UNIVERSIDADE ESTADUAL DE CAMPINAS
FACULDADE DE ODONTOLOGIA DE PIRACICABA

ANALU RODRIGUEZ MARCHESIN

RESULTADO DE UMA MICROCIRURGIA ENDODÔNTICA UTILIZANDO TERAPIA FOTODINÂMICA À BASE DE CURCUMINA: RELATO DE CASO

OUTCOME OF CURCUMIN-BASED PHOTODYNAMIC THERAPY IN ENDODONTIC MICROSURGERY: A CASE REPORT

Piracicaba
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Monografia apresentada à Faculdade de Odontologia de Piracicaba da Universidade Estadual de Campinas como parte dos requisitos exigidos para a obtenção do título de Especialista na área de Endodontia.

Monography presented to the Piracicaba Dental School of the University of Campinas in partial fulfillment of the requirements for the degree of Specialist in Endodontics area.

Orientador: Prof. Dr. Caio Cezar Randi Ferraz

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RESUMO

Introdução: A periodontite apical persistente após o tratamento endodôntico pode exigir retratamento cirúrgico quando as opções não cirúrgicas são ineficazes ou impraticáveis, devido aos desafios anatômicos ou erros iatrogênicos. A microcirurgia endodôntica (EMS) é uma técnica precisa que visa superar problemas que se referem ao biofilme extrarradicular e morfologia radicular. A terapia fotodinâmica (PDT) é uma abordagem de desinfecção suplementar que utiliza um agente fotossensibilizador e uma fonte de luz para eliminar microrganismos por meio de reações oxidativas. **Relato:** Um homem de 60 anos com periodontite apical persistente em um primeiro molar superior esquerdo foi submetido ao retratamento não cirúrgico do canal radicular seguido de reintervenção cirúrgica, devido à complexidades anatômicas. Durante a cirurgia, a PDT foi realizada utilizando um novo agente fotossensibilizador à base de curcumina. Após o procedimento, o dente foi retroobturado com cimento biocerâmico e foi aplicada fotobiomodulação para melhorar a cicatrização tecidual. Um ano após a cirurgia, o paciente apresentou reparo perirradicular completo e permaneceu assintomático. **Discussão:** A EMS é considerada o último recurso para salvar um dente tratado endodonticamente e tem mostrado moderadas taxas de sucesso. A PDT demonstrou ser promissora na melhoria da cicatrização periapical e na redução de microorganismos. Neste caso, a curcumina, diluída em gel de clorexidina a 2%, serviu como um agente fotossensibilizador eficaz com propriedades antimicrobianas. Além disso, a realização da fotobiomodulação auxiliou na recuperação celular e reduziu o desconforto pós-operatório. **Conclusão:** O protocolo de tratamento proposto com PDT utilizando curcumina produziu resultados positivos neste relato de caso. Mais ensaios clínicos randomizados são necessários para avaliar a eficácia desta abordagem em microcirurgias endodônticas. Além disso, recomenda-se mais pesquisas sobre agentes fotossensibilizadores à base de curcumina encapsulados em nanopartículas e agentes antimicrobianos aprimorados para refinar este protocolo de tratamento para uso rotineiro.

Palavras-chave: Endodontia, Cirurgia, Fotoquimioterapia, Microcirurgia Endodôntica

ABSTRACT

Introduction: Persistent apical periodontitis after root canal treatment may require surgical retreatment when non-surgical options are ineffective or impractical due to anatomical challenges or iatrogenic errors. Endodontic microsurgery (EMS) is a precise technique that aims to overcome extraradicular biofilm and root morphology issues. Photodynamic therapy (PDT) is an emerging supplementary disinfection approach that utilizes a photosensitizer agent and light to eliminate microorganisms through oxidative reactions. **Report:** A 60-year-old male with persistent apical periodontitis in a left maxillary first molar underwent non-surgical root canal retreatment followed by surgical reintervention due to anatomical complexities. During surgery, PDT was performed using a novel curcumin-based photosensitizer agent. After the procedure, the tooth was retrofilled with bioceramic cement, and photobiomodulation was applied to enhance tissue healing. One year post-surgery, the patient exhibited complete periradicular repair and remained asymptomatic. **Discussion:** EMS is considered a last resort to salvage an endodontically treated tooth and has shown moderate success rates. PDT has demonstrated promise in improving periapical healing and reducing microorganisms. In this case, curcumin, diluted with 2% chlorhexidine gel, served as an effective photosensitizer agent with antimicrobial properties. Moreover, performing photobiomodulation aided in cell recovery and reduced postoperative discomfort. **Conclusion:** The proposed EMS treatment protocol with PDT using curcumin yielded positive outcomes in this case report. Further randomized clinical trials are necessary to assess the efficacy of this approach in EMS. Additionally, further research on curcumin-based photosensitizer agents encapsulated in nanoparticles and enhanced antimicrobial agents is recommended to refine this treatment protocol for routine use.

