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Review Article

Comparative evaluation of cyclic fatigue resistance of trunatomy rotary endodontic file versus different rotary endodontic file system: A systematic review and meta-analysis

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Abstract

The performance of endodontic instruments is critically influenced by their ability to withstand cyclic fatigue, especially during root canal treatment in curved canals. This study investigates the cyclic fatigue resistance of the TruNatomy file system, a new generation of nickel-titanium (NiTi) endodontic instruments with different rotary file systems. The objective of this study was to conduct a systematic review of the literature and meta-analysis to evaluate and compare cyclic fatigue resistance of TruNatomy rotary endodontic file versus different rotary endodontic file systems. Research question was formulated based on the population, intervention, comparison, and outcomes strategy. A comprehensive electronic literature search was conducted through Cochrane, PubMed, and Google scholar using MeSH words, text words, and Boolean operators, independently by two reviewers. Based on the specified inclusion and exclusion criteria, the selected articles were subjected to quality assessment and the risk of bias (ROB) was evaluated. Risk of Bias assessment for invitro studies done in accordance with the Quality Assessment Tool for in Vitro Studies (QUIN Tool). Initially, 82 studies recovered, 8 articles were selected for systematic review and 8 articles could be included in the Meta-analysis. Among all the file systems - The number of cycles required to fail was significantly greater in the TruNatomy group than in the other file systems with standardized mean difference of 1.343 (95% CI = 0.645 to 2.042; p<0.001). TruNatomy provides a better cyclic fatigue resistance than other NiTi files when used in simple curved, moderately curved, and severely curved Root canals. Further studies using larger sample size with severely curved root canals are recommended.

Keywords: Cyclic fatigue resistance, Nickel − titanium file, TruNatomy, Canal curvature

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1. Introduction

Effective root canal treatment necessitates the removal of pulp tissue and the elimination of periapical infections through chemo-mechanical procedures. A crucial stage involves cleaning and shaping the root canal, a process significantly improved by nickel-titanium (NiTi) instruments. Numerous engine-driven NiTi systems are now available.[1] Despite their benefits, NiTi instruments can unexpectedly fracture within the canal. This breakage is mainly due to cyclic fatigue, which results from repeated bending stress on a freely rotating file, or torsional fatigue, which occurs when the file tip locks while the hand piece continues to rotate.[2]

Cyclic fatigue is responsible for the majority (65-70%) of file separations, while torsional fatigue accounts for the remaining 25-30%.[2] Many NiTi instruments are made from heat-treated alloys, a process known to enhance their resistance to cyclic fatigue. The TruNatomy system (Dentsply Sirona) employs heat-treated NiTi alloys and distinct mechanical designs in its three shaping instruments. The manufacturer states that these files undergo specific heat treatments to improve their elasticity and cyclic fatigue resistance. Considering the ongoing advancements in endodontic instruments, it is important to evaluate new systems.

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Although existing literature addresses cyclic fatigue in various NiTi files, no pooled evidence supports TruNatomy's Superiority. Furthermore, a preliminary search in PROSPERO, JBI, Cochrane, and PubMed found no planned or ongoing systematic reviews on this topic. Therefore, this review investigates the research question: Does the TruNatomy endodontic instrument exhibit superior cyclic fatigue resistance compared to other NiTi rotary file systems?

2. Materials and Methods

2.1. Protocol and registration

The present systematic review was registered at the National Institute for Health Research PROSPERO International Prospective Register of Systematic Reviews (Registration number: CRD42023422211) on 03/05/2023. This research protocol was designed according to the PRISMA guidelines 2020.

2.2. Structured question

Does TruNatomy endodontic instrument possess a better cyclic fatigue than other NiTi endodontic rotary file systems? Detailed search strategies were used for the databases for the identification of studies considered. The controlled vocabulary (MeSH terms) and free terms were used to define search strategy based on the elements of PICOS question as follow as:

1. Population (P): Artificial root canals.
2. Intervention (I): Root canal instrumentation with TruNatomy
3. Comparison (C): Other rotary endodontic NiTi file systems
4. Outcome (O): Cyclic fatigue resistance of TruNatomy rotary endodontic file.
5. Study design (S): Invitro studies

A systematic search following the principle of systematic review search was carried out in the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Google Scholar and PubMed using MeSH words, text words and Boolean operators. The articles in the English language were considered. The period of publication considered was between 01-01-2001 to 31-01-2022. The complete search methodology is described in **Table 1**

Reference lists of the reviews and the identified studies were also checked for possible additional studies.

