

Influence of root canal instrumentation file systems and obturating materials on the success of pulpectomized teeth: A secondary analysis from a randomized controlled trial

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Highlights

This study evaluates the impact of different root canal instrumentation systems and obturating materials on the success of pulpectomized primary molars.

Rotary file systems yielded superior obturation quality compared to manual files, though obturating material type did not significantly affect the outcome.

The type of instrumentation system used may enhance clinical success rates, but obturating material choice has less impact on pulpectomy success.

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Abstract

Aim: This study aimed determine the influence of the type of root canal instrumentation file systems and obturating materials on the success of pulpectomized teeth. **Methods:** Two hundred eighty-eight primary molars from children aged 4–7 years were selected and divided into three groups of 96 teeth each. In the first, second, and third groups, root canal instrumentation was performed using Kedo-SG pediatric rotary files (KS), HERO Shaper rotary files (HS), and manual Ni-Ti K-files (MF), respectively. Following instrumentation, these three groups were subdivided into three subgroups of 32 teeth each and obturated using zinc oxide eugenol, Endoflas®, and DiaPex Plus®. The quality of the root filling was assessed immediately and evaluated clinically and radiographically over two years. The Chi-Square Test was used to analyze the data, with the level of significance set at $P < 0.05$. **Results:** The quality of obturation was superior in root canals instrumented with rotary file systems compared to manual files. No significant difference in obturation quality was noted among the obturating materials used. The clinical success rate after two years was 100%. Radiologically, success rates were 97% for Kedo-SG, 94% for HERO Shaper, and 89% for manual file systems. For obturating materials, the success rates were 90%, 96%, and 94% for zinc oxide eugenol, Endoflas®, and DiaPex Plus®, respectively. **Conclusions:** The success of pulpectomized teeth was not significantly influenced by the type of root canal instrumentation file systems or the choice of obturating materials.

Keywords: Pulpectomy; Root Canal Filling Materials; Root Canal Preparation; Zinc Oxide

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INTRODUCTION

Using rotary file systems has demonstrated better predictability and helps prevent iatrogenic and procedural errors. Further, using these file systems has demonstrated superior clinical efficiency, with improved quality of obturation, reduced instrumentation and obturation time, less apical debris, decreased post-operative pain, and less stress for both the child and the operator during the procedure.¹⁻⁷ Additionally, the obturating materials that are currently available are effective against resistant root canal microflora due to their antimicrobial properties, and they also provide an impervious hermetic seal.⁸ The effectiveness of these materials has been observed with a wide range of success, varying from 53% to 100%.⁸⁻¹¹

The enhanced physical characteristics of rotary files and the chemical and biological qualities of the obturating materials are anticipated to affect the outcome of root canal treatments favourably. However, recent systematic reviews have not found conclusive evidence favouring rotary instruments over manual files for clinical and radiographic success in pulpectomized teeth.^{13,14} Further, the influence of the filling material used after canal shaping with rotary instruments on the success of pulpectomized teeth remains largely unexplored. In light of this, the earlier phase of this report assessed the combined effects of instrumentation types and obturating materials on success of pulpectomy. The results indicated that the outcome of pulpectomized teeth is not significantly influenced by the combined effect of advanced physical characteristics of rotary files and the chemical and biological qualities of the obturating materials.¹⁵ Consequently, additional analysis was deemed necessary as previous studies that have independently evaluated and compared the success of pulpectomized teeth according to the type of instrumentation and obturating materials have shown varying results.⁵⁻¹⁶

Thus, this report aims to analyze further (secondary analysis) the primary data and determine the influence of either the type of instrumentation or the obturating materials on the success of pulpectomized molars. This involved reorganizing the data of the primary study to group all pulpectomized teeth based on the type of instrumentation or obturating materials used, irrespective of the other variables. The null hypothesis was that the kind of root canal instrumentation file systems and obturating materials do not influence pulpectomized primary molars' outcome.

METHODS

The research protocol was approved by the Institutional Ethics Committee and conducted in line with the World Medical Association's Declaration of Helsinki and the Consolidated Standards of Reporting Trials (CONSORT) guidelines for clinical trials in Pediatric Endodontics. Informed consent was obtained from parents or guardians, and permission from children over 6 years.¹⁶ This report represents a secondary data analysis from a randomized controlled trial that investigated the combined effect of different instrumentation file systems and obturating materials on the outcome of pulpectomized primary molars.¹⁵

A detailed description of the methodology can be found in the primary study.¹⁵ Figure 1 represents the CONSORT flow chart followed during clinical trial. To explain briefly, the co-operative children aged 4 to 7 years requiring pulpectomy were selected. Standardized intraoral periapical radiographs were taken for teeth potentially needing a pulpectomy. Normal, healthy children without systemic diseases were included based on criteria such as teeth with carious pulp exposure, vital or non-vital molars without sinus

tracts, absence of pathological root resorption, and presence of sufficient root length.^{3,5-7} Exclusion criteria included teeth with abscesses, non-restorability, pulpal floor perforation, significant root resorption, or excessive bone support loss.^{3,5-7} The pulpectomy procedure was done by anaesthetizing the teeth with 2% lignocaine (2% lignocaine, Lignox, Bangalore, India). The procedure involved removing dental caries and establishing access to the pulp chamber, followed by the extirpation of radicular pulp tissue using H-files. Root canal patency was checked, and the working length was determined to be 1–2 mm short of the radiographic apex.^{3,5}

The 288 selected teeth were randomized into three groups [(Kedo-SG Blue files (KS), HERO Shapers files (HS), and Manual files (MF)] using a block randomization technique and SNOSE for unbiased allocation. Root canals were instrumented with Kedo-SG Blue pediatric rotary files (Reeganz Dental Care Pvt. Ltd., India), HERO Shaper rotary file system (Micromega, Geneva, Switzerland), and manual NiTi K-files (Dentsply, Switzerland) for the KS, HS, and MF groups, respectively. In the KS and HS groups, root canals were enlarged in the coronal third with an Endoflare® file (Endoflare® file-Micromega, Geneva, Switzerland), then the rotary files were used up to the working length as per the manufacturer's instructions.

