https://doi.org/10.54589/aol.37/3/203

Twelve-month healing rates after endodontic therapy with foraminal cleaning using 2% chlorhexidine in mandibular molars diagnosed with apical periodontitis: a prospective clinical study

Cassiano N Almeida[1], Carlos E da Siveira Bueno[2], Alexandre Sigrist De Martin[2], Carlos E Fontana[3], Augusto S Kato[2], Ana Grasiela Limoeiro[4], Wayne M Nascimento[2], Marília FV Marceliano-Alves[5,6,7], Ricardo Ferreira[1], Rina A Pelegrine[2]

1. *Department of Endodontics, Dentistry Course, School of Health Sciences, Vale do Itajaí University (UNIVALI), Itajaí, Santa Catarina, Brazil*
2. *São Leopoldo Mandic, São Leopoldo Mandic Research Institute, Department of Endodontics, Campinas, SP, Brazil.*
3. *PUC Campinas, Center of Life Sciences, Programa de pós-graduação em Ciências da Saúde, Campinas, SP, Brazil.*
4. *Department of Dentistry, Endodontics and Dental Materials, Bauru Dental School, University of Sao Paulo, Bauru, Brazil*
5. *Post-Graduate Program in Dentistry, Iguaçu University, Nova Iguaçu, RJ, Brazil*
6. *Department of Dental Research Cell, Dr. DY Patil Dental College and Hospital, Dr. DY Patil Vidyapeeth, Pune 411018, India.*

ABSTRACT

The success of endodontic treatment depends on the effective disinfection of the root canal system.The literature describes many treatment protocols. ***Aim:*** *The purpose of this prospective in vivo study was to evaluate the healing status observed after endodontic treatment performed with foraminal cleaning in mandibular molars with apical periodontitis.* ***Materials and Method:*** *Fifty mandibular molars were selected and instrumented with ProDesign Logic files. First, mechanized patency was performed with a 25/0.01 instrument; if it was easily achieved, a larger diameter instrument was chosen (30/0.01, 35/0.01, or 40/0.01) that best matched the apical foramen. Then, a respective shaping file corresponding to the patency file was selected for instrumentation. Irrigation was carried out with saline solution and 2% chlorhexidine gel. A 17% EDTA solution was used for the final irrigation and agitated with the EasyClean system. A device was used to standardize the initial, final, and subsequent digital radiographic examinations for the follow-up. A 3-level scoring system was used for evaluation, in which score 1 indicated complete lesion healing, score 2 incomplete healing, and score 3 no healing.* ***Results:*** *There was no significant difference between the frequencies of scores 1 and 2 assigned at the two assessment time points ($p > 0.05$). Complete healing (score 1) was observed in 58%, incomplete healing (score 2) in 42%, and no healing (score 3) in 0% of cases.* ***Conclusion:*** *The endodontic preparation protocol followed by foraminal cleaning favored the healing process in teeth with apical periodontitis.*

Key words: *dental pulp diseases - periapical diseases - root canal therapy - tooth apex - treatment outcome*

To cite:
Almeida CN, da Siveira Bueno CE, Sigrist De Martin A, Fontana CE, Kato AS, Limoeiro AG, Nascimento WM, Marceliano-Alves MFV, Ferreira R, Pelegrine RA. Twelve-month healing rates after endodontic therapy with foraminal cleaning using 2% chlorhexidine in mandibular molars diagnosed with apical periodontitis: a prospective clinical study. Acta Odontol Latinoam. 2024 Dec 30;37(3):203-209. https://doi.org/10.54589/aol.37/3/203

Corresponding Author:
Marilia Marceliano-Alves
mmarceliano@hotmail.com

Received: January 2024.
Accepted: November 2024.

A cicatrização em 12 meses após terapia endodôntica com limpeza foraminal após o uso de clorexidina a 2% em molares inferiores com periodontite apical: um estudo clínico prospectivo

