Australian Endodontic Journal
The Journal of the Australian Society of Endodontology Inc., the Australian and New Zealand Academy of Endodontists and the Asian Pacific Endodontic Confederation

Aust Endod J 2021; 47: 372–385

LITERATURE REVIEW

Clinical fracture incidence of rotary and reciprocating NiTi files: A systematic review and meta-regression

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Keywords
endodontics, iatrogenic disease, root canal preparation, root canal therapy.

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doi: 10.1111/aej.12484

(Accepted for publication 20 December 2020.)

Abstract

This systematic review was registered in PROSPERO (CRD42017075917) and aimed to investigate whether the available clinical evidence supports the hypothesis that reciprocating motion results in a lower incidence of nickel-titanium files fracture compared to continuous rotation. Clinical studies that reported the incidence of fracture of engine-driven nickel-titanium files were included. The main exposure was the kinematics, and the primary outcome was the incidence of files fracture. The overall incidence of files fracture was 2.27%, with a trend for higher incidence with rotary motion (2.43%) than with reciprocating (1.0%), though without significant differences. Multiple meta-regression models revealed that the use of nickel-titanium files in more than four teeth and less proficient operators were associated with a higher incidence of file fracture. There was no difference in the clinical incidence of fracture of nickel-titanium instruments between reciprocating and rotary motions; however, other factors were identified.

Introduction

Throughout recent decades, numerous systems and techniques have been proposed for root canal preparation aiming to reduce intra-operative complications and to increase ergonomy. Increased flexibility has been achieved in endodontic instruments by replacing stainless-steel (SS) files with alloys such as nickel-titanium (NiTi), as well as the use of alternative file designs (1). NiTi instruments have advantages when compared to SS files, including greater flexibility (2), shorter working time (3,4) and improved quality of preparation (5). In clinical practice, however, NiTi instruments may fracture during the preparation of the canal, mostly due to torsional stress (6) and/or repeated bending (6,7).

The clinical management of file fracture is challenging and may hamper the adequate disinfection of the root canal system, making patency at the apical terminus difficult to achieve, potentially impairing the outcome of the root canal treatment and increasing the chances of tooth loss (8). Specialist referral is commonly required, as file fracture can harm the patient's quality of life and patient–clinician relationship and possibly lead to litigation.

Current techniques for root canal preparation with engine-driven NiTi files use rotary and/or reciprocating movements. Overall, *in vitro* studies suggest that reciprocating motion improves the fatigue resistance and may reduce the risks of cyclic fatigue, as the instrument is not subject to the same stress levels caused by the rotary motion (9,10). A relief of the tension–compression related to cyclic stress on the instruments within the root canal provided by the reciprocating kinematics may be the reason for this lower fracture incidence (11–13). One *in vitro* study showed that the reciprocating movement almost doubled the resistance to flexural fracture of an instrument when compared to its use in continuous rotation (14).

Most of the evidence suggesting a higher fracture resistance of reciprocating instruments compared to

rotary ones is based on laboratory studies, with results that cannot be directly translated to the clinical setting. Thus, the present study aims to systematically review the literature for evidence on the clinical incidence of fracture of NiTi endodontic files used in rotary or reciprocating motions. The clinical question to be answered (the *PICO question*) was framed as follows: in *(P)* patients undergoing non-surgical root canal treatment with mechanical systems for root canal preparation, does *(I)* the reciprocating kinematics results in a lower *(O)* clinical incidence of NiTi files fracture, when compared to *(C)* the rotary motion?

Methodology

The methods of this study followed the recommendations of the PRISMA statement (15). Details of the protocol for this systematic review were approved and registered in the PROSPERO (CRD42017075917) database.

Search strategies

A search was undertaken to identify all clinical studies that reported the incidence of fracture of NiTi endodontic files used in continuous rotary and/or reciprocating kinematics. The PubMed, ISI Web of Science, Cochrane Library and EMBASE electronic databases were searched for clinical studies published from their inception up to 2020 (last accessed on 26 January 2020), with no language restriction. The search strategy and keywords used in different electronic databases are detailed in Appendix S1.

In addition, searches were performed on the grey literature (thesis and dissertations databases, as well as electronic searches on www.opengrey.eu, last accessed on 26 January 2020). Finally, the references of relevant studies were manually searched and, when necessary, the authors of component articles were contacted in an attempt to extract additional unreported data. In a preliminary analysis, titles and abstracts of all the selected studies were evaluated and the relevance of each study was determined. Duplicate studies were identified and discarded. The remaining articles were subjected to inclusion and exclusion criteria.

Study selection, inclusion and exclusion criteria

Two independent reviewers (R.M.V. and D.E.B.) examined the full text of the remaining articles, selecting observational or interventional clinical studies (randomised or non-randomised clinical trials) that reported the incidence of fracture of NiTi files when used in continuous rotation and/or reciprocating kinematics during root canal treatment in humans. Exclusion criteria included the following:

1 Laboratory studies.
2 *Ex vivo* studies.
3 Animal studies.
4 Observational or interventional clinical studies that reported only the incidence of fracture of hand SS or hand NiTi files used during root canal treatment in humans.

Cases of disagreement between reviewers were discussed until a consensus was reached.