The rotary file systems were operated with an endodontic motor (X-Smart, Dentsply Maillefer, OK, USA) at 300 rpm and 2.2-Ncm torque with a lateral brushing motion.^{3,17} In the MF group, canals were instrumented with manual NiTi K files using the quarter-turn-and-pullback technique.^{3,5} All root canals underwent intermittent irrigation with saline and a 17% EDTA gel (RC Help, Prime Dental Products, Pvt. Ltd.) as a lubricant.^{3,16} After final irrigation, the canals were dried with paper points.

The primary molars were further divided into three subgroups for obturation. The first two subgroups were obturated using zinc oxide eugenol cement (Zinc Oxide BP, Eugenol BP, Associated Dental Products Ltd) and Endoflas® (Sanlor Laboratories S.A.S, Cali-Colombia), respectively. A #25 lentulospiral on a slow-speed handpiece was used for obturation. In the third subgroup DiaPex Plus® (DiaDent Group International, Korea), a pre-mixed iodoform paste, was used for obturation.¹⁰ After obturation, the access cavity was sealed with type II glass ionomer cement. The treated teeth were restored with stainless steel crowns (3M ESPE, St.Paul, MN, USA).⁵⁻⁷ The stainless steel crowns were placed within a week to ensure comfort for the young patients and to maintain consistency in the treatment process. A skilled operator performed all pulpectomies in a single session, strictly adhering to aseptic protocols and the manufacturer's guidelines to ensure consistent results.

Quality of Obturation Evaluation

Two pediatric dentists (PK and AS) blinded for the specific instruments and materials used, evaluated the radiographs and graded the obturation as underfilled, optimally filled and overfilled.^{18,19} Discrepancies were resolved by defaulting to the lower classification of obturation quality.

Evaluation of Pulpectomized Teeth

Pulpectomized teeth underwent clinical and radiographic assessments every three months for two years. High kappa scores indicated strong examiner agreement, with disagreements resolved through discussion or marked as failures. A pulpectomy was considered clinically successful if there were no symptoms such as pain, tenderness to percussion, gingival swelling, sinus tract formation, or abnormal tooth mobility.^{20,21} Similarly, a pulpectomy was considered

radiographically successful if there was no increase in the size of preoperative furcal or periapical radiolucency, development of new radiolucency on subsequent follow-ups, or development of internal or external root resorption, changes in lamina dura/width of periodontal ligament space, and deviation in the path of succedaneous tooth eruption.^{20,21} Further, the radiographic examination also included the resorption of intraradicular material and extraradicularly extruded materials.²¹

The clinical and radiographic success was determined independently as not all radiographic failures are associated with clinical symptoms and vice versa.^{5,20}

To maintain the study's integrity, all participants, guardians, outcome assessors, and data analysts were blinded to the types of instrumentation systems and obturating materials used. The operator, however, could not be blinded due to the recognizable nature of the intervention materials.

