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GUSTAVO LUIZ ALKMIN PAIVA

O USO DA PENTOXIFILINA E DO TOCOFEROL (PROTOCOLO PENTO) ANTES DE EXTRAÇÕES DENTÁRIAS NA PREVENÇÃO DA OSTEORRADIONECROSE

THE USE OF PENTOXIFYLLINE AND TOCOPHEROL (PENTO PROTOCOL) BEFORE DENTAL EXTRACTIONS IN THE PREVENTION OF OSTEORADIONECROSIS

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Dissertação apresentada à Faculdade de Odontologia de Piracicaba da Universidade Estadual de Campinas como parte dos requisitos exigidos para a obtenção do título de Mestre em Estomatopatologia, na área de Estomatologia.

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Orientador: Prof. Dr. Alan Roger Santos-Silva

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RESUMO

Esta dissertação de mestrado foi motivada pela necessidade de desenvolvimento de novos protocolos de prevenção e tratamento da osteorradionecrose (ORN), uma toxicidade crônica da radioterapia que segue sendo uma doença frequente no mundo todo e que gera grande impacto em termos de morbidade, custos e qualidade de vida entre pacientes sobreviventes do câncer na região de cabeça e pescoço. A estratégia científica adotada foi a realização de uma revisão sistemática, cujo objetivo principal foi determinar se o protocolo medicamentoso que combina a pentoxifilina e o tocoferol (protocolo PENTO) é eficaz para reduz o risco de ORN em pacientes submetidos a extração dentária após a conclusão da radioterapia da região da cabeça e do pescoço. Para isso, foi realizado o registro do protocolo de revisão sistemática na plataforma PROSPERO (CRD42022321603) que foi sucedido por buscas nas bases de dados SCOPUS, LILACS, EMBASE, Web of Science, e Cochrane até agosto de 2022. Foram considerados somente estudos que incluíram pacientes diagnosticados com câncer de cabeça de pescoço que foram submetidos a extração dentária com profilaxia com o protocolo PENTO. Em termos de resultados, foram identificados inicialmente 642 estudos, sendo que após a leitura do título e do resumo, 6 artigos foram selecionados para leitura integral. Em seguida, um artigo foi excluído por não reportar a taxa de ORN e outro por ser resumo de conferência, resultando em 4 artigos para a análise qualitativa. Dois estudos foram considerados como baixo risco de viés, um estudo como risco moderado e um estudo como risco alto. Dentre os estudos incluídos, dados de 387 pacientes foram analisados em um contexto de 1.871 extrações dentárias sob profilaxia com protocolo PENTO. O tempo de profilaxia do protocolo PENTO difere entre os estudos incluídos, variando de 1 a 12 semanas no pré-operatório e de 4 a 14 semanas no pós-operatório. Efeitos colaterais da medicação foram observados entre 5% e 10% dos casos. No total, 12 (3,1%) dos pacientes cujos dados foram incluídos no estudo desenvolveram ORN, com uma taxa de ORN por dente extraído de 0,9%. Os estudos primários incluídos reportam os dados de maneiras distintas em relação ao número de pacientes ou ao número de extrações dentárias, o que dificultou a comparação entre eles. Além disso, os estudos diferem no tipo de radioterapia e na dose utilizada, no tempo do protocolo PENTO e na prescrição de antibióticos. Em conclusão, no momento, não existe evidência suficiente para promover o uso do protocolo PENTO antes da extração dentária com o objetivo de prevenir ORN.

