

Fracture resistance of endodontically treated teeth using three novel nickel-titanium file systems

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Abstract

Objective: The present study compared the fracture resistance of mandibular premolars instrumented using ProTaper NEXT, TruNatomy, and Neohybrid nickel-titanium (NiTi) file systems.

Methods: In this in vitro study, 56 extracted mandibular premolars were decoronated to obtain standardized root lengths of 16 mm. The samples were divided into four groups (n=14): Group I, no instrumentation (control); Group II, instrumentation with ProTaper NEXT files (Dentsply Maillefer); Group III, instrumentation with TruNatomy files (Dentsply Sirona); and Group IV, instrumentation with Neohybrid files (Orikam Healthcare). Following instrumentation, the samples were obturated using the cold lateral compaction technique with gutta-percha and AH Plus sealer. After one week, a vertical load was applied using a universal testing machine. The maximum load required to cause a root fracture was recorded in Newtons (N). Data were analyzed using one-way ANOVA and Tukey's post-hoc test at the significance level of $P < 0.05$.

Results: The control group exhibited the highest mean fracture resistance (774.31 ± 140.82 N), followed by TruNatomy (732.78 ± 128.24 N), Neohybrid (679.65 ± 185.78 N), and ProTaper NEXT (606.77 ± 144.85 N) groups. ANOVA revealed a statistically significant difference among the groups ($P = 0.031$). ProTaper NEXT showed significantly lower fracture resistance than the control group ($P < 0.05$). The TruNatomy and Neohybrid groups showed no statistically significant differences compared with either the control group or the ProTaper NEXT group ($P > 0.05$).

Conclusions: Within the limitations of this in vitro study, all file systems reduced root fracture resistance; however, only ProTaper NEXT caused a significant reduction compared with the control group.

Keywords: Dental instruments, Endodontically treated teeth, Fracture resistance, Nickel-titanium alloy, Root canal preparation, Root canal therapy

Introduction

Endodontic therapy involves the removal of infected pulp, followed by chemomechanical preparation and three-dimensional obturation of the root canal space (1). Endodontically treated teeth are structurally weaker and more prone to fracture than vital teeth. This reduced strength is primarily attributed to the loss of coronal and radicular dentin caused by caries, trauma, previous restorations, and endodontic procedures, which decreases the remaining tooth structure and alters stress distribution within the tooth (2, 3). In addition, several procedural factors during and after root canal treatment may further compromise tooth

strength, including access cavity preparation, overinstrumentation during root canal preparation, irrigation procedures, excessive pressure during obturation, preparation of intraradicular post space, and dentin dehydration (4, 5).

Effective root canal treatment requires chemomechanical cleaning, in which irrigation and mechanical preparation remove infected tissues, microorganisms, and debris and create a canal form suitable for obturation (1, 6). Endodontic rotary files facilitate canal shaping but may weaken dentin integrity and increase the risk of fracture (7). Vertical root fracture (VRF) is a common complication during or after endodontic treatment (7). VRF has a prevalence of 10.9–20% among endodontically treated teeth, which makes it the second cause of tooth loss following periodontal diseases (8, 9).

Instruments used for root canal shaping have evolved from conventional 2% taper hand instruments to modern rotary and reciprocating instruments with

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tapers ranging from 4% to 9%. Increased taper may result in more aggressive removal of radicular dentin and reduced fracture strength of endodontically treated teeth (10, 11). Preservation of tooth structure, particularly pericervical dentin, plays an important role in the fracture resistance and long-term prognosis of endodontically treated teeth (12). Therefore, conservative file systems have been designed to maintain the original canal anatomy while minimizing unnecessary dentin removal (6, 13).

ProTaper NEXT (Dentsply Maillefer, Ballaigues, Switzerland) is a rotary NiTi file system manufactured from M-Wire alloy and is commonly used as a reference system when compared with more conservative rotary systems. It has an off-centered rectangular cross-section and a variable taper design. The off-centered design produces an eccentric rotary motion, which enhances debris removal and reduces file engagement with the canal walls, thereby decreasing the risk of taper lock.

The system consists of five shaping files (X1–X5) with increasing tip sizes and tapers, allowing progressive enlargement of the root canal according to clinical requirements. In addition, the SX file may be used as an auxiliary instrument for coronal flaring and orifice enlargement, facilitating straight-line access to the canal. Although the variable taper design provides efficient cutting and shaping, the larger tapers used during preparation may result in greater dentin removal, particularly in the coronal and middle thirds of the canal, and increase the risk of canal transportation in severely curved/narrow canals compared with minimally invasive instrumentation systems (14, 15).