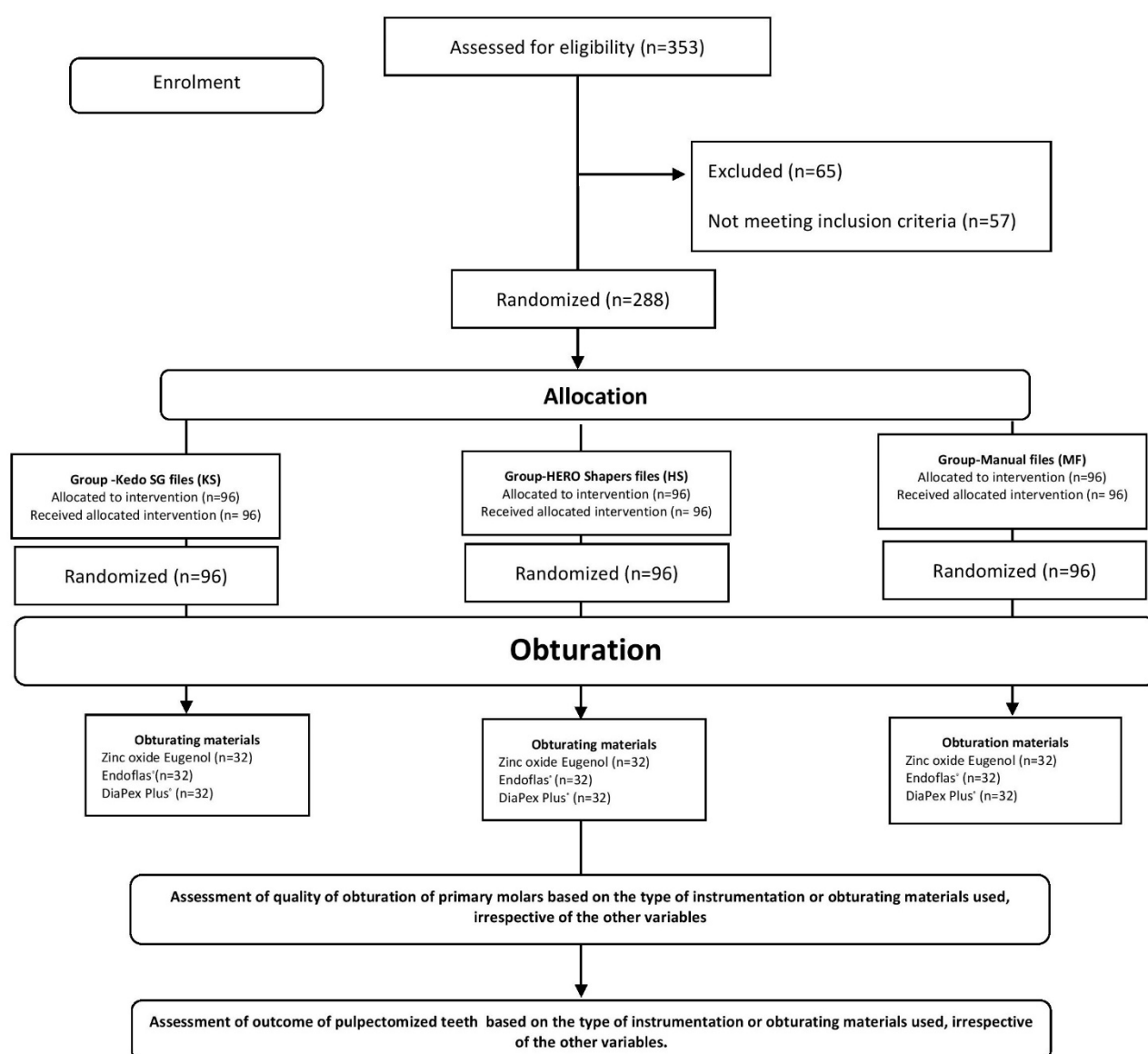


Figure 1. CONSORT flow chart followed during clinical trial

RESULTS

The research included 288 children, with a gender distribution of 102 males and 186 females, aged 4-7 years, averaging 5.31 ± 1.09 years. An equal number of maxillary and mandibular first and second molars were treated, with no dropouts.

Quality of Obturation

About the type of instrumentation, in the KS group, 8.3% of teeth were underfilled, 77.1% were optimally filled, and 14.6% were overfilled. In the HS group, 5.2% of teeth were underfilled, 72.9% were optimally filled, and 21.9% were overfilled. In the MF group, 32.3% were underfilled, 54.2% were optimally filled, and 13.5% were overfilled. There was a statistically significant difference ($p \leq 0.001$) in the quality of obturation on comparison of the three groups (Figure 2).

The quality of obturation was significantly superior in the KS and HS groups compared to the MF group, but there was no significant difference between the KS and HS groups (Table 1).

Regarding the type of obturating materials, 16.7% of teeth filled with zinc-oxide eugenol were underfilled, 65.6% were optimally filled, and 17.7% were overfilled. For teeth filled with Endoflas®, 14.6% were underfilled, 72.9% were optimally filled, and 12.5% were overfilled. For teeth filled with DiaPex Plus®, 14.6% were underfilled, 65.6% were optimally filled, and 19.8% were overfilled. In the comparison of the three obturating materials, there was no statistically significant difference ($p \leq 0.68$) in the quality of obturation (Figure 2 and Table 1).

