ESCOLA DE CIÊNCIAS DA SAÚDE
PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA
MESTRADO EM ODONTOLOGIA

ROSÂNGELA MELLO VIEIRA

INCIDÊNCIA CLÍNICA DE FRATURA DE LIMAS ENDODÔNTICAS DE NÍQUEL-TITÂNIO ACIONADAS EM CINEMÁTICA ROTATÓRIA CONTÍNUA VERSUS CINEMÁTICA RECIPROCANTE UMA REVISÃO SISTEMÁTICA E META-REGRESSÃO

Porto Alegre
2018

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Aprovada em: _____de _____de_____.

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"Só um sentido de invenção e uma necessidade intensa de criar

levam o homem a revoltar-se, a descobrir e a descobrir-se com lucidez"

(Pablo Picasso)

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RESUMO

Introdução: A fratura de instrumentos endodônticos de níquel titânio pode ter um impacto negativo no prognóstico do tratamento, sobretudo por bloquear ou impedir o acesso ao sistema de canais radiculares em toda sua extensão, comprometendo a sua modelagem e sanificação. Resultados de estudos *in vitro* sugerem que o movimento reciprocante pode reduzir os riscos de fratura por torsão e fadiga cíclica dos instrumentos de NiTi, comparado ao movimento de rotação contínua. Ainda assim, a maioria dos estudos que avaliam a resistência à fratura de instrumentos no movimento reciprocante e rotatório são estudos *in vitro*, cuja geração de evidências é limitada em comparação ao nível de evidência gerada por estudos clínicos em humanos. Portanto, a presente revisão sistemática investigou se a evidência disponível suporta a hipótese de que o movimento reciprocante resulta em uma menor incidência clínica de fratura de limas de NiTi, em comparação com a cinemática rotatória.

Metodologia: Foram pesquisadas as bases de dados PubMed, Embase, Isi Web of Science e Cochrane Library até agosto de 2017, sem restrição de idiomas. Além das buscas eletrônicas foram realizadas buscas manuais por referências adicionais em capítulos específicos de livros relevantes na área e também busca na literatura cinza. Com base nos critérios de inclusão e exclusão, dois revisores avaliaram independentemente a qualidade de cada estudo com base na escala de NewCastle Ottawa. A principal variável de exposição foi o tipo de cinemática empregada para o preparo do canal radicular (rotatória contínua ou reciprocante) e a variável de desfecho primário foi determinada pela incidência de fratura de instrumentos de NiTi em tratamentos endodônticos. A incidência de fratura foi registrada, tendo como unidade de análise: pacientes, dentes, instrumentos ou canais. Outras variáveis de confundimento coletadas incluiram: país, ano de publicação, desenho do estudo, tipo de sistema, grupo de dentes, número de sessões, operador e número de usos dos instrumentos de NiTi. As fontes de heterogeneidade foram exploradas e a meta regressão logística bi e multivariada foram realizadas para calcular as estimativas agrupadas – *odds ratios* (OR) e 95%IC – para a incidência de fratura de instrumentos, avaliando o papel da exposição principal e das co-variáveis, como moderadores do desfecho.

Resultados: Entre os 737 artigos inicialmente identificados, após remoção das duplicatas, 39 compuseram a análise quantitativa final, dos quais 32 reportavam o uso de rotação contínua e 7 o uso de cinemática reciprocante. Trinta e sete estudos foram incluídos na meta regressão (N=48.405 instrumentos). A incidência clínica agregada de fratura de limas de NiTi foi de 2,43%, sendo de 2,62% para o movimento rotatório contínuo e de 0,4% para a cinemática reciprocante. Na análise bivariada, o movimento rotatório contínuo demonstrou uma incidência maior de fratura em relação à cinemática reciprocante (OR=6,39, IC95%=1,10-36,9), e as outras covariáveis associadas ($p<0,05$) com a incidência de fratura foram: ano de publicação, operador e número de usos dos instrumentos. Os modelos multivariados revelaram que o número de usos de limas de NiTi em >1 dente (OR=6,46, IC95%=1,42-29,3) e que operadores clínicos gerais (OR=11,8, IC95%=1,49-93,5) foram associados de modo independente com uma maior incidência de fratura de limas de NiTi, enquanto que a cinemática demonstrou-se não-significante (OR=1,56, IC95%=0,24-10,0) após os ajustes.

Conclusões: A evidência disponível, oriunda de estudos observacionais, é limitada porém consistente, sugerindo que a cinemática reciprocante está associada com uma menor incidência de fratura de limas de NiTi, quando comparada ao movimento de rotação contínua. Além disso, os resultados revelaram que outros fatores clínicos relacionados

às habilidades do operador, ao número de usos dos instrumentos de NiTi, e aos avanços na composição das ligas bem como no desenho das limas, demonstraram ser fatores mais relevantes para a prevenção da fratura do que o tipo de cinemática empregada.

Palavras-chaves: Tratamento do canal radicular, Preparo do canal radicular, Níquel-Titânio, Movimento reciprocante, Movimento rotatório contínuo, Fadiga cíclica, Fratura, Desfechos clínicos.

ABSTRACT

Introduction: The fracture of nickel titanium endodontic instruments may have a negative impact on the prognosis of the treatment, mainly because it blocks or prevents access to the root canal system in all its extension, compromising its modeling and sanification. Results from in vitro studies suggest that reciprocating motion can reduce the risks of torsion fracture and cyclic fatigue of NiTi instruments, compared to the continuous rotation movement. However, most of the studies that evaluate fracture resistance of instruments in reciprocating and rotational motion are *in vitro* studies, the generation of evidence of which is limited in comparison to the level of evidence generated by clinical studies in humans. Therefore, the present systematic review investigated whether the available evidence supports the hypothesis that reciprocating motion results in a lower clinical incidence of NiTi limb fracture as compared to rotational kinematics.

Methodology: The PubMed, Embase, Isi Web of Science and Cochrane Library databases were searched until August 2017, without language restriction. In addition to the electronic searches, manual searches were made for additional references in specific chapters of relevant books in the area and also search in the gray literature. Based on the inclusion and exclusion criteria, two reviewers independently assessed the quality of each study based on the NewCastle Ottawa scale. The main exposure variable was the type of kinematics used to prepare the root canal (continuous or reciprocating) and the primary outcome variable was determined by the incidence of fracture of NiTi instruments in endodontic treatments. The incidence of fracture was recorded, having as unit of analysis: patients, teeth, instruments or channels. Other confounding variables collected included: country, year of publication, study design, type of system, group of teeth, number of sessions, operator and number of uses of NiTi instruments. The sources of heterogeneity were explored and the bi and multivariate meta logistic regression were performed to calculate the pooled estimates - odds ratios (OR) and 95% CI - for the incidence of instrument fracture, assessing the role of primary exposure and co- as moderators of the outcome.

Results: Among the 737 articles initially identified, after the duplicates were removed, 39 comprised the final quantitative analysis, of which 32 reported the use of continuous rotation and 7 the use of reciprocating kinematics. Thirty-seven studies were included in the meta regression (N = 48,405 instruments). The aggregate clinical incidence of fracture of NiTi files was 2.43%, being 2.62% for continuous rotational movement and 0.4% for reciprocating kinematics. In the bivariate analysis, continuous rotational motion showed a greater incidence of fracture in relation to the reciprocating kinematics (OR = 6.39, 95% CI = 1.10-36.9), and the other associated covariates ($p < 0.05$) with the incidence of fracture were: year of publication, operator and number of uses of the instruments. The multivariate models revealed that the number of uses of NiTi files in> 1 tooth (OR = 6.46, 95% CI = 1.42-29.3) and that general clinical operators (OR = 11.8, 95% CI = 1.49-93.5) were independently associated with a higher incidence of fracture of NiTi files, whereas kinematics was non-significant (OR = 1.56, 95% CI = 0.24-10, 0) after the settings.

Conclusions: Available evidence from observational studies is limited but consistent, suggesting that reciprocating kinematics is associated with a lower incidence of fracture of NiTi files when compared to continuous rotation. In addition, the results revealed that other related clinical factors to the abilities of the operator,to the number of uses of the NiTi instruments,

and to the advances in alloy composition as well as in the design of the files, have proved to be more relevant factors for fracture prevention than the type of kinematics employed.

Keywords: Root Canal Treatment, Root Canal Preparation, Nickel-Titanium, Reciprocating Movement, Continuous Rotational Movement, Cyclic Fatigue, Fracture, Clinical Outcomes.

INTRODUÇÃO

A terapia endodôntica tem por objetivo a limpeza e a modelagem dos canais radiculares, visando à diminuição da quantidade de microrganismos e seus subprodutos, além de permitir a realização do selamento deste sistema, prevenindo sua reinfecção (1). Dentre todas as fases do tratamento endodôntico, recai sobre a etapa de preparo químico-mecânico uma grande responsabilidade pela tarefa da desinfecção do sistema de canais radiculares, executada pela conjunção de meios químicos irrigantes e de uma modelagem mecânica que respeite a complexa anatomia dos condutos.

Do começo do século passado até a década de 1970, molares e dentes com canais radiculares muito curvos dificilmente eram tratados e, quando eram, resultavam em uma alta taxa de insucesso (2). O principal motivo era a inviabilidade de controlar ou eliminar a infecção em áreas de curvaturas dos canais radiculares, já que a maioria das limas endodônticas não eram flexíveis, tornando o acesso difícil para a adequada instrumentação e limpeza destas regiões (2). Embora a técnica de instrumentação tenha um papel decisivo na preparação dos canais radiculares, muitos dos erros processuais, como transporte apical, degraus, zips e perfurações radiculares, são causados pela rigidez e alto módulo de elasticidade das ligas de aço inoxidável utilizadas na fabricação das limas endodônticas (3).

O design e as propriedades mecânicas dos instrumentos endodônticos evoluíram significativamente nas últimas décadas. A introdução de ligas de níquel-titânio (NiTi) possibilitou maior flexibilidade a estes instrumentos, tornando-os capazes de acompanhar o trajeto original dos canais durante a realização do preparo químico-mecânico. O aumento da flexibilidade foi alcançado modificando as limas convencionais de aço inoxidável, utilizando novas ligas como a de NiTi (4). Esta liga caracteriza-se por apresentar memória de forma, e foi denominada de Nitinol no começo dos anos setenta pelo engenheiro metalúrgico Willian F. Buenler, pois os componentes são o níquel e o titânio, e também homenageando o laboratório onde foram desenvolvidos as pesquisas que deram origem à liga (Naval Ordenance Laboratory), na cidade de Silver Spring, Maryland, EUA, em 1965 (5).

Graças às propriedades mecânicas superiores deste material, como a superelasticidade e o efeito memória de forma, foi possível utilizar os instrumentos endodônticos acionados em motores elétricos de rotação contínua, aumentando a eficácia e a rapidez de corte. Na realidade, a primeira referência de instrumentação rotatória mecanizada data de 1892, feita por Oltramare, que utilizou agulhas de secção triangular acopladas em uma peça de mão (6). A preocupação em mecanizar o preparo do canal radicular teve outro impulso nos anos 60, através de contra ângulo acoplado ao micromotor do equipamento, utilizando instrumentos específicos, em forma de alargadores ou de limas farpadas (7).

Ainda assim, foi apenas a partir da introdução da liga de NiTi que uma grande variedade de instrumentos rotatórios foi introduzida no mercado, com o propósito de complementar ou mesmo substituir as limas manuais até então utilizadas. As limas endodônticas de NiTi possuem baixo módulo de elasticidade (8), maior resistência à fratura por torção, flexão rotativa ou suas combinações (8) e maior eficiência de corte (9), quando comparadas com limas de aço inoxidável usadas manualmente. Além disso, a utilização de instrumentos de NiTi acionados mecanicamente, oportunizou a diminuição do tempo de trabalho para a realização do preparo do canal radicular (10), reduzindo também a ocorrência da extrusão de detritos para o forame apical (9,11) . A introdução dessa nova liga trouxe uma melhoria significativa para o tratamento endodôntico, possibilitando melhores resultados em termos de limpeza e modelagem dos canais radiculares (11).

