures were executed by two operators with good agreement of reliability, thus eliminating

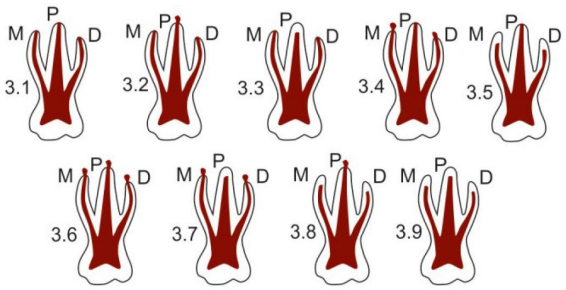
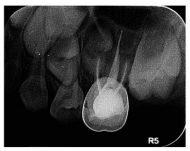
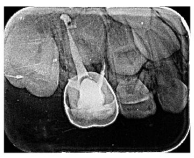
<table>
<tr><th colspan="3">KEDOO Class 3 Assessment of Primary Maxillary Teeth</th><th colspan="3">KEDOO Class 4 Presence of Voids in any canal</th></tr>
<tr><td colspan="3"> 
</td><td colspan="3">  </td></tr>
<tr><td colspan="6">Immediate post-operative radiograph of different quality of obturation (according to KEDOO Classification)</td></tr>
<tr><td>3.1</td><td>Mesial and distal - optimal
Palatal - optimal</td><td>  </td><td>3.6</td><td>Mesial and distal - over
Palatal - over</td><td>  </td></tr>
<tr><td>3.2</td><td>Mesial and distal - optimal
Palatal - over</td><td>  </td><td>3.7</td><td>Mesial and distal - over
Palatal - under</td><td>  </td></tr>
<tr><td>3.3</td><td>Mesial and distal - optimal
Palatal - under</td><td>  </td><td>3.8</td><td>Mesial and distal - under
Palatal - over</td><td>  </td></tr>
<tr><td>3.4</td><td>Mesial and distal - over
Palatal - optimal</td><td>  </td><td>3.9</td><td>Mesial and distal - under
Palatal - under</td><td>  </td></tr>
<tr><td>3.5</td><td>Mesial and distal - under
Palatal - optimal</td><td>  </td><td colspan="3"></td></tr>
</table>

FIGURE 1. Assessment of quality of obturation using KEDOO classification. KEDOO: Kids Endodontic Obturation Quality.

TABLE 1. Descriptive statistics.

Groups	N (Sample size)	Mean ± Standard Deviation of age (variance)	Male (48)	Female (42)
Group A	30	5.60 ± 1.21 (1.46)	46.7% (14)	53.3% (16)
Group B	30	5.60 ± 1.83 (3.35)	60% (18)	40% (12)
Group C	30	5.67 ± 1.49 (2.22)	53.3% (16)	46.7% (14)
Total	90	5.62 ± 1.24 (1.54)	53.3% (48)	46.7% (42)
		p value = 1.031	*p* value = 0.089	

Note: Group A—Kedo S Plus, Group B—Pro AF Baby file, Group C—Hand K File.

TABLE 2. Inter-examiner reliability using Cohen's kappa statistics.

Reliability type	Method/statistic		κ value	*p* value
Inter-rater reliability	Cohen's Kappa coefficient		0.72	0.05
Intra-rater reliability	Cohen's Kappa coefficient	Examiner 1	0.80	0.01
		Examiner 2	0.75	

TABLE 3. Comparison of quality of obturation among the different groups described in percentage.

Assessment of quality of obturation	Group A		Group B		Group C		Overall *p* value
	n (%)	Variance	n (%)	Variance	n (%)	Variance	
Class 3.1 mesial, distal-optimal; palatal-optimal	22 (73.3%)	0.0055	6 (20.0%)	0.0267	12 (40.0%)	0.0200	0.0005*
Class 3.2 mesial, distal-optimal; palatal-over	8 (26.7%)	0.0234	10 (33.3%)	0.0222	0	0	
Class 3.3 mesial, distal-optimal; palatal-under	0	0	0	0	6 (20.0%)	0.0267	
Class 3.4 mesial, distal-over; palatal-optimal	0	0	0	0	0	0	
Class 3.5 mesial, distal-under; palatal-optimal	0	0	0	0	6 (20.0%)	0.0267	
Class 3.6 mesial, distal-over; palatal-over	0	0	4 (13.3%)	0.0245	0	0	
Class 3.7 mesial, distal-over; palatal-under	0	0	0	0	0	0	
Class 3.8 mesial, distal-under; palatal-over	0	0	10 (33.3%)	0.0222	2 (6.7%)	0.0315	
Class 3.9 mesial, distal-under; palatal-under	0	0	0	0	4 (13.3%)	0.0245	