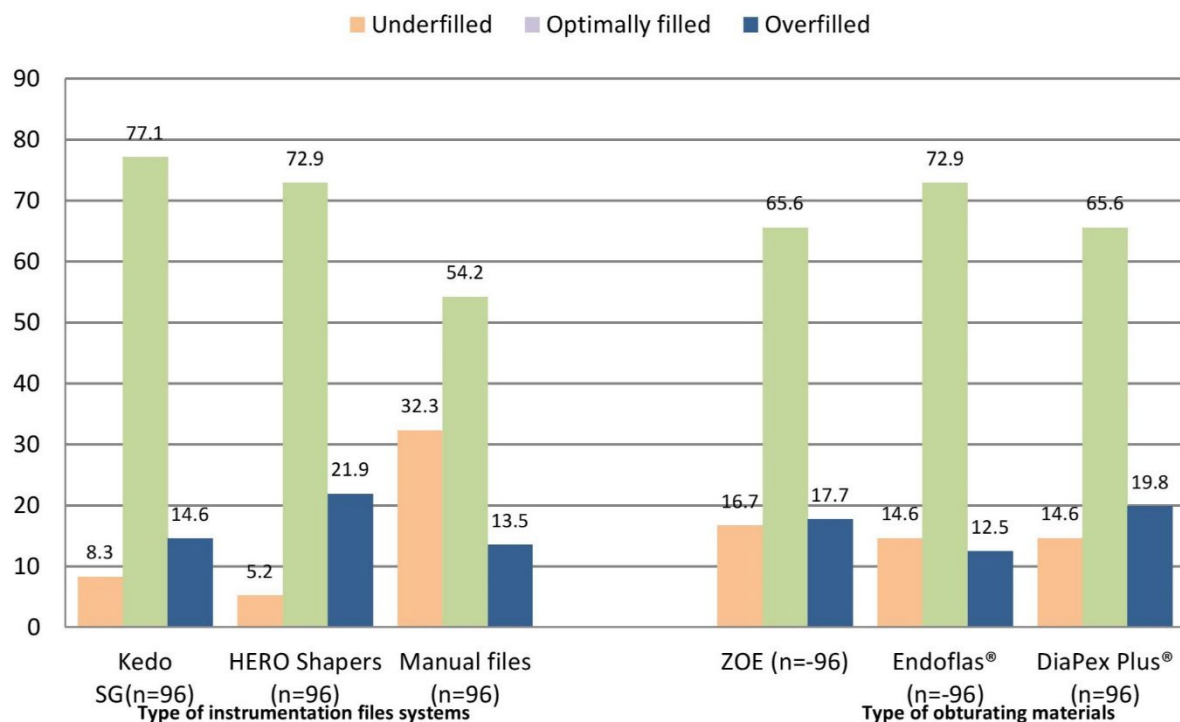


Figure 2. Comparison of obturation quality in primary molars by instrumentation file systems and obturating materials

Table 1. Multiple comparisons of obturation quality by instrumentation file systems and obturating materials

Groups	Instrumentation file systems			Obturating materials		
	Kedo-SG vs HERO Shapers	Kedo SG vs Manual files	HERO Shapers vs Manual files	ZOE vs Endoflas	Endoflas vs DiaPex Plus	DiaPex Plus vs ZOE
p-value	0.33	<0.001*	<0.001*	0.63	0.68	0.59

After the end of two years, the clinical success rate was 100% regardless of the type of instrumentation and obturating materials used. The radiological success rates varied depending on the kind of instrumentation, with rates of 97%, 94%, and 89% for groups KS, HS, and MF, respectively. When considering the type of obturating materials, the success rate was 90% for teeth filled with zinc oxide eugenol and 96% and 94% for those filled with Endoflas® and DiaPex Plus®, respectively.

Although not statistically significant, a slightly higher success rate was observed in the KS and HS groups compared to the MF group and in teeth filled with Endoflas® and DiaPex Plus® compared to those filled with zinc oxide eugenol. However, when comparing the clinical and radiographic success over 24 months, no statistically significant difference was found among the types of instrumentation or obturating materials (Table 2 and Figure 3).

