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Morphological alterations of the apical foramen after foraminal enlargement: a systematic review of *ex vivo* studies

Alterações morfológicas do forame apical após ampliação foraminal: uma revisão sistemática de estudos *ex vivo*

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ABSTRACT

Foraminal enlargement has been recommended to optimize the disinfection of infected root canals, although some authors still claim that the foramen should be kept in its original shape and position. This study aimed to evaluate morphological alterations of apical foramen after foraminal enlargement through a systematic review. An electronic search was conducted until April 2022. E*x vivo* studies evaluating influence of foraminal enlargement in the morphologic changes of apical foramen were included. Studies without a control group or available full text were excluded. Foraminal deformation and area increase were considered as primary outcomes. Risk-of-bias assessment was performed according to a modified Joanna Briggs Institute's Checklist. From 702 studies retrieved, five were eligible. Most studies used single-rooted teeth, and rotary systems for instrumentation ranging from – 2 mm to + 1 mm to the apex. All studies found increased major foramen deformation after foraminal enlargement. Among four studies that evaluated foraminal area, all found increased area after foraminal enlargement. Insufficient data for touched/untouched walls by instruments and dentinal microcrack formation was observed. A low risk of bias was found. Foraminal enlargement during root canal preparation seems to increase deformation and major apical foramen area. Future investigations with standardized methodologies are encouraged.

KEYWORDS

Apical foramen; Endodontics; Root canal preparation; Root canal therapy; Tooth apex.

RESUMO

A ampliação foraminal tem sido recomendada para otimizar a desinfecção de canais radiculares infectados, embora alguns autores ainda afirmem que o forame deve ser mantido em sua forma e posição originais. Este estudo teve como objetivo avaliar alterações morfológicas do forame apical após ampliação foraminal por meio de uma revisão sistemática. Uma busca eletrônica foi realizada até abril de 2022. Foram incluídos estudos *ex vivo* que avaliaram a influência da ampliação foraminal nas alterações morfológicas do forame apical. Foram excluídos estudos sem grupo controle ou com texto completo indisponível. A deformação foraminal e o aumento da área foram considerados desfechos primários. A avaliação do risco de viés foi realizada de acordo com uma lista de verificação modificada do Instituto Joanna Briggs. Dos 702 registros recuperados, cinco foram elegíveis. A maioria dos estudos utilizou dentes unirradiculares e sistemas rotatórios para instrumentação, com comprimento de trabalho variando de – 2 mm a + 1 mm até o ápice. Todos os estudos encontraram aumento da deformação do forame maior após ampliação foraminal. Dos quatro estudos que avaliaram a área foraminal, todos encontraram aumento de área após alargamento foraminal. Foram observados dados insuficientes para paredes tocadas/intocadas pelos instrumentos e formação de microfissuras dentinárias. Um baixo risco de viés foi encontrado. A ampliação foraminal durante o preparo do canal radicular parece aumentar a deformação e a área do forame apical. Futuras investigações com metodologias padronizadas são incentivadas.

PALAVRAS-CHAVE

Ápice dentário; Endodontia; Preparo de canal radicular; Tratamento do canal radicular; Forame apical.

INTRODUCTION

Chemical-mechanical preparation is an important step in endodontic treatment, which aims to eliminate microorganisms and their products from the root canal system in order to promote repair of periradicular tissues. In addition, this procedure aims at removing necrotic pulp tissue that can serve as a substrate for reinfection [1-3]. To achieve an effective chemical-mechanical preparation of the root canal system, the determination of an adequate working length (WL) is essential. Instrumentation below the appropriate WL can leave remnants of necrotic tissue [2,4], in which can maintain endodontic infection. Conversely, instrumentation beyond the apical foramen might exacerbate the inflammatory response in the periodontal tissue [5-7] and result in apical extrusion of debris and filling materials [8].

Traditionally, it was recommended that root canal instrumentation should be restricted to the interior of the dentinal canal. In practice, a WL of 0.5 mm to 1 mm short of the radiographic apex is considered acceptable, although it might be not possible to exactly determine the location of the cementum-dentin junction [9]. While some authors suggest that the penetration of an endodontic instrument through the apical foramen is necessary for an adequate root canal cleaning due to the presence of necrotic tissue occupying the apical portion [10-12], other point out the importance of avoiding the excessive removal of apical dentin and cementum [6,13]. Hence, a consensus among studies regarding the most ideal WL has not been reached yet [6,9,14].

