

In Vitro Cleaning Efficacy of Neolix and M3 Immatural Rotary Files in Comparison with Hand Files in Primary Molar Root Canals

Shabnam Maleki ¹, Effat Khodadadi ²✉, Elham Mahmoudi ³, Seyedali Seyedmajidi ²

¹ Student Research Committee, Babol University of Medical Sciences, Babol, Iran.

² Dental Materials Research Center, Health Research Institute, Babol University of Medical Sciences, Babol, Iran.

³ Oral Health Research Center, Health Research Institute, Babol University of Medical Sciences, Babol, Iran.

✉ **Corresponding author:**

Effat Khodadadi, Dental Materials Research Center, Health Research Institute, Babol University of Medical Sciences, Babol, Iran.

dr_ekhodadadi@yahoo.com

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Abstract

Background and Aim: This study assessed the cleaning efficacy of Neolix and M3 Immatural rotary files compared with hand K-files in primary molar root canals.

Materials and Methods: This in vitro study evaluated 40 primary maxillary and mandibular molars. After access cavity preparation, Indian ink was injected into the root canals of primary molars. The teeth were then randomly divided into three experimental and one control group (n=30 canals per group). In group 1, the root canals were instrumented with #20 M3 Immatural file and then with #25/4% to the working length. In group 2, the root canals were instrumented with #25/6% Neoniti A1 file. In group 3, hand K-files were used for instrumentation of the mesial canals of mandibular molars and buccal canals of maxillary molars to #25, and palatal canals of maxillary molars and distal canals of mandibular molars to #30. Group 4 served as the control group and was only rinsed with saline with no instrumentation. After clearing, the teeth were inspected under a stereomicroscope. Data were analyzed by the Kruskal-Wallis and Mann-Whitney U tests.

Results: No significant difference was noted among the groups in cleaning of the coronal third of the root canals ($P=0.174$). In the middle and apical thirds, two rotary systems showed significantly superior cleaning compared with hand files ($P=0.031$ and $P=0.007$, respectively), but there was no significant difference between the two rotary files ($P>0.05$).

Conclusion: Neolix and M3 Immatural files can serve as efficient alternatives to hand files for pulpectomy of primary molars.

Keywords: Instrumentation; Pulpectomy; Root Canal Therapy; Tooth, Deciduous

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Introduction

Due to the existing concerns about space loss, potential orthodontic problems, and the adverse effect of premature loss of primary teeth on

children's quality of life, pulpectomy is considered as a more conservative treatment option for primary teeth with irreversible

pulpitis or necrotic pulp compared to tooth extraction [1, 2]. Pulpectomy is commonly preferred for such teeth when the root canals are accessible, and there is evidence of normal supporting bone [2, 3]. However, pulp therapy treatments often require the children's cooperation and may necessitate multiple sessions or the use of general anesthesia [4]. An ideal pulpectomy procedure should be fast and optimally debride, clean, and shape the primary root canals without compromising the root structure or the permanent successor tooth bud [5, 6].

Preparation of primary root canals by using rotary instruments was first suggested by Barr et al. [7] in 1999, and they reported that it is an efficient technique for debridement of irregular primary root canal walls. Rotary instrumentation of the root canal system saves time, improves patient cooperation, and decreases the operator's fatigue [2, 8]. Moreover, nickel-titanium rotary instruments preserve the original path of the curved canals in primary teeth. However, it should be noted that rotary instruments have high technical sensitivity, and the operator should acquire the necessary skills to use them [9].

Difficult access to root canals due to limited mouth opening in children often complicates the pulpectomy treatment of primary molars. Short rotary files with optimal taper are more suitable for primary teeth. M3 Immatural files (United Dental, Shanghai, China) are short-length (16 mm) rotary files available in three sizes of #20, #25, and #30 with 4% taper, which are suitable for primary teeth. They have shape memory and a convex triangular cross-section [10, 11].

Different single-file rotary systems are available in the market, which can greatly save time. Neoniti A1 (Neolix Creative Dental Instruments, Chatres, La Foret, France) is a single-file rotary system with full-rotation movement. It is available in different tip sizes of

#20, #25, and #40. Heat treatment of files in this system results in their flexibility. Also, these files have a non-homogenous rectangular cross-section, which enables better instrumentation of curved canals while preserving their original anatomy [12].