Quality assessment and data extraction

The two reviewers independently obtained data from potentially relevant studies after a comprehensive full-text reading, which included data extraction, methodologic quality analysis and data synthesis and analysis. The parameters recorded for each study were names of the authors, date of publication (year), country of the study sample, study design, unit of analysis (patients/teeth/canals/instruments), type of kinematics (rotary or reciprocating), type of system of NiTi files, type of teeth, operator, number of visits necessary to complete the root canal treatment and number of uses of NiTi files. The reviewers independently rated the quality of each study based on the Newcastle–Ottawa Scale (NOS) (16), and a consensus was reached. After reviewing and rating the studies, the main results regarding the incidence of NiTi file fracture were recorded for each study.

Main exposures, outcome variables and covariates

The main exposure was determined by the type of kinematics (rotary or reciprocating movements), while the primary outcome variable was determined by the incidence of NiTi file fracture per instrument, considering the within-study group as the unit of analysis. Covariates were restrained by the reports in original articles; therefore, it was possible to get information for five variables: (i) year of publication; (ii) country of publication; (iii) operator; (iv) number of uses; and (v) type of tooth treated. Due to the variety of forms of reporting covariables in original studies, different patterns of categorising and combining variables were tested.

Statistical analysis

The estimated pooled incidence of fracture of NiTi files from all included studies was calculated for each study group when more than one group per study was possible to collect. Random-effect meta-analysis was used for descriptive purposes using the specific command

for meta-analysis of proportions, that is the incidence of fracture. Linear meta-regression of logit (incidence) was used to identify possible sources of heterogeneity between studies. Exponentiated coefficients were interpreted as odds ratio (OR). This analytic strategy evaluated which variables affected the incidence. Initially, bivariate analysis was performed; however, due to the low sample size, multicollinearity was a concern. To solve this problem, five models were estimated in which we created interaction categories combining all five covariates with kinetics in the bivariate meta-regression in logistic models. The pooled estimates for the incidence of files fracture were determined, and *odds ratios* (OR) and 95% confidence intervals (95% CI) were reported. Only variables with $P < 0.05$ in the final models were retained. To estimate explained variance (R^2), it was calculated the heterogeneity parameter (tau2) using empirical Bayes estimator that denotes the standard deviation of study-level variance. Due to the small number of included studies, the *P*-values were estimated from Monte Carlo non-parametric method (with 500 permutations) adjusted for multiple testing (17). All analyses were performed in Stata 13.1 (Stata Corp, College Station, TX, USA).

Results

The search strategy yielded a total of 1432 hits. After duplicate references were discarded, a subsequent search at the title and abstract level revealed 44 articles for full-text reading. At this stage, five studies were excluded, due to the following reasons: *in vitro* cyclic fatigue evaluation (7,18), fracture incidence not reported (19) or, due to overlap of study *per se* and subjects (20,21), merged with another included study (22,23). Figure 1 details the flow chart for the study selection process.