Keywords: Endodontics, Surgery, Photochemotherapy, Endodontic microsurgery

SUMÁRIO

1. INTRODUÇÃO

A periodontite apical pós-tratamento refere-se à manifestação de sinais e sintomas em dentes com tratamento endodôntico devido à infecção microbiana persistente (Siqueira et al., 2014). O sucesso do retratamento do canal radicular depende não apenas das técnicas de desinfecção, mas também da superação dos desafios do procedimento (Ng et al., 2008). O retratamento cirúrgico torna-se necessário quando as abordagens não cirúrgicas falham ou são impraticáveis devido a vários fatores relacionados aos dentes que podem dificultar a desinfecção adequada na região apical.

Esses fatores incluem desafios anatômicos complexos, como desenvolvimento radicular imaturo, curvaturas radiculares extremas ou em forma de “S”, bifurcações apicais, raízes excessivamente longas ou calcificações graves, bem como erros iatrogênicos cometidos anteriormente, como saliências, transporte apical, perfuração ou instrumentos fraturados. (Setzer et al., 2022)

A Microcirurgia Endodôntica moderna (EMS) é um procedimento cirúrgico preciso e previsível que visa eliminar o biofilme extrarradicular e enfrentar os desafios anatômicos encontrados na morfologia radicular. Envolve a ressecção cirúrgica de 3 mm da extremidade radicular, o retropreparo da cavidade e retropreenchê-la com material obturador da extremidade radicular (Kim et al., 2006). A EMS mostrou uma taxa de sucesso de até 92,5% durante um período de observação de 9 anos, tornando-o uma opção de tratamento válida para salvar dentes (Pallarés-Serrano et al., 2022; Weissman et al., 2022).

A Terapia Fotodinâmica (PDT) é uma abordagem de desinfecção suplementar que tem sido alvo de extensa investigação nos últimos anos (de Araújo et al., 2022). Seu mecanismo envolve a indução de espécies de oxigênio altamente reativas por meio de uma reação oxidativa pela excitação de um agente fotossensibilizador usando uma fonte de luz específica (Gursoy et al., 2013).

Relatórios anteriores demonstraram resultados bem sucedidos ao aplicar esta abordagem de PDT como método suplementar em procedimentos de EMS (de Oliveira et al., 2018; Abu Hasna et al., 2020; Poli et al., 2022). Além disso,

um ensaio clínico revelou que a PDT reduz significativamente a carga microbiana das cavidades radiculares quando comparada ao EMS sozinho (Garcez et al., 2015). Portanto, o objetivo deste relato de caso é descrever o resultado da cicatrização perirradicular de um primeiro molar superior esquerdo com periodontite apical persistente, que foi tratado com EMS e PDT com um novo agente fotossensibilizador.

2. ARTIGO: OUTCOME OF CURCUMIN-BASED PHOTODYNAMIC THERAPY IN ENDODONTIC MICROSURGERY: A CASE REPORT

Running title: Photodynamic therapy and endodontic microsurgery

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Outcome of curcumin-based photodynamic therapy in endodontic microsurgery: a case report

Abstract

Background: Persistent apical periodontitis after root canal treatment may require surgical retreatment when non-surgical options are ineffective or impractical due to anatomical challenges or iatrogenic errors. Endodontic microsurgery (EMS) is a precise technique that aims to overcome extraradicular biofilm and root morphology issues. Photodynamic therapy (PDT) is an emerging supplementary disinfection approach that utilizes a photosensitizer agent and light to eliminate microorganisms through oxidative reactions. **Report:** A 60-year-old male with persistent apical periodontitis in a left maxillary first molar underwent non-surgical root canal retreatment followed by surgical reintervention due to anatomical complexities. During surgery, PDT was performed using a novel curcumin-based photosensitizer agent. After the procedure, the tooth was retrofilled with bioceramic cement, and photobiomodulation was applied to enhance tissue healing. One year post-surgery, the patient exhibited complete periradicular repair and remained asymptomatic. **Discussion:** EMS is considered a last resort to salvage an endodontically treated tooth and has shown moderate success rates. PDT has demonstrated promise in improving periapical healing and reducing microorganisms. In this case, curcumin, diluted with 2% chlorhexidine gel, served as an effective photosensitizer agent with antimicrobial properties. Moreover, performing photobiomodulation aided in cell recovery and reduced postoperative discomfort. **Conclusion:** The proposed EMS treatment protocol with PDT using curcumin yielded positive outcomes in this case report. Further randomized clinical trials are necessary to assess the efficacy of this approach in EMS. Additionally, further research on curcumin-based photosensitizer agents encapsulated in nanoparticles and enhanced antimicrobial agents is recommended to refine this treatment protocol for routine use.

Keywords: Endodontics, Surgery, Photochemotherapy, Endodontic microsurgery

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Conflict of interest:

The authors deny any conflict of interest related to this study.