Additionally, assessment of the most appropriate apical foramen enlargement should be considered, to enhance root canals cleaning and disinfection, minimizing concerns associated with this procedure, such as foramen deviation [15,16], dentinal microcracks [15,17], extrusion of microorganisms beyond the apex [18] and filling materials [8]. According to some studies [16,19] foraminal enlargement can be conducted by expanding the foramen at least three diameters (of the ISO standard for endodontic instruments) larger than the initial apical file (IAF) (first file that binds canal walls in the WL), even although the actual canal diameter determination, by the IAF, is imprecise [20]. However, there is no well-defined protocol for performing foraminal enlargement in the literature, neither in relation to how much to expand, nor to the ideal WL.

At this point, it's important to distinguish between apical patency and foraminal enlargement. Apical patency maintains access to the apical foramen using a smaller instrument [14], while foraminal enlargement, focus of our study, cleans and disinfects the foraminal region for optimal healing [11,12]. The objective of the present study was to evaluate, through a systematic review, if the foraminal enlargement increases morphological alterations of the apical foramen, through the assessment of *ex vivo* studies.

MATERIAL & METHODS

Protocol

The present systematic review was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist [21]. A research protocol was registered in the Open Science Framework (OSF) register (https://osf.io/bxmt9).

Eligibility criteria

The inclusion criteria were: (1) studies that evaluated morphological alterations of the foramen using WL at the major foramen, and (2) studies that evaluated morphological alterations of the foramen using WL beyond the foramen. Exclusion criteria were as follows: (1) studies without a comparison group with WL short of the foramen; (2) case report studies; (3) studies for which the full text was unavailable; (4) studies that assessed only the secondary outcomes. There were no restrictions on the language and date of publication.

The population, intervention, comparison, outcome, and study design (PICOS) format was used to address the following research question: "Does foraminal enlargement influence morphologic changes of the apical foramen?" The study population was extracted human teeth submitted to root canal preparation. The intervention explored was root canal preparation with foraminal enlargement; the comparison used was root canal preparation without foraminal enlargement, when WL was set short of the foramen. The primary outcomes evaluated were the deformation and area of the apical foramen. Secondary outcomes were touched or untouched areas by the instruments and dentinal microcrack formation. The eligible study design was *ex vivo* studies.

Search strategy and sources of information

Electronic searches were conducted in PubMed/MEDLINE, Scopus, Web of Science, SciELO, Embase and Cochrane Library databases up to April 2022. Grey literature was consulted through Google Scholar, and manual searches were carried out in the reference list of the eligible articles. The search strategy used a combination of keywords and Medical Subject Heading (MeSH) terms associated with the Boolean operators 'AND' and 'OR' as shown in Table I.

Study selection

Study selection was carried out independently by two reviewers (I.F.A.M. and G.C.F.), in a two-step process. Duplicates were identified and removed using Mendeley Desktop software (version 1.19.8, Elsevier Inc. New York, US). In step 1, the reviewers appraised titles and abstracts of the records retrieved from the searches. In step 2, a full-text assessment of the remaining studies was performed by the authors. Studies complied with the eligibility criteria were included in this review.