Various techniques are available for assessing the cleaning efficacy of the root canal system, including scanning electron microscopy, micro-computed tomography imaging, stereomicroscopy, and longitudinal tooth sectioning for microscopic analysis [13]. Clearing of tissues is ideal for in vitro evaluation of the root canal system without damaging the tooth structure [14]. Tomar et al. [15] stated that stereomicroscopy offers a highly sensitive and reliable approach for three-dimensional evaluation of the root canal system. Additionally, this technique is more cost-effective compared to alternative methods.

Considering the gap of information regarding the cleaning efficacy of Neolix (#25-0.06) and M3 Immatural rotary files in primary root canals, this study aimed to compare the cleaning efficacy of Neolix and M3 Immatural rotary files with hand K-files for instrumentation of primary molar root canals by the clearing technique. The null hypothesis of the study was that there would be no significant difference in the cleaning efficacy of the files used in different sections of the root canal system.

Materials and Methods

This in vitro experimental study was conducted on primary molars with at least two-thirds of their sound root remaining, and a root length of 7-12 mm. The teeth had been extracted due to over-retention or severe bone resorption as noted on periapical radiographs. The selected teeth had sound crowns and roots without severe curvature, fracture, or resorption. The study protocol was approved by the ethics committee of Babol University of Medical Sciences

(IR.MUBABOL.REC.1399.486), and informed consent was obtained from the parents for the use of their children's extracted teeth for research purposes.

The minimum sample size was calculated to be 15 canals in each group based on the results of a previous study comparing rotary and hand files [16], with a 95% confidence level ($\alpha = 0.05$), 80% study power ($\beta = 0.2$), and an effect size (d) of 0.5. The sample size was determined using the following formula:

$$N \geq \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (\delta_1^2 + \delta_2^2)}{d^2}$$

Forty primary molars (including 20 maxillary and 20 mandibular primary molars) were evaluated in this study. The teeth were randomly divided into four groups (each group included 10 teeth and 30 canals).

The teeth were immersed in 0.5% sodium hypochlorite (Golrang, Tehran, Iran) for one week for disinfection, and stored in saline until the experiment [16].

Root canal preparation:

Access cavity was prepared in teeth using a round diamond bur (Mani Inc., Tokyo, Japan). After rinsing the root canals with saline (Samen, Mashahd, Iran), a #10 K-file (Mani Inc., Tokyo, Japan) was introduced into the canal until its tip was visible at the apex. The working length was determined 1 mm short of the apex. After introducing the file into the root canal, 1-2 mL of Indian ink was injected into the canal using an insulin syringe until ink leaked out from the apex. Ink injection was then repeated [16].

Study groups:

The teeth were randomly divided into four groups:

Group 1 (n=30 canals): Root canals were instrumented with #20 M3 Immatural file (M3; United Dental, Shanghai, China) and then #25 with 4% taper to the working length at 350 rpm

with 1.5 N/cm torque by the single-length technique.

Group 2 (n=30 canals): Root canals were instrumented with Neoniti A1 (Neolix Creative Dental Instruments, Châtres-La, Foret, France) #25 file with 6% taper and 21 mm length at a speed of 300-500 rpm and 1.5 N/cm torque by the single-length technique.

Group 3 (n=30 canals): The mesial canals of mandibular molars and buccal canals of maxillary molars were instrumented with hand K-files (Mani Inc, Tochigi, Japan) up to #25, and the palatal canals of maxillary molars and distal canals of mandibular molars were filed up to #30 by the standard technique.

Group 4 (n=30 canals): This group served as the control group. No instrumentation was performed in this group. The canals were only rinsed with saline [17, 18].

Instrumentation with rotary files was performed using an endo-motor (Endo-Mate DT, NSK, Nakanishi Inc., Tokyo, Japan). In groups 1 and 2, the files were used with light pecking motion until the working length was reached. After using each file, the root canals were rinsed with 1 mL of saline (Samen, Mashahd, Iran). All root canal preparations were performed by the same operator.