1 Introduction

Post-treatment apical periodontitis refers to the manifestation of signs and symptoms in root canal-treated teeth due to persistent microbial infection (1). The success of root canal retreatment depends not only on disinfection techniques but also on overcoming procedural challenges (2). Surgical retreatment becomes necessary when non-surgical approaches fail or are impractical due to various tooth-related factors that may hinder adequate disinfection at the apical region. These factors include complex anatomical challenges such as immature root development, extreme or S-shaped root curvatures, apical bifurcations, overly long roots, or severe calcifications, as well as previously committed iatrogenic errors like ledges, apical transportation, perforation, or separated instruments (3).

Modern endodontic microsurgery (EMS) is a precise and predictable surgical procedure aimed at eliminating extraradicular biofilm and addressing anatomical challenges encountered in the root morphology. It involves surgically resecting 3 mm of the root-end, retropreparing the cavity, and retrofilling it with a root-end filling materia (4). EMS has shown a success rate of up to 92.5% over a 9-year observation period, making it a valid treatment option for saving teeth (5,6). Photodynamic therapy (PDT) is a supplementary disinfection approach that has undergone extensive investigation in recent years (7) Its mechanism involves inducing highly reactive oxygen species through an oxidative reaction by exciting a photosensitizer agent using a specific light source (8).

Previous reports have demonstrated successful outcomes when applying this supplementary PDT approach in EMS procedures (9–11). Additionally, one clinical trial revealed that PDT significantly reduces the microbial load of root-end cavities when compared to EMS alone (12). Therefore, the aim of this case report is to describe the periradicular healing outcome of a left maxillary first molar with persistent apical periodontitis, which was treated with EMS and PDT with a novel photosensitizer agent.

2 Report

This case report has been written according to the *Preferred Reporting Items for Case reports in Endodontics* (PRICE) 2020 guideline (13). Moreover, all procedures were thoroughly discussed with the patient, encompassing a comprehensive review of the risks, benefits, and treatment alternatives. The patient's informed consent for the proposed treatments described in this case report was obtained, and the process was properly documented. The patient willingly signed a written consent form, indicating their understanding and agreement to undergo the outlined procedures.

A 60-year-old male patient in good health was referred to the author's private practice for treatment of his left maxillary first molar. The patient complained of pain and tenderness while chewing. During the clinical

examination, an inadequate restoration on tooth #26 was identified, along with mild pain during the vertical percussion test, a negative response to cold tests, normal apical palpation and periodontal probing. A digital periapical x-ray (CDR Elite size 2, Dentsply Sirona, Charlotte, NC, USA) was taken, revealing periapical radiolucencies and a previous root canal filling (Figure 1). Based on both clinical and radiographic evaluations, a diagnosis of persistent apical periodontitis was made for the referred tooth, and root canal retreatment was indicated. All the procedures described below were performed using a dental operating microscope (OPMI Pico, Zeiss, Oberkochen, Germany) for enhanced magnification and precision. Moreover, the procedure was recorded using a EOS Rebel T7i camera (Canon, Tokyo, Japan) coupled into a 50 T-type beam splitter (Zeiss).

Figure 1. Initial periapical radiographic of tooth #26

2.1 First intervention

In October 2021, a non-surgical root canal retreatment was performed on the patient. Buccal and palatal infiltrative anesthesias were administered using 1.8 mL of 4% articaine with 1:200.000 epinephrine (Articaine 4%, Nova DFL, Rio de Janeiro, Brazil). A rubber dam was applied, and the endodontic access was opened using high-speed burs. Root canal instrumentation followed a sequence of coronal preflaring, glide path, and apical preparation using manual stainless steel K files and reciprocating Reciproc R25 and Reciproc Blue R40 files (VDW GmbH, München, Germany). During the procedure, 2% chlorhexidine gel served as the auxiliary chemical substance, while bidistilled water acted as the active irrigant to remove the previous root canal fillings.

The lengths of the root canals were determined using an electronic apex locator (RomiApex A-15, Romidan LTD, Kiryat Ono, Israel). However, achieving apical patency in the mesiobuccal, second mesiobuccal, and distobuccal root canals proved challenging due to anatomical complexities. Consequently, the working lengths for these canals were defined as 1 mm from the root apex to prevent file fracture. In contrast, the root length of the palatal canal was measured as 22 mm, and the working length was set as 1 mm beyond the apical foramen.

To enhance the disinfection process, three cycles of passive ultrasonic irrigation were carried out using an Irrisonic tip (Helse Ultrasonics, São Paulo, Brazil) along with 17% EDTA. Subsequently, a final flush with bidistilled water was performed in each root canal before the filling procedure. Root canal filling was accomplished using the single-cone obturation technique, combined with AH Plus Jet sealer (Dentsply Sirona, Charlotte, NC, USA). Finally, the tooth was restored with a direct resin-based composite, and a postoperative periapical radiography was taken to assess the treatment quality (Figure 2).