No entanto, na prática clínica endodôntica, os instrumentos de NiTi acionados mecanicamente podem estar sujeitos à fratura acidental durante o preparo do canal. Devido às complexidades anatômicas, especialmente em canais severamente curvos, a ocorrência de fratura destes instrumentos representa um importante problema clínico, já que este tipo de acidente pode interferir decisivamente no prognóstico de manutenção do dente. A fratura de limas endodônticas dificulta ou impede o acesso para a correta limpeza e modelagem de toda a extensão do canal radicular. Nesse particular, um instrumento endodôntico fraturado e não removido pode ser um fator impeditivo para o controle da infecção endodôntica, levando à necessidade de tratamentos cirúrgicos complementares ou até mesmo à perda do dente envolvido (12).

Existem dois tipos principais de fraturas: por torção e por flexão (ou fadiga). A fratura por flexão ocorre principalmente devido aos repetidos movimentos de flexão, onde o instrumento não bloqueia no canal e gira livremente na curvatura, gerando ciclos de tensão/compressão no ponto de flexão máxima até a fratura ocorrer (13). Já na fratura do instrumento por torção, a ponta do instrumento endodôntico fica imobilizada e na outra extremidade (cabo) aplica-se um torque superior ao limite de resistência à fratura do instrumento (13).

Estudos *in vitro* (14-17) que reportam a incidência e as possíveis causas da separação são fartos na literatura, contudo estudos de natureza clínica são poucos. Neste particular, é preciso ressaltar que a capacidade de transposição dos resultados advindos de estudos laboratoriais diretamente para a prática clínica é muito limitada.

A ocorrência da fratura dos instrumentos endodônticos pode ser influenciada por quatro diferentes fatores: aqueles relacionados à estrutura dentária a ser tratada (geometria do canal e grupo dentário) (18, 19); fatores relacionados ao instrumento (design, secção transversal, tamanho do instrumento e processo de fabricação) (20-22), fatores ligados às propriedades do motor utilizado (velocidade de acionamento e torque aplicados ao

instrumento mecanizado) (23-25); e também aos fatores clínicos presentes durante a execução do preparo químico-mecânico (experiência do operador, técnica de instrumentação e dinâmica do uso do instrumento) (26, 27).

Com o propósito de minimizar os riscos de fratura dos instrumentos associado ao uso repetido e à contaminação cruzada associada com a incapacidade adequada de limpeza e esterilização, Yared (2008) (10) propôs a utilização de um único instrumento de NiTi para preparar o canal radicular. Foi utilizado uma única lima F2 do sistema de rotação contínua ProTaper (Dentsply, Mailefer, Suiça) que foi submetida ao movimento recíproco (oscilatório rotatório). Este estudo foi baseado no conceito de força balanceada de Roane (1985) (28), que foi proposto como uma alternativa nos tratamentos de canais curvos.

No preparo do canal radicular com cinemática reciprocante, o instrumento é inserido lentamente, e quando envolve a dentina no sentido horário, a rotação no sentido anti-horário solta o instrumento imediatamente, reduzindo o estresse mecânico ao qual o instrumento é submetido. Esta característica, potencialmente, diminui a chance de fratura por torção. As limas recentemente introduzidas de NiTi e desenhadas para trabalhar em movimento reciprocante (Reciproc®, VDW e WaveOne®, Dentsply Mailefer, entre outras) são feitas de uma liga especial chamada M-wire, que foi criada através de um processo inovador de tratamento térmico (29). Esse procedimento de processamento termomecânico exclusivo mostrou uma resistência à fadiga cíclica significativamente melhorada nas limas em comparação às fabricadas com ligas de NiTi convencionais (30), levando a uma menor probabilidade de erros processuais (31, 32).

Outros autores, também utilizando a lima F2 ProTaper, não constataram diferenças significativas com o uso de lima única em movimento reciprocante quando comparado com o movimento rotatório contínuo, em relação a eficiência no preparo de canais (33, 34) ou extrusão de debris (35). Entretanto, muitos estudos (10, 16, 36) verificaram que o movimento reciprocante poderia diminuir os riscos de fratura por torção e a fadiga cíclica, já que o instrumento não estaria sujeito aos níveis de estresse causado pelo movimento rotatório contínuo.

As possíveis vantagens do sistema de rotação reciprocante, em relação ao sistema de rotação contínua, podem ser comprovadas quando os dois sistemas foram comparados quanto à resistência à fadiga cíclica. Os resultados obtidos demonstraram que o sistema reciprocante apresentou propriedades mecânicas superiores ao sistema de rotação contínua (37-39). Em tese, um alívio das tensões dos instrumentos dentro do canal radicular proporcionado pela cinemática reciprocante gera um menor índice de fratura. Os resultados sugerem que a cinemática aplicada aos instrumentos possa influenciar significativamente na resistência à fadiga cíclica no instrumento. Estudos laboratoriais apontam que o movimento

de rotação reciprocante apresenta quase o dobro de resistência à fratura quando comparado aos mesmos instrumentos em rotação contínua (40).

A maioria de estudos que avaliam a resistência à fratura de instrumentos no movimento reciprocante e rotatório são estudos laboratoriais *in vitro,* cuja geração de evidências é limitada em comparação aos estudos clínicos em humanos, já que nem sempre é possível transpor os resultados oriundos de estudo *in vitro* para a realidade clínica. Estes testes de laboratório indicam apenas um risco relativo de deformação ou fratura sob um conjunto de condições particulares. Inúmeras variáveis clínicas, como acessibilidade do canal, força direcionada apicalmente, e outras relacionadas ao operador não são reproduzidas. Além da marca, tipo de liga, desenho e movimento, diversos outros fatores podem alterar a ocorrência de fratura.

Frente ao exposto, faz-se pertinente a realização de uma revisão sistemática da literatura a fim de identificar estudos clínicos que tenham avaliado a incidência de fraturas de instrumentos endodônticos quando o preparo dos canais radiculares foi realizado com movimento de rotação contínua ou rotação reciprocante. A realização desta revisão sistemática permitirá responder se a evidência disponível até o momento suporta a hipótese de que há diferença na incidência clínica de fraturas de limas de NiTi quando diferentes cinemáticas de preparo do canal radicular são empregadas.

Portanto, a pergunta clínica a ser respondida ("*PICO question"*, onde "P" representa pacientes submetidos a tratamento endodôntico com sistemas mecanizados de preparo dos canais e uso de limas de Ni-Ti, "I" representa sistemas de movimento reciprocante para o preparo do canal radicular, "C" diz respeito ao sistema de rotação contínua para o preparo do canal radicular, e "O" representa o desfecho a ser investigado, nesta revisão trata da incidência de fratura de limas endodônticas de Ni-Ti.) pode ser desenhada deste modo: em pacientes submetidos ao tratamento endodôntico não-cirúrgico com sistemas mecanizados de preparo do canal radicular, a cinemática reciprocante resulta em menor incidência clínica de fratura de limas de NiTi em relação ao movimento de rotação contínua?

2 OBJETIVOS

2.1. Objetivo geral

- Realizar uma revisão sistemática de estudos clínicos a fim de identificar se a evidência disponível permite inferir que a incidência de fratura de limas endodônticas de NiTi em casos tratados com cinemática rotatória contínua é maior do que em casos tratados com cinemática reciprocante.

2.2. Objetivos específicos

- Identificar, quantificar e descrever as principais características dos estudos clínicos em humanos que reportam a incidência de fraturas de instrumentos endodônticos de NiTi com cinemática rotatória contínua ou reciprocante;
- Avaliar a qualidade metodológica dos estudos identificados e incluídos na revisão sistemática.
- Identificar a incidência clínica agregadas de fratura de limas de NiTi acionadas mecanicamente;
- Identificar o peso de diferentes fatores sobre o desfecho analisado.

3 ARTIGO

Clinical Incidence of NiTi Files Separation with Rotary *versus* Reciprocating Kinematics: A Systematic Review and Meta Regression Analysis

Formatado segundo as normas do periódico *International Endodontic Journal*, fator de impacto 3.015 e classificação A1 segundo a CAPES.

Clinical Incidence of NiTi Files Separation with Rotary *versus* Reciprocating Kinematics: A Systematic Review and Meta Regression Analysis

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ABSTRACT

Introduction: Results from laboratory studies suggest that reciprocating motion may reduce the risk of torsional fracture and cyclic fatigue of endodontic NiTi instruments, compared to continuous rotation. This systematic review aimed to investigate whether available clinical evidence supports the hypothesis that reciprocating motion results in a lower incidence of NiTi files separation compared to the rotary kinematics in humans.

Methodology: The PubMed, EMBASE, Isi Web of Science and Cochrane Library databases were searched up to August 2017, with no language restriction. Additional searches were carried out manually and in the gray literature. Based on inclusion and exclusion criteria, two reviewers independently assessed the quality of each study based on the Newcastle Ottawa Scale. The main exposure was the kinematics (rotary or reciprocating), and the primary outcome was determined by the clinical incidence of NiTi files separation. Additional extracted co-variables included: year of publication, country, study design, file system, operator, group of teeth, number of sessions and number of uses of NiTi files. The sources of heterogeneity were explored, and bi and multivariate logistic meta regression were carried out to calculate the pooled estimates – *odds ratios* (OR) and 95%CI – for the incidence of files separation, evaluating the role of the main exposure and co-variables as moderators of the outcome.

Results: Among the 737 initially identified articles, 39 comprised the final qualitative synthesis. Thirty-seven studies were included in the meta regression (N=48,405 instruments). The overall clinical incidence of NiTi files separation was 2.43%. In the bivariate analysis, the rotary motion showed a higher incidence of file fracture compared to reciprocating kinematics (OR=6.39, 95%CI=1.10-36.9), and other co-variables were associated ($p<0.05$) with the fracture incidence: year of publication, operator and the number of uses of NiTi files. Multivariate models revealed that the number of uses of NiTi files in >1 teeth (OR=6.46, 95%CI=1.42-29.3) and clinicians operators (OR=11.8, 95%CI=1.49-93.5) were independently associated with a higher incidence of NiTi file separation, whereas the kinematics became non-significant (OR=1.56, 95%CI=0.24-10.0) after adjustments.

Conclusions: Available evidence from observational studies is limited but consistent, suggesting that reciprocating motion is associated with a lower clinical incidence of NiTi files separation compared to the rotary kinematics. Most importantly, other clinical factors related to the operator, the number of uses of NiTi instruments and modern file alloys and designs showed to be more critical to prevent fracture than the type of kinematics.

Keywords: Root canal treatment, Root canal preparation, Nickel-titanium, Reciprocating, Rotary, Cyclic fatigue, Fracture, Clinical outcomes.

Introduction

Endodontic therapy aims to cleanse and model the root canals by removing microorganisms and their by-products from the entire system, preserving its original course (1). To minimize undesirable changes in the original curved canal anatomy, different endodontic systems and techniques of root canal preparation have been developed in latest years. Recent endodontic instruments with increased flexibility were achieved by modifying the conventional stainless steel files using new alloys such as the nickel-titanium (NiTi) (2).

NiTi instruments have many advantages when compared to conventional files, such as greater flexibility (3) and shorter working time (4, 5). In clinical practice, however, these instruments may be subject to accidental fracture during the preparation of the canal, mainly due to repeated bending and torsional movements (6). The clinical management of a file separation is challenging and may hamper the adequate disinfection of the root canal system, making difficult to achieve the patency at the apical terminus, impairing the outcome of the root canal therapy and increasing the chances of tooth loss (7).

Current techniques for root canal preparation with NiTi files use rotary and/or reciprocating movements. Pooled results from *in vitro* studies suggest that reciprocating motion may reduce the risks of torsional fracture and cyclic fatigue, as the instrument is not subject to the same stress levels caused by the rotary motion (8, 9). In theory, a relief of the tensions of the instruments within the root canal provided by the reciprocating kinematics generates a lower fracture index (10-12). One *in vitro* study showed that the reciprocating movement presents almost twice the resistance to fracture when compared to the same instruments in continuous rotation (13).

Noteworthy, most of the evidence suggesting a higher fracture resistance of reciprocating compared to rotary instruments is raised by laboratory studies, whose results cannot be inferred to the clinical settings. Thus, the present study aims to systematically review the literature for evidence on the clinical incidence of NiTi endodontic files driven in rotary and reciprocating motions. The clinical question to be answered (the *PICO question*) may be framed as follows: in patients undergoing non-surgical root canal treatment with mechanical systems for root canal preparation, does the reciprocating kinematics results in a lower clinical incidence of NiTi files separation, when compared to the rotary motion?