2.3. Eligibility criteria

The studies were selected according to the inclusion and exclusion criteria as mentioned in **Table 2**.

2.4. Study selection

An overview of the selection process is shown in (**Figure 1**). From the 82 articles removing the duplicates, 49 full texts articles were screened on the basis of title and abstract. 34 articles were excluded as the measure of outcome was not relevant to the present study. A total of fifteen articles were assessed for eligibility, among them, seven articles were excluded due to following reasons:

1. Extracted natural teeth were used in three studies.
2. Length of fractured fragment was assessed as outcome in three studies.
3. Shaping ability of TruNatomy file was assessed in one study.

Hence total 8 articles were included for qualitative analysis

2.5. Data collection process

Data extraction was performed by the reviewers using a standardized form and recorded in Microsoft Office Excel 2013 (Microsoft Corporation, Redmond, Washington, U.S.). The reviewers compiled relevant data into an Excel spreadsheet. This spreadsheet included the characteristics of the analysed studies, specifically the author, publication year, study design, sample size, the endodontic files examined (TruNatomy and the comparison files), the type of root canal used in the study, the specific characteristics of the files tested, and the conclusions drawn by the study authors.

Following a comprehensive review of the full text of the selected articles, two independent reviewers extracted the required data using a standardized form. The quality of all included studies was assessed independently by two reviewers using the Cochrane Risk of Bias (ROB) Tool, as recommended by the Cochrane Handbook for Systematic Reviews of Interventions. The assessment involved evaluating seven criteria: random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, addressing incomplete outcome data, absence of selective reporting, and other potential biases. Disagreements in quality assessment were resolved through discussion or by consulting a third reviewer to reach a consensus.

3. Results

3.1. Quality of included studies

The quality of the selected studies was individually assessed. In accordance with the Quality Assessment Tool For In Vitro Studies (QUIN Tool), the following twelve different criteria were considered: clearly stated aims/objectives, detailed explanation of sample size calculation, detailed explanation of sampling technique, details of the comparison group, detailed explanation of methodology, operator details, randomization, method of measurement of outcome, outcome assessor details, blinding, statistical analysis, presentation of results. The risk of bias of included studies is summarized in the above-mentioned **Table 4**.

All the studies included presented with a moderate risk of bias, aims and objectives were mentioned in all the studies; however, only one study mentioned the sample size estimation in detail. Details of the comparison group and an explanation of the methodology were adequately presented in all the studies. The number of the operator were mentioned

only in two studies. Outcome assessor details were not reported in any of the studies. Blinding was not reported in any of the studies. Results were presented appropriately and statistical analysis was reported adequately in six studies. The risk of bias of included studies is summarized in the above-mentioned table. (**Table 4)**

Table 1: Search strategy in PubMed database

Category	**Keywords**
Population	Artificial canals Stainless steel blocks Acrylic resin blocks
Intervention	TruNatomy file [MeSH] OR TruNatomy rotary Endodontic file [MeSH] OR TruNatomy file system.
Comparison	Rotary endodontic NITI file systems [MeSH] OR Twisted Files (TF) [MeSH] OR ProTaper Next (PTN) [MeSH] OR HyFlex EDM [MeSH] OR Reciproc blue [MeSH] OR VDW.ROTATE [MeSH] OR 2 Shape [MeSH] OR HyFlex CM [MeSH] OR Aurum G
Outcome	Cyclic fatigue [MeSH] OR cyclic fatigue resistance
	1 AND 2 AND 3 AND 4

Table 2: Selection criteria for the systematic review

Inclusion criteria	**Exclusion criteria**
Invitro studies.	Studies which does not contain TruNatomy files were excluded
TruNatomy files. Rotary endodontic NITI file systems.	Studies which does not contain NiTi Rotary instruments/files were excluded.
NiTi rotary files included are: Twisted Files (TF), ProTaper Next (PTN), HyFlex EDM, Reciproc blue, VDW.ROTATE 2 Shape, HyFlex CM, Aurum G	Reused or damaged files were excluded
Only studies conducted from January 2001to Jan 2023 are included.	Studies conducted before January 2001and after January 2023
Allows the selection of English journal Articles.	Articles published in languages other than English
Studies have included which performs Cyclic fatigue test.	In vivo or animal studies were excluded
Studies that included cyclic fatigue model as artificial root canals or blocks	

Table 3: Characteristics of included studies

Author/Year Of Publication/Study Design	**Sample Size / Files Used – Intervention/Comparator**	**Artificial Canals/Block & Its Specification**	**Rotation Movement / Rotation Speed**	**Result**
Abdullah Mahmoud Riyahi (2020)[20] In-vitro study	45 (15/group) Trunatomy / Twisted Files / Protaper Next	Artificial SS canal 60° curvature and 5 mm radius	Continuous / 300 rpm	PTN had the lowest, and TN the highest, number of cycles to failure (NCF), with statistically significant differences between all three groups (PTN, TF, TN).

Mustafa Gündoğar (2020)[23] In-vitro study	80 (20/group) Trunatomy / VDW.ROTATE / 2Shape / Hyflex CM	Stainless steel artificial canals with a 60° curvature and a 5 mm radius	VDW – 300 rpm Trunatomy – 500 rpm 2Shape – 300 rpm Hyflex CM – 500 rpm	The NCF values from highest to lowest were: VDW.ROTATE > Hyflex CM > 2Shape TS1 > Trunatomy Prime ($p < 0.05$). No significant difference in the FL values among the NiTi groups ($p > 0.05$).
Gülşah Uslu (2020)[3] In-vitro study	80 (20/group) Trunatomy / VDW.ROTATE / Hyflex CM / 2Shape	Double-curved canal: 60°/5 mm coronal (8 mm from tip), 70°/2 mm apical (2 mm from tip)	VDW – 300 rpm Trunatomy – 500 rpm 2Shape – 300 rpm Hyflex CM – 500 rpm	Apical fractures were more common. VDW.ROTATE and Hyflex CM had higher fatigue resistance than 2Shape and Trunatomy. Fatigue resistance was similar within the VDW/Hyflex and 2Shape/Trunatomy pairs. Fracture fragment lengths were similar across all files and curvatures.
Ove A. Peters (2020)[22] In-vitro study	Total – 80 files Trunatomy / Protaper Next (n = 20 each for PTN, sizes X2 and X3, and TN Prime and Medium)	Rigid steel fixture: tapered canal, 75°/5 mm curve	Trunatomy – 500 rpm PTN – 300 rpm	TN files showed significantly higher cyclic fatigue resistance (NCF) than PTN files. TN Prime and Medium are predicted to last significantly longer than PTN X3 and X2.
Amr M. Elnaghy (2020)[24] In-vitro study	Total instruments: 480 (120 of each type) Trunatomy / Hyflex CM / Vortex Blue / Race (RC) Sizes: Each type includes sizes 20/.04-60 and 25/.04-60 Canal types: Each size is used in 30 single-curvature and 30 double-curvature canals	Custom steel block: Double (60°/5 mm coronal, 70°/2 mm apical) and single (60°/5 mm) curvature canals	(Not specified)	TRN and HCM revealed higher NCF compared with the other instruments for both tested sizes in single and double curvature canals ($p < 0.05$). TRN and HCM showed no statistically significant difference in the NCF ($p > 0.05$). The probability of survival was higher for HCM and TRN instruments than VB and RC instruments.
Bharath Naga Reddy (2021)[4] In-vitro SEM	96 (24/group) Trunatomy / Protaper Gold/ Hyflex EDM/ reciproc blue	SS blocks – 3 curvatures: Middle, apical, and double. subgroup A: 5.29mm straight cervical segment, 9.42mm arc, 6mm radius curve. Subgroup C and S shaped canal	(Not specified)	Trunatomy files demonstrated significantly higher cyclic fatigue resistance (NCF) than Protaper Gold files in apical, middle, and S-shaped canals.

		mprphology with a coronal 50%/ radius of 5mm and apical curve with a 70%/ radius 2mm		
Balaji Dhakshinamurthi (2023)[25] In-vitro study	30 (10/group) Trunatomy / Hyflex EDM / Aurum G	Double-curved artificial canal: 60°/5 mm coronal (8 mm from tip), 70°/2 mm apical (2 mm from tip)	Continuous movement	Trunatomy (NCF 950.70) had the highest cyclic fatigue resistance, followed by Hyflex EDM (NCF 861.0) and Aurum G (NCF 166.0). All differences were statistically significant ($p < 0.05$).
Rashid El Abed (2022)[21] In-vitro study	Total – 60 files Two NiTi files – Trunatomy / Protaper Gold (PG 25/.08, TN 26/.04) divided into 3 subgroups	J-shaped simulated canals in resin blocks with a 16.5 mm length and a 35° curvature	PTG – 300 rpm Trunatomy – 500 rpm	TN had significantly higher NCF than PG ($p < 0.05$). TN's NCF increased after use (subgroup 2) compared to new files (subgroup 1) ($p < 0.05$). TN's NCF decreased after sterilization (subgroup 3) compared to used (subgroup 2) ($p < 0.05$), returning to a similar level as new files.
Rashid El Abed (2022)[21] In-vitro study	(n = 10): 1) Baseline NCF, 2 & 3) Used in J-shaped resin canals	(As above)	(As above)	PG's NCF was similar between used (subgroup 2) and sterilized (subgroup 3). Fragment lengths differed significantly ($p < 0.05$). Showed typical cyclic fatigue fracture characteristics.

Table 4: Risk of bias assessment table

Criteria	**Peters 2020[22]**	**Dhakshinamurthi 2023[25]**	**Uslu 2020[3]**	**Riyahi 2020[20]**	**El Abed 2022[21]**	**Gündoğar 2020[23]**	**Naga Reddy 2021[4]**	**Elnaghy 2020[24]**
Clearly stated aims/objectives	2	2	2	2	2	2	2	2
Detailed explanation of sample size calculation	1	2	1	0	0	0	0	0
Detailed explanation of the sampling technique	NA	NA	NA	NA	NA	NA	NA	NA

Details of the comparison group	2	2	2	2	2	2	2	2
A detailed explanation of the methodology	2	2	2	2	2	2	2	2
Operator details	0	0	0	2	0	0	2	0
Randomization	NA	NA	NA	NA	NA	NA	NA	NA
Method of measurement of outcome	2	2	2	2	2	2	2	2
Outcome assessor details	0	0	0	0	0	0	0	0
Blinding	0	0	0	0	0	0	0	0
Statistical analysis	1	2	2	2	2	2	2	2
Presentation of results	2	2	2	2	2	2	2	2
Total Score	12	14	13	14	12	12	14	12
Total Score (in %)	60	70	65	70	60	60	70	60
Risk of Bias	Moderate	Moderate	Mode rate	Moderate	Moderate	Moderate	Moderate	Moderate

Table 5: Descriptive details of the number of cycles to failure among TruNatomy and other file systems

Study	**N1**	**N2**	**Total**	**SMD**	**SE**	**95% CI**	**t**	**p-value**	**Weight (%)**	
									Fixed	**Random**
Peters	20	20	40	6.635	0.804	5.007 to 8.262			0.46	4.35
Peters(a)	20	20	40	6.181	0.757	4.648 to 7.714			0.51	4.46
Dhakshinamurthi	20	20	40	1.692	0.363	0.957 to 2.427			2.24	5.28
Uslu	60	60	120	-1.233	0.198	-1.625 to -0.841			7.51	5.49
Usle(a)	60	60	120	-1.343	0.201	-1.741 to -0.945			7.29	5.49
Riyahi	30	30	60	4.313	0.469	3.374 to 5.251			1.34	5.09
El Abed	10	10	20	-0.0339	0.428	-0.934 to 0.866			1.61	5.17
El Abed(a)	10	10	20	1.315	0.476	0.315 to 2.316			1.3	5.08
El Abed(b)	10	10	20	0.337	0.432	-0.570 to 1.244			1.58	5.16
Gündoğar	60	60	120	-1.475	0.205	-1.881 to -1.069			7.02	5.49
Naga Reddy	24	24	48	0.994	0.302	0.387 to 1.601			3.24	5.37
Naga Reddy(a)	24	24	48	-2.133	0.358	-2.853 to -1.412			2.3	5.29
Naga Reddy(b)	24	24	48	3.159	0.43	2.295 to 4.024			1.6	5.17
Elnaghy	90	90	180	1.58	0.17	1.244 to 1.916			10.18	5.52
Elnaghy(a)	90	90	180	1.405	0.166	1.077 to 1.732			10.71	5.52
Elnaghy(b)	90	90	180	1.298	0.163	0.976 to 1.621			11.04	5.52
Elnaghy(c)	90	90	180	1.665	0.172	1.325 to 2.005			9.91	5.52
Elnaghy(d)	90	90	180	1.615	0.171	1.277 to 1.952			10.07	5.52
Elnaghy(e)	90	90	180	1.611	0.171	1.273 to 1.948			10.08	5.52
Total (fixed effects)	912	912	1824	0.864	0.0543	0.757 to 0.970	15.904	<0.001	100	100

Total (random effects)	912	912	1824	1.343	0.356	0.645 to 2.042	3.772	<0.001	100	100

Meta-analyses were conducted using a random effects model in comprehensive Meta-Analysis software v3. Heterogeneity between studies was evaluated using the Q test and quantified with the I^2 statistic. For each analysis, if substantial heterogeneity was detected ($I^2 > 50\%$), a random effects model was employed.[1] conversely, if heterogeneity was low ($I^2 \leq 50\%$), a fixed effects model would have been used. The meta-analysis included 19 comparisons derived from the eight eligible studies that provided the necessary quantitative outcome data for analysis.

The results of the overall comparison have been depicted as a forest plot. With the meta-analysis conducted for selected studies, heterogeneity was more than 50% (I2 = 97.51%); hence, a random effect model was applied.

The number of cycles required to fail was significantly greater in the TruNatomy group than in the other file systems with a standardized mean difference of 1.343 (95% CI = 0.645 to 2.042; p<0.001). **Figure 2** depicts Assessment of Publication Bias of included in vitro studies.

4. Discussion

Endodontics has advanced significantly with new NiTi rotary instrument designs, leading to improved root canal treatments. The TruNatomy system, known for its high cyclic fatigue resistance, is one such innovation. This review compares the cyclic fatigue resistance of TruNatomy files with other NiTi files.

This review analyzed cyclic fatigue resistance of TruNatomy and other NiTi endodontic files using artificial canals. Sample sizes ranged from 30 to 480 instruments. Canal curvature varied from straight to severely curved (up to 35°), including J-shaped and S-shaped canals. Comparison files included ProTaper Next, Twisted Files, ProTaper Gold, HyFlex EDM, Reciproc Blue, VDW.ROTATE, 2Shape, HyFlex CM, Aurum G, RaCe, and Vortex Blue.

Repetitive bending of metal, known as cyclic fatigue, causes it to harden and fracture. Recent advancements in treating Nickel Titanium (NiTi) instruments enhance their strength and flexibility. This increased flexibility arises from temperature-dependent transformations between austenite and martensite crystalline structures within the metal.[5]

Research suggests that austenite NiTi instruments may be more susceptible to breakage than martensite instruments. However, since most tests were conducted at room temperature, the behavior of these alloys could differ at higher temperatures.

The failure of NiTi alloys occurs in a three-step process: first, micro cracks initiate within the material; next, these cracks expand; and ultimately, the material fractures when it can no longer withstand the applied force.[5] A combination of austenite and martensite, particularly when martensite is the dominant phase, provides greater resistance to fatigue failure compared to having only austenite. Additionally, martensite is more effective at preventing cracks from spreading than stable austenite.[6]

In 1988, Walia et al. reported advancements in nitinol (NiTi) for use in endodontic devices.[7] Since then, engine-driven rotary NiTi instruments have significantly transformed root canal treatment by making preparation faster and easier.[8] As a result, numerous rotary systems using NiTi instruments with diverse designs and sizes are now commercially available for cleaning and shaping root canals.[9,10]

Despite improvements in NiTi rotary files, instrument breakage due to cyclic fatigue continues to be a concern.[10-12] this failure is abrupt and unpredictable.[13-14] Although factors such as speed, irrigation, surface treatments, and the alloy's characteristics affect how well the instruments resist fatigue,[15-18] there is currently no dependable way to determine how long an instrument will last. Furthermore, the ISO has not established standard procedures for fatigue testing.[19] Enhancements in manufacturing processes or the use of more advanced alloys are possible ways to improve fatigue resistance.[19]

To address the shortcomings of conventional NiTi endodontic instruments, manufacturers have introduced innovative production techniques. For instance, the GT series X instruments incorporate M-Wire, a new NiTi alloy developed in 2007.[19] This alloy, created using a specific heat treatment, is reported to provide greater flexibility and resistance to cyclic fatigue compared to standard NiTi instruments.[20]

SybronEndo developed Twisted Files (TF) using a unique manufacturing process.[21] This method involves heat-treating and twisting a NiTi blank in its R-phase (a specific crystalline structure) to improve its super elasticity and resistance to cyclic fatigue. The goal of this process is to align the grain structure for increased strength, unlike grinding which can introduce micro fractures and weaken the instruments.[19]

Several studies have investigated the cyclic fatigue resistance of NiTi rotary files. Uslu et al. (2020) reported that VDW.ROTATE and Hyflex CM files showed greater

resistance than 2Shape and TruNatomy in canals with double curvatures, with failure occurring first at the apical curve.[3]

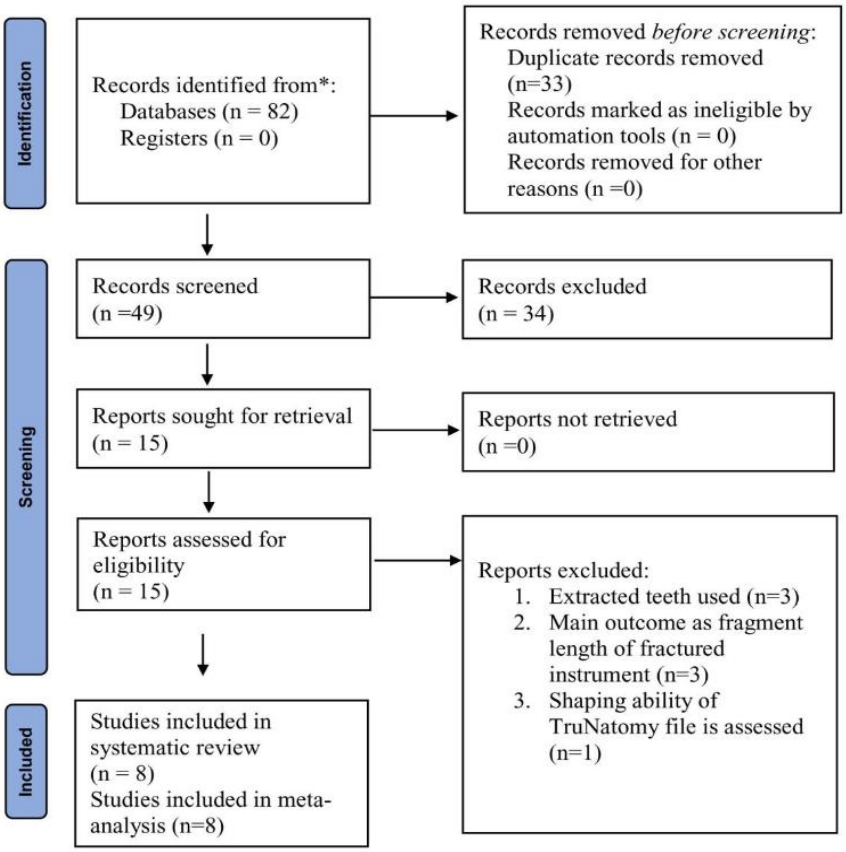

Figure 1: Flow chart of methodology according to preferred reporting items for systematic review and meta-analysis 2020 guidelines