RESUMO

O sucesso do tratamento endodôntico depende da desinfecção eficaz do sistema de canais radiculares e há uma abundância de protocolos de tratamento na literatura. ***Objetivo:*** *O propósito deste estudo prospectivo in vivo foi avaliar o estado de cicatrização observado após tratamento endodôntico realizado com limpeza foraminal em molares inferiores com periodontite apical crônica.* ***Material e Métodos:*** *Cinquenta molares inferiores foram selecionados e instrumentados com limas ProDesign Logic. Primeiro, foi realizada a patência mecanizada com instrumento 25/0.01; se foi alcançada facilmente, um instrumento de maior diâmetro foi escolhido (30/0.01, 35/0.01 ou 40/0.01) que melhor correspondesse ao forame apical. Em seguida, uma lima de modelagem respectiva a de patência foi escolhida para a instrumentação. A irrigação foi realizada com solução salina e gel de clorexidina a 2%. Uma solução de EDTA a 17% foi usada para a irrigação final e agitada com o sistema EasyClean. Um dispositivo foi usado para padronizar os exames radiográficos digitais inicial, final e subsequentes para o acompanhamento. Um sistema de pontuação de 3 níveis foi usado para avaliação, no qual a pontuação 1 é a cicatrização completa da lesão; a pontuação 2 é a cicatrização incompleta e a pontuação 3 se refere à ausência de cicatrização.* ***Resultados:*** *Não houve diferença significativa entre as frequências das notas 1 e 2 atribuídas nos dois momentos de avaliação ($p > 0,05$). Cicatrização completa (nota 1) foi observada em 58%, cicatrização incompleta (nota 2) em 42% e nenhuma cicatrização (nota 3) em 0% dos casos.* ***Conclusão:*** *Concluiu-se que o protocolo de preparo endodôntico seguido de limpeza foraminal favoreceu o processo de cicatrização em dentes com periodontite apical crônica.*

Palavras-chave: *doenças da polpa dentária - doenças periapicais - terapia de canal - ápice dentário - resultado do tratamento*

INTRODUCTION

In recent decades, there have been numerous technological advances in the field of endodontics aimed at improving treatment prognosis and thereby helping to preserve teeth[1]. The evaluation of the outcome of endodontic treatment is generally based on the analysis of radiographic findings and the assessment of clinical signs and symptoms associated with the treated tooth. In this context, instrumentation and irrigation play an important role in cleaning and disinfecting the root canal system, thereby contributing to the success of the endodontic treatment[2].

According to Metzger et al.[3], it is not uncommon for failures due to inadequate root canal obturation to result from poor preparation. If the preparation is inadequate, the filling will most likely not be effective, so biomechanical preparation is one of the most important phases in controlling endodontic infection. Cutting and removing tissue with endodontic instruments combined with the flow and antimicrobial action of irrigants can significantly reduce the number of microorganisms in the main root canal and on the dentin walls[4].

The new single-file concept for shaping root canals aims to simplify the preparation technique and reduce surgical time. The ProDesign Logic System (Bassi/Easy Equipamentos Odontológicos, Belo Horizonte, MG, Brazil) provides a simplified preparation procedure based on the use of a single instrument to shape the root canal[5], providing agility and more conservative preparation. This technical simplification shortens the learning curve and thus streamlines endodontic treatment[6].

Obturation of the root canal system with three-dimensional sealing is another important phase of endodontic treatment. Considering the high prevalence of root canal branching, the complexity of the root canal system should be considered. The continuous wave of condensation technique considers this three-dimensionality and enables the formation of a homogeneous, stable gutta-percha body that penetrates the ramifications[7].

Considering that the success of endodontic treatment depends on a combination of the several factors, it is important to establish an effective treatment protocol to promote and maintain disinfection of the root canal system. The aim of this prospective i*n vivo* study was to evaluate the healing status of 50 mandibular molars with apical periodontitis 12 months after endodontic preparation with foraminal cleaning.

MATERIAL AND METHOD

Sample size was calculated using a formula for sensitivity and specificity for diagnostic studies with the PASS 15 program. A power of 81% was used as the calculation assumption to detect a change in sensitivity from 0.8 to 0.9, and the significance level of the sensitivity test was 0.046. A sample size of 50 teeth was required.

This study was approved by the Institutional Research Ethics Committee of the São Leopoldo Mandic Research Institute (registration number 1.563.724), and conducted in compliance with all ethical standards of the Declaration of Helsinki of the World Medical Association. All patients voluntarily signed an informed consent form before being enrolled in the study. Fifty mandibular molars from patients referred to the Center for Dental Specialties at the Vale do Itajaí University (UNIVALI), Itajaí, Santa Catarina, Brazil, where the study was conducted, were treated and followed up over a 12-month period. All teeth were diagnosed clinically with pulp necrosis and radiographically with apical periodontitis.