Table I - Search strategy used for the electronic databases

DATABASE	SEARCH STRATEGY
Medline through PubMed (http://www.ncbi.nlm.nih.gov/pubmed)	("apical enlargement"[All Fields] OR "apical preparation"[All Fields] OR "apical expansion"[All Fields] OR "apical widening"[All Fields] OR "apical debridement"[All Fields] OR "foraminal enlargement"[All Fields] OR "foraminal expansion"[All Fields] OR "foraminal widening"[All Fields] OR "foraminal debridement"[All Fields]) AND ("endodontal"[All Fields] OR "endodontic"[All Fields] OR "endodontical"[All Fields] OR "endodontically" [All Fields] OR "endodontics"[MeSH Terms] OR "endodontics"[All Fields] OR ("instrumentation"[MeSH Subheading] OR "instrumentation"[All Fields] OR "instrumentation s"[All Fields] OR "instrumentational" [All Fields] OR "instrumentations"[All Fields] OR "instrumention"[All Fields]) OR "root canal instrumentation" [All Fields] OR "root canal preparation"[All Fields] OR "root canal therapy"[All Fields] OR "root canal treatment"[All Fields]) AND ("morpholog*"[All Fields] OR "geometr*"[All Fields] OR ("alter"[All Fields] OR "alterated"[All Fields] OR "alteration"[All Fields] OR "alterations"[All Fields] OR "altered"[All Fields] OR "altering"[All Fields] OR "alters"[All Fields]) OR ("change"[All Fields] OR "changed"[All Fields] OR "changes" [All Fields] OR "changing"[All Fields] OR "changings"[All Fields]) OR "apical transportation"[All Fields] OR ("abnormalities"[MeSH Subheading] OR "abnormalities"[All Fields] OR "deformities"[All Fields] OR "congenital abnormalities"[MeSH Terms] OR ("congenital"[All Fields] AND "abnormalities"[All Fields]) OR "congenital abnormalities"[All Fields] OR "deformity"[All Fields] OR "deform"[All Fields] OR "deformabilities"[All Fields] OR "deformability"[All Fields] OR "deformable"[All Fields] OR "deformably"[All Fields] OR "deformation"[All Fields] OR "deformational"[All Fields] OR "deformations"[All Fields] OR "deformative"[All Fields] OR "deformed"[All Fields] OR "deforming"[All Fields] OR "deforms"[All Fields]) OR "apical displacement"[All Fields] OR ("crack cocaine"[MeSH Terms] OR ("crack"[All Fields] AND "cocaine"[All Fields]) OR "crack cocaine"[All Fields] OR "crack"[All Fields] OR "crack s"[All Fields] OR "cracked"[All Fields] OR "cracking"[All Fields] OR "crackings" [All Fields] OR "cracks"[All Fields]) OR "micro*"[All Fields] OR ("struct equ modeling"[Journal] OR "scan electron microsc"[Journal] OR "sem"[All Fields]))
Scopus (http://www.scopus.com/)	TITLE-ABS-KEY (("apical enlargement" OR "apical preparation" OR "apical expansion" OR "apical widening" OR "apical debridement" OR "foraminal enlargement" OR "foraminal expansion" OR "foraminal widening" OR "foraminal debridement") AND (endodontic OR instrumentation OR "root canal instrumentation" OR "root canal preparation" OR "root canal therapy" OR "root canal treatment") AND (morpholog* OR geometr* OR alteration OR change OR "apical transportation" OR deformation OR "apical displacement" OR crack OR micro* OR sem))
Cochrane (https://www.cochranelibrary.com/)	("apical enlargement" OR "apical preparation" OR "apical expansion" OR "apical widening" OR "apical debridement" OR "foraminal enlargement" OR "foraminal expansion" OR " foraminal widening" OR "foraminal debridement") AND (endodontic OR instrumentation OR "root canal instrumentation" OR "root canal preparation" OR "root canal therapy" OR "root canal treatment") AND (morpholog* OR geometr* OR alteration OR change OR "apical transportation" OR deformation OR "apical displacement" OR crack OR micro* OR SEM) in Title Abstract Keyword
Web of Science (https://clarivate.com/webofsciencegroup/solutions/web-of-science-core-collection/)	("apical enlargement" OR "apical preparation" OR "apical expansion" OR "apical widening" OR "apical debridement" OR "foraminal enlargement" OR "foraminal expansion" OR "foraminal widening" OR "foraminal debridement") AND (endodontic OR instrumentation OR "root canal instrumentation" OR "root canal preparation" OR "root canal therapy" OR "root canal treatment") AND (morpholog* OR geometr* OR alteration OR change OR "apical transportation" OR deformation OR "apical displacement" OR crack OR micro* OR SEM) (All Fields)
Embase (https://www.embase.com)	('apical enlargement' OR 'apical preparation' OR 'apical expansion' OR 'apical widening' OR 'apical debridement' OR 'foraminal enlargement' OR 'foraminal expansion' OR 'foraminal widening' OR 'foraminal debridement') AND (endodontic OR 'instrumentation'/exp OR instrumentation OR 'root canal instrumentation' OR 'root canal preparation'/exp OR 'root canal preparation' OR 'root canal therapy'/exp OR 'root canal therapy' OR 'root canal treatment') AND (morpholog* OR geometr* OR alteration OR 'change'/exp OR change OR 'apical transportation' OR 'deformation'/exp OR deformation OR 'apical displacement' OR 'crack'/exp OR crack OR micro* OR 'sem'/exp OR sem)
Scielo (https://scielo.org/en/)	("apical enlargement" OR "apical preparation" OR "apical expansion" OR "apical widening" OR "apical debridement" OR "foraminal enlargement" OR "foraminal expansion" OR " foraminal widening" OR "foraminal debridement") AND (endodontic OR instrumentation OR "root canal instrumentation" OR "root canal preparation" OR "root canal therapy" OR "root canal treatment") AND (morpholog* OR geometr* OR alteration OR change OR "apical transportation" OR deformation OR "apical displacement" OR crack OR micro* OR SEM)
Google Scholar (https://scholar.google.com/)	("foraminal enlargement" OR "foramen enlargement" OR "foraminal debridement" OR "foraminal widening") AND (endodontic OR "root canal therapy") AND (morpholog* OR alteration OR "apical transportation" OR deformation OR micro* OR SEM)

Discrepancies were resolved through discussion, and when necessary, a third reviewer (A.H.R.P.) was consulted. Cohen's kappa coefficient for inter-investigator agreement during studies' selection was assessed [22].