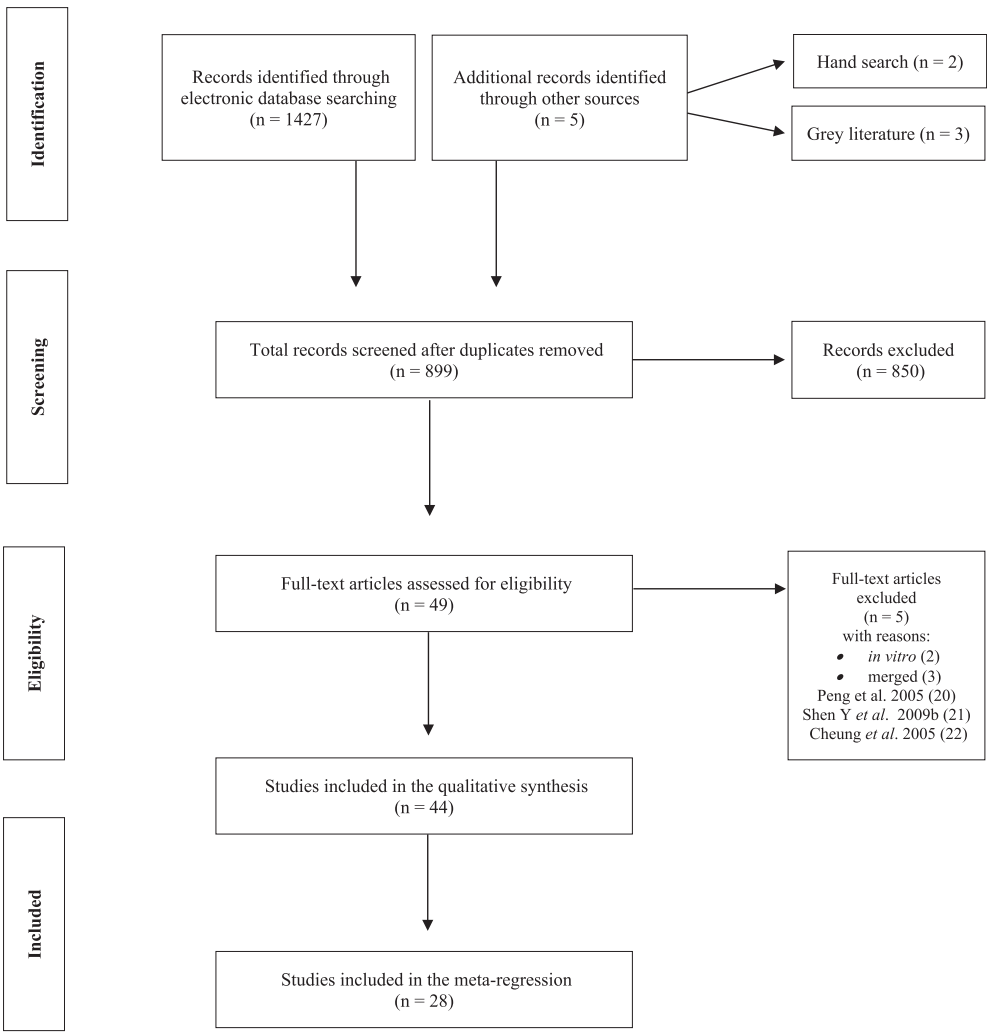

Figure 1 Flowchart for the study selection process.

Table 1 Characteristics and main results of the studies included in the systematic review (*N* = 44)

Author/year	Country	Study design	*N*/unit of analysis	Kinematics	System	Group of teeth	Operator	Number of visits	Number of uses of NiTi files	Incidence of fracture (*N*/%)
Abu-Tahum *et al*. 2014 (24)	Jordan	Prospective	96 teeth	Rotary	ProTaper	Molars	Undergraduate students	72 teeth: One visit 24 teeth: Two visits	1 molar	01/1.04
Al-Fouzan 2003 (25)	Saudi Arabia	Prospective	468 instruments 1457 canals 419 teeth 408 patients	Rotary	ProFile	Molars	Endodontists	NR	5 molars/set	21/4.49 21/1.44 21/5.01 21/5.15
Al-Fouzan & Jamleh 2018 (26)	Saudi Arabia	Retrospective	12 867 teeth	Rotary	K3	Molars Premolars Anterior	Endodontists	NR	5 teeth	182/0.14
Alapati *et al*. 2005 (27)	USA	Prospective	822 instruments	Rotary	Profile Profile GT ProTaper	NR	Undergraduate students	NR	6–8 uses	42/5.11
Arens *et al*. 2003 (28)	USA	Prospective	786 instruments	Rotary	Profile series 29	NR	Endodontists	One visit	1 tooth	07/0.89
Bueno *et al*. 2017 (29)	Brazil	Prospective	358 teeth 1130 canals 120 instruments	Reciprocating	WaveOne Reciproc	Molars Premolars	Endodontists	NR	3 teeth	03/0.84 03/0.27 03/0.26
Caballero-Flores *et al*. 2019 (30)	Brazil	Retrospective	2075 canals 328 instruments	Reciprocating	WaveOne Reciproc	Molars Premolars Anterior	Graduate students	NR	6 canals	19/0.91 19/5.79
Chakka *et al*. 2012 (31)	India	Prospective	64 instruments	Rotary	ProTaper Endowave	Anterior	Endodontists	NR	20 teeth	0/0
Chen *et al*. 2013 (32)	China	Prospective	88 teeth	Rotary Reciprocating	ProTaper Reciproc	Molars Premolars	NR	Two visits	15 canals	06/3.59 0/0.00
Cheung *et al*. 2007 (33)	China	Prospective	325 instruments	Rotary	ProTaper	Molars Premolars Anterior	General practitioners	One or two visits	4 molars 20 premolars 50 anteriors	44/13.54
Cunha *et al*. 2014 (34)	Canada	Prospective	711 teeth 2215 canals	Reciprocating	WaveOne	Molars Premolars	Endodontists	NR	1 tooth	03/0.42 03/0.13
Di Fiore *et al*. 2006 (35)	USA	Prospective	6661 instruments 3818 canals 1403 teeth 1235 patients	Rotary	Profile ProTaper Gt Rotary K3	Molars Premolars Anterior	Graduate students	One visit	3 canals	26/0.39
Ehrhardt *et al*. 2012 (36)	Brazil	Prospective	556 teeth	Rotary	Mtwo	Molars Premolars	Endodontists	NR	5 teeth	11/1.98

(continued)

Table 1 (continued)