Figure 2. Postoperative periapical radiographic after non-surgical root canal retreatment of tooth #26

2.2 Second intervention

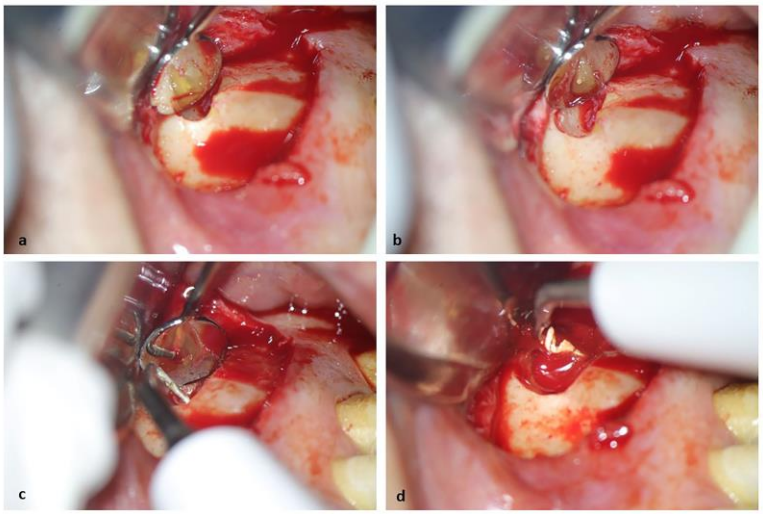
The patient returned for a follow-up visit in October 2022 and reported experiencing occasional mild tenderness while chewing. Upon repeating the clinical and x-ray exams, an increase in periapical radiolucencies was detected (Figure 3). A cone beam computed tomography (CBCT) scan was performed on tooth #26 to assess internal anatomical complexities, revealing severe apical curvature (< 30º) in the mesiobuccal and distobuccal roots at the foramen level, along with a hypodense lesion indicating persistent apical periodontitis despite the previous non-surgical retreatment (Figure 4).

Figure 3. One-year follow-up periapical radiographic of tooth #26 showing an increase in the apical radiolucencies

Figure 4. Preoperatory CBCT scan showing anatomical challenges

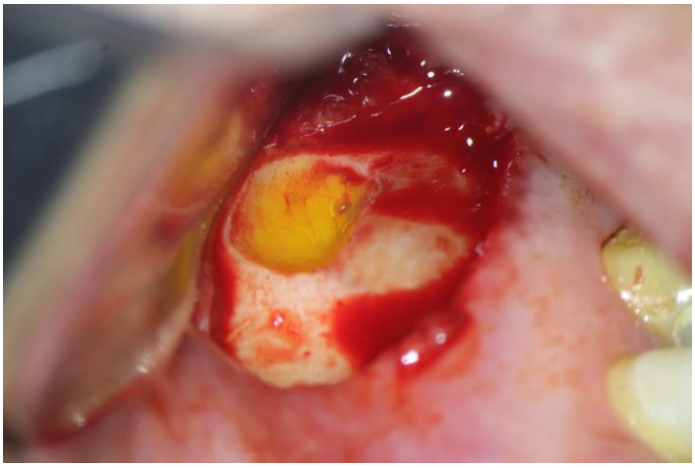
Considering these anatomical complexities, surgical reintervention was recommended. Firstly, the patient received preoperative oral administration of 4mg dexamethasone for improved postoperative recovery, followed by a 2-minute oral rinse with 0.12% chlorhexidine. Local anesthesia was administered using 1.8 mL of 4% articaine with 1:200.000 epinephrine (Articaine 4%, Nova DFL). A straight submarginal flap was raised to access the refereed tooth area, and osteotomy was performed using a round tungsten carbide bur coupled with a low-speed handpiece, irrigated with bidistilled water until optimal access to the mesiobuccal and distobuccal root-ends was achieved (Figure 5a and Figure 5b). Subsequently, manual curettage of the periapical lesion and external root surface was performed before executing the root-end section using a BladeSonic ultrasonic tip (Helse Ultrasonics). Retropreparation of the mesiobuccal and distobuccal root-end was carried out using the P1M tip (Helse Ultrasonics) associated with 2% chlorhexidine gel and bidistilled water (Figure 5c and Figure 5d) .

Figure 5. 5a. Resected mesiobuccal root-end; 5b. Resected distobuccal rood-end; 5c. Retropreparation of mesiobuccal root-end; 5c. Retropreparation of distobuccal rood-end



Photodynamic therapy (PDT) was conducted using a novel mixture of curcumin (Sigma-Aldrich, Missouri, USA) diluted in 2% chlorhexidine gel at a 500 mg/L concentration. The mixture was homogenized using a laboratory vortex mixer (Sigma-Aldrich) at 3000 rpm for 3 minutes. After applying the substance to the surgical cavity (Figure 6), a pre-irradiation time of 3 minutes allowed the substance to penetrate the root-end isthmuses. A blue LED light curing unit (Radii-Cal, SDI, Bayswater, Australia) was then used to photosensitize the agent for 5 minutes, followed by thorough washing with abundant bidistilled water to remove the substance completely from the surgical site.