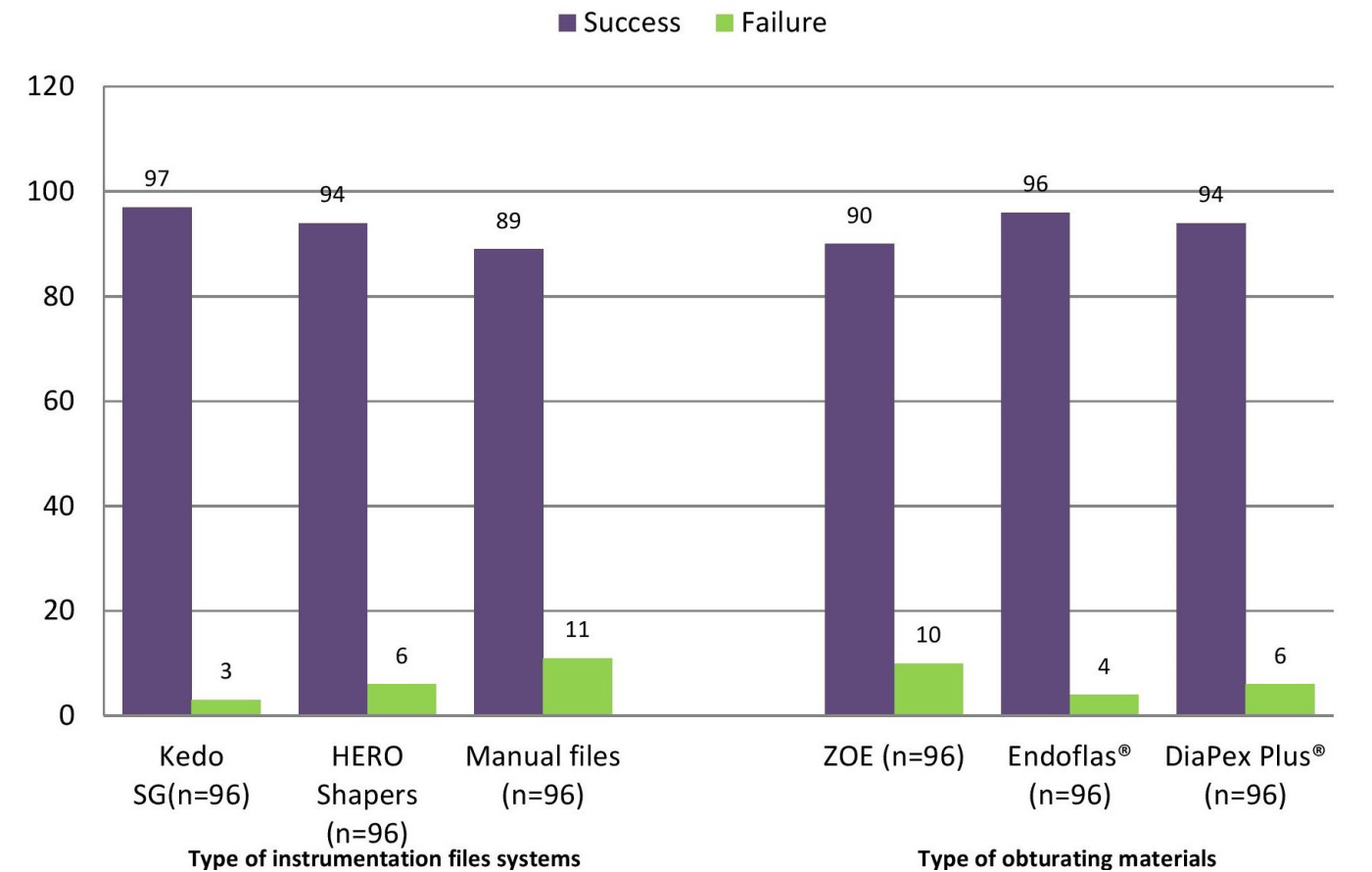


Figure 3. Outcomes of pulpectomized teeth by instrumentation file systems and obturating materials

Table 2. Success rates of pulpectomized teeth by instrumentation file systems and obturating materials

	Instrumentation file systems						Obturating materials					
	Clinical		success	Radiographic success			Clinical		success	Radiographic success		
	Kedo-	HERO	Manual	Kedo-	HERO	Manual	ZOE	Endoflas	DiaPex	ZOE	Endoflas	DiaPex
	SG	Shapers	files	SG	Shapers	files			Plus			Plus
	(n=96)	(n=96)	(n=96)	(n=96)	(n=96)	(n=96)	(n=96)	(n=96)	(n=96)	(n=96)	(n=96)	(n=96)
Evaluation period	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
3-month	96	96	96	96	96	96	96	96	96	96	96	96
	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
6-month	96	96	96	96	96	96	96	96	96	96	96	96
	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
9- month	96	96	96	96	96	96	96	96	96	96	96	96
	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
12- month	96	96	96	96	96	95	96	96	96	95	96	96
	(100)	(100)	(100)	(100)	(100)	(99)	(100)	(100)	(100)	(99)	(100)	(100)
15- month	96	96	96	95	96	92	96	96	96	93	95	95
	(100)	(100)	(100)	(99)	(100)	(96)	(100)	(100)	(100)	(97)	(99)	(99)
18- month	96	96	96	94	93	89	96	96	96	89	94	93
	(100)	(100)	(100)	(98)	(97)	(92)	(100)	(100)	(100)	(92)	(97)	(97)
24- month	96	96	96	93	90	86	96	96	96	87	92	90
	(100)	(100)	(100)	(97)	(94)	(89)	(100)	(100)	(100)	(90)	(96)	(94)
P value	-			0.13			-			0.42		

Correlation Between the Quality of Obturation and the Outcome of Pulpectomy

Regarding the type of instrumentation, the correlation between the quality of obturation and the outcome of pulpectomy showed that the optimally filled (66.3%) primary molars had a higher success rate compared to underfill (14.2%) or overfilled teeth (12.8%) at the end of the evaluation period. This difference was statistically significant ($p \leq 0.001$) (Table 3). Similarly, with obturating materials, a statistically significant success rate was observed in optimally filled primary molars (66.3%) compared to underfilled (13.8%) and overfilled teeth (13.1%) (Table 4). A 100% success rate was observed in the KS group using Endoflas.

Type of Radiographic Failures

After 24 months, in the KS group, 3 teeth had furcal radiolucency. The HS group had 3 teeth with furcal radiolucency, 2 with periapical radiolucency, and 1 with increased periodontal ligament space. The MF group showed radiographic failure in 10 teeth: 3 with furcal radiolucency, 4 with periapical radiolucency, and 4 with increased periodontal ligament space. Zinc oxide eugenol was associated with 9 failures: 5 with furcal radiolucency, 3 with periapical radiolucency, and 1 with increased periodontal ligament space. Endoflas had 4 failures: 3 with periapical radiolucency and 1 with increased periodontal ligament space. DiaPex Plus® showed 6 failures: 2 with furcal radiolucency, 1 with periapical radiolucency, and 3 with increased periodontal ligament space (Table 5).

Table 3. Correlation between instrumentation file systems and pulpectomized teeth outcomes based on obturation quality

Instrumentation file systems	Outcome	Underfilled n (%)	Optimally filled n (%)	Overfilled n (%)	P value
Kedo-SG (n=96)	Success	7 (97)	74(100)	12(85.7)	0.003*
	Failure	1(3)	0	2(14.3)	
Hero Shapers (n=96)	Success	4(97)	69(98.6)	17(82.2)	0.03*
	Failure	1(3)	1(1.4)	4(18.3)	
Manual files (n=96)	Success	30(96.8)	48(92.3)	8(61.5)	0.001*
	Failure	1(3.2)	4(7.7)	5(38.5)	
Total (n=288)	Success	41 (14.2)	191(66.3)	37(12.8)	0.001*
	Failure	3(1)	5(1.7)	11(3.8)	

Table 4. Correlation between obturating materials and pulpectomized teeth outcomes based on obturation quality

Obturating materials	Outcome	Underfilled n (%)	Optimally filled n (%)	Overfilled n (%)	P value
ZOE (n=96)	Success	14(87.5)	61(96.8)	12(70.6)	0.001*
	Failure	2(12.5)	2(3.2)	5(29.4)	
Endoflas (n=96)	Success	13(92.8)	70(100)	9(75)	<0.001*
	Failure	1(7.1)	0	3(25)	
DiaPex Plus (n=96)	Success	13(92.9)	60(95.2)	17(89.5)	0.65
	Failure	1(7.1)	3(4.8)	2(10.5)	
Total (n=288)	Success	40(13.8)	191(66.3)	38(13.1)	0.001*
	Failure	4(1.38)	5(1.7)	10(3.4)	