Patients were selected according to the following protocol: Medical history, extraoral and intraoral clinical examination, pulp sensitivity testing, and evaluation of a periapical radiography. Patients were excluded if they had advanced periodontal disease or combined endo-periodontal lesions, were taking analgesic, anti-inflammatory, antibiotic or immunosuppressive medications, or had undergone endodontic retreatment.

Initial radiographs of the teeth included in the study were obtained using a digital radiographic sensor (CDR Elite; Dentsply Sirona, York, PA, USA) and an X-ray device (Spectro 70X Eletronic; Dabi Atlante, Ribeirão Preto, SP, Brazil). A silicone mold (Clonage; Nova DFL, Rio de Janeiro, RJ, Brazil) was prepared and adapted to the X-ray positioner to ensure that the sensor was held in the same standardized position during X-ray examinations.

Endodontic treatment

After anesthesia and rubber dam isolation, coronal access was performed using a 1014 drill (KG Sorensen, Barueri, SP, Brazil) and carbide drills

2 and 3 (Injecta, São Bernardo do Campo, SP, Brazil). Initial decontamination of the pulp chamber was performed by completely filling it with 2% chlorhexidine gel (Visnature, Itajaí, SC, Brazil) for 1 minute. The endodontic treatment protocol began with the exploration of the cervical and middle third with #10 K-type hand files (Vdw Gmbh, Munich, Germany) using clockwise/counterclockwise movements (1/4 rotation to the right and ½ rotation to the left) to a point 5 mm short of the radiographic apex to establish a direction for the rotating files. Afterwards, ProDesign Logic System (Bassi/Easy) driven by an endodontic motor (EndoEasy SI; Easy Equipamentos Odontológicos, Belo Horizonte, MG, Brazil) set to a speed of 350 rpm and a torque of 1 N.cm was used to prepare the canal. In-and-out movements were performed with a maximum amplitude of 3 mm until the working length for exploration was reached, which was determined by subtracting 1 mm from the apparent length of the tooth measured on the first radiograph.

Then, the apical foramen was located with an electronic apex locator (Romiapex A-15; Romibras, Rio de Janeiro, RJ, Brazil) and the working length (WL) was considered in "zero". Hand-use K files #10 and #15 (Vdw GmbH, Munich, Germany) were inserted up to 1 mm beyond the apical foramen to achieve initial foraminal patency. Mechanized patency was then achieved with a 25/0.01 ProDesign Logic file designed to create glide paths. Whenever it reached the foramen effortlessly, a different size file (30/0.01, 35/0.01, or 40/0.01) was used until resistance was encountered.

The final shaping file was selected based on the file used to create the glide path that best matched the apical foramen. The correspondence between glide path and final shaping file is shown in Table 1. The selected final shaping file was coupled to the contra-angle handpiece of the endodontic motor, which was operated at setting #2 of the "Logic" program at a speed of 950 rpm and a torque of 4 N.cm. A brushing motion with light apical pressure was applied against the root canal walls until WL was reached. After three brushing movements, the file was removed, and its blades cleaned with sterile gauze.

During instrumentation, the canals were irrigated with 2% chlorhexidine gel (Visnature, Itajaí, SC, Brazil) using a 3 mL plastic syringe (BD, São Paulo, Brazil) and a 0.20 x 55 mm hypodermic needle (BD, São Paulo, SP, Brazil). Irrigation to remove canal debris was performed with saline (Laborasa, São Paulo, SP, Brazil) using a 5-mL plastic syringe (BD) and a hypodermic needle of the same size (BD).

Table 1. Correspondence between glidepath files and final shaping files (Easy Equipamentos Odontológicos, Belo Horizonte, MG, Brazil) used for the root canal treatments performed in the study.

Glidepath / patency file	Final shaping / preparation file
25/0.01 – red	25/0.06 - red
30/0.01 – blue	30/0.05 - blue
35/0.01 - green	35/0.05 - green
40/0.01 - black	40/0.05 - black

For final cleaning, 5 mL of a 17% EDTA solution (Biodynamic, Ibiporã, PR, Brazil) was added to the canal, and then mechanically agitated with an EasyClean insert (Bassi/Easy). The insert was positioned at WL and reciprocated in three cycles of 20 s. After each agitation cycle, the 17% EDTA solution was removed by rinsing with 5 mL of saline. The canals were then dried with absorbent paper tips (Tanariman Industrial, Manacapuru, AM, Brazil).