Figure 6. Photosensitizer agent based on curcumin mixed with 2% chlorhexidine gel pre-irradiating on the surgical site



The mesiobuccal and distobuccal root-ends were dried with size 80 absorbent paper tips (AllPrime, Santa Catarina, Brazil). The cavity was subsequently retrofilled with Bio C Repair (Angelus, Londrina, Paraná, Brazil) using Bernabe condensers (Thimon, São Paulo, Brazil) (Figure 7a and Figure 7b). Additionally, a bone graft (Nanosynt, FGM, Santa Catarina, Brazil) and synthetic membrane (Duosynt, FGM) were placed at the site (Figure 7c and Figure 7d), and the flap was sutured with 3-0 silk thread (Ethicon, Ohio, USA). To improve tissue healing and reduce postoperative pain, photobiomodulation was performed using a low-level diode laser at a near-infrared pre-set wavelength of 808nm and an output power of 100mW for 20 seconds at the surgical sutures (duo laser, MMO, Optics, São Carlos, Brazil), then a postoperative periapical radiography was taken (Figure 8). The patient was instructed to take ibuprofen 600mg every 6 hours and nimesulide 100mg every 12 hours for three days.

Figure 7. 7a. Retrofilled mesiobuccal root-end; 7b. Retrofilled distobuccal rood-end; 7c. Bone graft; 7d. Barrier membrane

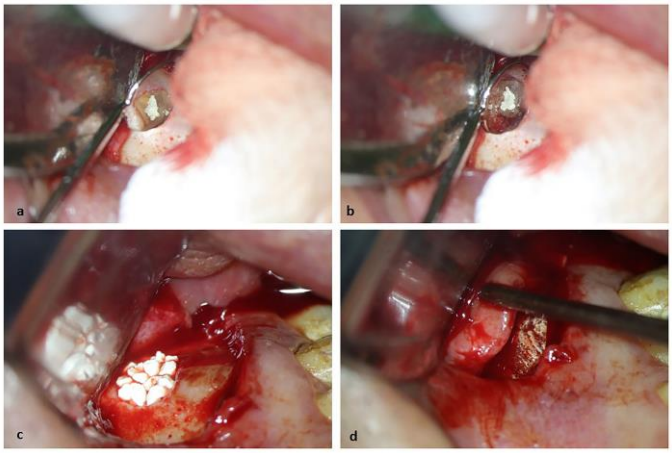
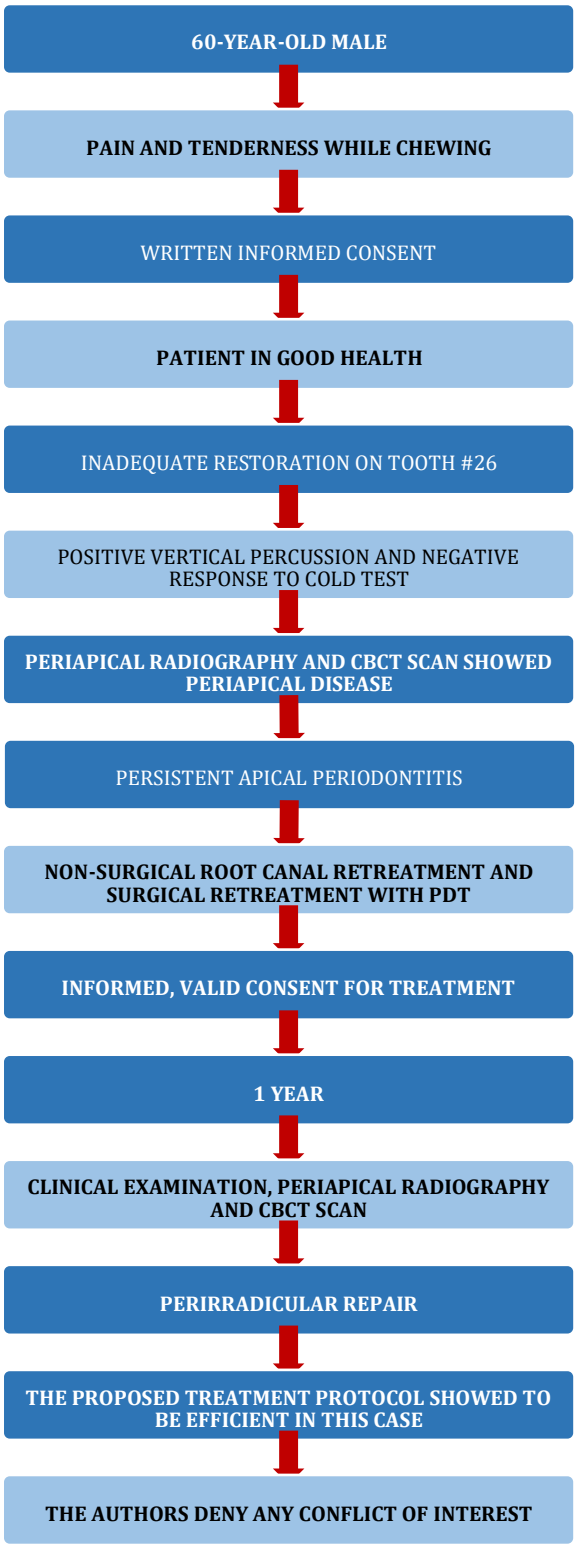