TruNatomy (Dentsply Sirona, Ballaigues, Switzerland) is considered a minimally invasive rotary system. It is manufactured from a specially heat-treated 0.8-mm NiTi wire, which provides enhanced flexibility and resistance to cyclic fatigue compared with conventional rotary instruments. The TruNatomy system includes an Orifice Modifier, a Glider file, and shaping files (Small, Prime, and Medium), all of which feature a slim design and regressive taper. The reduced taper and smaller maximum flute diameter decrease dentin removal, particularly in the coronal and pericervical regions, thereby preserving tooth structure and maintaining the original canal anatomy. These design features allow conservative canal enlargement while facilitating adequate cleaning and shaping of the root canal system (16, 17).

NeoHybrid (Orikam Healthcare Pvt. Ltd., Haryana, India) is a rotary NiTi instrumentation system manufactured from a thermally treated controlled-

memory alloy. This heat-treated alloy enhances flexibility and cyclic fatigue resistance compared with conventional NiTi files. Similar to ProTaper NEXT, NeoHybrid features an off-centered rectangular cross-section that generates an eccentric rotary motion, promoting debris removal while reducing screw-in forces and taper lock during instrumentation. The NeoHybrid system comprises a glide path file and a series of shaping files with varying tip sizes and tapers to accommodate different canal anatomies. Its enhanced flexibility and eccentric rotary motion may facilitate maintenance of the original canal anatomy and reduce canal transportation, particularly in curved canals (17).

Previous studies have evaluated the fracture resistance of endodontically treated teeth following instrumentation with conventional rotary systems, reciprocating systems, and, more recently, minimally invasive rotary systems (10, 18). However, evidence directly comparing minimally invasive heat-treated and controlled-memory rotary NiTi systems under standardized mechanical testing conditions remains limited. Therefore, the present study aimed to evaluate the fracture resistance of mandibular premolars instrumented with ProTaper NEXT, TruNatomy, and NeoHybrid rotary NiTi systems compared with an uninstrumented control group.

Materials and methods

Study design

The study protocol was approved by the Institutional ethics committee of Vishnu Dental College and Hospital (code: IECVDC/2021/PG01/CE/IVT/23).

A total of 56 freshly extracted human single-rooted mandibular premolars, extracted for orthodontic purposes, were collected. Teeth with previous endodontic treatment, fractures, pathological root resorption, or calcifications were excluded. The presence of a single root and canal in each tooth was confirmed radiographically. The extracted teeth were cleaned of soft tissue debris and disinfected by immersion in 0.1% thymol solution for 24 hours. The specimens were then rinsed with distilled water and stored in 0.9% saline to prevent dehydration. All samples were standardized to a length of 16 mm by decoronation using a double-faced diamond disc (KG Sorensen, Barueri, São Paulo, Brazil).

Sample size calculation

The sample size was calculated using G*Power software (version 3.1; Heinrich Heine University, Düsseldorf, Germany) based on the fracture resistance

data reported by Pawar et al (10). An effect size of 0.46, a statistical power of 80%, and a significance level (α) of 5% indicated that a minimum total sample size of 56 specimens was required.

Endodontic procedure

To ensure the use of standardized root dimensions, the buccolingual (BL) and mesiodistal (MD) dimensions of the roots were measured with a digital caliper. The BL and MD diameters were then multiplied, and this product (BL \times MD) was used as an index of root size. Root weight was also measured using a sensitive precision balance. Samples were evenly distributed among the four groups ($n = 14$) based on root weight and size. One-way ANOVA confirmed baseline homogeneity among the groups, with no significant differences in root weight ($P = 0.915$) or BL \times MD ($P = 0.998$) values (15). The study groups were as follows:

- Group I (Control, uninstrumented): No instrumentation or obturation was performed in the control group.
- Group II (conventional multi-file system, ProTaper NEXT): The canals were instrumented using ProTaper NEXT rotary files (Dentsply Maillefer, Ballaigues, Switzerland) at 300 rpm and 4 N-cm torque. The SX file was used as an orifice opener, followed by X1 (17/.04) and X2 (25/.06) files, according to the manufacturer's instructions, until the working length was reached. Instrumentation was performed using a gentle brushing motion.
- Group III (minimally invasive rotary system, TruNatomy): The canals were instrumented using TruNatomy rotary files (Dentsply Sirona, Ballaigues, Switzerland) at 500 rpm and 1.5 N-cm torque. The TruNatomy Orifice Modifier (20/.08) and Glider (17/.02) were used initially, followed by the Prime shaping file (26/.04), according to the manufacturer's instructions, until the working length was reached. Instrumentation was performed using a gentle passive in-and-out pecking motion with light apical pressure.
- Group IV (controlled-memory rotary system, NeoHybrid): The canals were instrumented using NeoHybrid rotary files (Orikam Healthcare Pvt. Ltd., Haryana, India) at 350 rpm and 1.5 N-cm torque. The NeoHybrid glide path file (17/.03) was used first, followed by the 20/.04 and 25/.04 shaping files, according to the manufacturer's instructions, until the working length was reached. Instrumentation was performed using a gentle brushing motion with light apical pressure.

Working length was defined as the distance from a coronal reference point to the point where canal preparation and obturation should terminate. It was determined by inserting a size 15 K-file (Mani, Tochigi, Japan) into the canal until the tip was visible at the apical foramen, and then subtracting 0.5 mm from this length.

During instrumentation, irrigation was performed with 2 mL of 3% sodium hypochlorite solution (Parcan; Septodont Healthcare Pvt. Ltd., Mumbai, India), delivered using a 27-gauge needle after each instrument cycle. Final irrigation was performed with 5 mL of 17% EDTA solution (Dent Wash; Prime Dental Pvt. Ltd., Ankleshwar, India), followed by 5 mL of 3% sodium hypochlorite and a final rinse with 5 mL of 0.9% normal saline. The canals were then dried using absorbent paper points.

Root canal instrumentation was performed using an endodontic motor (E-Connect S; Eighteeth, Changzhou, Jiangsu, China) according to the torque and speed settings recommended by the respective manufacturers. All procedures were performed by a single operator under standardized conditions. The duration of instrumentation was not standardized to a fixed time interval but was based on completion of the preparation protocol according to the manufacturer's instructions. However, all groups were standardized in terms of working length, instrument sequence, and irrigation protocol.

After instrumentation in Groups II–IV, master gutta-percha cones were selected and confirmed radiographically. The dentinal walls were coated with AH Plus sealer (Dentsply DeTrey, Konstanz, Germany) using a lentulo spiral. The master cone was seated, and lateral condensation was performed using a #25 NiTi finger spreader, followed by the insertion of accessory cones. Excess gutta-percha was removed using a hot hand plugger, and the canal orifices were sealed with Cavit-G (3M ESPE, Neuss, Germany). All samples were incubated for one week at 37°C and 100% humidity to allow complete setting of the sealer.

Mechanical testing

Root surfaces were wrapped in aluminium foil to simulate the periodontal ligament (PDL). Each root was placed vertically in a mold containing self-cure acrylic resin (DPI-RR; Dental Products of India, Mumbai, India), with the coronal 9 mm of the root left exposed above the resin. After the acrylic resin had set, the roots were removed, the foil was discarded, and light-body silicone (Reprosil; Dentsply Caulk, Milford, DE, USA) was injected

into the acrylic resin sockets. The roots were then repositioned, and excess silicone was removed.

Samples were subjected to fracture testing using a universal testing machine (Model 7200; Dak System Inc., Mumbai, India). Each acrylic block was placed on the lower plate of the machine (Figure 1). A conical steel rod with a diameter of 3 mm applied a vertical load at 1 mm/min to the canal orifice until fracture occurred. The maximum fracture load was recorded in Newtons (N).

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY, USA). Data normality was assessed using the Shapiro–Wilk test, which showed no significant deviation from normality in any group ($P > 0.05$). One-way analysis of variance (ANOVA) was used to compare mean fracture resistance among the groups. Intergroup differences were evaluated using Tukey's post hoc test. A significance level of $P < 0.05$ was used for all analyses.

Results

Table 1 presents the mean and standard deviation (SD) of fracture resistance values (N) in the study groups. The control group showed the highest mean fracture resistance (774.31 ± 140.82 N). Among the instrumented groups, Group III (TruNatomy) showed the highest mean fracture resistance (732.78 ± 128.24 N), followed by Group IV (NeoHybrid; 679.65 ± 185.78 N) and Group II (ProTaper NEXT; 606.77 ± 144.85 N). One-way ANOVA revealed a statistically significant difference in fracture resistance among the groups ($P = 0.031$).