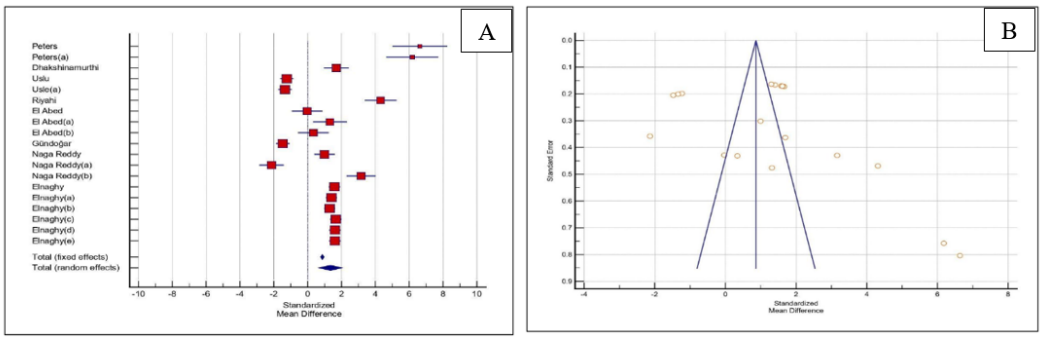

Figure 2: A and B Assessment of Publication Bias of included in vitro studies. The funnel plot showed a greater possibility of publication bias since few studies were lying outside the 95% confidence interval and the same was confirmed using the result of Egger's regression test (p=0.026).

In contrast, Riyahi et al. (2020) concluded that TruNatomy had superior cyclic fatigue resistance compared to Twisted Files (TF) and ProTaper Next (PTN), with TF being more resistant than PTN.[20] El Abed et al. (2022) also found TruNatomy to have higher resistance than ProTaper Gold, although sterilization reduced TruNatomy's resistance.[21] These studies highlight the inconsistency in cyclic fatigue performance across different NiTi file systems and the impact of factors such as canal curvature, file design, alloy properties, and sterilization. While some studies suggest TruNatomy performs better, others indicate different outcomes, emphasizing the need for more research.

Some studies present conflicting findings regarding the cyclic fatigue resistance of TruNatomy files. Reddy et al. (2021)[4] found TruNatomy to have the highest resistance, with HyFlex EDM and Reciproc Blue showing comparable resistance, and ProTaper Gold the lowest.[3] Conversely, Gündoğar et al. (2020) reported VDW.ROTATE as having the highest resistance, while TruNatomy and 2Shape had the lowest.[23] Peters et al. (2020) focused on TruNatomy versus

ProTaper Next, finding TruNatomy to be more fatigue resistant with more predictable torque and threading-in force.[22] These studies illustrate the difficulty in consistently ranking file systems because results vary depending on factors like canal shape, testing methods, and specific file characteristics.(**Table 3**) While TruNatomy shows promise in some research, others suggest different files exhibit superior fatigue resistance.

Studies comparing TruNatomy's cyclic fatigue resistance to other NiTi files have yielded varied results. While some found no significant difference, most studies indicated that TruNatomy files generally endured a greater number of cycles before fracturing.

5. Conclusion

This review and meta-analysis indicate that testing temperature, heat treatment, and canal curvature all affect NiTi file cyclic fatigue resistance. Specifically, increasing canal curvature negatively impacts resistance. While factors like alloy, cross-section, and glide path also play a role, TruNatomy files generally demonstrated better cyclic fatigue resistance than other NiTi files across various canal curvatures.

6. Source of Funding

None.

7. Conflict of Interest

None.

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