Methodology

The methods of this study followed the recommendations of the PRISMA statement (14). Details of the protocol for this systematic review were registered and approved on the PROSPERO (#CRD42017075917) and can be accessed at www.crd.york.ac.uk/prospero/display_record.php?RecordID=75917.

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 up to 2017 (last accessed on August 4th 2017), with no language restriction. allowing the export of the results to the bibliographic manager EndNote Web ®. The search strategy and keywords used in different electronic databases are detailed in Table 1.

Table 1 – Search strategies according to different electronic databases.

Database	Search Strategy
PubMed	#1 “root canal preparation” OR “root canal instrumentation” OR “instrumentation protocols” OR “glide path” OR “nickel titanium” OR “automated root canal” OR “NiTi instruments” #2 “cyclic fatigue” OR “fatigue life” OR “flexural fatigue” OR “broken instrument” OR “fracture” OR “broken” OR “failure” OR “deformation” OR “incidence” OR “prevalence” OR “separated instrument” OR “breakage” OR “defect” OR “file separation” OR “file breakage” OR “separation incidence” OR “instrument separation” OR “torsional failure” OR “instrument fracture” #3 “continuous rotation motion” OR “rotary file” OR “rotary instrument” OR “rotary nickel titanium file” OR “continuous rotation” OR “rotary” OR “rotary system” OR “Protaper” OR “Protaper Next” OR “twisted file” OR “Mtwo” OR “k3” OR “Hero” OR “fkg race” OR “Profile” OR “Quantec” OR “NiTi Tee” OR “nickel titanium rotary system” OR “nickel titanium rotatory instrument” #4 “reciprocating motion” OR “reciprocating” OR “WaveOne” OR “WaveOne Gold” OR “Reciproc” OR “Reciproc Blue” OR “reciprocating file” OR “reciprocating instrument” OR “reciprocation” #5 (#1 AND #2 AND #3) #6 (#1 AND #2 AND #4) #7 (#6 OR #5) #8 (#6 OR #5 Filters: Humans)
ISI Web of Science	#1 TS= (“root canal preparation” OR “root canal instrumentation” OR “instrumentation protocols” OR “glide path” OR “nickel titanium” OR “automated root canal” OR “NiTi instruments”) #2 TS= (“cyclic fatigue” OR “fatigue life” OR “flexural fatigue” OR “broken instrument” OR “fracture” OR “broken” OR “failure” OR “deformation” OR “incidence” OR “prevalence” OR “separated instrument” OR “breakage” OR “defect” OR “file separation” OR “file breakage” OR “separation incidence” OR “instrument separation” OR “torsional failure” OR “instrument fracture”) #3 TS=(“continuous rotation motion” OR “rotary file” OR “rotary instrument” OR “rotary nickel titanium file” OR “continuous rotation” OR “rotary” OR “rotary system” OR “Protaper” OR “Protaper Next” OR “twisted file” OR “Mtwo” OR “k3” OR “Hero” OR “fkg race” OR “Profile” OR “Quantec” OR “NiTi Tee” OR “nickel titanium rotary system” OR “nickel titanium rotatory instrument”) #4 TS=(“reciprocating motion” OR “reciprocating” OR “WaveOne” OR “WaveOne Gold” OR “Reciproc” OR “Reciproc Blue” OR “reciprocating file” OR “reciprocating instrument” OR “reciprocation”) #5 (#4 OR #3) #6 (#5 AND #2 AND #1) #7 TS= (incidence OR prevalence)

Cochrane Library	#8 (#7 AND #6) #9 TS= ("in vitro" or "simulated canal" or "extracted teeth" or "extracted tooth" or "tooth extraction" or "teeth extraction" or "extracted human teeth") #10 (#8 AND #9) #1 “root canal preparation” OR “root canal instrumentation” OR “instrumentation protocols” OR “glide path” OR “nickel titanium” OR “automated root canal” OR “NiTi instruments” (word variations have been searched) #2 “cyclic fatigue” OR “fatigue life” OR “flexural fatigue” OR “broken instrument” OR “fracture” OR “broken” OR “failure” OR “deformation” OR “incidence” OR “prevalence” OR “separated instrument” OR “breakage” OR “defect” OR “file separation” OR “file breakage” OR “separation incidence” OR “instrument separation” OR “torsional failure” OR “instrument fracture” (word variations have been searched) #3 “continuous rotation motion” OR “rotary file” OR “rotary instrument” OR “rotary nickel titanium file” OR “continuous rotation” OR “rotary” OR “rotary system” OR “Protaper” OR “Protaper Next” OR “twisted file” OR “Mtwo” OR “k3” OR “Hero” OR “fkg race” OR “Profile” OR “Quantec” OR “NiTi Tee” OR “nickel titanium rotary system” OR “nickel titanium rotatory instrument” (word variations have been searched) #4 “reciprocating motion” OR “reciprocating” OR “WaveOne” OR “WaveOne Gold” OR “Reciproc” OR “Reciproc Blue” OR “reciprocating file” OR “reciprocating instrument” OR “reciprocation” (word variations have been searched) #5 (#1 AND #2 AND #3) #6 (#1 AND #2 AND #4) #7 (#6 OR #5) #8 "in vitro" or "simulated canal" or "extracted teeth" or "extracted tooth" or "tooth extraction" or "teeth extraction" or "extracted human teeth" (word variations have been searched) #9 (#7 NOT #8
EMBASE	#1 ‘root canal preparation’/exp OR ‘root canal preparation’ OR ‘root canal intrumentation’ OR ‘instrumentation protocols’ OR ‘glide path’ OR ‘nickel-titanium’ OR ‘automated root canal’ OR ‘niti instruments’ #2 ‘cyclic fatigue’ OR ‘fatigue life’ OR ‘flexural fatigue’ OR ‘broken instrument’ OR ‘fracture’/exp OR ‘fracture’ OR ‘broken’ OR ‘failure’/exp OR ‘failure’ OR ‘deformation’/exp OR ‘deformation’ OR ‘incidence’/exp OR ‘incidence’ OR ‘prevalence’/exp OR ‘prevalence’ OR ‘separated instrument’ OR ‘breakage’ OR ‘defect’ OR ‘file separation’ OR ‘file breakage’ OR ‘separation’/exp OR ‘separation’ OR ‘instrument fracture’ #3 ‘continuous rotation motion’ OR ‘rotatory file’ OR ‘rotatory instrument’ OR ‘rotatory nickel titanium file’ OR ‘continuous rotation’ OR ‘rotary’ OR ‘rotary system’ OR ‘protaper’ OR ‘protaper next’ OR ‘twisted file’ OR ‘mtwo’ OR ‘k3’ OR ‘hero’ OR ‘fkg-race’ OR ‘profile’ OR ‘quantec’ OR ‘niti tee’ OR ‘nickel titanium rotary system’ OR ‘nickel titanium rotatory instrumet’ #4 ‘reciprocating motion’ OR ‘reciprocating’ OR ‘waveone’ OR ‘waveone gold’ OR ‘reciproc’ OR ‘reciproc blue’ OR ‘reciprocating file’ OR ‘reciprocating instrument’ OR ‘reciprocation’ #5 (#1 AND #2 AND #3 AND #4) #6 ‘clinical article’/de OR ‘human’/de OR ‘randomized controlled trial’/de #7 (#5 AND #6) #8 (#1 AND #2 AND #3) OR (#1 AND #2 AND #4) #9 ‘case report’/de OR ‘clinical article’/de OR ‘clinical trial’/de OR ‘cross-sectional stydy’/de OR ‘human’/de OR ‘human experiment’/de OR ‘major clinical study’/de OR ‘pilot study’/de OR ‘prospective study’/de OR ‘randomized controlled trial’/de OR ‘retrospective study’/de #10 (#8 AND #9)

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 September 15th 2017). Finally, the bibliography of relevant studies was manually searched and, when necessary, the authors of relevant articles were contacted in an attempt to extract additional unreported data.

In a preliminary analysis, titles and abstracts of all the selected studies where scanned, and the relevance of each study was determined. Duplicate studies were identified and discarded. The remaining articles were subjected to stricter inclusion and exclusion criteria.

Study Selection and Inclusion and Exclusion Criteria

Two independent reviewers (R.M.V., D.E.B.) examined the full texts of the remaining articles, based on the following inclusion criteria:

1. Observational or interventional clinical studies (randomized or non-randomized 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 stainless steel 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: author´s names, 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, group of teeth, operator, number of visits necessary to complete the root canal treatment, number of uses of NiTi files. The reviewers independently rated the quality of each study based on the Newcastle-Ottawa Scale (NOS) (15), and a consensus was reached. After reviewing and rating the studies, the main results regarding the incidence of NiTi file separation was recorded for each study.

Main Exposures, Outcome Variables and Statistical Analysis

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 separation, considering the instrument as the unit of analysis. The estimated pooled incidence of separation of NiTi files from all included studies was calculated by using a random-effect method. Logistic meta-regression was used to identify possible sources of heterogeneity between studies. This analytic strategy evaluated which variables affected the results. Initially, bivariate analysis was performed, and related variables ($P < .20$) in the univariate analysis were included in the final multivariate meta-regression models. The pooled estimates for the

incidence of files separation were determined, and *Odds ratios* (OR) and 95% confidence intervals (95% CI) were reported. Only variables with P <.05 in the final models were considered statistically significant. All analyses were performed in Stata 13.1 (Stata Corp, College Station, TX).

Results

Results from the search strategy yielded a total of 737 hits. After duplicate references were discarded, a subsequent search at the title and abstract level revealed 44 articles for full-text reading. At this level, 5 studies were excluded, due to the following reasons: *in vitro* cyclic fatigue evaluation (16, 17), fracture incidence not reported (18) or similarity of study design and subjects (19, 20) with other merged included study (21, 22). Figure 1 details the flowchart for the study selection process.

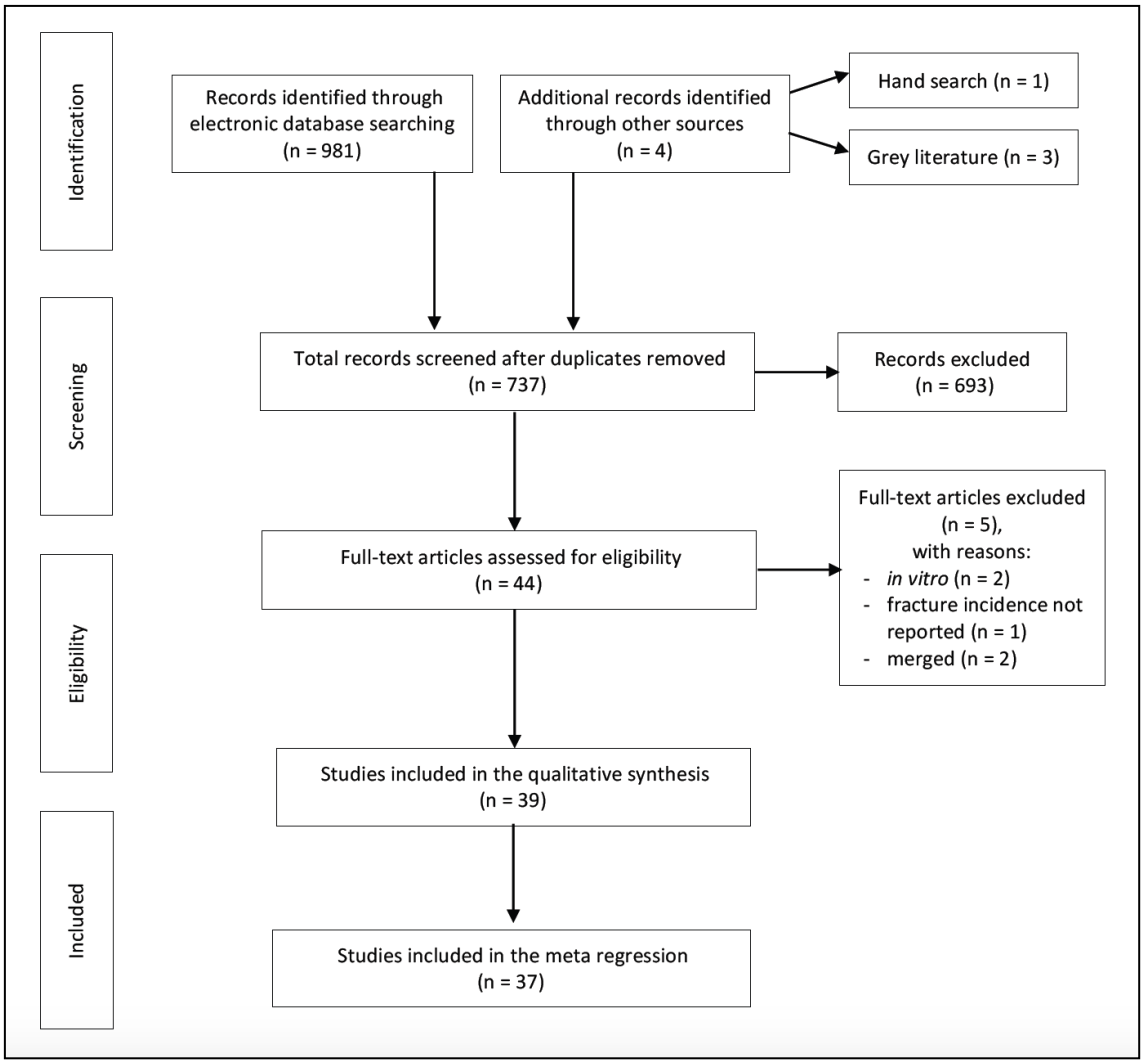

Figure 1 – Flowchart for the study selection process.