The canals were obturated with gutta-percha cones (Odous De Deus, Belo Horizonte, MG, Brazil), the tips of which were placed 2 mm short the WL, and endodontic sealer (Endomethasone; Septodont, Saint-Maur-des-Fossés Cedex, France) was used according to the manufacturer's instructions. The continuous compaction wave technique[7] was applied with the thermoplasticizing tip of the Easy Thermo "FM" device (Bassi/Easy Equipamentos Odontológicos, Belo Horizonte, MG, Brazil) positioned 5 mm short of the WL. After sealing the apical third of the canal, the rest was filled with heated gutta-percha, using the thermal injector of the same system. Coronal sealing was performed with a temporary sealer (Coltosol; Vigodente, Rio de Janeiro, RJ, Brazil) and composite resin (Z250; 3M, Sumaré, SP, Brazil).

Patients were then referred to a healthcare facility to receive a definitive restoration. A final radiography was obtained and stored in a digital file, using the same standardized procedures as the initial radiography. Patients were re-examined 12 months after the procedure, and new clinical and radiographic examinations were performed to re-evaluate the endodontic treatment performed. The initial, final,

and subsequent radiographs were evaluated by two trained investigators performed the measurements at two different time points, 15 days apart, to verify the agreement of the assessments.

The clinical radiographic assessments were based on the European Society of Endodontology outcome classification criteria, and classified using the following scoring system: score 1, complete healing: no clinical symptoms or presence of lamina dura demonstrated radiographically; score 2, incomplete healing: no clinical symptoms and regression of apical periodontitis demonstrated radiographically; Score 3, no healing: Presence of clinical symptoms and no evidence of regression of apical periodontitis or else progression of apical periodontitis demonstrated radiographically[8]. Figures 1 and 2 show two cases evaluated with scores 1 and 2, respectively.

Statistical analysis

The intraclass correlation test was applied to evaluate the agreement between the investigators. The Shapiro-Wilk normality test, complemented by the nonparametric Mann-Whitney test, was used to compare the scores assigned to the healing status observed in the radiographs. BioEstat v. 5.3 software (Instituto de Desenvolvimento Sustentável Mamirauá, Belém, PA, Brazil) was used to perform the analyses. The significance level applied was 5%.

RESULTS

The correlation test showed that the agreement between the investigators was excellent (Table 2). No significant difference was found between the frequencies of scores 1 and 2 assigned to the radiographs at the two evaluation times (p = 1.00, Table 3). Score 3 was not assigned to any of the radiographs.

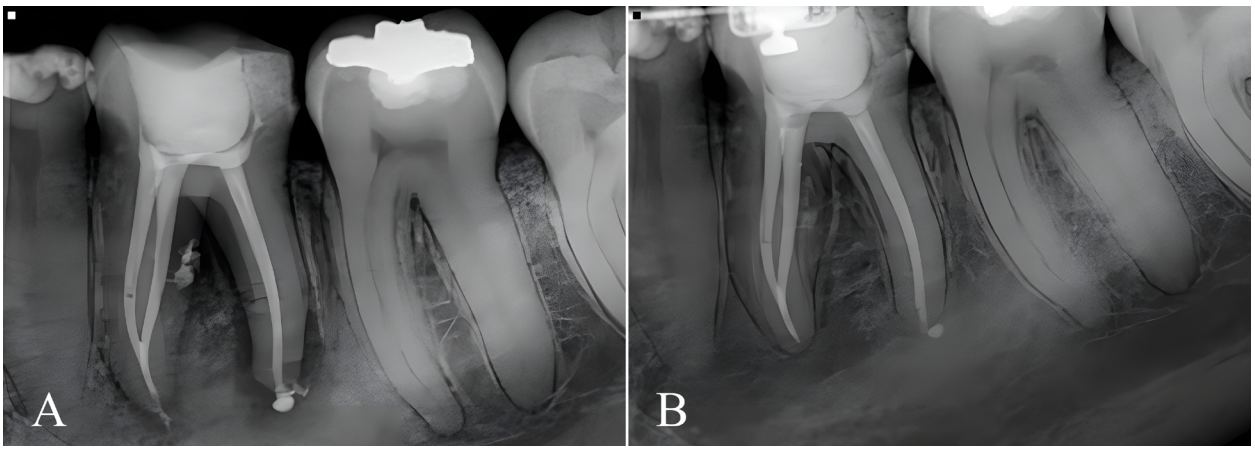

Fig. 1: Representative images of the outcome of endodontic treatment performed with foraminal cleaning. ***A:*** *Radiograph taken immediately after treatment;* ***B:*** *Radiograph taken 12 months post-operatively, classified as Score 1 (complete healing).*