The mean fracture resistance was significantly higher in the control group than in the ProTaper NEXT group ($P < 0.05$). However, no statistically significant differences were observed between the control group and the TruNatomy or NeoHybrid groups ($P > 0.05$). Similarly, no statistically significant differences were found among

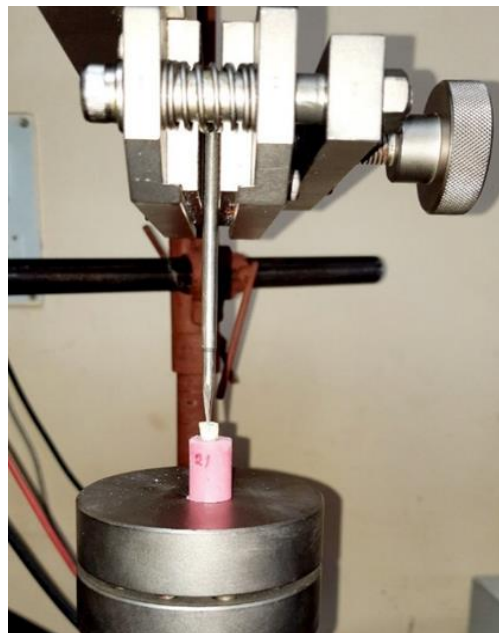


Figure 1. A sample mounted on the universal testing machine for fracture resistance measurement

the three instrumented groups: ProTaper NEXT, TruNatomy, and NeoHybrid ($P > 0.05$).

Discussion

The present study evaluated the fracture resistance of endodontically treated mandibular premolars instrumented with three NiTi rotary file systems, ProTaper NEXT, TruNatomy, and NeoHybrid, and compared them with an uninstrumented control group. Sample standardization is a critical factor in mechanical testing, as variations in root dimensions, extraction time, and storage conditions can significantly influence study outcomes (19). In the present study, efforts were made to select morphologically similar teeth and to balance the roots among the groups based on buccolingual and mesiodistal diameters and root weight, thereby minimizing dimensional variability as a confounding factor.

Table 1. Mean and standard deviation (SD) of fracture resistance (N) in the study groups

| Groups | Definition | Mean \pm SD (N)* |
|---------|--------------------------|---------------------------|
| Group 1 | Control (Uninstrumented) | 774.31 ± 140.82^a |
| Group 2 | ProTaper Next | 606.77 ± 144.85^b |
| Group 3 | TruNatomy | $732.78 \pm 128.24^{a,b}$ |
| Group 4 | Neohybrid | $679.65 \pm 185.78^{a,b}$ |
| P-value | | 0.031 |

* Different superscript letters indicate a significant difference according to Tukey's post-hoc test ($P < 0.05$).

The results of this study showed that the control group had the highest fracture resistance. Among the instrumented groups, TruNatomy exhibited the highest mean fracture resistance, followed by NeoHybrid and ProTaper NEXT. ProTaper NEXT showed significantly lower fracture resistance than the control group, whereas TruNatomy and NeoHybrid did not differ significantly from either the control group or the ProTaper NEXT group.

The higher fracture resistance of the uninstrumented control group may be explained by the preservation of radicular dentin. In this group, no canal preparation was performed; therefore, dentin removal and instrumentation-related stresses were avoided. In contrast, canal preparation in the experimental groups may have reduced the remaining dentin thickness and increased stress concentration within the root. This may explain the lower mean fracture resistance observed in the instrumented groups.

ProTaper NEXT demonstrated the lowest mean fracture resistance among the instrumented groups. Although the difference among the instrumented groups was not significant, ProTaper NEXT showed a significantly lower fracture resistance value than the control group. In this group, canal preparation was completed using the X2 file (size 25/.06). The lower fracture resistance observed in the ProTaper NEXT group may be attributed to the greater final taper of the X2 file, which could increase dentin removal and stress concentration within the root structure during canal preparation (20). In addition, ProTaper NEXT differs from TruNatomy and NeoHybrid in alloy composition. ProTaper NEXT is manufactured from M-Wire alloy, whereas TruNatomy utilizes a specially heat-treated NiTi wire and NeoHybrid employs a thermally treated controlled-memory alloy. The greater flexibility of heat-treated and controlled-memory instruments may allow better preservation of the original canal anatomy and reduce unnecessary dentin removal during preparation.