Figure 8. Postoperative periapical radiographic after surgical root canal retreatment of tooth #26

One week later, the patient returned to have the stitches removed and reported being free of postoperative symptoms and discomfort. During the subsequent visit to the author's private practice in September 2023 for a routine dental procedure, clinical and radiographic exams were conducted on tooth #26. The patient reported using the tooth for chewing as usual and stated that it was completely asymptomatic. The follow-up radiographic image showed clear signs of complete periradicular repair, with the lamina dura and periodontal ligament space surrounding the root structure and hard tissue covering the resected root-end area (Figure 9). Furthermore, no sensitivity on percussion or palpation was observed, confirming a successful outcome for this case. Figure 10 represents a flowchart outlining the clinical steps of this report, and Table 1 presents the treatment timeline.

Figure 9. Follow-up periapical radiographic showing periradicular healing

Figure 10. PRICE 2020 flowchart



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For further details visit: http://pride-endodonticguidelines.org/price/

Table 1. Treatment timeline

Time	Event	Symptons
0	Non-surgical root canal retreatment	Pain and tenderness while chewing along with mild pain on vertical percussion test.
+1 year	Follow-up visit	Occasional mild tenderness while chewing and persistency of pain on vertical palpation.
+3 days	Surgical root canal retreatment and PDT	
+7 days	Suture removal	No sensitivity on percussion or palpation.
+1 year	Follow-up visit	The tooth is fully functional without any pathological signs or symptoms.

3 Discussion

EMS is considered the last approach in an attempt to save an endodontically treated tooth. This technique has a high periapical healing rate, with better results observed when associating the use of microscope magnification and retro-filling with bioceramic cement. (14,15). Surgical reintervention in endodontically treated teeth is indicated in cases in which the conventional non-surgical retreatment was not able to eliminate persistent microorganisms present in apical branches or isthmuses, resulting in the perpetuation of periradicular diseases, either due to difficulties in the chemo-mechanical preparation and/or due to anatomical complexities of the root canal system (16) as was the present case report.

The endodontics specialty has always sought supplementary disinfection methods to optimize clinical outcomes (17). Thus, in the present case report, PDT was used for this purpose. Studies have shown that teeth with apical periodontitis achieved better periapical healing repair and reduction of microorganisms after treatment associated with PDT (18–20). Moreover, a case series that evaluated microbiological molecular analysis of teeth that underwent EMS and PDT showed that PDT significantly reduced total bacteria levels in the retrograde cavity and root-end surface, enhancing the disinfection and the periradicular healing process (21)

Although PDT is commonly performed by photosensitizing phenothiazine agents such as methylene blue and toluidine blue O with a low-level diode laser (22), studies have shown that other classes of photosensitizing agents such as

curcumin are also effective against the endodontic microbiome (23,24). Curcumin is a plant-derived natural compound that is known for its antimicrobial and anti-inflammatory characteristics (25) that can be effectively used for different purposes in endodontics: from irrigating the root canal system, as part of an intracanal medication or photoactivated during PDT (26). The maximum light absorbance peak of curcumin when used as a photosensitizer agent is around 425nm which is the same wavelength as the conventional light curing units used in dentistry (27). Moreover, no clinical side effects have been reported to date related to PDT in endodontics (28) or the use of curcumin (29), which is labeled as “Generally Recognized as Safe” by the US Food and Drug Administration (FDA). In the present case report, curcumin was diluted on 2% chlorhexidine gel to increase this approach’s antimicrobial spectrum.

Furthermore, the material of choice for the retrofilling procedure was a premixed bioceramic cement (Bio-C Repair, Angelus) which in addition to having the advantage of being a ready-to-use cement, also has the ideal basic properties of a bioceramic repair cement (e.g., biocompatibility and biomineralization capacity), this type of bioceramic cement has shown advantages upon conventional MTA due to less tooth discoloration, being easy to handle and manipulate, and have no differences on their antimicrobial properties, sealing ability and biocompatibility compared to MTA, showing highly favorable outcomes on EMS (30). Finally, photobiomodulation (PBM) was performed in order to assist in cell recovery and accelerate bone healing (31), and reduce postoperative pain, tenderness, and edema by modulating the inflammatory process (32).