After instrumentation, the access cavity was temporarily sealed with Cavit™ (3M, Germany), and the teeth were stored in saline.

Clearing and evaluation of cleaning efficacy:

Root canal clearing was performed according to Silva et al. [19] in order to reveal the three-dimensional structure of the root canal system and assess the quality of cleaning by the files.

For the clearing process, each tooth was immersed in 10% hydrochloric acid in capped glass containers for 3 days. The acid was refreshed daily until the teeth were completely decalcified. The teeth were then rinsed under

running water for 8 hours. This was followed by sequential dehydration in 70% ethanol for 16 hours (refreshed every 8 hours), 90% ethanol for 3 hours, and 100% ethanol for 3 hours (all alcohols from Merck, Darmstadt, Germany).

After dehydration, the teeth were immersed in methyl salicylate (Merck, Darmstadt, Germany) for final clearing. After clearing, assessment of the removal of Indian ink from the apical, middle, and cervical thirds of the root canals was performed under a stereomicroscope (Dewinter, Italy) at $\times 10$ magnification by one examiner who was blinded to the group allocation of the teeth, and scored as follows (Figure 1):

- **Score 0:** Completely clean canal with no ink remaining (Figure 1a)
- **Score 1:** More than 50% of the ink removed, with some remaining ink at certain points (Figure 1b)
- **Score 2:** Less than 50% of the ink removed, with visible ink lines in the canal (Figure 1c).
- **Score 3:** No ink removal (Figure 1d) [19].

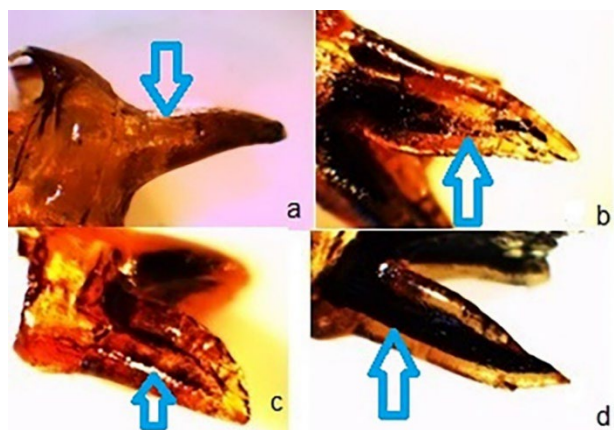


Figure 1. Scoring of the quality of root canal cleaning: (a) score 0, (b) score 1, (c) score 2, (d) score 3

Statistical analysis:

Data were analyzed using SPSS version 26. For comparison of the cleaning efficacy of the groups in different parts of the roots, the Kruskal-Wallis followed by the Mann-Whitney U test, was applied at 0.05 level of significance.

Results

Table 1 presents the frequency of different cleaning scores. Since no cleaning was performed in the control group, all teeth in this group were scored 3.

Comparison of the quality of cleaning revealed that the hand K-file group was significantly inferior to the M3 Immatural ($P=0.001$) and Neolix ($P<0.001$) groups; while no significant difference was noted in this respect between the two rotary systems ($P=0.538$; Figure 2).

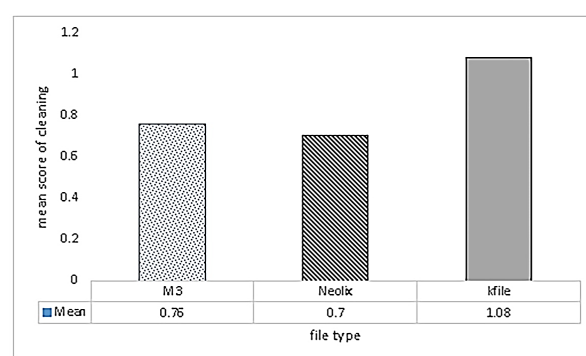


Figure 2. Comparison of the cleaning efficacy of the files in the entire root canal length of primary molars