Data extraction

One reviewer (I.F.A.M.) collected data from the included studies using a guided data extraction form in a Microsoft Excel spreadsheet. The following data were retrieved: first author's last name, year of publication, teeth used, sample size, groups, and experimental protocol. Data were also collected on the analysis concerning evaluation methods and the main findings of the study. Unavailable data were classified as "not informed". Subsequently, a second author (A.C.D.V.) revised the data.

Critical appraisal of studies

The risk of bias of the selected studies was independently assessed by two reviewers (I.F.A.M and G.O.C.), in compliance with a modified version of the Joanna Briggs Institute Critical Appraisal Checklist for Experimental Studies (JBI) [23-25]. The items included in the checklist were: clearly stated aim, justification of sample size, sample randomization, blind treatment allocation, baseline equivalence of control and treatment groups, possibility of comparison between control and treatment groups, clear description of root canal preparation, measurement method, measurement standardization, and statistical analysis. Each item was assessed on a two-point scale: 0, *not reported or reported inadequately*; 1, *reported and adequate*. Doubts and discrepancies between investigators were discussed to reach a consensus, and when necessary, a third investigator (A.H.R.P.) was consulted.

RESULTS

Study selection

Figure 1 shows de flowchart of the selection process the studies. A total of 702 studies were found after searching the databases and through manual search in the references lists. After the first screening (Step 1), twenty-eight studies were selected and submitted to a full-text reading (Step 2). Then, 23 studies were excluded [15,26-47] with reasons being available in Figure 1. Finally, five studies were included in the qualitative analysis [16,48-51].

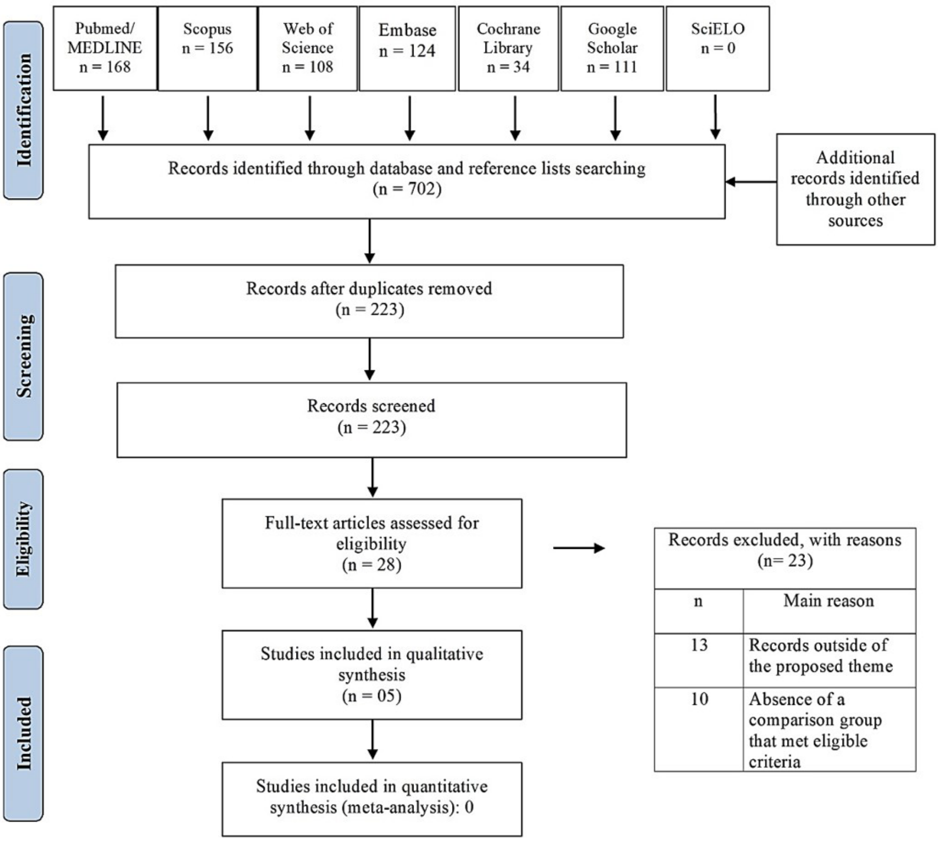

Figure 1 - Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart.

The assessed Cohen's kappa coefficient for inter-investigator agreement during the studies' selection was, equal to 0.917 for Pubmed, 0.922 for Scopus, 0.867 for Web of Science, 1.000 for the Cochrane Library, 0.905 for Embase, and 0.955 for Google Scholar. These values indicated an almost perfect level of agreement between reviewers during the selection of studies according to the scale of Landis and Koch [22].