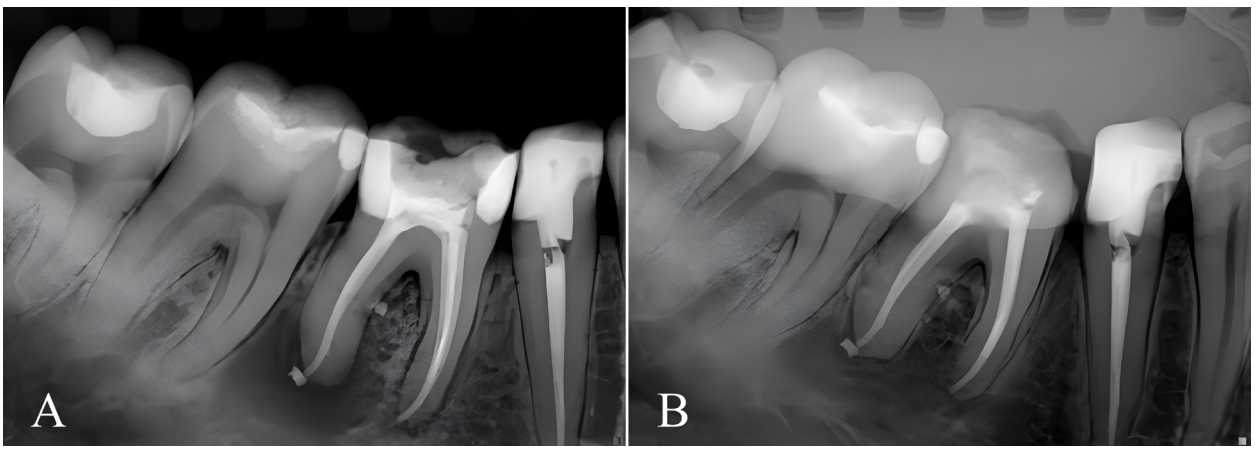

Fig. 2: Representative images of the outcome of endodontic treatment performed with foraminal cleaning. ***A:*** *Radiograph taken immediately after treatment;* ***B:*** *Radiograph taken 12 months post-operatively, classified as Score 2 (incomplete healing).*

Table 2. Results of the intra-class correlation test performed to evaluate inter-examiner agreement in the assessment of the healing status observed in radiographic images taken 12 months after root canal therapy with foraminal cleaning.

Variance between groups	**0.2323**
Experimental error	0.0048
Degree of freedom 1	49
Degree of freedom 2	50
p-value	< 0.0001
Intraclass correlation	0.9595
Replicability	Excellent

Table 3. Median, interquartile deviations and comparison of the scores assigned to the healing status observed in radiographic images taken at two evaluation time points after root canal therapy with foraminal cleaning.

	12 months	12 months and 15 days	p-value
Median (interquartile deviation)	1.00 (1.00) [A]	1.00 (1.00) [A]	1.00
% Score 1	58%	58%	
% Score 2	42%	42%	

Same letters indicate lack of statistically significant differences (Mann Whitney test; p > 0.05).

DISCUSSION

The sample in this study consisted of 50 mandibular molars with pulp necrosis and an initial radiograph suggestive of apical periodontitis, according to a previous study[9]. The overall response rate of patients was 100%, undoubtedly because they were all participants in an oral health program conducted at the University where the study was conducted. Patients were asked to return for follow-up by phone and reminded of the follow-up appointment every 3 months during the 12-month interval.

Initial, final, and follow-up digital radiographs were obtained, the last of which was taken 12 months after completion of endodontic treatment. A silicone mold was made and adapted to the positioner of the radiographic sensor in order to keep it in the same standardized position, thus ensuring higher sensitivity and diagnostic specificity for the assessment of the disease and healing processes[10,11].

