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Evaluation of the Cyclic Fatigue Resistance and Mode of Failure of XP-4D Rotary Files at Different Rotational Speeds and File Sizes: An In-Vitro Study

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We use this protocol and it's working

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Keywords: root canal treatment, instrument separation during root canal treatment, mechanical stress on the file, evaluation of the cyclic fatigue resistance, cyclic fatigue resistance, taper file, cyclic fatigue, apical third

Abstract

Repeated clinical use, sterilization, and exposure to irrigants can further deteriorate the surface and reduce fatigue resistance (Hamdy et al., 2023). When large or wide-taper files are used at high rotational speeds, the mechanical stress on the file increases considerably. If this is combined with reduced flexibility or compromised surface integrity, the chances of early failure rise significantly. Instrument separation during root canal treatment not only complicates access to the apical third but can also affect cleaning and shaping quality, leading to poorer treatment outcomes. Understanding how cyclic fatigue, failure pattern, interact under different operating conditions is therefore crucial for improving file design, alloy treatment, and safe clinical use.

Guidelines

****Calculated Sample Size:** A power analysis was conducted to ensure adequate power to detect a significant effect of the tested variables on cyclic fatigue resistance. Using an alpha (α) level of (0.05), a beta (β) level of (0.2) corresponding to (80%) statistical power and effect size (Cohen's f) of (7.52) derived from the results of a previous study (Adiguzel, Isken, 26 Pamukcu, 2018); the total required sample size (n) was found to be (12) samples. Sample size was increased to enhance robustness of statistical testing to be (60) samples (i.e., 20 samples per group and 10 samples per subgroup). The sample size was calculated using G*Power version 3.1.9.7. (Faul, Franz, et al., 2007)

****Eligibility Criteria:****

Inclusion Criteria:

- New, unused XP-4D rotary files (25 mm length)
- Files free from manufacturing defects

Exclusion Criteria:

- Files with visible deformation or surface irregularities before testing
- Files used or sterilized prior to the experiment

****Grouping of Samples:****

Group	File Type	Designation	Speed (rpm)	n
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Group 1a	XP-4D Starter (20/.03v)	S-Files	1000	10
Group 1b	XP-4D Starter (20/.03v)	S-Files	3000	10
Group 2a	XP-4D Standard (30/.03v)	ST-Files	1000	10
Group 2b	XP-4D Standard (30/.03v)	ST-Files	3000	10
Group 3a	XP-4D Medium (40/.03v)	M-Files	1000	10
Group 3b	XP-4D Medium (40/.03v)	M-Files	3000	10

Materials

A total of 60 XP-4D endodontic files (Starter, Standard, and Medium; length 25 mm) will be utilized in this study. All instruments will be new and unused and will undergo a thorough inspection under a dental operating microscope at 25× magnification to identify any manufacturing defects or surface imperfections. Instruments exhibiting any such defects will be excluded and replaced to maintain consistency.

Introduction

- 1 Root canal instrumentation remains one of the most important yet challenging steps in endodontic treatment. Nickel-titanium (NiTi) rotary files have become a cornerstone in modern endodontics because their super-elasticity and shape-memory properties allow them to navigate curved canals much more efficiently than traditional stainless-steel instruments (Walia et al., 1988; Schäfer & Dammaschke, 2019). Still, despite the continuous improvements in alloy technology, file design, and instrumentation techniques, the unexpected separation of NiTi rotary files inside curved canals is a persistent clinical concern (Camargo et al., 2021). Among the two main causes of file failure torsional overload and cyclic fatigue cyclic fatigue is the one most frequently encountered. It occurs when the file is repeatedly bent inside a curved canal, which subjects it to alternating compression and tension forces until micro-damage accumulates and fracture takes place (Tanomaru-Filho et al., 2018; Berutti et al., 2020; Ribeiro Camargo et al., 2020). The file's fatigue resistance is known to depend on several factors, including the canal curvature, instrument design, and operating parameters such as rotational speed (Loios et al., 2022; Pereira et al., 2023). Repeated clinical use, sterilization, and exposure to irrigants can further deteriorate the surface and reduce fatigue resistance (Hamdy et al., 2023). When large or wide-taper files are used at high rotational speeds, the mechanical stress on the file increases considerably. If this is combined with reduced flexibility or compromised surface integrity, the chances of early failure rise significantly. Instrument separation during root canal treatment not only complicates access to the apical third but can also affect cleaning and shaping quality, leading to poorer treatment outcomes. Understanding how cyclic fatigue, failure pattern, interact under different operating conditions is therefore crucial for improving file design, alloy treatment, and safe clinical use.
- 2 The XP-4D file system offers 3 sizes (Starter, Standard, Medium,) with adaptive alloy (MaxWire) design. While manufacturer guidelines recommend operation at 1,000 rpm and torque limit of 1 N·cm, many clinicians may use higher speeds (e.g. 3,000 rpm) for efficiency. Yet, it is unknown how increased speed combined with different file sizes affects fatigue life and mode of failure for XP-4D. Understanding these effects could help optimize safe usage, extend file longevity, and reduce risk of file separation. This study aims to evaluate and compare the Cyclic Fatigue Resistance and Mode of Failure of XP-4D rotary files in three different sizes (Starter, Standard, Medium) when operated at two different rotational speeds (1000 rpm and 3000 rpm).