Characteristics of the included studies

Table II summarizes the main characteristics and results of the selected studies. All evaluations were performed in extracted human teeth, especially molars, with different root curvatures, such as straight root canal [51], mild [16], and moderate to severe degree of curvature [50]. Two studies did not report root curvature of evaluated teeth [48,49].

Table II - Characteristics and main results of included *ex vivo* studies

Author/ Year	Teeth used	n	Groups	Estimated final FD according to MAF nominal diameter (mm)*	Outcomes/ Analysis	Main results
Souza et al., 2021 [48]	Human mandibular premolars	10	G1: Largo #2, Hero (#20/.06), GG drills (#5, #4, #3, #2), Mtwo (#40/.04), WL = +1 mm; G2 (control): Largo #2, Hero (#20/.06), GG (#5, #4, #3, #2), Mtwo (#40/.04), WL = -1 mm. For all groups, irrigation was performed with 2% CHX gel, 0.9% saline solution, 17% EDTA.	G1: 0.44 G2: n/a	Foraminal area and foraminal transportation using SEM.	Foraminal enlargement increased foraminal area and increased foraminal transportation
Marin, 2019 [49]	Single-rooted human teeth; FD ≤ 0.40 mm	12	G1 (control): PDL (#25/.06 and #40/.05), WL = -1 mm; G2: PDL (#25/.06, #40/.05 and Glide Path file #45/.01), WL = 0.0; G3: PDL (#25/.06, #40/.05 and Glide Path file #45/.01), WL = +1 mm; G4: PDL (#25/.06, #40/.05 and Glide Path file #50/.01), WL = 0.0; G5: PDL (#25/.06, #40/.05 and Glide Path file #50/.01), WL = +1 mm. For all groups, irrigation was performed with 2.5% NaOCl and 17% EDTA	G1: ≤ 0.40 G2: 0.45 G3: 0.46 G4: 0.50 G5: 0.51	Foraminal area and foraminal transportation using SEM	Foraminal enlargement increased foramen area compared to instrumentation 1 mm short of the foramen (control); it increased foraminal transportation compared to control
Schmidt, 2019 [50]	MB and ML canals of human mandibular molars (curvature <30°)	10	G1 (control): R25 (#25/.08) WL = -1 mm, K #10 at foramen; G2: R25 WL = -1 mm, FF (#20, #25 or #30) at foramen; G3: PDS (#25/.01, #30/.10, #25/.06, #25/.08), WL = 0.0; G4: R25, WL = 0.0; G5: PDS (#25/.01, #30/.10, #25/.06, #25/.08), WL = +1 mm; G6: R25, WL = +1 mm. For all groups, irrigation was performed with 2.5% NaOCl	G2: 0.20, 0.25 or 0.30 G3: 0.25 G4: 0.25 G5: 0.33 G6: 0.33	Foraminal area, perimeter, and untouched cementum wall using a stereomicroscope, and apical transportation using μ-CT	Foraminal enlargement increased foraminal area and deviation; instrumentation 1 mm beyond the foramen did not influence untouched cementum walls compared to instrumentation 1 mm short of apical foramen
Silva et al., 2016 [16]	Palatal roots of human molars (curvature ≤ 5°)	15	For all groups, instrumentation in cervical and middle thirds was performed with K3 files (#25/.10, #25/.08) and apical third with IAF + 3 with a .06 taper. G1 (control): WL= -1 mm; G2: WL = 0.0; G3: WL = +1 mm. For all groups, irrigation was performed with 2% CHX, saline solution and 17% EDTA	n/a	Foraminal area, transportation using SEM images	Foraminal enlargement increased cementum removal, and instrumentation + 1mm beyond the foramen led to greater foraminal deviation
Liu et al., 2013 [51]	Human mandibular incisors with straight roots	20	G1: GG drills (#2 and #1), K3 rotary files (#35/.04 up to #25/.06), WL = - 2 mm; G2: GG drills (#2 and #1), K3 rotary files (#35/.04 - #25/.06), WL = -1 mm; G3: GG drills (#2 and #1), K3 rotary files (#35/.04 - #25/.06), WL = 0.0; G4: GG drills (#2 and #1), K3 rotary files (#35/.04 - #25/.06), WL = +1 mm; G5: GG drills (#2 and #1), ProTaper (SX up to F3), WL= -2 mm; G6: GG drills (#2 and #1), ProTaper (SX up to F3), WL = -1 mm; G7: GG drills (#2 and #1), ProTaper (SX up to F3), WL = 0.0 mm; G8: GG drills (#2 and #1), ProTaper (SX up to F3), WL = +1 mm; G9: GG drills (#2 and #1), Flex HF (20-35, SB: 40-50), WL = -2 mm; G10: GG drills (#2 and #1), Flex HF (20-35, SB: 40-50), WL = -1 mm; G11: GG drills (#2 and #1), Flex HF (20-35, SB: 40-50), WL = 0.0 mm; G12: GG drills (#2 and #1), Flex HF (20-35, SB: 40-50), WL = +1 mm. For all groups, irrigation was performed with 2% NaOCl	G1: n/a G2: n/a G3: 0.35 G4: 0.39 G5: n/a G6: n/a G7: 0.30 G8: 0.39 G9: n/a G10: n/a G11: 0.35 G12: 0.40	Dentinal detachments and apical cracks using stereomicroscope	Foraminal enlargement increased dentinal detachments and cracks than controls, especially when using mechanized files