Palavras-chaves: extração dentária, pentoxifilina, alfa-tocoferol, osteorradionecrose, revisão sistemática

ABSTRACT

This master's thesis was motivated by the need to develop new protocols for the prevention and treatment of osteoradionecrosis (ORN), a chronic toxicity of radiotherapy that continues to be a frequent disease worldwide and that generates a great impact in terms of morbidity, costs, and quality of life among survivors of head and neck cancer. The scientific strategy adopted was to carry out a systematic review whose main objective was to determine whether the drug protocol that combines pentoxifylline and tocopherol (PENTO protocol) is effective in reducing the risk of ORN in patients submitted to tooth extraction after the completion of radiotherapy treatment in head and neck region. To achieve this goal, the systematic review protocol was registered at PROSPERO platform (CRD42022321603), which was followed by searches in the SCOPUS, LILACS, EMBASE, Web of Science, and Cochrane databases until August 2022. It was considered only studies that included patients diagnosed with head and neck cancer who were submitted to tooth extraction with PENTO protocol prophylaxis. In terms of results, 642 studies were initially identified, and after reading the title and abstract, 6 articles were selected for full reading. After, one article was excluded for not reporting the ORN rate and another for being a conference abstract, resulting in 4 articles for qualitative analysis. Two studies were considered with low risk of bias, one study with moderate risk and one study with high risk. Among the included studies, data from 387 patients were analyzed in a context of 1,871 tooth extractions with PENTO protocol prophylaxis. The prophylaxis time of PENTO protocol differs between the included studies, ranging from 1 to 12 weeks preoperatively and 4 to 14 weeks postoperatively. Medication side effects were observed in between 5% and 10% of cases. In total, 12 (3.1%) of the patients whose data were included in the study developed ORN, with an ORN per extracted tooth rate of 0.9%. The primary studies report data in different ways in relation to the number of patients or the number of dental extractions, which made comparation difficult. In addition, the studies differ in the type of radiotherapy and in the dose used, in the time of PENTO protocol and in the prescription of antibiotics. In conclusion, at moment, there is not enough evidence to promote the use of PENTO protocol prior to tooth extraction with the aim of preventing ORN.

Key-words: tooth extraction, pentoxifylline, alpha-tocopherol, osteoradionecrosis, systematic review

SUMÁRIO

1 INTRODUÇÃO

O câncer de cabeça e pescoço representa 6% de todas as neoplasias malignas que ocorrem na população mundial em base anual, cenário onde o carcinoma espinocelular (CEC) da cavidade oral e da orofaringe são considerados mais frequentes, excluindo os tumores da pele (Elicin e Mahmut-Ozsahin, 2018). O tratamento dos CECs de cavidade oral e orofaringe envolve abordagem cirúrgica do tumor primário e das metástases regionais (vias de drenagem linfáticas cervicais), seguido de radioterapia e quimioterapia adjuvantes. Em casos de tumores avançados loco-regionalmente, com frequência, os pacientes são tratados por meio da quimiorradioterapia concomitante, muitas vezes associada à terapia alvo molecular (Chow, 2020).

Neste contexto clínico, a radioterapia em cabeça e pescoço é aplicada como terapia curativa (neoadjuvante ou adjuvante), paliativa, ou hemostática e se baseia no princípio de que a radiação ionizante provoca efeitos físico-químicos nas células malignas conduzindo-as à morte celular (Langendijk, 2007). Contudo, os efeitos da radioterapia não estão específicos para as células tumorais, acarretando toxicidades aos tecidos sadios contidos nos campos de radiação. As toxicidades agudas da radioterapia se desenvolvem durante as fases iniciais do tratamento e continuam no período imediato pós-tratamento, durante até aproximadamente duas ou três semanas após a conclusão da radioterapia. Contudo, as toxicidades crônicas costumam se manifestar clinicamente nas últimas semanas da radioterapia e muitas vezes se estendem por muitos meses após o tratamento ou até mesmo se mantém de modo permanente. Dentre as toxicidades da radioterapia em região de cabeça e pescoço, pode-se citar a hipossalivação (alterações do fluxo salivar), a disgeusia, a mucosite oral, a candidose pseudomembranosa, a radiodermite, o trismo, a cárie de radiação e a osteorradionecrose, entre outras (Sroussi et al., 2017).