Table 5. Radiographic evaluation of pulpectomized teeth by instrumentation file systems and obturating materials

Follow-up		Type of instrumentation			Type of obturating materials		
		Kedo-SG	HERO Shapers	Manual file	ZOE	EF	DP
		n=96	n=96	n=96	n=32	n=32	n=32
Radiographic findings		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
12-Mon	FR	-	-	-	-	-	-
	PR	-	-	-	-	-	-
	PDL	-	-	1(3)	1(1)	-	-
15-Mon	FR	1(1)	-	1(1)	2(2)	-	-
	PR	-	-	1(1)	-	1(1)	-
	PDL	-	-	1(1)	-	-	1(1)
18-Mon	FR	1(1)	2(2)	1(1)	3(3)	-	-
	PR	-	1(1)	1(1)	2(2)	1(1)	1(1)
	PDL	-	-	1(1)	-	-	1(1)
24-Mon	FR	1(1)	1(1)	-	-	-	2(2)
	PR	-	1(1)	2(2)	1(1)	1(1)	-
	PDL	-	1(1)	1(1)	-	1(1)	1(1)
Total	Failures	3(3)	6(6)	10(10)	9(9)	4(4)	6(6)
	Success	93(97)	90(94)	86(90)	87(91)	92(96)	90(94)
p-value		0.37			1.00		

FR: Furcal Radiolucency; PR: Periapical Radiolucency; PDL: increase in the width of periodontal ligament space; ZOE: Zinc Oxide Eugenol; EF:Endoflas®; DP: DiaPex Plus®

Radiographic evaluation of obturating materials' longevity

Both intraradicular resorption and the resorption of extruded materials were first noticed during the 9-month and persisted until the end of the 24 months. Intraradicular resorption of the obturating materials was seen in three teeth, each in the KS, HS, and MF groups. All of these teeth were filled with DiaPex Plus®. The other obturating materials, Endoflas® and zinc-oxide eugenol were not associated with intraradicular resorption. The resorption of extruded materials was observed in 9 teeth in the KS group, 13 in the HS group, and 6 in the MF group. Extruded materials were absorbed in 12 teeth filled with Endoflas® and 19

teeth filled with DiaPex Plus®, but not in any teeth filled with zinc oxide eugenol (Table 6).

DISCUSSION

The secondary analysis revealed that the primary molars instrumented with rotary file systems resulted in superior obturation quality compared to those treated with manual NiTi file systems. Further, after a 2-year follow-up, there was no significant difference in the success rate between primary molars instrumented with rotary or manual file systems. Furthermore, the choice of obturation materials did not significantly affect the overall success rate.

Table 6. Radiographic evaluation of obturating materials' longevity

Evaluation period (month)	Type of instrumentation						Type of obturating materials					
	Intraradicular resorption of obturating material			Resorption of extruded material (Overfilled teeth)			Intraradicular resorption of obturating material			Resorption of extruded material (Overfilled teeth)		
	KS (n=96)	HS (n=96)	MF (n=96)	KS (n=96)	HS (n=96)	MF (n=96)	ZOE (n=96)	EF (n=96)	DP (n=96)	ZOE (n=96)	EF (n=96)	DP (n=96)
3	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
9	Nil	01	01	2	3	2	Nil	Nil	2	Nil	2	5
12	01	Nil	Nil	4	4	2	Nil	Nil	1	Nil	5	5
15	01	01	Nil	2	5	4	Nil	Nil	2	Nil	3	8
18	01	Nil	01	1	1	1	Nil	Nil	2	Nil	2	1
24	Nil	01	01	-	-	-	Nil	Nil	2	Nil	Nil	Nil
TOTAL	03	03	03	09	13	06	Nil	Nil	09	Nil	12	19
	09			31			09			31		

KS: Kedo-SG; HS: HERO Shapers; MF: Manuel files; ZOE: Zinc Oxide Eugenol; EF: Endoflas®; DP: DiaPex Plus®

The observation of more optimally filled root canals using rotary files can be attributed to their design. The unique design of rotary file systems, featuring elastic memory and radial land, helps them stay centered in the canal, leading to more uniformly conical canal shapes than those formed by manual files. This conical configuration, achieved by rotary files, is conducive to improved obturation quality.¹⁻⁷ Additionally, pre-flaring the coronal third of the canal with instruments like the Endoflare® removes any obstructions at the canal entrance, ensuring unimpeded access to the canal's apical part.^{2,4-7} The larger rotary file taper also shapes the canal into a more conical form, facilitating a smoother flow of the obturating material to the apex. These aspects are believed to enhance the density, uniformity, and overall quality of the obturation.^{5-7,20} This finding is consistent with prior research indicating that rotary files are more effective at cleaning the irregular surfaces of primary root canals, thereby achieving better obturation quality than manual files.^{1,3-7} Consistent with previous research, this study found no significant difference in obturation quality between molars treated with pediatric or adult rotary file systems, supporting that rotary file systems

improve obturation quality in primary teeth, regardless of the file system type.^{3,5-7} However, some studies have found no difference in obturation quality between rotary and manual files, suggesting that further investigation is needed.^{20,22}