The symbol < indicates 'less than', ≤ indicates 'less than or equal to', ≅ indicates 'approximately equal to', mm: millimeters. CHX: chlorhexidine, μ-CT: micro-computed tomography, EDTA: ethylenediaminetetraacetic acid, FD: foraminal diameter, FF: Flexofile, G: group, GG: Gates-Glidden, HF: hand files, IAF: initial apical file (first file that binds the foramen), MAF: master apical file (larger file used to enlarge apical region), MB: mesiobuccal, ML: mesiolingual, n/a: not applicable, NaOCl: sodium hypochlorite, PDL: ProDesign Logic, PDS: ProDesign S, SB: step-back, SEM: scanning electron microscopy, WL: working length. *This column refers to the final FD, considering the determined WL and file tip and taper described by the manufacturers.

Regarding the instrumentation protocol, one study used rotary and reciprocating systems in their experimental groups [50], while the other four used only rotary systems for foraminal enlargement [16,48,49,51]. Two studies also used hand-files in their groups [50,51]. Most studies had groups with WL that ranged between – 1 mm and + 1 mm from the apex [16,48-50]. Additionally, one study had groups ranging between – 2 mm and + 1 mm from the apical foramen [51].

Deformation and area of the apical foramen

Foraminal deformation was mostly assessed using scanning electron microscopy (SEM). Out of the five studies that evaluated foraminal deformation or transportation after foraminal enlargement, three presented descriptive results based on qualitative analysis of images [16,48,51]. Other two studies presented results through measurement and numerical parameters [49,50].

The five studies observed that foraminal instrumentation led to higher deformation compared to control groups, in which instrumentation occurred short of the apical foramen [16,48-51]. Comparing the foraminal deviation when WL was determined at the foramen or beyond it, two studies did not observe a statistically significant difference among the experimental groups [50,51]. Other two studies observed that WL beyond the foramen led to more cases of foraminal deviation compared to WL at the foramen [16,49].

Four studies evaluated the increase in foraminal area after foraminal instrumentation, and comparing with the control groups, in general, foraminal enlargement increased foraminal area [16,48-50]. Regarding the different experimental WL, one study did not observe significative difference when the same file systems were used [50]. One study observed that the #45.01 (WL=0) group had a lower average wear during foraminal enlargement compared to the other experimental groups (#45.01 WL= +1; #50.01 WL = 0, WL = +1) [49].

Secondary outcomes

Two studies evaluated the amount of untouched cementum walls after instrumentation using a stereomicroscope [50] or SEM [16] and showed that the percentage of all touched cementum walls were similar when instrumentation was performed at the foramen or 1 mm beyond.

The occurrence of dentinal microcracks were evaluated in only one study using a stereomicroscope. Instrumentation short of the foramen caused less cracks than WL = 0 or +1 mm [51].

Critical appraisal of included studies

Table III and Figure 2 summarize the results of the risk of bias assessment by using the JBI tool. All the included articles showed a clearly stated aim, baseline equivalence of control and treatment groups, clear root canal preparation protocol, measurement standardization, reliable measurement method, and adequate statistical approach. However, a high risk of bias was noticed for some domains, including justification of sample size, sample randomization and blind treatment allocation.

Synthesis of results

Meta-analysis was not performed due to wide variations in methods for assessment, anatomical variation of samples, NiTi systems and protocols used for root canal preparation among the included *ex vivo* studies. In addition, a lack of available data was observed for some evaluated outcomes.

DISCUSSION

This systematic review primarily investigated the morphological changes of the major apical foramen after foraminal enlargement with data from five *ex vivo* studies. All studies demonstrated increased foraminal deformation and area, though one study did not measure the latter parameter.

Besides the different WL considered for foraminal enlargement in the literature, such as instrumentation at the major foramen [43] or beyond [41,48], the size of the endodontic instrument used during instrumentation is also an important consideration. In this procedure, the endodontic instrument diameter must guarantee the preparation of the cemental canal [16,49]. Clinically, a common practice is to firstly estimate the apical foraminal size, known as the IAF, and subsequently, choose the instrument that will be used for foraminal enlargement [16]. The chosen IAF is normally smaller than the actual size of the foramen [20], from that, one possibility to determine how much to enlarge, in terms of instrument diameter, is increasing apical enlargement to three ISO diameters larger than IAF [16].