Study characteristics

Thirty-nine studies were included in the final analysis. Their main characteristics and findings are presented in Table 2. A total of 33 studies reported the incidence of fracture of NiTi files under rotary kinematics, while 7 studies presented data on the separation incidence of reciprocating NiTi files. The incidence of fracture varied from zero (23, 24) to 22% (25).

Noteworthy, only one clinical study comparing the incidence of fracture of NiTi files with both kinematics in the same sample was identified (26). The most prevalent study design was prospective observational studies (n=32). Most included studies were conducted in Chinese populations (n=12), followed by Canadian (n=6) and North-American (n=6) studies. The "instrument" was the most common unit of analysis to report the incidence of NiTi files separation, with a total of 22 studies. Interestingly, only two studies (27,34) presented detailed information on the incidence of fracture in all different units of analysis (patients, teeth, root canals and instruments).

The Protaper rotary system was the most prevalent, evaluated by 19 included studies, while the most prevalent 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 groups of teeth, while in 8 studies the sample was restricted to molar teeth. In 7 studies, the group of teeth was not reported. The most frequent operators were endodontists (n=24), followed by graduate (n=7) and undergraduate students (n=6). Most studies (n=27) failed to report the number of visits necessary 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 teeth, and only 11 studies restricted the use of the NiTi endodontic instruments to one teeth. The quality ratings of each study as evaluated according to the NOS criteria are presented in Table 3.

Table 2 – Characteristics and main results of the studies included in the systematic review (N=39).

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 separation (N / %)
AbuTahum *et al*, 2014 (28)	Jordan	Prospective	96 teeth	Rotary	ProTaper	Molars	Undergraduate students	72 teeth: One visit 24 teeth: Two visits	01 molar	01 / 1.04
Alapati et al, 2005 (29)	USA	Prospective	822 instruments	Rotary	Profile Profile GT ProTaper	NR	Graduate students	NR	6-8 uses	42 / 5.10
Al-Fouzan 2003 (27)	Saudi Arabia	Prospective	456 instruments 1457 canals 419 teeth 408 patients	Rotary	Profile	first and second Molars	Endodontists	One visit	05 molars	21 / 4.6
Arens et al, 2003 (30)	USA	Prospective	786 instruments	Rotary	Profile series 29	NR	Endodontists	One visit	01 tooth	07 / 0.89
Bueno et al, 2017 (31)	Brazil	Prospective	358 teeth 1130 canals	Reciprocating	WaveOne Reciproc	Molars Premolars	Endodontists	NR	03 teeth	03 / 0.26
Chakka et al, 2012 (23)	India	Prospective	64 instruments	Rotary	ProTaper Endowave	Anterior	Endodontists	NR	20 teeth	0 / 0
Chen et al, 2013 (26)	China	Prospective	88 teeth 273 canals	Rotary & Reciprocating	ProTaper Reciproc	Molars Premolars	Endodontists	Two visits	15 canals	02 / 2.41 04 / 4.76
Cheung et al, 2005 (21)	China	Prospective	122 instruments	Rotary	ProTaper S1	Molars Premolars Anterior	Endodontists	One visit	04 molars 20 premolars 50 anterior	27 / 22.13
Cheung et al, 2007 (32)	China	Prospective	325 instruments	Rotary	ProTaper	Molars Premolars Anterior	Clinicians	One visit	04 molars 20 premolars 50 anterior	16 / 5.0
Cunha et al, 2014 (33)	Canada	Prospective	711 teeth 2215 canals	Reciprocating	WaveOne	Molars Premolars	Endodontists	NR	01 tooth	03 / 0.13 03 / 0.42
Di Fiore et al, 2006 (34)	USA	Prospective	6661 instruments 3818 canals 1403 teeth 1235 patients	Rotary	Profile ProTaper Gt Rotary K3	Molars Premolars Anterior	Endodontists	One visit	01 molar	26 / 1.9

Ehrhardt et al, 2012 (35)	Brazil	Prospective	681 instruments 556 teeth	Rotary	Mtwo	Molars Premolars	Endodontists	One visit	01 tooth	11 / 1.98
Hu et al, 2005 (36)	China	Prospective	100 teeth	Rotary	Hero 642 ProTaper	Molars Premolars	Endodontists	NR	NR	05 / 5.0
Inan et al, 2009 (37)	Turkey	Retrospective	593 instruments	Rotary	MTwo	Molars	Endodontists	NR	02 to 04 molars	95 / 16.2
Iqbal et al, 2006 (38)	USA	Retrospective	4865 teeth 4107 instruments	Rotary	Profile S29 Profile GT LightSpeed	Molars Premolars Anterior	Graduate students	NR	NR	69 / 1.68
Knowles et al, 2006 (39)	USA	Prospective	3543 canals	Rotary	LightSpeed	Molars Premolars Anterior	Undergraduate students	NR	NR	46 / 1.30
Plotino et al, 2015 (40)	Italy	Prospective	1696 instruments 3780 canals	Reciprocating	Reciproc	Molars Premolars Anterior	Endodontists	NR	01 tooth	08 / 0.47
Ramirez-Solomon *et al*, 1997 (41)	Mexico	Prospective	52 teeth 162 canals	Rotary	LightSpeed	First Molars	Endodontists	NR	11 to 13 molars	06 / 3.70
Rodrigues et al, 2016 (42)	Brazil	Prospective	277 teeth 673 canals	Reciprocating	Reciproc	Molars Premolars Anterior	Endodontists	One visit	01 tooth	03 / 0.44
Sattapan et al, 2000 (43)	Australia	Prospective	378 instruments	Rotary	Quantec	NR	Endodontists	NR	NR	79 / 21.0
Schäfer et al, 2004 (44)	Germany	Prospective	110 canals	Rotary	FlexMaster	Molars Premolars	Clinicians	NR	06 teeth	02 / 1.81
Shen S et al, 2016 (45)	China	Prospective	2397 instruments	Rotary	K3	NR	Graduate students	NR	30 canals	86 / 3.59
Shen Y *et al*, 2013 (24)	Canada	Retrospective	468 instruments	Rotary	HyFlex	Molars Premolars	Graduate students	NR	03 teeth	0 / 0

Shen Ya et al, 2012 (46)	China	Prospective	2203 instruments	Rotary	Profile Vortex	Molars Premolars Anterior	Undergraduate Students	NR	01 tooth	01 / 0.04
Shen Ya et al, 2009 (47)	Canada	Retrospective	3706 instruments	Rotary	Profile	NR	Undergraduate Students	NR	03 teeth	12 / 0.32
Shen et al, 2016 (48)	Canada	Prospective	438 instruments 294 teeth	Reciprocating	WaveOne	Molars Premolars Anterior	Graduate students & Endodontists	NR	01 tooth	02 / 0.50
Shen et al, 2006 (49)	China	Prospective	487 instruments	Rotary	Profile ProTaper	Molars Premolars Anterior	Clinicians	One visit	04 molars 20 premolars 50 anterior	57 / 11.7
Shen et al, 2009 (22)	China	Prospective	1402 instruments	Rotary	ProTaper K3	Molars Premolars Anterior	Endodontists	NR	30 canals	68 / 4.85
Shen et al, 2015 (50)	Canada	Prospective	1466 instruments 459 teeth	Rotary	Profile Vortex Profile Vortex Blue	Molars	Graduate students	NR	03 molars	02 / 0.13
Shen et al, 2009 (51)	Canada	Prospective	3398 instruments	Rotary	Profile Profile S29 ProTaper	NR	Endodontists	One visit	01 tooth	05 / 0.26
Spili et al, 2005 (52)	Australia	Retrospective	5103 teeth	Rotary	ProTaper Profile Quantec K3	NR	Endodontists	Multiple visits	NR	226 / 1.83
Tzanetakis et al, 2008 (53)	Greece	Retrospective	1367 patients 2180 teeth 4897 canals	Rotary	Hero Profile ProTaper	Molars Premolars Anterior	Graduate students	NR	NR	28 / 1.33
Vieira et al, 2008 (54)	Brazil	Prospective	18 molars	Rotary	ProTaper	Molars	Endodontists & Undergraduate students	NR	05 to 08 molars	06 / 3.57
Wang Y. et al, 2010 (55)	China	Prospective	90 teeth	Rotary	ProTaper MTwo K3	Molars	Endodontists	NR	NR	08 / 8.88

Wang Q. et al, 2010 (56)	China	Prospective	432 patients	Rotary	ProTaper	Molars	Endodontists	NR	NR	27 / 6.25
Wei et al, 2007 (57)	China	Prospective	774 instruments	Rotary	ProTaper	Molars Premolars	Undergraduate Students	NR	30 canals	100 / 12.91
Wolcott et al, 2006 (58)	USA	Retrospective	4652 canals	Rotary	ProTaper	Molars Premolars Anterior	Endodontists	NR	05 uses	113 / 2.4
Wu et al, 2011 (59)	China	Prospective	6154 canals 2654 teeth	Rotary	ProTaper	Molars Premolars Anterior	Endodontists	NR	03 molars 10 premolars 30 anterior	70 / 1.1 70 / 2.6
Zuolo et al, 2015 (60)	Brazil	Prospective	174 MB canals	Reciprocating	Reciproc	First and second Molars	Endodontists	NR	01 tooth	03 / 1.72

Table 3 – Methodologic quality assessment of observational studies according to the Newcastle-Ottawa Scale criteria (N= 39).