Author/year	Country	Study design	*N*/unit of analysis	Kinematics	System	Group of teeth	Operator	Number of visits	Number of uses of NiTi files	Incidence of fracture (*N*/%)
Fife *et al*. 2004 (7)	USA	Prospective	90 teeth 150 instruments	Rotary	ProTaper	Molars	Graduate students	NR	4 molars	0/0.00
Hamid *et al*. 2018 (37)	USA	Retrospective	200 teeth	Rotary Reciprocating	Gt Rotary Wave One	Molars	Undergraduate students	Two visits	NR	4/4.00 1/1.00
Haug *et al*. 2018 (38)	Norway	Prospective	116 instruments 116 teeth	Reciprocating	Wave One	Molars Premolars Anterior	Undergraduate students	Two visits	1 tooth	5/4.31
Hu *et al*. 2005 (39)	China	Prospective	100 teeth 339 canals	Rotary	Hero 642 ProTaper	Molars	Undergraduate students	Two visits	10 molars	05/5.0 5/1.47%
Inan & Ganulol 2009 (40)	Turkey	Prospective	593 instruments	Rotary	MTwo	Molars	Endodontists	NR	4 molars	95/16.02
Iqbal *et al*. 2006 (41)	USA	Retrospective	4865 teeth	Rotary	ProTaper Profile GT Profile S29 LightSpeed K3	Molars Premolars	Graduate students	NR	NR	69/1.68
Knowles *et al*. 2006 (42)	USA	Prospective	3543 canals	Rotary	LightSpeed	Molars Premolars	Undergraduate students	NR	NR	46/1.30
Ma *et al*. 2010 (43)	China	Prospective	270 instruments 432 patients	Rotary	ProTaper	Molars Premolars Anterior	NR	NR	>20 uses	27/10.00
Machado *et al*. 2018 (44)	Brazil	Retrospective	1031 teeth 2355 canals	Rotary	Pro Taper U	Molars Premolars Anterior	Graduate students	One visit	4 uses	45/0.44 45/0.19
Plotino *et al*. 2015 (45)	Italy	Prospective	1696 instruments 3780 canals	Reciprocating	Reciproc	Molars Premolars Anterior	Endodontists	One or two visits	1 tooth	08/0.47 08/0.21
Ramirez-Solomon *et al*. 1997 (46)	Mexico	Prospective	52 teeth 162 canals	Rotary	LightSpeed	First Molars	Endodontists	NR	11 to 13 molars	6/11.53 06/3.70
Rodrigues *et al*. 2016 (47)	Brazil	Prospective	277 teeth 673 canals	Reciprocating	Reciproc	Molars Premolars Anterior	Endodontists	One visit	1 tooth	03/1.08 03/0.44
Sattapan *et al*. 2000 (48)	Australia	Prospective	378 instruments	Rotary	Quantec	NR	Endodontists	NR	NR	79/20.90
Schäfer *et al*. 2004 (49)	Germany	Randomised clinical trial	110 canals	Rotary	FlexMaster	Molars Premolars	General practitioners	Two visits	6 teeth	02/1.82
Shen *et al*. 2016 (50)	China	Prospective	2397 instruments	Rotary	K3	NR	Graduate students	NR	30 canals	86/3.59

(continued)

Table 1 (continued)

Author/year	Country	Study design	*N*/unit of analysis	Kinematics	System	Group of teeth	Operator	Number of visits	Number of uses of NiTi files	Incidence of fracture (*N*/%)
Shen *et al*. 2006 (51)	China	Prospective	491 discarded instruments (NiTi) 827 used instruments (NiTi) 166 discarded instruments (PF) 325 discarded instruments (PT)	Rotary	Profile ProTaper	Molars Premolars Anterior	General practitioners	NR	4 molars 20 premolars 50 anteriors	57/11.61 57/6.89 12/7.00 45/14.00
Shen *et al*. 2009 (23)	China	Prospective	1108 PT instruments 294 K3 instruments	Rotary	ProTaper K3	Molars Premolars Anterior	Endodontists	NR	30 canals	68/4.85 9/3.06
Shen *et al*. 2009 (52)	Canada	Retrospective	3706 instruments	Rotary	Profile	NR	Undergraduate Students	NR	3 teeth	12/0.32
Shen *et al*. 2009 (53)	Canada	Prospective	1895 PT instruments 3398 PF instruments	Rotary	ProTaper Profile Profile S29	Molars Premolars Anterior	Endodontists	One visit	1 tooth	05/0.26 5/0.15
Shen *et al*. 2012 (54)	China	Prospective	2203 instruments	Rotary	Profile Vortex	Molars Premolars Anterior	Undergraduate Students	NR	1 tooth	01/0.05
Shen *et al*. 2013 (55)	Canada	Prospective	468 instruments	Rotary	HyFlex	Molars Premolars	Graduate students	NR	3 teeth	0/0.00
Shen *et al*. 2015 (56)	Canada	Prospective	330 Vortex instruments 1136 Vortex Blue instruments	Rotary	Profile Vortex Profile Vortex Blue	Molars	Graduate students	NR	3 molars	0/0.00 02/0.14
Shen *et al*. 2016 (57)	Canada	Prospective	438 instruments 294 teeth	Reciprocating	WaveOne	Molars Premolars Anterior	Graduate students & Endodontists	NR	1 tooth	02/0.50
Spili *et al*. 2005 (58)	Australia	Retrospective	5103 teeth	Rotary	ProTaper Profile Quantec K3	NR	Endodontists	Two visits	NR	226/4.43
Tzanetakis *et al*. 2008 (59)	Greece	Retrospective	2098 instruments	Rotary	ProTaper Profile Hero	Molars Premolars Anterior	Graduate students	NR	NR	28/1.33

(continued)

Table 1 (continued)

Author/year	Country	Study design	*N*/unit of analysis	Kinematics	System	Group of teeth	Operator	Number of visits	Number of uses of NiTi files	Incidence of fracture (*N*/%)
Vieira *et al.* 2008 (60)	Brazil	Prospective	120 instruments	Rotary	ProTaper	Molars	Endodontists & Undergraduate students	NR	5 to 8 molars	06/5.00
Wang *et al.* 2010 (61)	China	Prospective	90 teeth	Rotary	ProTaper MTwo K3	Molars	NR	NR	NR	08/8.88
Wei *et al.* 2007 (62)	China	Prospective	774 instruments	Rotary	ProTaper	Molars Premolars	Undergraduate students	NR	30 canals	100/12.92
Wolcott *et al.* 2006 (63)	USA	Prospective	4652 canals	Rotary	ProTaper	Molars Premolars Anterior	Endodontists	NR	5 uses	113/2.40
Wu *et al.* 2011 (64)	China	Prospective	6154 canals 2654 teeth	Rotary	ProTaper U	Molars Premolars Anterior	Undergraduate students	NR	3 molars 10 premolars 30 anterior	70/2.60 70/1.10
Zuolo *et al.* 2015 (65)	Brazil	Prospective	174 teeth	Reciprocating	Reciproc	Maxillary Molars	Endodontists	NR	1 tooth	03/1.72

NR, not reported.

Study characteristics

Data for 54 groups were extracted from 44 articles and, due to a lack of reporting of several variables, the final analysis included 32 groups from 28 studies. Corresponding authors from 10 studies were contacted to obtain further detail (20,28,33,40,48,50,52–54,62) with response was obtained regarding one study (48), with no additional data included in the analysis. The qualitative synthesis, with the main characteristics and findings from the 44 included studies, is presented in Table 1. A total of 32 studies reported the incidence of fracture of NiTi files under rotary kinematics, while seven studies presented data on the fracture incidence of reciprocating NiTi files. The incidence of fracture ranged from zero (31,55) to 22% (22).

Several features of the component studies should be mentioned. Only one clinical study comparing the incidence of fracture of NiTi files with both kinematics in the same sample was identified (32). The most frequent study design was prospective observational studies (n = 32). Most included studies were conducted in Chinese populations (n = 12), followed by studies in Canada (n = 6) and USA (n = 6). The 'instrument' was the most common unit of analysis to report the incidence of NiTi files fracture, with a total of 20 studies. Interestingly, only one study presented detailed information on the incidence of fracture in all different units of analysis (patients, teeth, root canals and instruments) (25).

The ProTaper rotary system was the most commonly used (19 studies), whereas the most frequently used reciprocating system was Reciproc (n = 4). A total of 15 different types of NiTi endodontic file systems were identified. In 14 studies, the root canal treatments were performed in all type of teeth, while in eight studies, the sample was restricted to molar teeth. In seven studies, the group of teeth was not reported. The most frequent operators were endodontists (n = 24), followed by postgraduate (n = 7) and undergraduate students (n = 6). Most studies (n = 27) failed to report the number of visits required to complete the root canal treatment, and in 10 studies, the treatment was performed in single visit. Twenty studies reported that the NiTi files were used to treat more than one tooth and only 11 studies restricted the use of the NiTi endodontic instruments to one tooth. The quality ratings of each study as evaluated according to the NOS criteria are presented in Appendix S2.

Meta-regression analysis

From twenty-eight studies, six studies presented sufficient data on the outcome and on different covariables, which

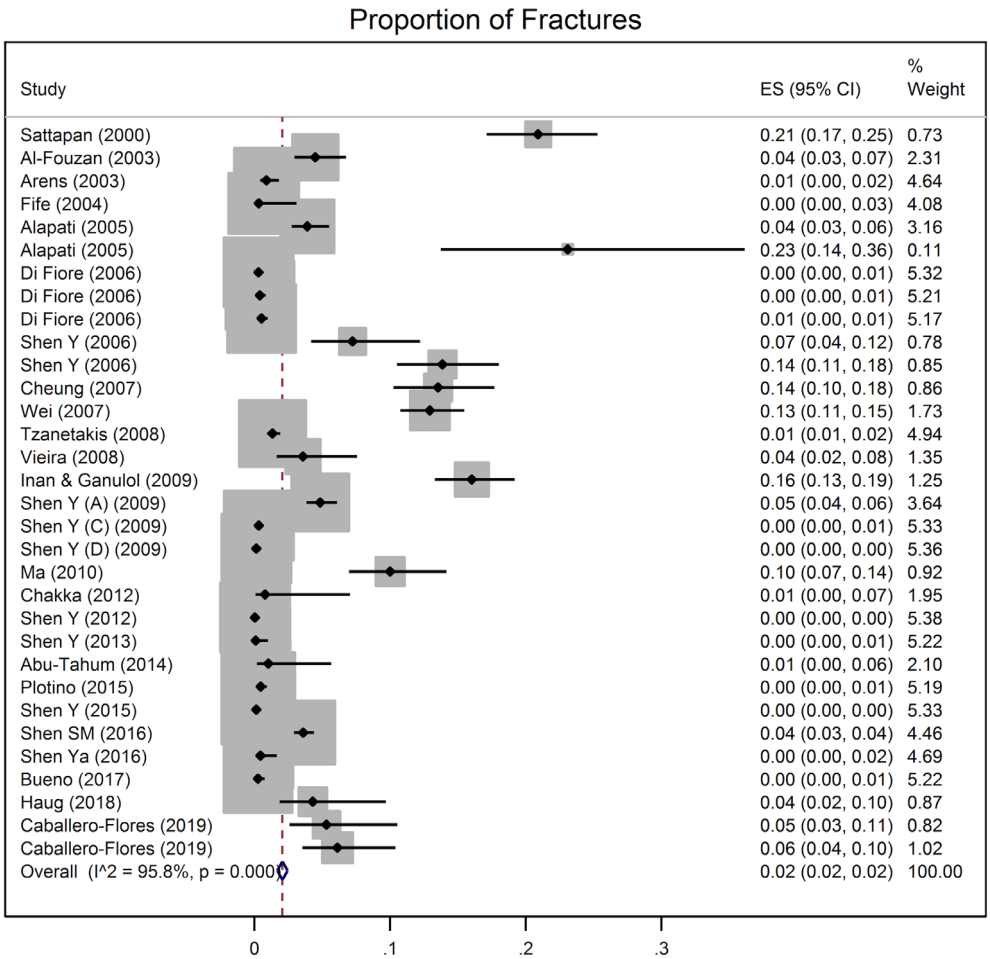

Figure 2 Forest plot for the overall clinical incidence (ES), as probabilities of fracture of NiTi endodontic instruments from random-effect meta-analysis.

allowed dismembering these in more than one study group to carry out further analysis (27,30,35,41,50,51). Thus, the meta-regression at the group level was carried out considering more than one group per study (three studies contributed with seven groups and 25 studies with one group each). As a result, a total of 32 groups were included in the meta-regression, consistently considering the 'number of instruments' as the denominator of analysis. Figure 2 shows the forest plot for the clinical incidence of fracture of NiTi endodontic instruments, based on a random-effect model. The overall estimated pooled incidence of files fracture was 2.27%, with a total of 32 892 clinically used instruments included. Heterogeneity was present (I^2 = 95.8%), and the weights of the included studies varied from 0.11% to 5.38%.

Table 2 summarises the results of the bivariate meta-regression analysis, with the pooled incidence of fracture of NiTi instruments, according to different exposure variables. In the non-adjusted analysis, the incidence of file fracture was not statistically different (OR = 1.4, 95% CI = 0.26–7.48, P = 0.69) between the two kinematics, but there was a trend for higher crude rates with rotary motion (2.43%) than with reciprocating kinematics (1.0%). The country of publication was significantly associated with the outcome, with studies carried out in Brazil (1.72%), China (6.75%) and other countries (4.31%) revealing significantly higher incidences of file fracture (P < 0.01) compared to those from USA/Canada (0.49%). Regarding the year of publication, there was a trend for older studies (before 2005) presenting a higher but borderline non-significant chance of fracture (OR = 5.74, 95% CI = 0.98–35.1, P < 0.14) than more recent studies (2011–2019). In addition, the pooled incidence of fracture among general practitioners (12.4%) was significantly higher (OR = 17.2, 95% CI = 1.66–178.02), compared to the incidence of post-graduate

Table 2 Pooled incidence of fracture of NiTi instruments, according to different exposure variables. Odds ratio (OR) and 95% confidence interval (CI) for the bivariate meta-regression analysis

Variables	*N* (groups)	*N* (instruments)	Incidence[†] (%)	Odd Ratio[‡]	(95% CI)		*P*-value[§]	R^2
Kinematics								
Reciprocating	6	3708	1.00	Ref.			0.69	−2.80%
Rotary	26	29 184	2.43	1.40	0.26	7.48		
Country								
USA/Canada	13	20 098	0.49	Ref.			<0.01	37.9%
Brazil	4	1626	1.72	6.41	1.66	24.71		
China	7	5659	6.75	17.28	4.48	66.61		
Other countries	8	5509	4.31	4.80	0.90	25.65		
Year of publication								
2011–2019	12	10 402	1.23	Ref.			0.14	7.9%
2006–2010	14	19 886	2.35	3.12	0.77	12.63		
1997–2005	6	2604	5.74	5.86	0.98	35.06		
Group of teeth								
Anterior	1	64	0.78	Ref.			0.84	−6.6%
Posterior	9	5313	4.31	2.00	0.02	255.67		
Posterior/anterior	16	19 426	1.49	2.22	0.02	259.89		
Not reported	6	8089	2.79	4.99	0.04	672.40		
Operator								
Graduate students	9	11 171	0.68	Ref.			0.23	6.6%
Endodontists	7	8449	2.58	2.46	0.41	14.91		
Undergraduate students	8	10 114	2.44	3.44	0.59	20.02		
General practitioners	3	816	12.38	17.20	1.66	178.02		
Mixed professional	3	2008	3.78	3.01	0.28	32.82		
Not reported	2	334	8.23	5.73	0.29	114.82		
Number of uses of NiTi instruments								
1 tooth	7	8733	0.33	Ref.			<0.01	75.8%
up to 4 teeth	8	13 581	0.32	0.55	0.18	1.67		
>4 teeth	15	8102	6.98	14.73	5.77	37.61		
Not reported	2	2476	4.32	11.08	2.50	49.12		
Overall	30	32 892	2.27	-			-	

[†]Weighted incidence of fractures from pooled groups sample size.

[‡]Odds ratio from random effects.

[§]Obtained from 500 Monte Carlo permutations.

students (0.68%). Finally, the number of uses of NiTi files showed to be strongly associated with the incidence of fracture, since the use in more than four teeth presented a combined incidence of fracture (6.98%) significantly higher (OR = 14.73, 95% CI = 5.77–37.61) than the incidence when the use was limited to one tooth (0.33%).

The adjusted meta-regression models for the incidence of fracture of NiTi instruments, according to different kinematics, are reported in Table 3. Comparison between rotatory and reciprocating motions within each strata of the covariate, using meta-regression models, showed no difference in the incidence of fracture (all *P*-values > 0.05). Interestingly, two covariables showed to be independent predictors of the clinical incidence of fracture of NiTi files, irrespectively of the type of kinematics: the operator (general practitioners compared to endodontists) (OR = 34.9, 95% CI = 2.1–578.8) and the number of uses of the instruments (>4 teeth or uses) with both rotary (OR = 11.3, 95% CI = 3.6–35.3) and reciprocating (OR = 8.1, 95% CI = 1.5–42.9) kinematics.

Discussion

The present meta-regression showed that kinematics is a less important clinical factor regarding NiTi instrument fracture than others, such as the number of uses and the type of operator. These findings, with a robust clinical translation, represent the synthesis of the best available scientific evidence to date on this topic, since, to the best of our knowledge, the present systematic review (SR) is the first aiming to identify potential predictors for this iatrogenic error.

Table 3 Multiple meta-regression models for the incidence of fracture of NiTi instruments. Odds ratios (OR) and 95% confidence intervals (CI)

Interacting variables		*N* (groups)	*N* (instruments)	Incidence[†] (%)	Odd ratio[‡]	(95% CI)		*P*-value[§]	R^2
Country	Kinematics								
USA/Canada	Reciprocating	1	438	0.46	Ref.			<0.01	40.3%
	Rotary	12	19 660	0.49	1.20	0.05	29.60		
Other countries	Reciprocating	5	3270	1.07	4.14	0.15	117.03		
	Rotary	14	9524	6.43	14.66	0.61	352.87		
Year of publication	Kinematics								
2011–2019	Reciprocating	6	3708	1.00	Ref.			0.16	9.0%
	Rotary	6	6694	1.36	0.27	0.03	2.26		
2006–2010	Reciprocating	–							
	Rotary	14	19 886	2.35	1.73	0.32	9.36		
1997–2005	Reciprocating	–							
	Rotary	6	2604	5.74	3.26	0.43	24.57		
Group of teeth	Kinematics								
Anterior	Reciprocating	–	–					0.80	−9.7%
	Rotary	1	64	0.78	Ref.				
Posterior	Reciprocating	1	1130	0.27	0.34	0.00	157.82		
	Rotary	8	4183	5.40	2.52	0.02	357.72		
Posterior and/or Anterior	Reciprocating	5	2578	1.32	2.05	0.02	269.40		
	Rotary	11	16 848	1.52	2.67	0.02	414.74		
Not reported	Reciprocating	–							
	Rotary	6	8089	2.79	4.99	0.03	729.90		
Operator	Kinematics								
Endodontist	Reciprocating	2	2826	0.39	Ref.			0.01	30.3%
	Rotary	5	5623	3.68	9.37	0.70	125.03		
Graduate students	Reciprocating	2	328	5.79	16.81	0.77	368.68		
	Rotary	7	10 843	0.53	1.04	0.08	13.17		
General practitioners	Reciprocating	–							
	Rotary	3	816	12.38	34.94	2.11	578.77		
Any other	Reciprocating	2	554	1.26	4.28	0.18	101.59		
	Rotary	11	11 902	2.89	8.31	0.75	92.27		
Number of uses	Kinematics								
Up to 4 teeth (or uses)	Reciprocating	4	3380	0.53	Ref.			<0.01	75.7%
	Rotary	11	18 934	0.29	0.41	0.12	1.39		
>4 teeth (or uses)	Reciprocating	2	328	5.79	8.07	1.52	42.99		
	Rotary	13	7774	7.03	11.28	3.60	35.32		
Not reported	Reciprocating	–							
	Rotary	2	2476	4.32	8.13	1.62	40.77		

[†]Weighted incidence of fractures from pooled groups.

[‡]Odds ratio from random effects.

[§]Obtained from 500 Monte Carlo permutations.

The fracture of instruments during root canal preparation may hamper the control of endodontic infection by precluding access to the apical terminus. Although there is a paucity of long-term clinical studies relating to the influence of file separation on root canal treatment outcomes, instrument fracture may represent a predictor of persistent apical periodontitis and consequent failure for treatment of infected teeth (66). Even taking into account the possibility of bypassing the fragment, incorporating the fractured instrument into the filling material, or still removing it, this complication is a stressor for the operator who needs to spend further time to address this issue, which commonly requires specialist referral.

Evidence from laboratory studies has purported that reciprocating kinematics would be a strategy to reduce the occurrence of instrument fracture, since alternating clockwise and counter-clockwise rotation would decrease tensional stress on the instrument, thus preventing cyclic fatigue or torsional fractures (6,11–13). This *in vitro* assumption was, in part, endorsed by the results from the pooled data collected in the present SR, which suggested a crude pooled lower clinical incidence of fracture of NiTi

instruments when reciprocating kinematics was used. However, the meta-regression highlighted that the influence of reciprocation may be less important as other confounding factors were noted. When other factors were taken into account, for example, the number of uses for the instruments, significant differences were not found.

A higher number of uses were significantly associated with higher chances of fracture of the NiTi instruments. Studies that limited the use of instruments to one tooth presented a lower fracture incidence (24,28,34,53,54,57,65). It should be noted that manufacturers' recommendations for reciprocating systems are to restrict the use of the instruments to one tooth, which was followed by the researchers that evaluated their fracture incidence (34,45,47,57,65). In other words, most of the instruments evaluated during reciprocating kinematics were used only once, whereas in some investigations, files in continuous rotation were used for up to 20–30 teeth (31,64). Still, when rotary systems were used in only one tooth (24,28,53,54), the fracture incidence was close to 1% or lower, similar to the results from studies evaluating reciprocating systems.

Based on the collected data and the associated factors evaluated by the meta-regression, it can be suggested that, in addition to the influence of kinematics, the evolution of the NiTi alloys and designs and the more recent tendency to consider instruments as single use translated in the reduction of the fracture incidence. The current alloys and designs have characteristics that favour elasticity and, consequently, may prevent fracture by improving the resistance to the torsional forces generated during their use (67). This is seen from the trend of reduction of fractures observed in the most recent studies (2011–2019, with a pooled incidence of 1.23%), compared to older studies (pooled incidence of 5.74%, from 1997 to 2005), with a borderline non-significant estimate (OR = 5.86, 95% CI = 0.98–35.1). In addition, it can be inferred that the trend of a reduced fracture incidence in the most recent studies may be in part attributable to an increased availability of hands-on training courses and continuing education in the field. Furthermore, it should be highlighted that the reciprocating motion was tested in more recent studies (34,45,47,57,65).

Multivariable models revealed a significantly higher pooled incidence of fracture when root canal treatment was performed by general practitioners using rotary files compared to endodontists, reaching a 30-fold greater chance (OR = 34.9). These results strongly suggest that, despite the use of engine-driven files, the operator's technical ability is still of paramount importance. Finally, the lower fracture incidence for students may be influenced by various factors, including case selection, level of supervision and reduced time pressure.

One important limitation of the present SR is that, among the included studies, only three were specifically designed to evaluate the incidence of fracture (35,41,42). This impeded carrying out a traditional meta-analysis; therefore, a meta-regression strategy was used to deal with the high heterogeneity among component studies. In most investigations, the main outcome was different from the incidence of fracture of the NiTi instruments: the quality of the root canal preparation (24), type of fracture (33), the impact of file fracture on the prognosis of the treatment (58), the influence of the type of teeth and the number of uses before fracture (43), the formation of ledges and apical zips (28), postoperative pain (32), the time required for root canal preparation (32), or the adequacy of the root canal filling (32). Even though most included studies did not evaluate the fracture of NiTi files as their primary outcome, it did not represent a hindrance to extract the data of interest for this SR. Another limitation is that the role of size and taper of the instrument as a covariate was not analysed, which might influence the incidence of file fracture (68). Unfortunately, data from available component studies were limited and did not allow the assessment of the possible influence of this and other factors on the outcome. The corresponding authors were contacted when considered necessary, though no additional data were included in the analysis.

Regarding the quality assessment of the studies, minor adaptations were necessary for the use of the NOS classification. The item 'selection of the non-exposed cohort' was not applicable, as it was not possible to obtain a group of 'non-exposed to the risk factors', since once the use of the file is started, every instrument is susceptible to fracture. Additionally, in the item 'comparability' of the NOS criteria, the operator (i.e. specialist) and the number of uses of the instruments (i.e. single use) were considered controlled factors. Based on the interpretation of the present results, it was decided to consider these factors as 'protectors' for the reduction of fracture occurrence, which would isolate the influence of the kinematics that was the main outcome. One study was a randomised clinical trial and was ranked with two stars in the 'comparability' item of the NOS criteria (49). Several studies had a higher quality rating for the evaluation of the kinematic influence on the fracture incidence (28,34,35,36,45,47,65). Finally, the general methodological quality of the included observational studies was high, with most articles achieving 6–8 out of 9 possible stars.

The summary of available evidence shows that the overall clinical incidence of fracture of engine-driven NiTi files was 2.27%, which represents useful information for clinicians to advise patients about the general risks of this undesirable accident related to RCT. Noteworthy, the occurrence of fracture reduced throughout the years, which is an encouraging observation with a robust clinical translation. The hypothesis raised in the present SR was rejected, suggesting that the type of kinematics might not be a decisive issue to reduce the incidence of fracture of NiTi instruments, even if there was a trend for higher crude rates with rotary motion (2.43%) than with reciprocating kinematics (1.0%). It must be highlighted that other factors were found to be stronger predictors of NiTi file fracture and these were the single use of the NiTi instruments and the ability of specialist operators.

Overall, the findings from the present SR encourage the development of future prospective controlled clinical trials designed to compare the incidence of fracture of NiTi files with both rotary and reciprocating kinematics in the same study. In addition, future clinical studies on this topic should present detailed information on the incidence of fracture in the different units of analysis (e.g. patients, teeth, root canals and instruments), to allow further pooled comparisons. Finally, future clinical studies dedicated to identify a safe clinical protocol regarding the maximum number of (re)uses of engine-driven NiTi files would be of significant clinical, economic and social relevance.

Conclusions

The evidence available from observational studies is limited but consistent and indicates there is no significant difference in the clinical incidence of fracture of NiTi instruments between reciprocating and rotary motion. Other clinical factors related to the operator and the number of uses of NiTi instruments showed to be more critical to prevent fracture than the type of kinematics.

Authorship declaration

All authors have contributed significantly, and all authors are in agreement with the manuscript.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1 Search strategies according to different electronic databases.

Appendix S2 Methodological quality assessment of observational studies according to the Newcastle–Ottawa Scale criteria (N = 44).