Table III - Critical appraisal of included studies

Quality criteria	Was the aim of the study clearly stated?	Was the sample size justified?	Was the assignment to treatment groups truly random?	Were those assessing the outcomes blind to the treatment allocation?	Were control and treatment groups comparable at entry?	Were groups treated identically other than for the named interventions?	Was root canal preparation clearly described?	Were outcomes measured in the same way for all groups?	Were outcomes measured in a reliable way?	Was appropriate statistical analysis used?	Total score
Souza et al., 2021 [48]	1	1	1	1	1	1	1	1	1	1	10
Marin, 2019 [49]	1	0	0	0	1	1	1	1	1	1	7
Schmidt, 2019 [50]	1	0	0	0	1	1	1	1	1	1	7
Silva et al., 2016 [16]	1	0	0	1	1	1	1	1	1	1	8
Liu et al., 2013 [51]	1	0	0	0	1	1	1	1	1	1	7

0, not reported or reported but inadequate; 1, reported and adequate.

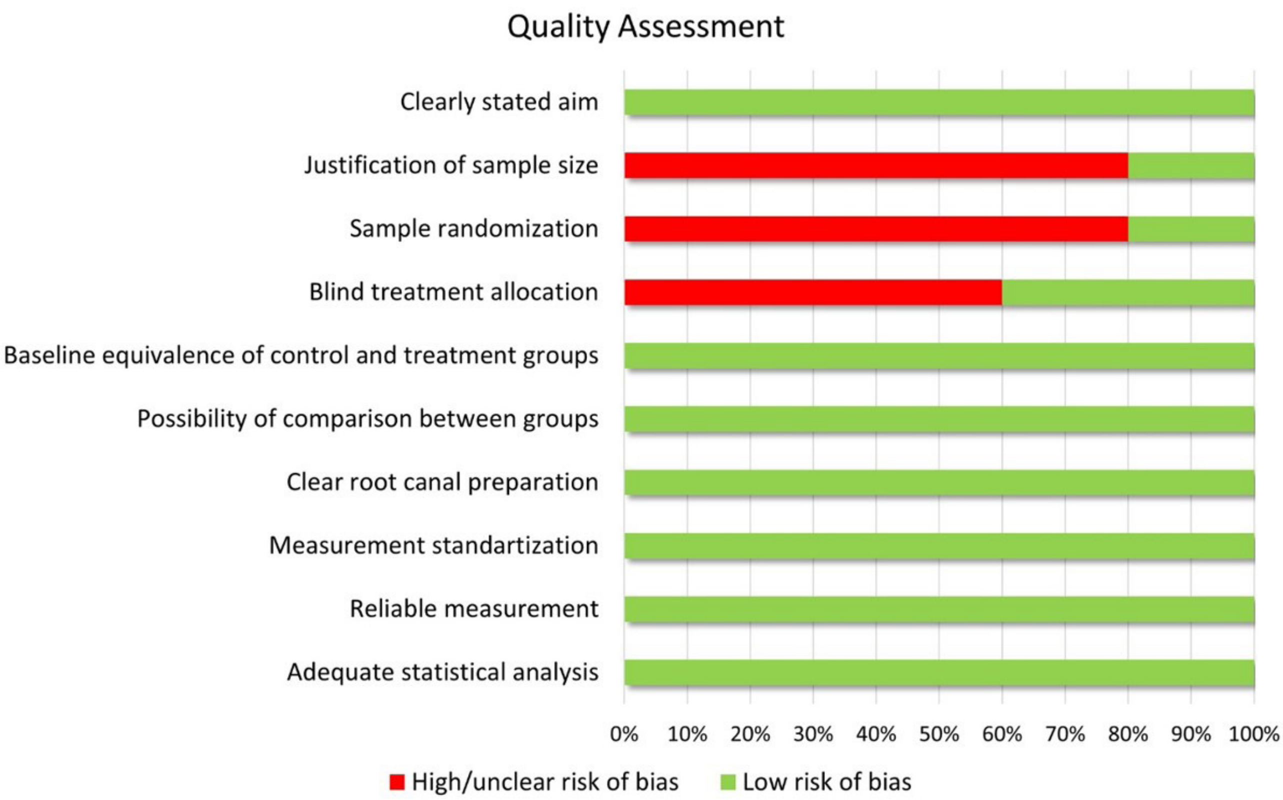

Figure 2 - Assessment of the risk of bias in the included studies according to the percentage of the scores attributed to each evaluated study.