In alignment with the previous studies, the occurrence of underfilled root canals was more frequent with the use of manual NiTi files.^{3,5-7} The limited taper of these manual files may result in narrow and uneven canal shapes, obstructing the proper distribution of the filling material.²³ It's crucial to recognize that underfilled canals are susceptible to infiltration by tissue fluids, which can stagnate and possibly cause infection, a situation referred to as the 'Hollow Tube Effect'.⁸

Teeth treated with the adult rotary file system exhibited a higher incidence of overfilling. As the adult rotary file system is primarily designed for permanent teeth, its use in primary teeth would have led to over-instrumentation due to their increased length and taper, causing overfilling.⁵ Additionally, incorrect maintenance of the working length of the file or lentulospiral could also lead to overfilling.^{5,23} In contrast, using the pediatric rotary file system resulted in fewer overfilled root canals

than the adult rotary file system. This could be because it is an exclusive pediatric file system that causes minimal apical enlargement, thus preventing over-preparation and extrusion of the obturating material.³ The least number of overfilled canals were observed using manual files. This could be due to under preparation of the root canals that have resulted in fewer overfilled canals.²³ Despite this, some studies have reported a higher incidence of overfilling with manual files, suggesting that preexisting conditions of the primary roots may play a role.^{8,24}

In terms of obturation materials used, no marked difference in obturation quality was noted, aligning with previous studies.^{8,10} Endoflas® had a marginally higher rate of optimally filled canals, yet comparable to Zinc Oxide Eugenol and DiaPex Plus®. The obturation technique and material consistency may influence these results.¹⁰ Both Endoflas® and DiaPex Plus® had equivalent underfilled canals, with Zinc Oxide Eugenol showing a slightly higher rate. Underfilling typically results from incomplete chemo-mechanical preparation, imprecise working length determination, or insufficient canal irrigation. Underfilling may occur if the working length is based on average anatomical measurements rather than the actual apical foramen, leading to voids that could cause reinfection.^{5,8,23,25}

Overfilling occurred with all the obturating materials used. This may be due to the rotary lentulospiral ability to carry low-viscosity materials like Zinc Oxide, Eugenol, and Endoflas® deeper into the canal.²³ Some studies did not find a higher rate of overfilling with Endoflas®, attributing it to specific techniques used.^{10,24} The thinner consistency of DiaPex Plus® might explain its higher incidence overfilling. The application of this technique could also influence this, where the material is actively pushed into the canal.¹⁰ Overfilling may sometimes be an inevitable

consequence of the delicate and fragile dentinal walls near the developing permanent tooth, which may collapse during the procedure.^{5,20}

The success of a pulpectomy is measured by the tooth's ability to function properly until it naturally exfoliates without any clinical or radiographic signs of failure. Clinically, all teeth demonstrated a 100% success rate after two years, irrespective of the instrument type used for root canal preparation. This is in accordance with Babu et al., who found a 100% clinical success rate over 24 months using both adult and pediatric rotary file systems and manual files.⁵ Similarly, comparing three pediatric rotary file systems with manual files showed a 100% clinical success rate after two years.¹⁶ Amorim et al. reported a 100% clinical success rate at 12 months for primary molars treated with rotary and manual techniques.²² Elheeny et al. observed a higher clinical success rate for rotary instruments than manual ones after 12 months.²⁶ However, an Indian study indicated lower clinical success rates for rotary techniques than manual ones after 24 months.²⁰

In the current study, a 100% clinical success rate was observed regardless of the chosen material for obturation. This means that the type of material did not affect the clinical outcome of the treated teeth. This finding aligns with an Indian study which reported a 100% success rate in teeth filled with Endoflas®, Metapex®, and zinc oxide eugenol.¹⁰ Similarly, Pramila et al. observed a 100% success rate using RC Fill®, Pulpdent®, and Vitapex® after 30 months.²¹ Previous studies have also reported a 100% success rate with zinc oxide eugenol over a 24-month follow-up.^{5,16} Ozalp et al. noted a 100% success rate at 18 months using zinc oxide eugenol and Vitapex®.²⁷ Chen et al. found success rates of 92.2% with zinc oxide eugenol and 71.4% with Vitapex®.¹¹ In contrast, Pandranki et al. reported a higher success rate with Endoflas® compared to zinc oxide eugenol cement.⁸ Ramar et

al. documented success rates of 96.8% with Metapex® and 100% with Endoflas® at 9 months,⁹ while Fuks et al. reported a 70% success rate with Endoflas®²⁴ and Nakornchai et al. reported a high success rate of 96% with Vitapex®.²⁸

By the end of the study, teeth treated using rotary file systems exhibited a marginally higher radiographic success rate than those treated with manual file systems. However, the difference was not statistically significant. The enhanced success rate of rotary file systems could be attributed to the minimized extrusion of apical debris.² Conversely, the increased failure rates for manual files might be due to the accumulation of dentinal shavings in the periapical area, a problem potentially exacerbated by the rhizolysis in primary teeth.²² While this study supports the notion of rotary files achieving better outcomes,^{5,17,26} other research has indicated the opposite, with hand files sometimes showing superior radiographic success compared to rotary instruments.^{20,22}

In this study, Endoflas® had a higher success rate, followed closely by DiaPex Plus® and zinc oxide eugenol. This finding is in consistent with previous studies.^{10,27,21} Contrasting these results, lower radiographic success rates have been observed with Endoflas®, zinc oxide eugenol, and iodoform-based materials like Vitapex® (53%) and Metapex®.^{8,9,11}

Previous studies have documented an overall success rate of 95% to 100% for teeth treated with rotary and hand files over various follow-up periods.^{5,12,16,17,26} Similarly, success rates for teeth filled with different obturating materials have been reported to range from 53% to 100%.^{8-11,21,27,28} It is important to highlight that these studies presented their findings as a combined success/survival rate without distinguishing between clinical and radiographic success or sorting the results by specific groups (rotary vs. hand files).