Choice of comparative variables

- 3 A comparison of the cyclic fatigue resistance and mode of failure of XP-4D rotary files at two rotational speeds (1000 rpm and 3000 rpm) and three file sizes (Starter, Standard, and Medium) will clarify how operating speed and instrument size influence their

mechanical behavior. These variables are clinically relevant because both rotational speed and file size affect the stresses generated during canal preparation, which may alter fatigue resistance and fracture patterns under simulated clinical conditions.

Aim of the Study

- 4 To evaluate the effect of different rotational speeds and file sizes on the cyclic fatigue resistance, and mode of failure of XP-4D rotary files in an in-vitro setting. The findings will help determine the optimal combination of speed and file size to enhance the durability, safety, and clinical performance of these instruments.

Research Question

- 5 How do variations in rotational speed (1000 rpm vs. 3000 rpm) and file size (Starter, Standard, and Medium) affect the cyclic fatigue resistance, and mode of failure of XP-4D rotary files in an in-vitro setting?

Research question Using PICO

- 6

Population(P): XP 4D files (Starter, Standard, Medium)

Intervention (I):

 - I1: XP-4D Starter files operated at 1000 rpm
 - I2: XP-4D Starter files operated at 3000 rpm
 - I3: XP-4D Standard files operated at 3000 rpm
 - I4: XP-4D Medium files operated at 1000 rpm
 - I5: XP-4D Medium files operated at 3000 rpm

Comparison (C):

 - XP-4D Standard files operated at 1000 rpm

Outcomes(O):

 - O1: cyclic fatigue resistance
 - O2: Structural change and mode of failure

Outcome

- 7

Prioritization of Outcome

Primary outcome: Cyclic Fatigue Resistance

Method of Measurement: Cyclic fatigue test in stainless-steel artificial canal (60°)

Unit of Measurement: Cycles to Failure (NCF)

Secondary outcome: Evaluation of Structural Change and Mode of Failure

Method of Measurement: Scanning Electron Microscopy (SEM)

Unit of Measurement: Qualitative (observational)

Hypothesis

- 8 Null Hypothesis: There is no significant difference in the cyclic fatigue resistance or mode of failure of XP-4D rotary files when operated at different rotational speeds and file sizes.

Materials and Methods

- 9 A power analysis was conducted to ensure adequate power to detect a significant effect of the tested variables on cyclic fatigue resistance. Using an alpha (α) level of (0.05), a beta (β) level of (0.2) corresponding to (80%) statistical power and effect size (Cohen's f) of (7.52) derived from the results of a previous study (Adiguzel, Isken, & Pamukcu, 2018); the total required sample size (n) was found to be (12) samples. Sample size was increased to enhance robustness of statistical testing to be (60) samples (i.e., 20 samples per group and 10 samples per subgroup). The sample size was calculated using G*Power version 3.1.9.7. (Faul, Franz, et al., 2007)
- 10 A total of 60 XP-4D endodontic files (Starter, Standard, and Medium; length 25 mm) will be utilized in this study. All instruments will be new and unused and will undergo a thorough inspection under a dental operating microscope at 25 $\times$ magnification to identify any manufacturing defects or surface imperfections. Instruments exhibiting any such defects will be excluded and replaced to maintain consistency.
- 11 Inclusion Criteria:
New, unused XP-4D rotary files (25 mm length)
Files free from manufacturing defects
- 12 Exclusion Criteria:
Files with visible deformation or surface irregularities before testing
Files used or sterilized prior to the experiment
- 13 Grouping of Samples:
Group 1a: XP-4D Starter (20/.03v) S-Files, 1000 rpm, $n=10$
Group 1b: XP-4D Starter (20/.03v) S-Files, 3000 rpm, $n=10$
Group 2a: XP-4D Standard (30/.03v) ST-Files, 1000 rpm, $n=10$
Group 2b: XP-4D Standard (30/.03v) ST-Files, 3000 rpm, $n=10$
Group 3a: XP-4D Medium (40/.03v) M-Files, 1000 rpm, $n=10$
Group 3b: XP-4D Medium (40/.03v) M-Files, 3000 rpm, $n=10$

Intervention for each group

- 14 Cyclic Fatigue Resistance Testing
- 15 Preparation and Calibration
Cyclic fatigue testing will be performed using a custom-made stainless-steel artificial canal designed to simulate clinical conditions. The canal will have a 60° curvature angle

and a 3 mm radius of curvature, with an internal diameter of 1.5 mm, standardized and verified (Azim et al., 2018).

A water bath maintained at 37 ± 1 °C will be used to simulate body temperature, and all testing will be performed with the files submerged to mimic intraoral conditions (de Vasconcelos et al., 2016).

16 Experimental Procedure

The XP-4D files will be randomly assigned into six groups based on file type and rotational speed:

Group 1a (n=10): Starter files at 1000 rpm

Group 1b (n=10): Starter files at 3000 rpm

Group 2a (n=10): Standard files at 1000 rpm

Group 2b (n=10): Standard files at 3000 rpm

Group 3a (n=10): Medium files at 1000 rpm

Group 3b (n=10): Medium files at 3000 rpm

Each instrument will be rotated inside its assigned stainless-steel canal using a Rooter X3000 endomotor (FKG Dentaire, Switzerland) at the designated rotational speed and torque of 1 N·cm, until visible fracture occurs. This setup simulates the flexural stresses encountered during root canal instrumentation.

A secondary operator, blinded to the group allocation, will record the time to fracture for each file using a stopwatch (Faus Matoses et al., 2022).

17 The number of cycles to fracture (NCF) will be calculated using the following formula: (Adiguzel et al., 2018)

Step 1: Convert time from seconds to minutes:

Time (minutes) = $\left(\frac{\text{Time (seconds)}}{60} \right)$

Step 2: Calculate NCF:

NCF = Time to fracture (in minutes) × Speed of rotation (rpm)

18 SEM Analysis of Fractured Surfaces

After cyclic fatigue testing, the fractured XP-4D instruments will be examined using scanning electron microscopy (SEM) to determine whether failure occurred by cyclic fatigue, torsional overload, or a mixed mode. (Elnaghy & Elsaka, 2018)

19 Who Was Involved in the Intervention:

The primary investigator will oversee the experiment, ensuring that all procedures are followed correctly and the equipment is set up appropriately for each test.

A secondary operator will handle the timing of the instruments during the testing process, ensuring that the time to fracture is recorded accurately.

The lab technician will be responsible for setting up the apparatus, ensuring the water bath is at the correct temperature, and maintaining the artificial canal setup.

20 Intervention Timeline:

The testing procedure for each instrument will involve setting up the apparatus and running each test until failure occurs. The expected duration for each test will depend on



the time to failure, which will be recorded.

After the testing is completed, the instruments will be properly sterilized, and any remaining instruments or equipment will be disposed of according to university protocols.

Protocol references

Walia et al., 1988; Schäfer 26 Dammaschke, 2019; Camargo et al., 2021; Tanomaru-Filho et al., 2018; Berutti et al., 2020; Ribeiro Camargo et al., 2020; Loios et al., 2022; Pereira et al., 2023; Hamdy et al., 2023; Elnaghy 6 Elsaka, 2018.