Table 2 compares the cleaning efficacy of the three types of files in different parts of the root. Comparison of the quality of cleaning in different parts of the root canals indicated no significant difference among the three groups in the coronal third ($P=0.174$). In the middle third, the difference was significant among the three groups ($P=0.031$), and hand K-files had a significantly lower performance than Neolix ($P=0.024$) and M3 Immatural ($P=0.025$) files but the two rotary systems were not significantly different in cleaning of the middle third of the root canals ($P=0.711$). Pairwise comparisons of the files in the apical third revealed significant differences between the hand K-files and the Neolix ($P=0.004$) and M3 Immatural file ($P=0.015$); but the two rotary systems were not significantly different in cleaning of the apical third of the root canals ($P=0.611$).

Table 1. Frequency of different cleaning scores in different parts of the root canal in the three study groups

File	Score	Coronal third N (%)	Middle third N (%)	Apical third N (%)
M3 Immatural files	0	5(17%)	8(27%)	18(60%)
	1	18(60%)	21(70%)	11(37%)
	2	7(23%)	1(3%)	1(3%)
Neolix	0	4(13%)	11(37%)	20(67%)
	1	22(74%)	16(53%)	9(30%)
	2	4(13%)	3(10%)	1(3%)
K-files	0	1(3%)	5(17%)	9(30%)
	1	20(67%)	16(53%)	17(57%)
	2	9(30%)	9(30%)	4(13%)

Table 2. Comparison of the cleaning efficacy of the three types of files in different parts of the root canal

Location	File type	M3 Immatural	Neolix	K-file	P value*
Cervical third		1.07±0.64	1±0.53	1.27±0.52	0.174
Middle third		0.77±0.5	0.73±0.64	1.13±0.68	0.031
Apical third		0.43±0.57	0.37±0.56	0.83±0.65	0.007
P value*		<0.001	<0.001	0.03	

* Kruskal-Wallis test

In general, the cleaning efficacy of all three files was higher in the apical third. In the hand K-file group, the difference between the coronal and middle thirds ($P=0.475$), or middle and apical thirds ($P=0.086$) was not significant; however, the cleaning efficacy was significantly higher in the apical third than the coronal third ($P=0.008$).

The difference in cleaning efficacy was not significant between the coronal and middle thirds in the M3 Immatural and Neolix rotary files ($P=0.055$ and $P=0.072$, respectively). However, in both the M3 Immatural file and Neolix groups, cleaning in the apical third was significantly superior to that in the coronal third ($P<0.001$ for both) and middle third ($P=0.014$ and $P=0.019$, respectively).

Discussion

This study assessed the cleaning efficacy of Neolix and M3 Immatural files in comparison with hand K-files. The results showed no significant difference among the three groups in the coronal third. However, in the middle and apical thirds, both rotary file systems

demonstrated significantly superior cleaning compared to hand K-files, with no significant difference between the two rotary systems. Therefore, the null hypothesis of the study was rejected.

Pulpectomy is the treatment of choice for primary teeth with pulpal involvement. The success of pulpectomy in primary teeth relies on effective biomechanical instrumentation, using an appropriate obturating material with minimal voids, and achieving a strong, airtight seal [20]. The primary objective of pulpectomy is to establish an effective hermetic seal, which is influenced by several factors, including proper biomechanical preparation, type of obturating material, and the quality of obturation [21].

M3 Immatural is a multi-file rotary system designed for primary teeth. It has a constant taper of 4%, which decreases the risk of root perforation. In the present study, the cleaning efficacy of Neolix and M3 Immatural files in primary teeth was compared for the first time. The results indicated that the overall efficacy of both rotary systems was significantly higher than

that of hand K-files. The present results were generally in line with those of Katge et al. [17]. They showed that DXL Pro and Prime Pedo file systems, which have been specifically designed for primary teeth, were superior to hand H-files in preparation of coronal and apical thirds of the root canals; however, the difference between the two files was not significant. In the present study, rotary files showed greater cleaning efficacy than hand K-files in the apical and middle thirds. Although both studies showed greater cleaning by rotary files, compared with hand files, fewer number of files used in the present study is an advantage, since it decreases the working time.

Jeevanandan and Govindaraju [22] in a clinical trial showed that the Kedo-S rotary file, which has been designed for primary teeth, yielded a higher obturation quality, and pulpectomy with this file had a higher success rate than K files in primary molars. Their results were in agreement with the present findings although they clinically evaluated the quality of obturation and treatment success. The files used in the present study had a lower and constant taper throughout their working length compared to files used in their study, which decreases the risk of procedural errors such as perforation. Conversely, Rathi et al. [13] reported that the Pro AF Baby Gold rotary system outperformed the Kedo-S system in terms of root canal cleaning efficacy. This difference may be attributed to variations in file design, metallurgical properties, and taper, which influence the cleaning efficiency.

While the findings of this study are consistent with those of Katge et al. [17] and Jeevanandan and Govindaraju [22], they differ from those of Katge et al. [3] and Nazari Moghaddam et al. [23]. The latter studies found no significant difference in cleaning efficacy between the rotary and hand files in the middle and apical thirds of primary molar root canals, with hand files being superior in the coronal third. Nazari Moghaddam et al. [23] found no significant difference between the

efficacy of Flex Master rotary file with 4% taper and hand K-files in the middle and apical thirds of primary molar root canals. However, hand K-files were superior to rotary files only in the coronal third of the root canals. Katge et al. [3] found no significant difference between Mtwo rotary files and H-files in primary molars. This discrepancy may be attributed to several factors such as the irrigation protocol, file design, and number of instruments used, operator skills and technique, and clearing and evaluation techniques.

In the present study, only saline was used for irrigation to isolate the mechanical cleaning effect of the files, eliminating the influence of irrigants. This approach is considered a strength of the present study. In contrast, other studies used additional irrigants like sodium hypochlorite and EDTA, which may have contributed to differences in cleaning efficacy by enhancing debris removal, particularly in the coronal region [3, 23].

The current study used Neolix and M3 Immatural files, both of which have flexible structures with heat-treated properties, contributing to improved adaptation to the canal walls and debris removal. Katge et al. [3] used Mtwo rotary files, and their study involved a higher number of rotary instruments. Additionally, they used H-files instead of K-files for manual instrumentation, which may explain the observed differences.

The expertise of the operator in using hand files can influence the results. Hand K-files require a more labor-intensive technique, and their performance may vary depending on the clinician's proficiency. The discrepancy in the results of previous studies may be due to variations in the operator technique, particularly in the use of hand files, where a more rigid cross-section could enhance coronal cleaning, as observed in the study by Nazari Moghaddam et al. [23].

The present study used the tissue clearing method with Indian ink, which provides a reliable

visualization of root canal cleaning [14]. Similar methodologies were employed by Honardar et al. [24] and de Souza et al. [25], who confirmed that stereomicroscopy with the diaphanization process is a highly sensitive and cost-effective method for evaluation of cleaning efficacy. Score 3 in all canals in the control group indicated complete penetration of ink into the canals and the optimal efficacy of the clearing technique by using Indian ink. Based on the current results, the cleaning efficacy of all three file systems was higher in the apical third than the middle and coronal thirds of the root canals. Considering the fact that ink is injected into the canals by an insulin syringe through the canal orifice, the maximum concentration of ink is found in the coronal, and then the middle, and apical thirds, which may explain less cleaning of the root canals in the coronal third, as explained by Ramezanali et al. [16].

Clinical implications and limitations:

This study provides valuable insights into the mechanical cleaning efficacy of different instrumentation systems in primary molars. However, as an in vitro study, its findings should be interpreted with caution when applied to clinical settings. Factors such as irrigation dynamics, intracanal medicaments, and in vivo biological responses may influence the cleaning efficacy in actual patient scenarios. Future clinical trials are recommended to validate these results in real-world conditions.

Conclusion

The present results showed that the hand K-file group demonstrated significantly lower cleaning efficacy compared to both the M3 Immatural and Neolix rotary files, with no significant difference between the two rotary systems. Overall, all three file types performed better in the apical third of the root canal. Both M3 Immatural and Neolix rotary files showed

superior cleaning efficacy in the apical third compared to the coronal and middle thirds.

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