NOS criteria	Abu Tahum *et al* (2014)(28)	Alapati *et al* (2005)(61)	Al-Fouzan (2003)(27)	Arens *et al* (2003)(30)	Bueno *et al* (2017)(31)	Chakka *et al* (2012)(23)	Cheng *et al* (2013)(26)	Cheung *et al* (2005)(21)	Cheung *et al* (2007)(32)
Selection									
1 Representativeness of the exposed cohort	*	*	*	*	*	*	*	*	*
2 Selection of the non-exposed cohort	NA	NA	NA	NA	NA	NA	NA	NA	NA
3 Ascertainment of exposure	*	*	*	*	*	*	*	*	*
4 Demonstration that outcome of interest was not present at start of study	*	-	*	*	*	*	*	*	*
Comparability									
1 Comparability of cohorts on the basis of the design or analysis	*	-	*	*	*	-	*	-	-
Outcome									
1 Assessment of outcome	*	*	*	*	*	*	*	*	*
2 Was follow-up long enough for outcomes to occur	*	*	*	*	*	*	*	*	*
3 Adequacy of follow-up of cohort (<20%)	*	*	*	*	*	*	*	*	*
Total awarded stars	**7**	**5**	**7**	**7**	**7**	**6**	**7**	**6**	**6**

NOS criteria	Cunha *et al* (2016)(33)	Di fiore *et al* (2006)(34)	Ehrhardt *et al* (2012)(35)	Hu *et al* (2005)(36)	Inan *et al* (2009)(37)	Iqbal *et al* (2006)(38)	Knowles *et al* (2006)(39)	Ma *et al* (2010)(56)	Plotino *et al* (2015)(40)	Ramirez-Solomon *et al* (1997)(41)
Selection										
1 Representativeness of the exposed cohort	*	*	*	*	*	*	*	*	*	*
2 Selection of the non-exposed cohort	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
3 Ascertainment of exposure	*	*	*	*	*	*	*	*	*	*
4 Demonstration that outcome of interest was not present at start of study	*	*	*	*	*	*	*	*	*	*
Comparability										
1 Comparability of cohorts on the basis of the design or analysis	*	-	*	*	-	-	*	-	*	*
Outcome										
1 Assessment of outcome	*	*	*	*	*	*	*	*	*	*
2 Was follow-up long enough for outcomes to occur	*	*	*	*	*	*	*	*	*	*
3 Adequacy of follow-up of cohort (<20%)	*	*	*	*	*	*	*	*	*	*
Total awarded stars	**7**	**6**	**7**	**7**	**6**	**6**	**7**	**6**	**7**	**7**

NOS criteria	Rodrigues *et al* (2016)(42)	Sattapan *et al* (2000)(43)	Schäfer *et al* (2004)(44)	Shen S *et al* (2016)(45)	Shen Y *et al* (2013)(24)	Shen Y *et al* (2012)(46)	Shen Y *et al* (2009)(22)	Shen Y *et al* (2016)(48)	Shen *et al* (2006)(62)
Selection									
1 Representativeness of the exposed cohort	*	*	*	*	*	*	*	*	*
2 Selection of the non-exposed cohort	NA	NA	NA	NA	NA	NA	NA	NA	NA
3 Ascertainment of exposure	*	*	*	*	*	*	*	*	*
4 Demonstration that outcome of interest was not present at start of study	*	*	*	*	*	*	*	*	*
Comparability									
1 Comparability of cohorts on the basis of the design or analysis	**	*	-	-	-	*	*	**	*
Outcome									
1 Assessment of outcome	*	*	*	*	*	*	*	*	*
2 Was follow-up long enough for outcomes to occur	*	*	*	*	*	*	*	*	*
3 Adequacy of follow-up of cohort (<20%)	*	*	*	*	*	*	*	*	*
Total awarded stars	**8**	**7**	**6**	**6**	**6**	**7**	**7**	**8**	**7**

NOS criteria	Shen *et al* (2009)(47)	Shen *et al* (2015)(50)	Shen *et al* (2009)(63)	Spili *et al* (2005)(52)	Tzanetakis *et al* (2008)(53)	Vieira *et al* (2008)(54)	Wang Y *et al* (2010)(55)	Wei *et al* (2007)(57)
Selection								
1 Representativeness of the exposed cohort	*	*	*	*	*	*	*	*
2 Selection of the non-exposed cohort	NA	NA	NA	NA	NA	NA	NA	NA
3 Ascertainment of exposure	*	*	*	*	*	*	*	*
4 Demonstration that outcome of interest was not present at start of study	*	*	*	*	*	*	*	*
Comparability								
1 Comparability of cohorts on the basis of the design or analysis	*	-	*	*	*	*	*	-
Outcome								
1 Assessment of outcome	*	*	*	*	*	*	*	*
2 Was follow-up long enough for outcomes to occur	*	*	*	*	*	*	*	*
3 Adequacy of follow-up of cohort (<20%)	*	*	*	*	*	*	*	*
Total awarded stars	**7**	**6**	**7**	**7**	**7**	**7**	**7**	**6**

NOS criteria	Wolcott *et al* (2006)(58)	Wu *et al* (2011)(59)	Zuolo *et al* (2015)(60)
Selection			
1 Representativeness of the exposed cohort	*	*	*
2 Selection of the non-exposed cohort	NA	NA	NA
3 Ascertainment of exposure	*	*	*
4 Demonstration that outcome of interest was not present at start of study	*	*	*
Comparability			
1 Comparability of cohorts on the basis of the design or analysis	*	-	**
Outcome			
1 Assessment of outcome	*	*	*
2 Was follow-up long enough for outcomes to occur	*	*	*
3 Adequacy of follow-up of cohort (<20%)	*	*	*
Total awards stars	**7**	**6**	**8**

Meta regression analysis

Five studies (29, 45, 49, 64, 65) presented sufficient data on the outcome and on different co-variables, which allowed its dismemberment in more than one "sub-study". Thus, the meta regression was carried out considering these "sub-studies" as different separated studies. As a result, a total of 37 studies/sub-studies were included in the meta regression, invariably considering the "instrument" as the unit 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 separation was 2.43%, with a total of 48,405 clinically used instruments included. Heterogeneity was present (I^2 = 97.4%), and the weights of the included studies varied from 1.23% to 3.06%.

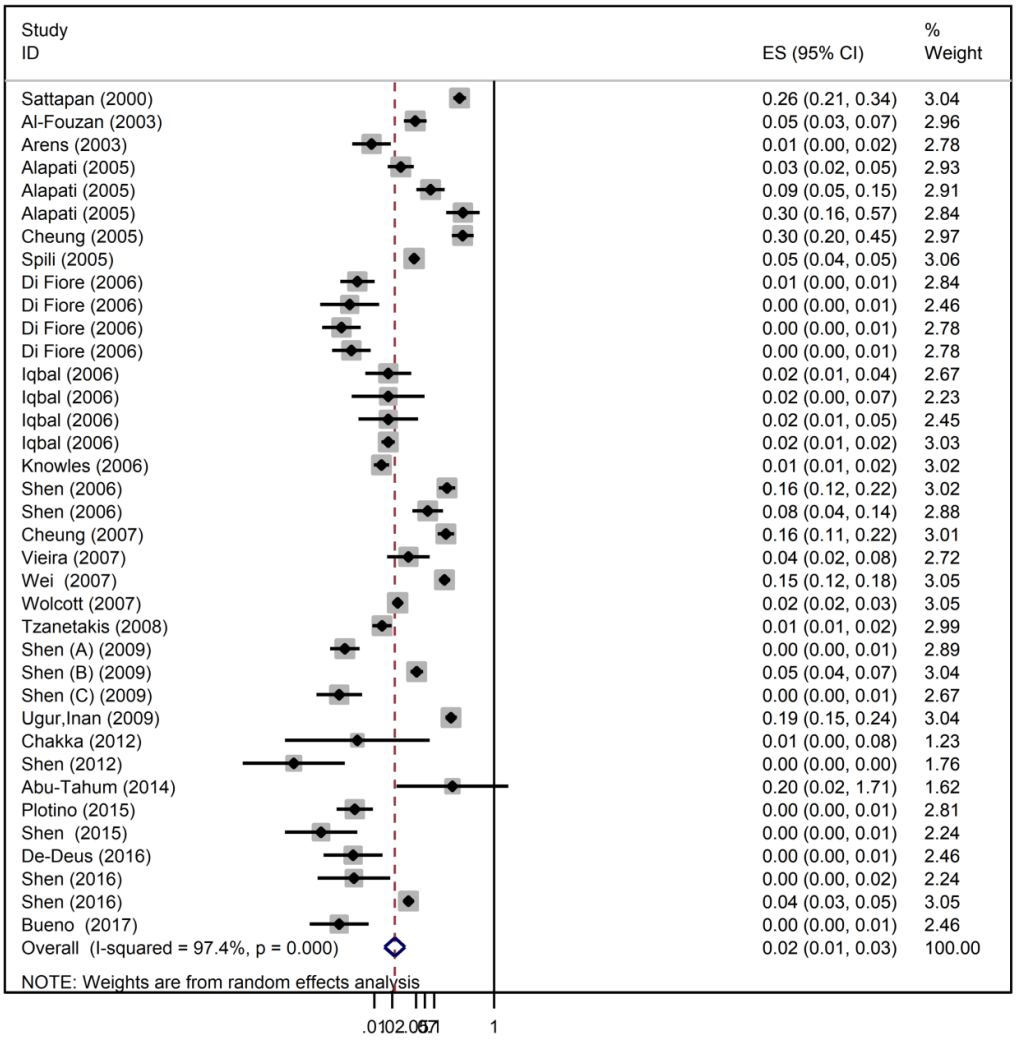

Figure 2 – Forest plot for the overall clinical incidence of fracture of NiTi endodontic instruments.

The Table 4 expresses the results of the bivariate meta regression analysis, with the pooled incidence of fracture of NiTi instruments, according to different exposure variables. The incidence of file separation was significantly higher (OR=6.4, 95%CI=1.1-36.9, *p*=0.04) with rotary motion (2.6%), compared to the reciprocating kinematics (0.4%). The year of publication was strongly associated with the incidence of fracture, with older studies (before 2005) presenting a higher chance of fracture (OR=13.6, 95%CI=3.1-59.8, *p*<0.01) than recent studies (2011-2017). In addition, the pooled incidence of fracture among clinicians (12.4%) was significantly higher (OR=11.9, 95%CI=1.1-126.0), compared to the incidence of graduate students (1.26%). Finally, the number of uses of NiTi files showed to be associated with the incidence of separation, since the use in more than one teeth presented a combined incidence of fracture (2.8%) significantly higher (OR=8.7, 95%CI=2.4-31.9) than the incidence when the use was limited to one tooth (0.3%).

The adjusted models for the incidence of fracture of NiTi instruments, according to different kinematics, are expressed in Table 5. The Model C reveals that rotary kinematics (OR=1.6, 95%CI=0.2-10.0, *p*=0.63) was not significantly associated with the incidence of separation of NiTi files if adjusted for both the number of uses of NiTi files and the operator. Interestingly, these two co-variables showed to be independently associated with the clinical incidence of fracture of NiTi files (p=0.02), irrespectively of the type of kinematics employed.

Table 4 – 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	Incidence (%)	N (studies)	N (instruments)	OR (95%CI)	*p*-value
Kinematics					0.04
Reciprocating	0.40	4	3,968	Ref.	
Rotary	2.62	33	44,437	6.39 (1.10 - 36.92)	
Country					0.18
Other countries	3.77	11	12,468	Ref.	
China	4.17	10	9,406	1.42 (0.33 - 6.13)	
USA / Canada	1.19	16	26,531	0.44 (0.21 - 1.64)	
Year of publication					<0.01
2011-2017	1.04	9	10,208	Ref.	
2006-2010	2.19	20	30,497	3.62 (1.03 - 12.74)	
2000-2005	5.23	8	7,700	13.59 (3.08 -59.83)	
Group of teeth					0.88
Anterior	0.52	1	96	Ref.	
Molars	3.27	6	3,914	4.75 (0.04 - 550.9)	
Molars and Bicuspids	2.55	6	8,419	4.56 (0.04 - 523.3)	
Multiple groups (all)	2.32	16	25,964	3.09 (0.03 - 308.0)	
Not reported	2.31	8	10,012	5.70 (0.05 - 615.6)	
Operator					0.12
Graduate students	1.26	5	5,645	Ref.	
Undergraduate students					
Clinicians	2.27	11	16,953	2.85 (0.48 - 16.95)	
Endodontists	12.44	3	812	11.92 (1.13 - 126.0)	
	2.49	18	24,995	1.38 (0.26 - 7.40)	
Number of uses of NiTi instruments					<0.01
1 teeth	0.32	7	10,203	Ref.	
>1 teeth	2.83	25	27,039	8.69 (2.37 - 31.92)	
Not reported	3.40	4	11,157	11.43 (1.82 - 71.83)	
Overall	**2.43**	**37**	**48,405**	**-**	**-**

Table 5 – Multivariate meta-regression models for the incidence of fracture of NiTi instruments, according to different kinematics, adjusted for number of uses (Model A), operator (Model B) or both (Model C). Odds-ratios (OR) and 95% confidence intervals (CI). N = number of studies in the model.

Model	Variables	OR (95%CI)	*p*-value
A (N=32)	**Kinematics**		
	Reciprocating	Ref.	
	Rotary	1.73 (0.26 - 11.62)	0.56
	Number of uses		
	1 teeth	Ref.	
	>1 teeth	7.00 (1.53 - 31.96)	0.01
B (N= 37)	**Kinematics**		
	Reciprocating	Ref.	
	Rotary	5.27 (0.85 - 32.51)	0.07
	Operator		
	Graduate students	Ref.	
	Undergraduate students	2.84 (0.51 - 15.96)	0.22
	Clinicians	11.89 (1.22 - 115.4)	0.03
	Endodontists	1.98 (0.37 - 10.46)	0.41
C (N=32)	**Kinematics**		
	Reciprocating	Ref.	
	Rotary	1.56 (0.24 - 10.00)	0.63
	Number of uses		
	1 teeth	Ref.	
	>1 teeth	6.46 (1.42 - 29.26)	0.02
	Operator		
	Graduate students	Ref.	
	Undergraduate students	3.59 (0.68 - 18.87)	0.13
	Clinicians	11.81 (1.49 - 93.51)	0.02
	Endodontists	2.37 (0.47 - 11.79)	0.28

Discussion

The fracture of instruments during root canal preparation may represent a predictor of failure for endodontic therapy (66, 67). Even considering the possibility bypassing the fragment, incorporating the fractured instrument into the filling material, or still removing it, improving the chances of a favorable prognosis (52), this accident is a stressor for the operator who needs to spend more time to solve this clinical accident. In view of these setbacks, the present study represents a significant contribution to the body of evidence in the field of clinical Endodontics, since to the best of the authors knowledge, this systematic review (SR) is novel on identifying the predictors associated with the incidence of NiTi files separation, aiming to support a clinical practice based on the prevention of this accident.

Evidence from laboratory studies have hypothesized that reciprocating kinematics would be one of the primary aspects in order to avoid the occurrence of instrument fracture, since alternating clockwise and counterclockwise rotation would decrease tensional stress on the instrument, preventing torsional fractures (10-12). This *in vitro* assumption was, in part, endorsed by the results from the pooled data collected in the present SR, which suggested a lower clinical incidence of fracture of NiTi instruments when reciprocating kinematics was used, compared to the rotary motion, confirming the tested hypothesis. Nevertheless, present meta-regression analysis showed that the nature of the kinematics is a less important clinical factor regarding the risk of fracture than other aspects such as the number of uses of the NiTi instruments, the type of operator and the year of publication (this, a possible surrogate measure of the evolution of the file alloys and designs). These findings, of a high clinical relevance, represent the synthesis of the best available scientific evidence to date.

The number of uses was significantly associated with the risk of fracture of the NiTi instruments. Studies that limited the use of instruments to one tooth presented a lower fracture incidence (28, 30, 33, 46, 48, 60, 63). Notably, the manufacturers' recommendations for reciprocating systems is to restrict the use of the instruments to one tooth. Accordingly, this indication was maintained by the researchers that evaluated the fracture incidence of reciprocating NiTi files (33, 40, 42, 48, 60). In other words, all the instruments evaluated during reciprocating kinematics were used only once, differently from some investigations in which the continuous rotation systems were used for up to 20-30 teeth (23, 59, 68). Still, when rotary systems were used in only one tooth (28, 30, 46, 63), the fracture incidence was close to 1% or lower, similar to the results from studies evaluating reciprocating systems.

Considering the interpretation of the collected data and the risk factors evaluated by the meta regression, one can make the assumption that, in addition to the influence of kinematics, the evolution of the NiTi alloys and designs positively interfered in the reduction of the fracture incidence. The current alloys have characteristics that favor elasticity and, consequently, may prevent fracture by improving the resistance to the tensile and torsional forces generated during its use inside the root canal (16). This is perceived from the reduction of fracture observed in the most recent studies (2011-2017, with a pooled incidence of 1.04%), compared to older studies (pooled incidence of 5.23%, from 2000-2005), with a significant OR=13.6 (3.1-59.8). Anyway, it should be highlighted that, among the most recent studies, are those in which the reciprocating movement is tested (33, 40, 42, 48, 60).

In addition, multivariate models revealed a significantly higher pooled incidence of fracture when root canal treatment was performed by clinicians compared to graduate students, reaching an eleven-fold greater risk (OR=11.8, 95%CI=1.5-93.5), independently of the reciprocating movement or the number of uses of the instruments. These results strongly suggest that, despite the use of mechanized technology, the operator's technical ability and the respect for established clinical protocols is still of paramount importance. Accordingly, it can be inferred that the learning curve, allowing the familiarization with the mechanized techniques for root canal preparation, ends up developing the ability of the operator, reducing the risk of file separation and favoring the outcome of endodontic therapy.

One important limitation of the present SR is that, among the included studies, only a few (38, 39, 69) were specifically designed to evaluate the incidence of separation. This feature hampered to carry out a traditional meta-analysis, and motivated the meta regression strategy to deal with the high heterogeneity. In most investigations, the main outcome was other than the incidence of fracture of the NiTi instruments: the quality of the root canal preparation (28), the type of fracture (32), the impact of file separation on the prognosis of the therapy (52), the influence of the group of teeth and the number of uses on fracture (70), the formation of ledge and apical zip (30), the post-operative pain (26), the time of root canal preparation (26), or the adequacy of the root canal filling (71). Even though most included studies did not evaluate the separation of NiTi files as the primary outcome, it didn’t represent a hindrance to extract the data of interest for this SR.

Regarding the quality evaluation of the studies, some adaptations were necessary for the use of the NOS classification. The item “selection of the non-exposed cohort”, could not be applied to any included study: even if the incidence of fracture was evaluated, 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 (specialist) and the number of uses of the instruments (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 is the main outcome. So, some studies (42, 48, 60) presented a higher quality rating for the evaluation of the kinematic influence on the fracture incidence. Finally, the general methodologic quality of the included observations 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 mechanized NiTi files was 2.4%, which may represent a useful information for clinicians to advise patients about the general risks of this undesirable accident related to RCT. Noteworthy, the occurrence of fracture is reducing over time, which is an encouraging observation under the clinical settings. Even if the hypothesis raised in the present SR was confirmed, suggesting that reciprocating motion reduces the incidence of fracture of NiTi instruments, it must be very clear that other factors concomitant to the popularization of this kinematics were found to be stronger predictors of NiTi file separation: the modern NiTi alloys and designs, a compulsory single use of the NiTi instruments and the ability of specialized operators.

Implications for further research

Taken together, 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 sample. In addition, future clinical studies on this topic should present detailed information on the incidence of fracture in all different units of analysis (patients, teeth, root canals and instruments), in order to allow further pooled comparisons. Finally, future clinical studies dedicated to identify a safe clinical protocol regarding the maximum number of (re)uses of both rotary and reciprocating systems would be of great therapeutic, economic and social relevance.

Conclusions

Available evidence from observational studies is limited but consistent, suggesting that reciprocating motion is associated with a lower clinical incidence of NiTi files separation compared to the rotary kinematics. Most importantly, other clinical factors related to the operator, the number of uses of NiTi instruments and modern file alloys and designs showed to be more critical to prevent fracture than the type of kinematics.

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CONSIDERAÇÕES FINAIS

O presente estudo contribui de modo importante com a construção do conhecimento no campo da Endodontia clínica, já que esta parece ser a primeira revisão sistemática (RS) conduzida com o intuito de analisar a incidência clínica de fratura de instrumentos de NiTi acionados mecanicamente. Os dados coletados permitiram a realização de uma meta-regressão, oferecendo a oportunidade de analisar também os fatores clínicos que estão relacionados à ocorrência deste importante acidente, que não raro é capaz de afetar o prognóstico da terapia endodôntica.

Desse modo, esta RS inova ao apresentar resultados construídos a partir da agregação de dados de mais de trinta estudos clínicos incluídos que, em conjunto, sugerem que a incidência de fratura de limas de NiTi acionadas em cinemática reciprocante é menor do que a incidência agregada de fratura de instrumentos endodônticos acionados em rotação contínua. Ainda assim, as análises de meta-regressão evidenciam que o tipo de cinemática é um fator clínico menos importante, no que tange à chance de fratura, do que outros fatores como o número de usos dos instrumentos, o tipo de operador e o ano de publicação. Estes achados, de alta relevância clínica, representam a síntese do mais elevado nível de evidência científica disponível até o momento.

O conhecimento atual sobre resistência à fadiga cíclica dos instrumentos endodônticos é, em grande parte, oriundo de estudos laboratoriais. O emprego de metodologias *in vitro* tem seu nível de importância, já que são capazes de isolar uma série de variáveis importantes, porém os resultados advindos destes modelos experimentais não podem ser integralmente transpostos para o cenário clínico. As análises de testes laboratoriais (41, 42), que utilizam canais simulados ou modelos *ex vivo* com dentes humanos extraídos, não contemplam uma constelação de covariáveis que podem impactar na ocorrência de um acidente como a fratura de um instrumento de NiTi, tais como: nível de colaboração do paciente com o tratamento, fadiga do paciente e do operador, variações anatômicas do sistema de canais radiculares, fatores sócio-econômicos e culturais presentes na complexa interação profissional-paciente, nível de experiência e habilidade do operador, variáveis relativas aos métodos de esterilização e armazenamento dos instrumentos endodônticos, dentre muitos outros, até mesmo fatores ainda desconhecidos, porém presentes na prática clínica.

Dentre os estudos incluídos nesta RS, com base nos critérios de inclusão e exclusão, poucos estudos clínicos foram desenhados especificamente para analisar incidência de fratura (18, 19, 43). Na maioria dos estudos incluídos, o desfecho principal era outro: qualidade do preparo do canal radicular (44), tipo de fratura (45), impacto da fratura no desfecho do tratamento (46), influência do grupo dentário e número de usos dos instrumentos (47), formação de degrau e desvio apical (48), ou avaliação da dor pós operatória, do tempo

utilizado para preparo do canal radicular e do preenchimento do canal radicular (49). Ainda assim, esta característica não impediu a extração dos dados necessários para contemplar sua inclusão nesta RS.

Neste particular, cumpre destacar que a metodologia empregada na presente RS teve a iniciativa de enviar cartas a autores correspondentes de dez estudos incluídos, na tentativa de obter dados adicionais, não reportados na íntegra dos textos originais. De modo surpreendente, infelizmente apenas um dos autores contatados respondeu à nossa solicitação (Anexo 4). Desse modo, o volume de dados não reportados descrito na síntese dos dados (Tabela 2 do artigo) foi maior do que o desejado.

Ainda em relação ao método empregado, na fase de buscas optou-se por utilizar as bases eletrônicas PubMed, EMBASE, Isi Web of Science e Cochrane Library. Consideramos que o conjunto destas quatro bases compõe um rico universo de pesquisa, contemplando a maior parte das fontes eletrônicas disponíveis atualmente. Estas bases foram relevantes para o acesso das informações no desenvolvimento desta pesquisa. Elas permitiram buscas exaustivas sobre o tema, com resumos e indicações de textos completos que foram acessados e disponibilizados pela Biblioteca Irmão José Otão da PUCRS, em especial permitindo a exportação dos resultados para o gerenciador bibliográfico EndNote Web®. Complementarmente às buscas eletrônicas, foram realizadas buscas manuais (que resultou na identificação de um estudo adicional) e buscas na literatura cinza (cujo resultado não implicou em novos estudos incluídos). Neste contexto, acredita-se que a estratégia de buscas eletrônicas aqui desenhada demonstrou amplitude e precisão adequadas.

A escala de Newcastle-Ottawa (50) foi utilizada para avaliar a qualidade metodológica dos estudos incluídos nesta RS. A avaliação da qualidade de estudos observacionais é mais difícil do que a avaliação da qualidade de ensaios clínicos randomizados e outros modelos de estudos clínicos experimentais. Julgar estudos observacionais com listas ou verificações concebidas para ensaios clínicos randomizados pode não ser apropriado. Percebe-se que foram necessárias algumas adaptações para emprego da escala NOS nesta RS, já discutidas no artigo. Ainda que a qualidade geral dos estudos incluídos tenha sido alta, é preciso lembrar que não existe uma padronização metodológica dos estudos identificados, e nenhum dos 39 estudos incluídos foi marcado com nove estrelas (o grau máximo de qualidade da NOS).