A osteorradionecrose pode ser definida clinicamente pela presença de exposição óssea em pele ou mucosa, sem sinais clínicos de recorrência da neoplasia, que não cicatriza por um período de três a seis meses, em um paciente submetido a radioterapia de cabeça e pescoço (Lyons e Ghazali, 2008). Contudo, esta definição não considera os casos de aparência radiográfica de osso necrótico sem exposição óssea em mucosa ou pele (Store e Boysen, 2000; He et al., 2015). O estadiamento clínico pode ser baseado por diferentes parâmetros: pela resposta ao tratamento com oxigenioterapia hiperbárica e cirurgia (Marx, 1983), levando em consideração o grau de resposta da doença ao tratamento, a presença de fratura óssea (Epstein

et al., 1987) e grau acometimento em relação ao osso alveolar e canal mandibular (Notani et al., 2003). Além disso, as características radiográficas e a integridade da mucosa ou pele foram incorporadas em sistemas de classificação mais atuais (Store e Boysen, 2000; He et al., 2015).

A combinação dos avanços tecnológicos dos protocolos de radioterapia com um entendimento mais apurado dos danos teciduais não-alvo causados pela radiação e com a ampliação do acesso ao tratamento odontológico para pacientes oncológicos contribuiu para a redução da incidência de osteorradionecrose ao longo dos últimos anos. Acredita-se, contudo, que o risco global estimado de desenvolvimento de osteorradionecrose varia de 4,3% a 6,6% (Kuhnt et al., 2016; Studer et al., 2016; Owosho et al., 2017), sendo que a taxa de osteorradionecrose espontânea pode variar de 10,6% (Curi e Dib, 1997) até 82% dos casos (Owosho et al., 2017). Uma revisão sistemática mostrou um risco estimado de 2% de desenvolvimento de osteorradionecrose após radioterapia de cabeça e pescoço (Nabil e Samman, 2012). Contudo, Após a extração dentária o risco estimado de desenvolvimento de osteorradionecrose varia entre 3,7% a 7,1% (Fritz et al., 2010; Nabil e Samman, 2011), dependendo do tipo de terapia adjuvante utilizada.

Pacientes com osteorradionecrose apresentam piora significativa na qualidade de vida em relação a população geral e em relação a pacientes irradiados sem osteorradionecrose. Os domínios dor, mastigação, fala e deglutição representam as piores pontuação na escala de qualidade de vida (Tassone et al., 2022). O tratamento da osteorradionecrose é complexo e pode envolver múltiplas abordagens, incluindo adequação odontológica com descontaminação por meio de bochechos com solução aquosa de clorexidina, modalidades farmacológicas (analgésicos, antibióticos e protocolo PENTO), oxigenioterapia hiperbárica, fotobiomodulação, terapia fotodinâmica antimicrobiana, procedimentos cirúrgicos conservadores (curetagem, sequestrectomia e debridamento ósseo) e intervenções cirúrgicas mais abrangentes (ressecções segmentares com ou sem reconstrução) (Lyons e Ghazali, 2008).

A extração dentária é notoriamente reconhecida como um fator de risco para a osteorradionecrose, contudo, em muitos casos, ela não pode ser evitada. Portanto, diversos métodos são sugeridos para prevenir a osteorradionecrose incluindo intervenções pré-extração baseadas no uso da oxigenioterapia hiperbárica (Marx et al., 1985; Fritz et al., 2010), antibióticos (Kanatas et al., 2002) e o uso do protocolo PENTO (Paiva et al., 2023). Em termos intra-operatórios, é recomendada a realização de alveoloplastia e sutura por primeira intenção (Samani et al., 2022) e o uso de plasma rico em fibrina (Serrano et al., 2022).

Inicialmente, o protocolo PENTO foi utilizado como tratamento para a fibrose induzida por radiação, na pele e tecido subcutâneos, após a radioterapia para o câncer de cabeça

e pescoço e mama. Para a realização deste protocolo medicamentoso, são prescritos em combinação 400mg de Pentoxifilina (800 mg/dia), 500 U.I. de Tocoferol (1000 U.I./dia) (Delanian et al., 1999, 2005a). Em seguida, o protocolo PENTO foi utilizado para o tratamento da osteorradionecrose com a adição do Clodronato (protocolo PENTOCLO) e uma fase inicial de descontaminação com antibióticos antifúngicos e glicocorticoides (Delanian et al., 2005b, 2011; Robard et al., 2014). Contudo, o uso do Clodronato, um bifosfonato, é questionável devido ao risco de osteonecrose medicamentosa. Além disso, o Clodronato não pode ser administrado próximo a ingestão alimentar contendo cálcio, dificultando o suporte alimentar em pacientes com câncer de cabeça e pescoço (Patel et al., 2021). Portanto, o protocolo PENTO também é utilizado para o tratamento da osteorradionecrose (McLeod et al., 2011; Patel et al., 2016), no qual há evidência de resolução ou estabilização da doença com melhora dos sintomas clínicos demonstrados através de revisão sistemática (Kolokythas et al., 2019). Os principais protocolos estão sumarizados na Tabela 1. Recentemente foi sugerido, que o protocolo PENTO poderia ter efeito profilático na prevenção da osteorradionecrose após a extração dentária em pacientes submetidos a radioterapia de cabeça e pescoço (Lyons e Ghazali, 2008).

Tendo em vista o exposto, essa dissertação de mestrado se propôs a determinar, por meio de uma revisão sistemática dos estudos clínicos já publicados na literatura científica e indexados nas principais bases de dados em saúde, se o protocolo PENTO pode ser considerado eficaz para reduz o risco de osteorradionecrose em pacientes submetidos a extração dentária após a conclusão da radioterapia em campos da região da cabeça e do pescoço.

Tabela 1: protocolos PENTO/PENTOCLO utilizados na literatura para tratamento de osteorradionecrose. (continua)

	Fase II: Protocolo PENTO/PENTOCLO				**Fase I: descontaminação**
	Pentoxifilina	**Tocoferol**	**Clodronato**	**Outros**	
Delanian et al., 2005	800 mg	1000 U.I.	1600 mg* - 5 dias	Ciprofloxaxino 1 g; Metilprednisolona 16 mg - 2 dias	Previamente ao protocolo PENTOCLO (2 a 4 semanas): Amoxicilina-ácido clavulânico 2 g; Fluconazol 50 mg; Metilprednisolona 16 mg
Delanian et al., 2011	400 mg (2x/dia)	500 U.I. (2x/dia)	1600 mg (1x/dia) - 5 dias	Ciprofloxaxino 1 g; Prednisona 20 mg - 2 dias	Previamente ao protocolo PENTOCLO (4 semanas) Amoxicilina-ácido clavulânico 2 g; Ciprofloxaxino 1 g; Fluconazol 50 mg; Prednisona 20 mg
McLeod et al., 2012	400 mg (2x/dia)	1000 U.I. (1x/dia)	-	-	-
Robard et al., 2014	800 mg	1000 U.I.	1600 mg - 5 dias	Prednisona 20 mg - 2 dias	Previamente ao PENTOCLO (4 a 6 semanas): Amoxicilina-ácido clavulânico 2 g; Ciprofloxaxino 1 g; Fluconazol 50 mg; Prednisona 20 mg; Omeprazol 20 mg
D'souza et al., 2014	400 mg (2x/dia)	1000 U.I. (1x/dia)	-	Doxicilina 100 mg (1x/dia)	-
Hayashi et al., 2015	400 mg (2x/dia)	1000 U.I. (1x/dia)	-	-	-
Patel et al., 2016	400 mg (2x/dia)	1000 U.I. (1x/dia)	-	-	Simultaneamente ao PENTO: na evidência clínica de infecção
Dissard et al., 2019	400 mg (2x/dia)	500 U.I. (2x/dia)	800 mg 2x/dia - 5 dias	Prednisona 20 mg (1x/dia); Omeprazol 20 mg (1x/dia) - 2 dias	Previamente ao protocolo PENTOCLO (28 dias): Ciprofloxaxino 500 mg (2x/dia); Clindamicina 600 mg (3x/dia); Fluconazol 50 mg (1x/dia); Prednisona 20 mg (1x/dia); Omeprazol 20 mg (1x/dia)
Patel et al., 2022	400 mg (2x/dia)	1000 U.I. (1x/dia)	800 mg (2x/dia)*	-	Previamente ao PENTO: na evidência clínica de infecção Amoxicilina 500 mg 3x/dia (7 dias) + Doxicilina 100 mg 1x/dia (30 dias)