The root canals were irrigated with saline and 2% chlorhexidine gel as an auxiliary chemical. A previous study found that both chlorhexidine gluconate and sodium hypochlorite significantly reduced the number of microorganisms in teeth with necrotic pulp or periapical disease, indicating that both solutions can be used successfully as irrigants[12]. These results are in accordance with other studies that showed that chlorhexidine has a broad antimicrobial spectrum, high substantivity, and lower cytotoxicity than sodium hypochlorite[9,13]. In addition, chlorhexidine has shown satisfactory clinical performance, lubricating properties and rheological effect. It inhibits metalloproteinases, is chemically stable, does not stain tissues, and is odorless and water-soluble[14]. Furthermore, because the present study used a technique that promotes targeted cleaning of the apical foramen, the use of a sodium hypochlorite solution could cause accidents[15] or lead to an undesirable inflammatory process[16].

The files used to create the glide path were selected according to the original anatomy of the apical foramen. The criterion for file selection was based on the resistance encountered when attempting to pass them through the apical foramen. This approach was intended to ensure effective cleaning of the apical foramen. A study suggests that foraminal cleaning should be performed to increase the predictability of endodontic treatment and that it is not associated with increased postoperative pain[17].

Final canal irrigation was performed before obturation with a total 5 mL of 17% EDTA solution. After filling each root canal with the EDTA solution to its cervical apical opening, the solution was mechanically agitated with the polymer-based EasyClean instrument, which was positioned at WL and reciprocated in 20-s cycles. A study concluded that irrigation with the EasyClean system was more effective than passive ultrasonic irrigation in removing debris from the more apical regions of the root canal[18].

Root canal orifices were sealed with Coltosol (Vigodente, Rio de Janeiro, RJ, Brazil) and the pulp chamber was sealed with composite resin. Sealing is performed after obturation to prevent bacterial contamination. Teeth with adequate root canal fillings and restorations have a more favorable prognosis considering the basic biological principle of preventing bacterial penetration through the crown[19].

In this study, a clinical and radiographic follow-

up was performed 12 months after treatment, the same follow-up period as used in some other studies[10,11,20], and the results were confirmed after the initial assessment at 12 months. According to a prospective study[21], one of the prerequisites for more favorable periapical healing is the absence of apical periodontitis before endodontic treatment. In the current study, all cases had previous apical periodontitis, which may have contributed to the fact that only 58% of patients achieved complete healing at 12 months. This rate was similar to that reported in a study conducted on teeth with apical periodontitis treated in a single session[11]. In contrast, another study found a radiographic success rate of 80% 12 months after completion of endodontic treatment, although their sample included only 19 cases, which are fewer than the 50 cases followed up in the present study[10].

Another prospective clinical and radiographic study, similar to the current study, but using asymptomatic teeth with pulp necrosis found a 92.9% success rate at the 12-month follow-up, with complete regression of apical periodontitis[20], similar to the present results. However, in that study, success was defined as partial or complete regression of the disease. In contrast, in the present study, partial regression (or incomplete healing) was observed in 42% of cases.

Another study assessed teeth with apical periodontitis and found that at a follow-up period of two years, 96.57% of cases had healed[22]. It has been reported that the maximum expected time for complete radiographic healing of periapical lesions is four to five years[8]. In exceptional cases, teeth have been followed up for up to 17 years. The use of a 12-month follow-up period may be considered a limitation of the present study because longer periods are usually required to allow more reliable follow-up of the healing process.

The incompletely healed apical periodontitis observed in 42% of the cases in the present study showed radiographic signs of regression and no clinical symptoms, but lamina dura formation was not observed in these cases, in contrast to the cases scored 1. This may be attributed to the fact that foraminal preparation was performed in the present study and that compression of the filling material caused a sealer extrusion and it could serve as a tissue irritant or the healing was through fibrous tissue. In order for this treatment outcome can be considered acceptable, it should show a reduction in periapical radiolucency for up to 2 years postoperatively; therefore, longer follow-up periods are recommended for apical periodontitis[23].

Based on the results of this prospective *in vivo* study, it can be concluded that the protocol with foraminal cleaning for the treatment of mandibular molars with a clinical diagnosis of nonvital pulp and a radiograph suggestive of apical periodontitis leads to favorable results in terms of regression of periapical disease. However, further studies with longer observation periods are needed for a more reliable evaluation.

CONFLICT INTERESTS

The authors declare no potential conflicts of interest regarding the research, authorship, and/or publication of this article.

FUNDING

This study was supported by grants from Fundação Carlos Chagas Filho de Amparo à Pesquisa do Estado do Rio de Janeiro (FAPERJ) (E-26/200.184/2023) and Conselho Nacional de Desenvolvimento Científico e Tecnológico (200280/2022-8), both of which are Brazilian Government Institutions.

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