O presente estudo teve como foco principal analisar a incidência de fratura de limas de NiTi acionadas em diferentes movimentos, não tendo sido nossa principal preocupação avaliar a diferença na incidência de fratura ocorrida entre sistemas acionados com uma mesma cinemática. Neste aspecto, vale questionar se os diferentes desenhos e composição de ligas destes diferentes sistemas (51, 52) não representam fatores tão ou mais importante do que a própria cinemática em si, no que diz respeito à chance de fratura. Ressalte-se que os resultados da presente meta regressão evidenciaram que o ano de publicação foi um fator

de alta influência na incidência geral de fratura, com estudos mais antigos usualmente reportando taxas maia elevadas de fratura dos estudos mais recentes. Neste sentido, inferimos que o ano de publicação seja uma variável sub-rogada do processo de evolução temporal de três fatores relevantes: 1- o desenho das limas endodônticas de NiTi; 2- a composição das ligas que compõe as limas de NiTi, com recentes avanços como ligas produzidas a partir de tratamento térmico (M-wire e CM-wire), conferindo maior estabilidade e flexibilidade (53, 54); 3- a curva de aprendizado inerente ao treinamento dos operadores ao longo dos anos de utilização dos sistemas mecanizados de preparo dos canais radiculares.

Os resultados apresentados nesta RS revelam que há falta de padronização em relação ao limite de usos dos instrumentos de NiTi. Alguns estudos utilizam as limas em um único caso clínico, enquanto outros reutilizam os instrumentos por várias vezes. Portanto, parece clara a necessidade de desenvolver futuros estudos, tanto de natureza laboratorial quanto estudos clínicos, com o intuito de identificar um protocolo clínico seguro para o limite de (re-?)usos de instrumentos de NiTi acionados mecanicamente. A resposta a esta questão, que permanece em aberto, pode oferecer um avanço terapêutico, econômico e social de grande impacto.

Os motivos pelos quais a cinemática reciprocante parece reduzir a fadiga do instrumento dentro do canal radicular podem ser explicados pelo fato da lima girar em um certo ângulo na direção de corte e, logo após, girar na direção oposta, em um ângulo menor, o que parece aliviar drasticamente o estresse torsional sofrido pelo instrumento (10, 36). Ainda assim, os resultados da presente RS e meta regressão mostraram que a cinemática, quando ajustada para outros fatores clínicos (número de usos, tipo de operador e evolução das ligas e desenhos das limas), revelou-se um fator menos importante no que tange à incidência de fratura dos instrumentos de NiTi.

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ANEXOS

Anexo 1 – Carta de aprovação do projeto na Comissão Científica.

SIPESQ

Sistema de Pesquisas da PUCRS

Código SIPESQ: 7879 Porto Alegre, 23 de março de 2017.

Prezado(a) Pesquisador(a),

A Comissão Científica da FACULDADE DE ODONTOLOGIA da PUCRS apreciou e aprovou o Projeto de Pesquisa "Incidência de fratura de limas endodônticas de níquel-titânio com cinemática rotatória contínua versus cinemática reciprocante em humanos: uma revisão sistemática da literatura".

Atenciosamente,

Comissão Científica da FACULDADE DE ODONTOLOGIA

Anexo 2 – Protocolo de registro no PROSPERO

PROSPERO Registration message [75917]

CRD-REGISTER <irss505@york.ac.uk>

ter 17/10/2017 11:36

Para:Maximiliano Schunke Gomes <maximiliano.gomes@pucrs.br>;

Dear Dr Gomes,

Thank you for submitting details of your systematic review "The clinical incidence of Ni-Ti endodontic file separation associated with rotary or reciprocating movements: a systematic review" to the PROSPERO register. We are pleased to confirm that the record will be published within the next hour.

Your registration number is: CRD42017075917

You are free to update the record at any time, all submitted changes will be displayed as the latest version with previous versions available to public view. Please also give brief details of the key changes in the Revision notes facility. You can log in to PROSPERO and access your records at http://www.crd.york.ac.uk/PROSPERO

Comments and feedback on your experience of registering with PROSPERO are welcome at: crd-register@york.ac.uk

Best wishes for the successful completion of your review.

Yours sincerely,

PROSPERO Administrator
Centre for Reviews and Dissemination
University of York
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PROSPERO
International prospective register of systematic reviews

NHS
National Institute for
Health Research

The clinical incidence of Ni-Ti endodontic file separation associated with rotary or reciprocating movements: a systematic review

Maximiliano Gomes, Rosangela Vieira, Daiana Bottcher

Citation

Maximiliano Gomes, Rosangela Vieira, Daiana Bottcher. The clinical incidence of Ni-Ti endodontic file separation associated with rotary or reciprocating movements: a systematic review. PROSPERO 2017 CRD42017075917 Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017075917

Review question

To investigate whether there is available evidence to support the hypothesis that reciprocating motion leads to a lower clinical incidence of Ni-Ti file separation than rotary kinematics in humans.

Searches

The electronic databases PubMed, EMBASE, ISI Web of Science and The Cochrane Library will be searched from their respective dates of inception to September 2017.
A secondary search will be performed of the unpublished or grey literature using the OpenGrey database, and a hand search of the reference lists of all potentially eligible papers will also be undertaken to identify any studies omitted from the initial searches.

Types of study to be included

Inclusion criteria:

Observational clinical studies or interventional (randomized or non-randomized clinical trials) studies that have reported the incidence of fracture of NI-TI files when used in continuous rotation kinematics and/or reciprocating kinematics during endodontic treatments.

Exclusion criteria:
1 - Laboratory studies.
2 - Ex vivo studies.
3 - Animal studies.
4 - Observational or interventional clinical studies that have reported the incidence of fracture of the stainless steel files only when used in manual preparation for endodontic treatments.

Condition or domain being studied

Endodontic therapy aims to cleanse and model the root canals by removing bacteria and their by-products from the entire system, preserving its original course. To minimize any undesirable changes in the original curved root canal anatomy, different endodontic systems and techniques have been developed in recent years, and newer endodontic instruments with increased flexibility have now been made available by modifying conventional stainless steel files using new alloys such as nickel-titanium (NiTi).
NiTi instruments have many advantages when compared to conventional files, such as greater flexibility and a shorter working time. In clinical practice, however, these instruments may be subject to accidental fracture during the preparation of the canal, mainly due to repeated bending and torsional movements. The clinical management of file separation is challenging, and may hamper the adequate disinfection of the root canal system, thereby impairing the outcome of root canal therapy.
Current techniques for root canal preparation with NiTi files use rotary and/or reciprocating movements.

Pooled results from laboratory studies suggest that the reciprocating motion may reduce the risks of torsional fracture and cyclic fatigue as the instrument is not subject to the same stress levels as are caused by rotary motion, and in theory, the relief of the tensions in the instruments within the root canal provided by the reciprocating kinematics generates a lower fracture index. Some in vitro studies have also shown that the reciprocating movements present almost double the resistance to fracture when compared with the same instruments undergoing continuous rotation.
It is important, however, to note that most of the evidence suggesting a higher fracture resistance associated with reciprocating instruments compared with rotary equipment derives from laboratory studies, the results of which cannot be inferred to clinical settings.

Participants/population
Patients undergoing endodontic treatment.

Intervention(s), exposure(s)
Endodontic treatment, and the clinical incidence of Ni-Ti endodontic file separation associated with rotary or reciprocating movements.
Exposure variables will include: the operator's level of expertise (undergraduate student/general dentist/specialist), the groups of teeth treated, the type of endodontic system used, whether the treatment was conducted as a single session or not, and the number of times the Ni-Ti file has been used.

Comparator(s)/control
No control group will be investigated.

Primary outcome(s)
The incidence of Ni-Ti file separation, with reference to the patient, tooth, root canal or instrument in question.

Timing and effect measures
The incidence of file fractures (as a percentage).

Secondary outcome(s)
None.

Data extraction (selection and coding)
Two reviewers will separately examine the studies identified as being potentially relevant to the review, and will determine which are actually eligible for inclusion. Any cases of disagreement between the two will be discussed until a consensus is reached.
Data will then be extracted from the studies finally selected for inclusion.

Risk of bias (quality) assessment
Two reviewers will independently rate the quality of each study based on pre-determined criteria and using the Newcastle-Ottawa Scale (for observational studies).

Strategy for data synthesis
Incidence of Ni-Ti file separation during root canal treatment will be determined, as assessed with reference to the patient, the teeth treated, the root canal, or the instrument used.
Different studies reporting the same outcomes using the same units of analysis may be grouped together for the purposes of conducting a meta-analysis of pooled incidence for each technique (rotary or reciprocating kinematics).
If heterogeneity is detected, subgroup analysis may be carried out by grouping studies involving the same kind of exposures (possible confounders), as follows: operator expertise (undergraduate student/general dentist/specialist), the group of teeth treated, the type of endodontic system used, whether the treatment was conducted as a single session or not, and the number of uses of the Ni-Ti file which were involved in the treatment.

Anexo 3 – Cópia das cartas enviadas aos autores

Dear Dr. Messer and Colleagues,

We read with great interest your article "Defects in Rotary Nickel-Titanium Files After Clinical Use", published in the Journal of Endodontics, 26(3) in 2000.

We are conducting a systematic review about the clinical incidence of file separation of different NITI file systems.

The above mentioned study is one of the potential selected studies to be included in our SR. However, during data extraction we could not access some valuable information. Thus, we would appreciate if you could send us the following unreported data:

- **How many patients were treated with the 378, Quantec Series 2000 instruments?**
- **How many teeth were treated with the 378 , Quantec Series 2000 instruments?**
- **How many root canals were treated with the 378, Quantec series 2000 instruments?**

Thank you very much for you time and attention.

Sincerely,

Maximiliano Schünke Gomes
DDS, MSc, PhD Endodontia
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endomax@gmail.com
http://lattes.cnpq.br/2994376278903171
Phones: +55 51 33203562 / +55 51 999569626 / +55 51 32882966

Address requests for reprints to Professor Harold H. Messer, School of Dental Science, University of Melbourne, 711 Elizabeth Street, Melbourne, Victoria 3000, Australia.

Obs.: carta registrada enviada pelo correio convencional brasileiro em agosto de 2017.

Dear Dr. F. Charles Arens and colleagues,

We read with great interest your article "Evaluation of single-use Rotary Nickel-titanium instruments", published in the Journal of Endodontics, 29(10) in 2003.

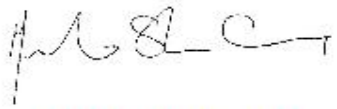
We are conducting a systematic review about the clinical incidence of file separation of different NITI file systems.

The above mentioned study is one of the potential selected studies to be included in our SR. However, during data extraction we could not access some valuable information. Thus, we would appreciate if you could send us the following unreported data:

- **How many patients were treated with the 786 instruments?**
- **How many teeth were treated with 786 instruments?**
- **How many root canals were treated with the 786 instruments?**

Thank you very much for you time and attention.

Sincerely,



Maximiliano Schünke Gomes
DDS, MSc, PhD Endodontia
Adjunct Professor, PUCRS School of Dentistry, Brazil
Captain, Medical and Dental Center of the Military Police of RS, Brazil
Maximiliano.gomes@pucrs.br
endomax@gmail.com
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Address requests for reprints to Dr. F. Charles Arens, 8638 Gairloch Ct., Dublin, OH 43017.

Obs.: carta registrada enviada pelo correio convencional brasileiro em agosto de 2017.

Information regarding your article in the JOE- 33(3)2007

Maximiliano Schunke Gomes

sex 11/08/2017 16:56

Itens Enviados

Para:lingjq@mail.sysu.edu.cn <lingjq@mail.sysu.edu.cn>;

Cc:rosangela.vieira@acad.pucrs.br <rosangela.vieira@acad.pucrs.br>;

Dear Dr. Ling and colleagues,

We read with great interest your article "Modes of Failure of ProTaper Nickel-Titanium Rotary Instruments after Clinical Use", published in the Journal of Endodontics, 33(3) in 2007.

We are conducting a systematic review about the clinical incidence of file separation of different NITI file systems.