4 Conclusion

The proposed EMS treatment protocol showed to be efficient in the periradicular healing and postoperative pain outcome in this case, suggesting that photodynamic therapy and photobiomodulation have good results as a supplementary approach to conventional EMS. High-quality randomized clinical trials are needed to further assess this approach in EMS, and the research and development of curcumin-based photosensitizer agents encapsulated on nanoparticles and enhanced antimicrobial agents are still required to recommend this treatment protocol as routine.

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Figure legends

Figure 1. Initial periapical radiographic of tooth #26

Figure 2. Postoperative periapical radiographic after non-surgical root canal retreatment of tooth #26

Figure 3. One-year follow-up periapical radiographic of tooth #26 showing an increase in the apical radiolucencies

Figure 4. Preoperatory CBCT scan showing anatomical challenges

Figure 5. 5a. Resected mesiobuccal root-end; 5b. Resected distobuccal rood-end; 5c. Retropreparation of mesiobuccal root-end; 5c. Retropreparation of distobuccal rood-end

Figure 6. Photosensitizer agent based on curcumin mixed with 2% chlorhexidine gel pre-irradiating on the surgical site

Figure 7. 7a. Retrofilled mesiobuccal root-end; 7b. Retrofilled distobuccal rood-end; 7c. Bone graft; 7d. Barrier membrane

Figure 8. Postoperative periapical radiographic after surgical root canal retreatment of tooth #26

Figure 9. Follow-up periapical radiographic showing periradicular healing

Figure 10. PRICE 2020 flowchart

3. CONCLUSÃO

O protocolo de tratamento de EMS proposto mostrou-se eficiente na cicatrização perirradicular e no resultado da dor pós-operatória neste caso, sugerindo que a terapia fotodinâmica e a fotobiomodulação apresentam bons resultados como abordagem complementar ao EMS convencional. Ensaios clínicos randomizados de alta qualidade são necessários para avaliar melhor esta abordagem, e mais pesquisas e desenvolvimento de agentes fotossensibilizadores à base de curcumina encapsulados em nanopartículas e agentes antimicrobianos aprimorados ainda são necessários para recomendar este protocolo de tratamento como rotina.

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Anexo 1 – Verificação de originalidade e prevenção de plágio.

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Apêndice 1 – Termo de consentimento livre e esclarecido.

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TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO (TCLE)

APRESENTAÇÃO DA PESQUISA:

Você está sendo convidado a participar como voluntário da pesquisa "Resultado da terapia fotodinâmica à base de curcumina em microcirurgia endodôntica", que será realizado em consultório particular localizado em Pelotas, Rio Grande do Sul, sob a responsabilidade dos pesquisadores Lucas Peixoto de Araújo, Analu Rodriguez Marchesin e Caio Cezar Randi Ferraz. As informações presentes neste documento foram fornecidas pelo pesquisador Lucas Peixoto de Araújo.
Este documento, chamado Termo de Consentimento Livre e Esclarecido, visa assegurar seus direitos como participante e é elaborado em duas vias, uma que ficará com você e outra que ficará com o pesquisador.

Por favor, leia com atenção e calma, aproveitando para esclarecer suas dúvidas. Se tiver perguntas antes ou mesmo depois assinar o Termo, você poderá esclarecê-las com o pesquisador. Se preferir, você pode levar este Termo para casa e consultar seus familiares ou outras pessoas antes de decidir participar. Não haverá qualquer tipo de penalização ou prejuízo se você não quiser participar ou se retirar sua autorização em qualquer momento, mesmo depois de iniciar sua participação na pesquisa. É importante realizar esta pesquisa porque irá colaborar para que novas opções de tratamentos complementares possam ser propostas.

INFORMAÇÕES SOBRE A PESQUISA:

Objetivos: O objetivo desta pesquisa será avaliar a ação da curcumina como um novo agente que pode contribuir na descontaminação do local, como método complementar ao tratamento convencional.

Procedimentos e metodologias: Participando do estudo você está sendo convidado a preencher corretamente uma ficha de anamnese, em que nos será fornecido toda e qualquer informação sobre sua saúde, e participar do tratamento proposto normalmente, que envolverá uma microcirurgia endodôntica, com anestesia local, na tentativa de eliminar a infecção persistente. Como método complementar a esse tratamento, será realizada a terapia fotodinâmica, em que será utilizado uma fonte de luz (led) e um agente fotossensibilizante (curcumina), procedimento esse que já possui embasamento científico. Você **não** deve participar deste estudo se possuir algum tipo de alergia aos produtos utilizados, como à curcumina ou similares.

Métodos alternativos: Podemos oferecer as seguintes opções de tratamento: o retratamento endodôntico não cirúrgico do elemento; a intervenção cirúrgica com a Microcirurgia Endodôntica, caso a primeira opção não apresente os resultados desejados; e, como última opção, a extração do elemento dental e posterior colocação de implante no local.

Desconfortos e riscos previstos: Os riscos e desconfortos estão diretamente ligados aos métodos utilizados. Você poderá sentir leve dor ou desconforto pós-operatório, porém serão utilizados medicamentos para auxiliar nesse controle. Os resultados esperados poderão não se concretizar por alguns motivos, como a resposta biológica desfavorável do organismo. A pesquisa em si não apresenta riscos previsíveis.