The four studies, of the five included, that evaluated foraminal area after foraminal enlargement, observed that this procedure increased foraminal area, as expected. It demonstrates that foraminal enlargement really happened within the parameter used by the authors [16,48-50]. Some articles point out the importance of performing foraminal enlargement for microbial reduction [12,52] as it was associated with a greater reduction in the amount of bacteria within root canals and better periapical healing compared to root canal preparation without foraminal enlargement. On the other way, foraminal enlargement may increase amount of apically extruded debris and irrigants to the periapical area [53]. Although it would be expected to see an increase in the prepared cemental walls when using the same instrument at the level of the foramen or 1 mm beyond, some articles in this study did not observe a significant difference in these parameter [16,50]. Surprisingly, one study showed that over-instrumentation, regardless of kinematics, did not differ significantly from instrumentation short of the foramen while keeping it patent [50].

Regarding deformation of the apical foramen, most studies used SEM images for evaluation, in which a magnification ranging from $\times 50$ to $\times 100$ was reported [16,48,49]. Photomicrographs were analysed with the aid of a software to perform measurements and comparisons after different instrumentation moments. SEM allows increasing measurement accuracy and is a viable method when analysing a large sample [43], meanwhile it requires a device to standardize the acquisition of the consecutive images [48]. All studies concluded that instrumentation at the major foramen or beyond the apex promoted foraminal deformations [16,48-51]. Instruments with #25 tip size already showed to be able to cause apical transportation when instrumentation reached foramen or was beyond it, in comparison to WL = -1 mm plus patency with #10 SS file [50].

The occurrence of foraminal deformation or transportation may negatively impact in the quality of obturation [8,54] and one of the major concerns regarding performing foraminal widening is the possibility of increased risk of endodontic sealer extrusion. The possibility for overflow of filling materials into the perirradicular tissues [8] can increase the risk of tissue irritation or delayed healing. Conversely, two included studies demonstrated that sealing ability is not affected by over-instrumentation [16,48].

Regarding shape analysis, few data were found. One study demonstrated that original oval foramens turned into more circular shape. The use of instruments with greater tip size and reduced taper may provide greater flexibility than larger taper files, in which may reduce irregular deformation [49].

Only one study evaluated the occurrence of dentinal microcracks showing that foraminal enlargement increased the occurrence of this outcome [51].

A modified JBI critical appraisal tool assessed study quality, revealing methodological limitations in sample size justification, randomization, and blinding across most included studies. Enhanced, standardized evaluations considering anatomical variations are needed for robust evidence. Despite this, many studies exhibited low bias risk and adequate reporting, contributing to overall high-quality evidence.

Laboratory studies commonly exhibit methodological heterogeneity [55]. This review found variability in instrumentation protocol, instrument tip and taper sizes, working length determination, and root canal curvature. Inconsistent methodologies hampered comparisons between studies. Additionally, only *ex vivo* models using extracted human teeth were selected, which must be considered when interpreting the findings and making assumptions to the clinical setting. It is important to emphasize that it is only through *ex vivo* studies that the selected outcomes can be analysed more precisely, since, clinically, microscopy or microtomography, for example, cannot be performed in clinical studies. However, future clinical research should delve into long-term consequences of foraminal enlargement.

CONCLUSION

This review showed that foraminal enlargement, whether performed at the apical foramen or beyond it, causes both an increase in foraminal area and its deformation. It was not possible to conclude if there is a conservative, but effective, protocol for foraminal enlargement due to great methodological heterogeneity of studies. Well-designed evaluations with standardized methodologies are necessary. Clinicians must weigh benefits (e.g., bacterial reduction) against possible risks of the foraminal deformation (e.g., material leakage, debris and irrigating solution extrusion) when choosing foraminal enlargement, considering individual cases.

Author's Contributions

IFAM: Conceptualization, Investigation, Data Curation, Formal Analysis, Writing – Original Draft Preparation. AHRP: Methodology, Software, Formal Analysis, Writing – Original Draft Preparation. GCF: Investigation, Formal Analysis, Visualization. GOC: Investigation, Formal Analysis, Visualization. ICF: Conceptualization, Validation, Visualization. FB: Methodology, Resources, Supervision and Validation. IFCP: Resources, Supervision and Validation. WLFT: Conceptualization, Writing – Review & Editing, Project Administration. ACDV: Conceptualization, Investigation, Formal Analysis, Resources, Supervision, Writing – Review & Editing, Project Administration.

Conflict of Interest

No conflicts of interest declared concerning the publication of this article.

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Regulatory Statement

A regulatory statement is not applicable as this is a systematic review study conducted through an electronic database search.

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