**Group A—Kedo S Plus, Group B—Pro AF Baby file, Group C—Hand K File, $p < 0.05$: statistical significance.*

TABLE 4. Pairwise comparison for quality of obturation using Bonferroni test.

Groups	Groups	Mean Difference	*p* value (Bonferroni)
A	C	2.400	0.0010*
A	B	2.933	0.0007*
C	B	0.533	0.9990

**Group A—Kedo S Plus, Group B—Pro AF Baby file, Group C—Hand K File, $p < 0.05$: statistical significance.*

operational bias within the research.

The quality of obturation relies on several factors including the root canal filling material, root canal anatomy, and the ease of accessing the canals in different types of primary molars [21]. Significant variations exist in the number of roots and root canal anatomy in primary molars, necessitating consideration during pulpectomy procedures [22]. Maxillary primary molars were selected for this study due to their complex root canal anatomy, which typically includes more canals and greater curvatures compared to mandibular molars. There is a lack of extensive research specifically assessing obturation quality in maxillary primary molars, highlighting the study's value in addressing a literature gap and improving clinical decision-making in pediatric endodontics.

To minimize variability and enhance the specificity of the study, focusing on a single type of primary molar—the second was considered. The first and second primary molars differ in terms of their root canal anatomy, with variations in root numbers, canal configurations and overall complexity. For instance, the first primary molar often has fewer canals compared to the second primary molar, which may influence the instrumentation and obturation quality. By limiting the study to the second primary molar, the research could more precisely control for these anatomical differences, thereby providing more consistent and reliable results. The presence of a second mesiobuccal canal in primary maxillary molars varies significantly. A study has reported rates ranging from 75% to 95% in these molars [23]. Additionally, three mesiobuccal canals have been documented [24]. Conversely, Aminabadi *et al.* [25] (2008) found no second mesiobuccal canals in 76 maxillary primary molars, while Zoremchhingi *et al.* [26] (2005) identified a second mesiobuccal canal in only 6.67% and 53.3% of first and second primary maxillary molars, respectively [25, 27]. In a previous study, anatomical variations

were identified between first and second upper primary molars, reporting two second mesiobuccal canals in the first molars and none in the second molars [28]. The distobuccal root in upper molars typically has a single radicular canal, but the presence of a second distobuccal canal has been reported in up to 27.8% of cases [25]. Similarly, the palatal root typically contains a single radicular canal, although the occurrence of a second palatal canal in second upper primary molars may be rare [27]. Only one of the molars in the present study, exhibited second mesiobuccal canal.

In this study, we utilized Photostimulable Phosphor (PSP) imaging primarily to minimize radiation exposure, a crucial factor in pediatric dentistry, rather than focusing solely on enhancing contrast and resolution, crucial for accurately evaluating obturation quality and detecting small voids than conventional two dimensional imaging techniques [29, 30]. PSP systems require significantly less radiation than conventional film and metallic sensors, making them especially beneficial for children. Consistent with the findings of Vijayan *et al.* [31], we observed that despite the reduced radiation dose, the images obtained with PSP displayed good density and contrast. Therefore, the wider dynamic range of PSP is instrumental in achieving lower radiation exposure while still providing diagnostic-quality images.

The standard method proposed by Coll and Sadrian in 1996 remains the benchmark for assessing obturation quality in primary teeth [32–34]. According to this criterion, underfilling is identified when all canals are filled more than 2 mm short of the apex, while optimal obturation is achieved when one or more canals display obturating material extending to the radiographic apex or within 2 mm of it. Over obturation is indicated if any canal exhibits obturated material extending beyond the radiographic apex. Notably, there was no provision to evaluate void presence in this standard and canal specific evaluation was not possible. In our investigation, no voids were identified in teeth treated with any of the file systems. However, if voids were detected within the obturation material, regardless of the arch or segment, the tooth was categorized under Class 4 of the KEDOO classification, signifying the presence of voids.

Our study introduces the Kids Endodontic Obturation Quality (KEDOO) classification to assess obturation quality and void presence in primary maxillary posterior teeth. Presence of optimal obturations were seen more with Kedo S Plus group. The characteristics of the obturation material, including its form, consistency and viscosity, along with the technique employed for delivery, and the operator's proficiency and experience, collectively influence the presence and size of voids [29].

Coll and Sadrian observed that teeth filled up to the apex exhibited a higher success rate compared to those that were underfilled or overfilled [34]. Conversely, Bawazir and Salama reported that canals optimally filled and overfilled demonstrated superior performance compared to underfilled canals [35]. In the current investigation, over obturation was predominantly observed in the group treated with Pro AF Baby files (40%, n = 12) in the distal canal, while under obturation noted was similar in the Pro AF Baby group (26.7%, n = 8) and hand instrumentation group (26.7%, n = 8). A higher number of optimal obturations were observed in the Kedo S plus group (73.3%, n = 22). The observation of more over-filling cases in the rotary file groups and increased under-filling in the hand-file group can be attributed to several factors. Rotary file systems generally facilitate a more uniform canal preparation, which enhances the efficiency of the obturation process. When using the pressure syringe technique, the increased adaptability and consistent shaping provided by rotary files can lead to a higher incidence of over-filling, as the material may flow beyond the apex more easily. Conversely, hand files often require a higher degree of manual dexterity and may not achieve the same level of canal shaping consistency. This variability can result in under-filling, as operators may find it challenging to navigate the complex anatomy of the canals effectively, leading to incomplete filling. Thus, the differences in filling outcomes between the two groups highlight the distinct operational characteristics, endodontic instrument variations and challenges associated with each technique.

The obturation material used in this study was Metapex (Metapex, Meta Biomed Co., Ltd., Korea), a calcium hydroxide-based paste. This material was introduced uniformly across all groups to ensure consistency in the evaluation of the quality of obturation. By using Metapex in each group, the study aimed to control for variability related to different obturation materials and focus solely on the impact of the different instrumentation systems on obturation quality [29, 35, 36].

The rotary file systems used in this study are Kedo S Plus and Pro AF Baby Gold files. The Kedo-S Plus is the latest innovation from Kedo, designed with a uniform cross-section and constructed using dual core material that undergoes heat treatment. This controlled memory (CM) file system is notable for its titanium oxide (TiO) coating on the apical and middle regions, while the coronal third is made of heat-treated Nickel-Titanium (Ni-Ti). This unique design enables precise apical preparation without increasing the risk of lateral perforation, making it a preferred choice for pediatric endodontic procedures.

The Pro-AF Baby Gold file system by Kids-e-dental Pvt. Ltd. in India is a five-file rotary system utilizing Ni-Ti CM wire technology with a constant taper of either 4% or 6%. The system includes five files: B1 (#20–04%), B2 (#25–04%), B3 (#25–06%), B4 (#30–04%) and B5 (#40–04%). Files B1 and B2 are specifically designed for narrow canals, while B3 and B4 cater to wide canals, such as the distal and palatal canals. With a shortened length of 17 mm, these files prioritize safety and ease of use during pediatric dental procedures. The system's advanced Ni-Ti heat-treated M wire technology enhances canal centricity, ensuring a smoother and more efficient shaping process [37–39].

In this study, we utilized rotary instrumentation systems, including the Kedo-S Plus, which features a controlled memory file with an apical blue titanium coating and a coronal portion constructed of Ni-Ti, as well as the Pro-AF Baby gold files, also made of controlled memory Ni-Ti.

In contrast, stainless steel (SS) hand files, such as K-Files, exhibit inherent stiffness that poses challenges when employed in narrow, curved canals, ultimately restricting apical enlargement and undermining the quality of obturation. However,

nickel-titanium rotary files effectively preserve the original shape of curved canals and mitigate procedural mishaps, attributable to their super-elasticity, shape memory and inherent strength. The constant taper of Ni-Ti-TiO pediatric rotary files facilitates coronal expansion and straight-line access, thereby optimizing canal preparation while minimizing the risk of over-instrumentation of the root canal walls. The progressive taper design enhances cervical expansion and limits apical preparation compared to fixed taper files, leading to improved obturation quality, as demonstrated in the studies by Kohli *et al.* [40] and Shah HS *et al*. [41]. Additionally, the flexibility provided by Ni-Ti materials allows for superior adaptation to the curvature of the principal canal, enhancing obturation outcomes in contrast to manual instrumentation, which may result in complications such as zipping and transportation. The increased cervical enlargement and conical preparation achieved with rotary files further streamline the obturation process when compared to the less conical preparations associated with manual files [40, 41].

For gauging the obturation efficiency, various methods, including radiographs, fluid filtration, bacterial leakage, radioisotopes, microscopic examination, dye penetration, clearing techniques and micro-computerized tomography can be used. Among these, radiographic assessment of obturation is the most prevalent *in vivo* approach, utilizing both traditional and digital imaging methods [19, 42–44]. Although they are two-dimensional, radiographs are reliable in detecting voids smaller than 300 μm.

5. Limitations

Despite the valuable insights gained from this observational study, several limitations must be acknowledged. The non-randomized design introduces a risk of selection bias, potentially affecting the comparability of the groups and the generalizability of the results. The study's reliance on two-dimensional radiographic images may not fully capture the three-dimensional complexity of root canal systems, which could lead to an underestimation of voids and gaps in obturation. Additionally, while the included sample size provides preliminary insights, it may not be adequately powered to detect subtle differences or to generalize findings across a broader population. Variability among different operators, with varying levels of experience, could also influence procedural consistency and outcome results. The short-term nature of the study does not address the long-term durability and clinical outcomes of the obturation quality, necessitating further research with extended follow-ups. Furthermore, although efforts were made to ensure reliable assessments, the moderate intra- and inter-observer agreement (Cronbach's alpha = 0.72) indicates potential variability in subjective evaluations. The KEDOO classification system, while comprehensive, has not been used yet to evaluate additional canals such as mesiobuccal or distobuccal, potentially overlooking aspects of canal anatomy that could influence obturation quality. The shaping efficacy of individual file systems need to be compared. Addressing these limitations through randomized controlled trials and longer-term studies would provide more robust and generalizable data on the efficacy of different file systems in pediatric endodontics.

6. Conclusions

In this study, obturation quality was evaluated using the KEDOO classification system, which assesses outcomes based on the presence and location of voids as well as the extent of material fill. The Kedo-S Plus system demonstrated a higher frequency of Class 3.1 obturations compared to the Pro AF Baby sequential file system and the conventional Hand K File system. Overall, the results indicated that the Kedo S Plus, Pro AF Baby file, and Hand K File systems each achieved varying levels of obturation quality. For primary maxillary second molars, the majority of obturations were classified as Class 3.1 (40 teeth), followed by Class 3.2 (18 teeth) and Class 3.8 (12 teeth). Notably, none of the file systems resulted in voids in the assessed obturations.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study is available from the corresponding author upon reasonable request.

AUTHOR CONTRIBUTIONS

NDM, GJ—conceptualization; data curation; investigation; methodology; roles/writing-original draft. MDB, DR, MC, MMM, GM—formal analysis. GJ, MDB, DR, MC, MMM, GM—project administration. GJ—supervision. NDM, GJ, MDB, DR, MC, MMM, GM—writing-review and editing. All the authors critically reviewed and revised the manuscript and gave final approval of the version to be published and agreed to be accountable for all aspects of the work.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was registered under the Clinical Trials Registry of India (CTRI) with the registration number CTRI/2024/06/069200. Ethical clearance for the trial was obtained from the Institutional Scientific Review Board (IHEC/SDC/PEDO-2102/23/048). Before commencing the trial, parental or guardian consent was secured from recruited participants, aligning with STROBE guidelines for observational studies.

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CONFLICT OF INTEREST

The authors declare no conflict of interest. Giuseppe Minervini is serving as one of the Editorial Board members of this journal.

We declare that Giuseppe Minervini had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to ZCC.

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