The above mentioned study is one of the potential selected studies to be included in our SR. However, during data extraction we could not access some valuable information.
Thus, we would appreciate if you could send us the following unreported data:

- **How many patients were treated with the 774 ProTaper instruments?**
- **How many teeth were treated with the 774 ProTaper instruments?**
- **How many root canals were treated with the 774 ProTaper instruments?**

Thank you very much for you time and attention.
Sincerely,

Maximiliano Schünke Gomes
DDS, MSc, PhD Endodontia
Professor Adjunto, Departamento Clínico, Faculdade de Odontologia da PUCRS
Adjunct Professor, Clinical Department, PUCRS School of Dentistry, Brazil
http://lattes.cnpq.br/2994376278903171
Phones: +55 51 33203562 / +55 51 99569626

Information regarding your article in the JOE- 35(10)2009

Maximiliano Schunke Gomes

sex 11/08/2017 17:06

Itens Enviados

Para:ugurinan29@hotmail.com <ugurinan29@hotmail.com>;

Cc:rosangela.vieira@acad.pucrs.br <rosangela.vieira@acad.pucrs.br>;

Dear Dr. Inan and colleagues,

We read with great interest your article "Deformation and Fracture of Mtwo Rotary Nickel-Titanium Instruments After Clinical Use", published in the Journal of Endodontics 35(10) in 2009.

We are conducting a systematic review about the clinical incidence of file separation of different NITI file systems.

The above mentioned study is one of the potential selected studies to be included in our SR. However, during data extraction we could not access some valuable information.
Thus, we would appreciate if you could send us the following unreported data:

- **How many patients were treated with the 593 Mtwo rotary NiTi instruments?**
- **How many teeth were treated with the 593 Mtwo rotary NiTi instruments?**
- **How many root canals were treated with the 593 Mtwo rotary NiTi instruments?**

Thank you very much for you time and attention.

Sincerely,

Maximiliano Schünke Gomes
DDS, MSc, PhD Endodontia
Professor Adjunto, Departamento Clínico, Faculdade de Odontologia da PUCRS
Adjunct Professor, Clinical Department, PUCRS School of Dentistry, Brazil
http://lattes.cnpq.br/2994376278903171
Phones: +55 51 33203562 / +55 51 99569626

Information regarding your article in the IEJ 49 2016

Maximiliano Schunke Gomes

sex 11/08/2017 16:45

Itens Enviados

Para:chenxinmei61@126.com <chenxinmei61@126.com>;

Cc:rosangela.vieira@acad.pucrs.br <rosangela.vieira@acad.pucrs.br>;

Dear Dr. Chen and colleagues,

We read with great interest your article "Deformation and fracture of K3 rotary nickel-titanium endodontic instruments after clinical use", published in the International Endodontic Journal, 49(11) in 2016.
We are conducting a systematic review about the clinical incidence of file separation of different NITI file systems.
The above mentioned study is one of the potential selected studies to be included in our SR. However, during data extraction we could not access some valuable information. Thus, we would appreciate if you could send us the following unreported data:

- **How many patients were treated with the 2397 K3 instruments?**
- **How many teeth were treated with the 2397 K3 instruments?**
- **How many root canals were treated with the 2397 K3 instruments?**

Thank you very much for you time and attention.

Sincerely,

Maximiliano Schünke Gomes
DDS, MSc, PhD Endodontia
Professor Adjunto, Departamento Clínico, Faculdade de Odontologia da PUCRS
Adjunct Professor, Clinical Department, PUCRS School of Dentistry, Brazil
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Phones: +55 51 33203562 / +55 51 99569626

Information regarding your article in the JOE- 38(12)2012

Maximiliano Schunke Gomes

seg 14/08/2017 22:35

Itens Enviados

Para:markush@dentistry.ubc.ca <markush@dentistry.ubc.ca>;

Cc:rosangela.vieira@acad.pucrs.br <rosangela.vieira@acad.pucrs.br>;

Dear Prof. Markus Haapasalo and colleagues,

We read with great interest your article "Profile Vortex Instruments after Clinical Use: A Metallurgical Properties Study", published in the Journal of Endodontics, 38(12) in 2012.

We are conducting a systematic review about the clinical incidence of file separation of different NITI file systems.

The above mentioned study is one of the potential selected studies to be included in our SR. However, during data extraction we could not access some valuable information. Thus, we would appreciate if you could send us the following unreported data:

- **How many patients were treated with the 2203 Profile Vortex instruments?**
- **How many teeth were treated with the 2203 Profile Vortex instruments?**
- **How many root canals were treated with the 2203 Profile Vortex instruments?**

Thank you very much for you time and attention.

Sincerely,

Maximiliano Schünke Gomes
DDS, MSc, PhD Endodontia
Professor Adjunto, Departamento Clínico, Faculdade de Odontologia da PUCRS
Adjunct Professor, Clinical Department, PUCRS School of Dentistry, Brazil
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Information regarding your article in the JOE- 35(10)2009

Maximiliano Schunke Gomes

seg 14/08/2017 22:33

Itens Enviados

Para:markush@interchange.ubc.ca <markush@interchange.ubc.ca>;

Cc:rosangela.vieira@acad.pucrs.br <rosangela.vieira@acad.pucrs.br>;

Dear Dr. Markus Haapasalo and colleagues,

We read with great interest your article "Defects in Nickel-Titanium Instruments after Clinical Use. Part 5: Single Use From Endodontic Specialty Practices", published in the Journal of Endodontics, 35(10) in 2009.

We are conducting a systematic review about the clinical incidence of file separation of different NITI file systems.

The above mentioned study is one of the potential selected studies to be included in our SR. However, during data extraction we could not access some valuable information. Thus, we would appreciate if you could send us the following unreported data:

- **How many patients were treated with the 1895 ProTaper instruments?**
- **How many teeth were treated with the 1895 ProTaper instruments?**
- **How many root canals were treated with the 1895 ProTaper instruments?**

Thank you very much for you time and attention.

Sincerely,

Maximiliano Schünke Gomes
DDS, MSc, PhD Endodontia
Professor Adjunto, Departamento Clínico, Faculdade de Odontologia da PUCRS
Adjunct Professor, Clinical Department, PUCRS School of Dentistry, Brazil
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Information regarding your article in the JOE- 35(2)2009

Maximiliano Schunke Gomes

seg 14/08/2017 22:38

Itens Enviados

Para: markush@interchange.ubc.ca <markush@interchange.ubc.ca>;

Cc: rosangela.vieira@acad.pucrs.br <rosangela.vieira@acad.pucrs.br>;

Dear Dr. Markus Haapasalo and colleagues,

We read with great interest your article "Defects in Nickel-Titanium Instruments after Clinical Use. Part 3: A 4-Year Retrospective Study from an Undergraduate Clinic", published in the Journal of Endodontics, 35(2) in 2009.

We are conducting a systematic review about the clinical incidence of file separation of different NiTi file systems.

The above mentioned study is one of the potential selected studies to be included in our SR. However, during data extraction we could not access some valuable information. Thus, we would appreciate if you could send us the following unreported data:

- **How many patients were treated with the 3706 Profile instruments?**
- **How many teeth were treated with the 3706 Profile instruments?**
- **How many root canals were treated with the 3706 Profile instruments?**

Thank you very much for you time and attention.

Sincerely,

Maximiliano Schünke Gomes
DDS, MSc, PhD Endodontia
Professor Adjunto, Departamento Clínico, Faculdade de Odontologia da PUCRS
Adjunct Professor, Clinical Department, PUCRS School of Dentistry, Brazil
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Information regarding your article in the IEJ-40(3) 2007

Maximiliano Schunke Gomes

sex 11/08/2017 17:27

Itens Enviados

Para:yashen36@hotmail.com <yashen36@hotmail.com>;

Cc:rosangela.vieira@acad.pucrs.br <rosangela.vieira@acad.pucrs.br>;

Dear Dr. Shen and colleagues,

We read with great interest your article "Comparison of defects in Pro Taper hand-operated and engine-driven instruments after clinical use", published in the International Endodontic Journal, 40(3) in 2007.

We are conducting a systematic review about the clinical incidence of file separation of different NITI file systems.

The above mentioned study is one of the potential selected studies to be included in our SR. However, during data extraction we could not access some valuable information.

Thus, we would appreciate if you could send us the following unreported data:

- **How many patients were treated with the 564 engine-driven Pro Taper instruments?**
- **How many teeth were treated with 564 engine-driven PT instruments?**
- **How many root canals were treated with the 564 engine-driven PT instruments?**

Thank you very much for you time and attention.

Sincerely,

Maximiliano Schünke Gomes
DDS, MSc, PhD Endodontia
Professor Adjunto, Departamento Clínico, Faculdade de Odontologia da PUCRS
Adjunct Professor, Clinical Department, PUCRS School of Dentistry, Brazil
http://lattes.cnpq.br/2994376278903171
Phones: +55 51 33203562 / +55 51 99569626

Information regarding your article in the IEJ-38(11) 2005

Maximiliano Schunke Gomes

sex 11/08/2017 17:17

Itens Enviados

Para:yashen36@hotmail.com <yashen36@hotmail.com>;

Cc:rosangela.vieira@acad.pucrs.br <rosangela.vieira@acad.pucrs.br>;

Dear Dr. Shen and colleagues,

We read with great interest your article "Defects in Pro Taper S1 instruments after clinical use: fractographic examination", published in the International Endodontic Journal, 38(11) in 2005.

We are conducting a systematic review about the clinical incidence of file separation of different NITI file systems.

The above mentioned study is one of the potential selected studies to be included in our SR. However, during data extraction we could not access some valuable information.

Thus, we would appreciate if you could send us the following unreported data:

- **How many instruments were used but not discarded over the 17-month period of the study (from January 2003 to May 2004)?**
- **How many patients were treated with the 122 Pro Taper S1 instruments?**
- **How many teeth were treated with the122 PT S1 instruments?**
- **How many root canals were treated with the 122 PT S1 instruments?**

Thank you very much for you time and attention.

Sincerely,

Maximiliano Schünke Gomes
DDS, MSc, PhD Endodontia
Professor Adjunto, Departamento Clínico, Faculdade de Odontologia da PUCRS
Adjunct Professor, Clinical Department, PUCRS School of Dentistry, Brazil
http://lattes.cnpq.br/2994376278903171
Phones: +55 51 33203562 / +55 51 99569626

Anexo 4 – Cópia das cartas-resposta recebidas dos autores

De: HAROLD MESSER <hhm888@btinternet.com>
Enviado: domingo, 1 de outubro de 2017 13:57:11
Para: Maximiliano Schunke Gomes; endomax@gmail.com
Assunto: Systematic review

Dear Dr Gomes,
I apologise for my slow response to your letter. I have been retired for some years and no longer live in Australia.

In response to your questions: I no longer have access to any details of the study and cannot provide you with specific responses. However, this study was one of the early studies published on the topic, and the files were accumulated by specialist endodontists in a private practice. The files were discarded when problems became apparent (fracture, unwinding etc) or after an uncontrolled number of uses, since there were no criteria at the time for number of uses etc. No history was recorded for each individual file.

I hope that this is of some assistance for your review. You may be able to gain additional information from Professor Peter Parashos as the Melbourne Dental School, but I do not have his email address to hand.

With best wishes,
Harold Messer

Anexo 5 - Escala Newcastle Ottawa

NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE - COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Selection

1) Representativeness of the exposed cohort
   a) truly representative of the average _____ (describe) in the community ✵
   b) somewhat representative of the average _____ in the community ✵
   c) selected group of users eg nurses, volunteers
   d) no description of the derivation of the cohort

2) Selection of the non exposed cohort
   a) drawn from the same community as the exposed cohort ✵
   b) drawn from a different source
   c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure
   a) secure record (eg surgical records) ✵
   b) structured interview ✵
   c) written self report
   d) no description

4) Demonstration that outcome of interest was not present at start of study
   a) yes ✵
   b) no

Comparability

1) Comparability of cohorts on the basis of the design or analysis
   a) study controls for _____ (select the most important factor) ✵
   b) study controls for any additional factor ✵ (This criteria could be modified to indicate specific control for a second important factor.)

Outcome

1) Assessment of outcome
   a) independent blind assessment ✵
   b) record linkage ✵
   c) self report
   d) no description

2) Was follow-up long enough for outcomes to occur
   a) yes (select an adequate follow up period for outcome of interest) ✵
   b) no

3) Adequacy of follow up of cohorts
   a) complete follow up - all subjects accounted for ✵
   b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) ✵
   c) follow up rate < ____% (select an adequate %) and no description of those lost
   d) no statemen

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Porto Alegre - RS - Brasil
Fone: (51) 3320-3500 - Fax: (51) 3339-1564
E-mail: prograd@pucrs.br
Site: www.pucrs.br