Benefícios: Ao participar desta pesquisa, além de podermos obter resultados satisfatórios, o seu caso pode contribuir para novos estudos e inovar em protocolos de tratamento, que visam melhorar ainda mais o tratamento proposto.

Rubrica do pesquisador: _____ Rubrica do participante: _____

Prof. Dr. Lucas Peixoto
Universidade Católica de Pelotas
Endodontista - CRO/RS 2603

Acompanhamento e assistência: Você será acompanhado por até 1 ano para avaliação dos resultados. Este acompanhamento será baseado em consultas em que avallaremos os sinais e sintomas presentes. Em casos de urgências, mesmo que "fora-de-hora", nos responsabilizaremos por qualquer atendimento necessário.

Forma de contato com os pesquisadores: Em caso de dúvidas sobre a pesquisa, você poderá entrar em contato com os pesquisadores Lucas Peixoto de Araújo, lucas.araujo@ucpel.edu.br; Analu Rodriguez Marchesin, analu.marchesin@hotmail.com; e Caio Cezar Randi Ferraz, crandiferraz@gmail.com.

Forma de contato com Comitê de Ética em Pesquisa (CEP): O papel do CEP é avaliar e acompanhar os aspectos éticos das pesquisas envolvendo seres humanos, protegendo os participantes em seus direito e dignidade. **Em caso de dúvidas, denúncias ou reclamações sobre sua participação e sobre seus direitos como participante da pesquisa, entre em contato com a secretaria do Comitê de Ética em Pesquisa (CEP)** da Faculdade de Odontologia de Piracicaba/UNICAMP: Av Limeira 901, FOP-Unicamp, CEP 13414-903, Piracicaba – SP. Fone/Fax 19-2106.5349, e-mail cep@fop.unicamp.br e Web Page www.fop.unicamp.br/cep.

GARANTIAS AOS PARTICIPANTES:

Esclarecimentos: Você será informado e esclarecido sobre os aspectos relevantes da pesquisa, antes, durante e depois da pesquisa, mesmo se esta informação causar sua recusa na participação ou sua saída da pesquisa.

Direito de recusa a participar e direito de retirada do consentimento: Você tem o direito de se recusar a participar da pesquisa e de desistir e retirar o seu consentimento em qualquer momento da pesquisa sem que isso traga qualquer penalidade ou represálias de qualquer natureza e sem que haja prejuízo ao seu tratamento iniciado ou por iniciar.

Sigilo e privacidade: Você tem a garantia de que sua identidade será mantida em sigilo e as informações obtidas durante a pesquisa só serão acessadas pelos pesquisadores. Na divulgação dos resultados desse estudo, informações que possam identificá-lo não serão mostradas ou publicadas.

Ressarcimento: Você não terá qualquer despesa por participar na pesquisa.

Indenização e medidas de reparação: Não há previsão de indenização ou de medidas de reparo, pois não há previsão de risco ou de dano pela participação na pesquisa, mas você tem o direito de buscar indenização e reparação se se sentir prejudicado pela participação na pesquisa.

Entrega de via do TCLE: Você receberá uma via deste Termo assinada e rubricada pelo pesquisador.

CONSENTIMENTO LIVRE E ESCLARECIDO:

Após ter recebido esclarecimentos sobre a natureza da pesquisa, seus objetivos, métodos, benefícios previstos, potenciais riscos e desconfortos que esta pode acarretar, aceito participar e declaro ter recebido uma via original deste documento rubricada em todas as folhas e assinada ao final, pelo pesquisador e por mim:

Nome do (a) participante: Alcimir Leite de Moraes

Contato telefônico: (53) 9939 1787

e-mail (opcional): _____

_____ Data: ___/___/_____.
(Assinatura do participante ou nome e assinatura do seu RESPONSÁVEL LEGAL)

Rubrica do pesquisador: Prof. Dr. Lucas Peixoto, Universidade Católica de Pelotas, Endodontista - CRO/RS 26037

Rubrica do participante: _____

Responsabilidade do Pesquisador:

Asseguro ter cumprido as exigências da resolução 466/2012 CNS/MS e complementares na elaboração do protocolo e na obtenção deste Termo de Consentimento Livre e Esclarecido. Asseguro, também, ter explicado e fornecido uma via deste documento ao participante. Informo que o estudo foi aprovado pelo CEP perante o qual o projeto foi apresentado. Comprometo-me a utilizar o material e os dados obtidos nesta pesquisa exclusivamente para as finalidades previstas neste documento ou conforme o consentimento dado pelo participante.

Data: 04/10/2022.

(Assinatura do pesquisador)

Rubrica do pesquisador:

Prof. Dr. Lucas Peixoto
Universidade Católica de Pelotas
Endodontista - CRO/RS 7607

Rubrica do participante: