

Defects Appearing to the Unaided Eye vs. Magnification in a Pediatric Rotary NiTi File

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Abstract

The objective of the study was to examine with the unaided eye, the defects appearing in a pediatric rotary NiTi file following clinical use and compare the observations to examination under magnification. Ten "Pro AF – Gold Baby file number B4" were used in the study. After every clinical use (Maximum five uses), the files were examined by a single observer with the unaided eye for gross distortions. The tip and flutes on each file were then observed under a stereomicroscope at 20× magnification and the defects scored. None of the files showed any distortion when observed with the unaided eye after five clinical uses. Under stereomicroscopic examination, file tips showed no significant difference in the percentage of damaged files compared to the percentage of normal files (files without defects) whereas flutes showed a significant difference (p value 0.031) compared to the percentage of normal files after the second use.

The flutes of all the files showed some degree of defect following the third use. We concluded that examination of the Pro AF – Gold Baby file number B4 with the unaided eye is not a reliable indicator of the actual physical state of the file. At the end of five clinical uses, nine files out of ten showed "mild" and one file showed a "severe" defect under magnification. None of the files fractured after five clinical cases.

Though the results cannot be extrapolated to other pediatric rotary NiTi file systems, the study provides a strong case for the routine use of dental loupes/magnification in a pediatric endodontic practice.

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Introduction

Pulpectomy in primary teeth have been traditionally performed using hand files¹. Though rotary instruments have been widely used for endodontic treatment of permanent teeth, their use in pediatric dentistry is still an emerging practice². Kuo et al in 2006 suggested the need for exclusive pediatric rotary files with modified length, taper and tip size to effectively perform pulpectomy in primary teeth³. A lot of pediatric rotary file systems have been introduced since

then. They have begun to be positively received by practitioners owing to the reduced procedural time which in turn enhances positive child behavior^{4,5}.

Nickel Titanium (NiTi) files were introduced in 1988 with special properties of super elasticity and shape memory. They were found to be more flexible, biocompatible, corrosion-resistant, and resistant to torsional stress compared to stainless steel files⁶. Despite these advantages, a major problem with NiTi files are the unexpected instrument separations during use⁷.

Rotary endodontics using NiTi files for permanent teeth is now a long established clinical practice. But, notwithstanding their long presence, there are still no concrete recommendations from the manufacturers of various rotary NiTi systems or in literature on the possible number of cases they can be used in

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vivo. This is understandable, as each rotary NiTi file system is different and each root canal configuration is also different. The continued use or discard of a rotary NiTi file thus becomes an individual clinical decision. Though rotary NiTi files should ideally be disposed after a single use, practical economics of practice dictate otherwise. Surveys in literature have reported that practitioners used rotary NiTi files on an average five to ten times before discarding them⁸. Rotary NiTi file systems for permanent teeth have received varied recommendations in literature on the potential number of uses depending on the system and the clinical scenarios of use^{9,10}. But, these are only recommendations and the clinician, as a good clinical practice, should examine the files for distortions after every use and discard the rotary file as necessary to prevent an arbitrary number of uses.

The pediatric rotary NiTi files are intended to work in primary tooth root canal systems which have different considerations in terms of root canal morphology and the stress the rotary file will be subjected compare to permanent teeth. Many pediatric rotary NiTi file systems have flooded the market recently. Unlike permanent teeth rotary NiTi file systems, there are no indications or recommendations for clinicians on the potential number of uses for the various pediatric rotary NiTi file systems. In this scenario, the question, *"Is physical examination of the rotary file with the unaided eye after each use a reliable indicator of the actual physical state of the file?"* becomes very important.

There are dearth of clinical studies on pediatric rotary NiTi files in this area. Hence we aimed to provide initial clinical data to this question by examining a pediatric rotary NiTi file for defects after every clinical use, with the unaided eye, and compared the observations following examination under magnification.

Materials and methods

The study was approved by the Institutional Ethics Committee. Parents/guardians of the study subjects were given the complete details of the study and informed consent was obtained. The null hypothesis was that there will be no defects observed in the pediatric rotary NiTi file following multiple clinical uses. American Society of Anesthesiologists - category one children with primary maxillary anterior teeth

indicated for pulpectomy were included in the study. Frankl definitely negative children were excluded from the study.

Sample Size

Asthana et al¹¹ in their study, reported defects in 20% of the total number of rotary NiTi files following fifteen uses. Considering this, to assume clinical significance, at least 25% of the total number of files used in this study will have to show defects following five clinical uses. Based on this assumption, using the following formula for sample size calculation for one proportion, the sample size required for the study was found to be ten.

$$n = \left(\frac{Z_{\alpha/2}}{d} \right)^2 p(1-p)$$

The Pro AF- Gold Baby Files, Dentobizz, India was the pediatric rotary NiTi file system used in the study. The pulpectomy was performed by a single operator familiar with the pediatric rotary NiTi file system. Following administration of local anesthesia (Lignox, Indoco Remedies Ltd, India), a no.330 bur was used to remove carious tissue and obtain access to the root canals. A size ten hand K-file was used to explore the patency of the root canals. A size fifteen hand K-file was used to record the working length radiograph followed by preparation with the size twenty hand K -File. As per manufacturers protocol, the canal was prepared to working length with the Pro AF – Gold Baby file number B3 and finally with the Pro AF – Gold Baby file number B4 . The recommended irrigation protocols for primary teeth pulpectomies were followed¹². The canal was obturated with a calcium hydroxide iodoform paste. (Metapex, Meta Biomed Co. Ltd. Chungbuk, Korea). The Pro AF – Gold Baby file number B4 which has been recommended by the manufacturer for primary maxillary anterior teeth was used for evaluation of the defects. Baseline evaluation of the B4 rotary NiTi file was done under a stereomicroscope before its clinical use to check for any manufacturing defects. After every use, the B4 rotary NiTi files were ultrasonically cleaned, sterilized, and examined by a single observer with an unaided eye for gross distortions. The files were then observed under a stereomicroscope at 20× magnification (Stereo Zoom microscope, India mart, India). The tips and flutes were observed separately after each use. Flutes of each file was divided into five parts

for the ease of examination under the stereomicroscope and each part was scored separately. The highest score was taken to grade the flute. The scoring system recommended by Chakka et al was used to grade the file defects¹³. Each B4 rotary NiTi file was intended to be used in five cases within this study. But, if a defect was detected on the file post its clinical use indicating “severe damage” according to the scoring system¹³, then those files were to be discarded.

According to the scoring system by Chakka et al¹³. Defects on the rotary NiTi files can be divided into two groups depending on the severity as;

1. Defects indicating mild damage:
 - a. Bent instrument/tip deformation.
 - b. Stretching/straightening of twist contour.
 - c. Cutting edge changes.
2. Defects indicating severe damage.
 - a. Partial reverse twisting.
 - b. Change in length.
 - c. Fracture of instruments.

The files were then scored depending on the degree of deformation/defects from zero to eight as;

1. No changes.
2. Bent instrument.
3. Tip deformation.
4. Straightening.
5. Cutting edge changes.
6. Reverse twisting.
7. Change in length.
8. Fracture of file.

Results

All data were analyzed using Statistical Packages for Social Sciences version 20.0 (SPSS Inc., Chicago, IL, USA) .The level of significance was set to 5 %.

None of the files showed any distortion when observed with the unaided eye after each use.

The data obtained as percentage of files with defects (damaged files), after each use, at the tip and the flutes compared to the percentage of files without defects (normal files) after stereomicroscopic examination were analyzed using the chi-square test. This is presented in Table 1 and 2 respectively.

Stereomicroscopic examination of the file tips showed no significant difference in the

percentage of files showing defects compared to the percentage of normal files.

	Normal Files	Damaged Files	p value
Tip 1st use	10(100%)	0(0)	NS
Tip 2nd use	8(80%)	2(20%)	NS
Tip 3rd use	8(80%)	2(20%)	NS
Tip 4th use	6(60%)	4(40%)	NS
Tip 5th use	7(70%)	3(30%)	NS

Table 1. Percentage of defects seen at the file tip after each use.

	Normal Files	Damaged Files	p value
Flute 1st use	9(90%)	1(10%)	NS
Flute 2nd use	3(30%)	7(70%)	0.031
Flute 3rd use	0(0)	10(100%)	NS
Flute 4th use	0(0)	10(100%)	NS
Flute 5th use	0(0)	10(100%)	NS

Table 2. Percentage of defects seen on the flutes after each use.

File Number	Score of the defect
File no 1	5
File no 2	5
File no 3	5
File no 4	5
File no 5	6
File no 6	5
File no 7	5
File no 8	5
File no 9	5
File no 10	5

Table 3. The final scores of the degree of the defect seen on the file flutes.

Stereomicroscopic examination of the file flutes showed a significant difference (p value 0.031) in the percentage of files showing defects at the flutes compared to the percentage of normal files after the second use. The flutes of all files showed some degree of defect following the third use.

The final scores of the degree of the defect seen on the file flutes in each of the ten B4 rotary NiTi files after five uses are shown in Table 3.

So, at the end of five uses, all the files except one file scored five on the scale of the degree of defects at the flutes. The defect scored five (cutting edge changes) is shown in figure 1.

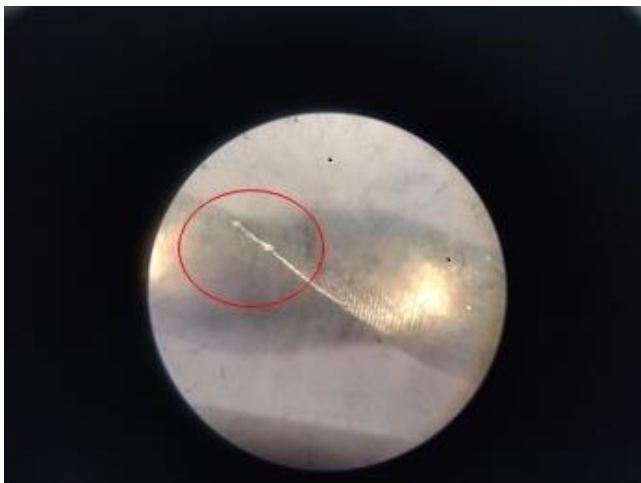


Figure 1. The defect scored five (cutting edge changes).