The discrepancies in success rates can be linked to multiple factors. One key issue is the difference between clinical and radiographic outcomes, where silent radiographic failures, clinically asymptomatic, are counted as radiographic failures.²⁰ Other variables affecting success rates include individual immune response, the pre-treatment pathological state of the tooth, independent assessments of clinical and radiographic outcomes, the inclusion of pathological root resorption and radiological alterations in furcal or periapical regions as radiographic failures, and the criteria used to select primary molars for treatment. Additionally, the instrumentation method, the type of irrigation solutions, the obturating materials used, the practitioner's skill and expertise, post-treatment restorations, and the length of the follow-up period are significant contributors.^{12,19,26,29} The healing process, which may require more time to be detectable radiographically, is another vital aspect. Moreover, interpreting furcal and radicular radiolucencies can be highly subjective, potentially leading to 'observer bias', even when the same observer conducts subsequent evaluations.^{22,26}

The present study's findings align with previous studies that reported no marked difference in the success rates of pulpectomized primary molars, regardless of whether they were prepared using rotary or hand file systems or filled with various materials.^{5,8-10,16,17,20,22,26,29,30} This might be because the variation in root canal instrumentation was only in terms of the technique or type of instrumentation and filling materials, while all other factors remained constant.²⁰ This uniformity likely contributed to the similar clinical and radiographic outcomes observed after 24 months.

The correlation between the obturation quality and the success of pulpectomized teeth indicates that rotary file systems may lead to a higher proportion of optimally filled teeth, thereby

enhancing the overall success rate. This improvement could be attributed to the diminished presence of apical debris, which correlates with decreased radiographic failures and an increase in adequately filled root canals.^{2,5,16} Regarding the filling materials, teeth obturated with Endoflas® have demonstrated a higher success rate, potentially due to Endoflas®'s robust antibacterial properties associated with its alkaline pH.^{8,10} Moreover, Endoflas® is known to facilitate healing in the periapical area and support bone regeneration.⁸ Further, the superior success rate could also be attributed to the higher number of optimally filled teeth and the resorption of only extraradicularly extruded material.

The success rate for optimally filled canals was notably higher, corroborating prior research findings.^{5,8-10,16,24,30} In consistent with previous studies, the overfilled canals had a lower success rate.^{24,30} Failures in overfilled canals may be associated with preoperative conditions like radiolucency or root resorption, adversely affecting prognosis. Yet, some studies have reported high success rates even for overfilled root canals.^{18,31}

The underfilled canals may foster bacterial proliferation within the narrow channels, potentially leading to reinfection and a consequent increase in failure rates.⁸ Earlier studies have substantiated this trend.^{8,10} Intriguingly, Moskovitz et al.³² observed a high success rate in underfilled canals treated with Endoflas®, surpassing even flush-filled and overfilled canals. They posited that discrepancies between the radiographic and anatomical apex, resulting from physiological or pathological root resorption in primary teeth, could cause misinterpretations of 'flush fill' and 'failure' as 'over-fill'.³²

In summary, the secondary analysis suggests that the success of pulpectomized molars is not significantly affected by the choice of instrumentation file systems or obturating

materials. Nonetheless, observations indicate a trend where the use of rotary file systems, particularly those designed for pediatric use, and obturation with Endoflas® correlate with higher success rates. This could be attributed to their role in achieving a greater proportion of optimally filled root canals, a key factor in treatment success. Dental practitioners must enhance their proficiency in rotary endodontics, given its emerging importance in pediatric dentistry, and deepen their knowledge of obturating materials chemical and biological properties.

The study acknowledges limitations, such as a limited sample size, reliance on two-dimensional radiographic imaging, and the challenge of blinding the operator due to the instruments and materials distinct nature. Future research should incorporate more sophisticated imaging modalities, like cone beam computed tomography (CBCT) or micro-CT, expand the sample size, and extend the follow-up period until natural exfoliation of the teeth.

CONCLUSIONS

Primary molars treated with rotary file systems demonstrated better obturation quality than those treated with manual NiTi file systems. However, there was no significant difference in obturation quality between the Kedo-SG pediatric rotary and HERO Shaper rotary file systems. The choice of obturation materials did not markedly impact obturation quality. After two years, the clinical success rate was 100%. Radiologically, success rates were 97% for Kedo SG, 94% for HERO Shaper, and 89% for manual file systems. Primary molars with optimal filling demonstrated higher success rates than underfilled or overfilled cases. Using rotary file systems and Endoflas® resulted in more optimal fillings and better outcomes, although statistical significance was not observed. Thus, it can conclude that the success of pulpectomized teeth is not significantly influenced

by the type of root canal instrumentation file systems or obturating materials offering operators a wide range of choices for pulpectomy procedures based on individual preferences and clinical considerations.

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