TruNatomy demonstrated the highest mean fracture resistance among the instrumented groups, although the differences were not statistically significant. The TruNatomy system has a conservative taper design and is manufactured from heat-treated NiTi wire with a small diameter of 0.8 mm, which may contribute to the preservation of radicular dentin. The Prime shaping file, which is commonly used as the primary preparation instrument, has an apical size of 26 and a 0.04 taper. This taper design may reduce dentin removal and help preserve structural integrity while providing adequate canal shaping (21). In addition, the improved flexibility

and reduced file-induced stress associated with the heat-treated alloy may help reduce stress concentration within root dentin (22).

NeoHybrid also displayed a higher mean fracture resistance than ProTaper NEXT, although no statistically significant difference was observed among the instrumented groups. In the present study, canal preparation in the NeoHybrid group was performed using the 20/.04 and 25/.04 shaping files. The NeoHybrid system is manufactured from controlled thermal activation wire and has an off-centered rectangular cross-section designed to improve flexibility and reduce canal wall engagement. This design may decrease file binding within the canal and limit apically directed pulling forces during instrumentation, thereby helping to preserve radicular dentin (23). In addition, the lower torque settings used with this system may have contributed to the higher fracture resistance observed in this group.

Although fracture resistance did not differ significantly among the instrumented groups, the higher mean values observed in the TruNatomy and NeoHybrid groups compared with the ProTaper NEXT group may be partly explained by the use of 0.04-taper shaping files, as opposed to the 0.06 final taper of the ProTaper NEXT X2 file. Fracture resistance after canal preparation may also be influenced by other instrument-related factors, including alloy treatment, cross-sectional design, flexibility, shaping motion, and the amount of remaining radicular dentin.

The findings of this study are consistent with previous studies reporting that conservative shaping may help preserve fracture resistance. Sabeti et al. (24) reported that rotary instruments with a 25/.04 taper showed greater fracture resistance than instruments with 25/.06 or 25/.08 tapers. Similarly, Doğanay Yıldız et al. (25) emphasized that greater taper and apical preparation size may reduce the fracture resistance of roots. Pawar et al. (10) also reported improved fracture resistance with rotary systems associated with conservative shaping compared with systems involving greater dentin removal.

The outcomes of this study reveal that root canal instrumentation may reduce fracture resistance through dentin removal, stress generation, or dentinal microcrack formation during canal preparation. A greater taper may further weaken radicular dentin by reducing the remaining dentin thickness. Previous studies have also emphasized that the taper of an endodontic instrument should provide adequate

cleaning and obturation while avoiding unnecessary dentin removal (26, 27).

This study has some limitations. Static vertical loading does not fully replicate the complex multidirectional and cyclic forces present in the oral environment. Another limitation is that microcrack formation was not assessed before or after instrumentation. Future studies on endodontically treated teeth should include cyclic loading protocols, finite element analysis, and microscopic evaluation of microcracks before and after instrumentation.

Conclusions

Within the limitations of this *in vitro* study, it can be concluded that instrumentation with the tested rotary NiTi file systems, including ProTaper NEXT, TruNatomy, and NeoHybrid, reduced the mean fracture resistance of mandibular premolar roots. However, this reduction was statistically significant only in the ProTaper NEXT group. The lower fracture resistance observed with ProTaper NEXT may be related to its greater final taper and the associated increase in dentin removal. TruNatomy and NeoHybrid showed no statistically significant difference compared with either the control group or the ProTaper NEXT group.

Acknowledgments

Not applicable.

Conflict of interest

The authors declare no conflict of interest.

Author contributions

D.B.P. contributed to the study's conceptualization, design, and formal analysis. S.R.K.M. contributed to study design, investigation, and visualization. G.S. and J.B.M. contributed to data curation and preparation of the original draft manuscript. M.V.K. contributed to data curation, software, supervision, and manuscript review and editing. P.D. contributed to data curation and manuscript editing. All authors critically reviewed the manuscript and approved the final version for publication.

Ethical considerations

The study protocol was approved by the Institutional ethics committee of Vishnu Dental College and Hospital (code: IECVDC/2021/PG01/CE/IVT/23).

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