Discussion

Rotary NiTi files were introduced to improve the procedural time and quality of endodontic treatment compared to conventional hand instrumentation. But, the unexpected separation of rotary instruments inside the root canals remain a concern. This study examined and evaluated with the unaided eye, defects occurring in the Pro AF – Gold Baby file number B4 following its multiple in vivo use and compared the observations to examination under magnification.

Rotary NiTi files are subjected to two types of fatigue, flexural and torsional. Flexural fatigue on the file occurs during its use in curved canals when each rotation of the file inside the canal causes the instrument to undergo a cycle of tension and compression¹⁴. This is also called

cyclic fatigue. Cyclic fatigue resistance of NiTi instruments depends on various factors such as instrument size, taper, cross-sectional design, and manufacturing techniques¹⁵. Torsional fatigue is the stress, the file is subjected to during its rotation inside the canal¹⁶. In this study, the B4 file was used only in primary maxillary anterior teeth and was thus subjected to only torsional fatigue. Hence a scoring system which visually and microscopically gauged torsional fatigue was used to evaluate the defects¹³ over other scoring systems reported in literature^{14,17}.

In the current study, we examined each B4 rotary NiTi file baseline, under a stereomicroscope before its clinical use, to check for any manufacturing defects as inherent defects during manufacture can fracture the instruments even during the first use¹⁸.

After every use, the B4 rotary NiTi files were ultrasonically cleaned before sterilization. This was done to clear the dentin chips possibly incorporating into the file during use which may enhance the degree of torsional fatigue the instrument would be subjected to in its next use¹⁹.

The file tips and the flutes were examined separately under magnification after each use in this study. This was because, in torsional fatigue, the tips and flutes of the rotary instruments are subjected to different frictional forces depending on the canal size and configuration¹¹.

In a study by Chakka et al, the authors reported that rotary NiTi files showed defects following their use in vivo when examined with the unaided eye¹³. In the same context, Asthana G and coworkers¹¹ also reported no statistical significance when files were observed with the unaided eye or the stereomicroscope (20 \times). But results from our study are contradictory to these findings. We found no changes on visual examination after each use or at the end of five cases even though defects along the flutes were seen under the stereomicroscope after the second use. Our findings were in sync with Pruett et al.²⁰, who in their study suggested that visual examination is not a reliable method for evaluating used Ni-Ti files. Sattapan et al.¹⁸ also suggested a magnification of at least 10 \times to examine the files following clinical use, reasoning that the unaided eye may not detect minor defects. Defects detected by magnification can provide a caution to the clinicians against the further use of the rotary file.

The study by Sattapan et al.¹⁸ also stated that files subjected to torsional fatigue showed definite signs of deterioration before fracture, while files subjected to flexural fatigue did not show any defects prior to their eventual fracture. In this study, the B4 files were subjected to torsional fatigue and the flutes of all files showed a degree of defect following the third use.

It was noted that there was a significant difference in the percentage of files showing some degree of defect at the flutes compared to the normal files after the second use. None of these defects scored above five i.e. "cutting edge changes" when examined under magnification after each use. This indicated a "mild" defect according to the scoring system used. At the end of five cases, nine files indicated a "mild" defect signifying "cutting edge changes". Only one file showed reverse twisting after the last use indicating a "severe" defect. None of the files scored eight (fracture of file) after use in five cases.

An important merit of this study was that it provided data for defects appearing to the unaided eye following multiple clinical uses of a pediatric rotary NiTi file. Though the results cannot be extrapolated to other pediatric rotary NiTi file systems, the study provides a strong case for the routine use of dental loupes/magnification in a pediatric endodontic practice.

The study was limited considering the defects in the Pro AF – Gold Baby file number B4 were evaluated to a maximum of five clinical uses in primary upper anterior teeth. Further data on the number of uses, when defects start appearing to the unaided eye will be possible only through multiple uses in an in vitro study. The cutting efficiency of the file could also be affected with the increasing number of uses and this is also a relevant avenue for future research.

Conclusions

Within the limitations of this study on the Pro AF – Gold Baby file number B4,

1. None of the files showed any defects or any sign of distortion when observed with the unaided eye after each use or at the end of five clinical uses. Unaided eye examination is hence not a reliable indicator of the actual physical state of the file.

2. There was no significant difference in the percentage of files showing defects at the tips compared to the percentage of normal files at the end of five uses.
3. There was a significant difference in the percentage of files showing defects at the flutes compared to the percentage of normal files after the second use.
4. At the end of five clinical uses, nine files out of ten indicated "mild" defects showing "cutting edge changes".
5. None of the files fractured after five clinical cases.

Declaration of Interest

There is no conflict of interest associated with the study.

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