* Alguns casos com uso do Clodronato.

2 ARTIGO:

Can the prophylactic use of pentoxifylline and tocopherol before dental extractions prevent osteoradionecrosis? A systematic review

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Keywords: tooth extraction, pentoxifylline, alpha-tocopherol, osteoradionecrosis, systematic review

Abstract

Purpose: This systematic review aimed to determine whether the pentoxifylline and tocopherol (PENTO) protocol effectively reduce the risk of osteoradionecrosis (ORN) in patients undergoing tooth extraction after head and neck radiotherapy. Methods: We searched PubMed, SCOPUS, LILACS, EMBASE, Web of Science, and Cochrane databases up to August 2022. We considered only studies that included patients diagnosed with head and neck cancer undergoing tooth extraction with PENTO prophylaxis after radiotherapy. Results: Of the 642 studies identified, 4 were included. Across the included studies, 387 patients had 1871 teeth extracted while on PENTO prophylaxis. The interval of the PENTO protocol differed among the studies included. Overall, a total of 12 (3.1%) patients had ORN, whereas at the individual tooth level analysis the ORN rate was 0.9%. Conclusions: Insufficient evidence exists to promote using the PENTO protocol before dental extractions to prevent ORN.

Introduction

The treatment of head and neck cancer may have acute and chronic sequelae. Among the chronic toxicities, osteoradionecrosis (ORN) is the most demanding complication and has challenging surgical control. The main triggering factor for ORN is tooth extraction in patients who have undergone head and neck radiotherapy.[1] The risk for ORN increases depending on the total radiation to the jaws. Osteoradionecrosis is unlikely to occur if the radiation dose is <60 Gy^{-2}

Few theories exist for the development of ORN. Marx proposed the theory of 3H (hypoxic-hypocellular-hypovascular).[3] This theory was the critical point in proposing the use of hyperbaric oxygen (HBO) for preventing[4,5] and treating[3] ORN before and after surgical procedures. Radiation-induced fibrosis is a new theory suggesting that the critical event in the progression of ORN is the dysregulation of fibroblastic activity that leads to the formation of atrophic tissue within a previously irradiated area.[6] To reverse changes in reactive oxygen species that produce radiation-induced fibrosis and ultimately ORN, a therapeutic regimen with PENTO has been developed to treat ORN.[7]

Although tooth extraction should be ideally panned and performed before head and neck radiotherapy to minimize the risk of ORN,[8] real-world evidence shows that post-radiation extractions are a clinical reality in which preoperative antibiotics,[9,10] HBO,4,[11] and, more recently, the PENTO protocol[12-15] are used to prevent ORN. In this sense, pentoxifylline exerts an anti-TNF effect, increases erythrocyte flexibility, dilates blood vessels, and increases collagenase activity in vitro, whereas tocopherol (vitamin E) scavenges reactive oxygen species and inhibits Transforming Growth Factor-b1 as well as the expression of procollagen genes. Therefore, when combined and administered twice a day, pentoxifylline (400 mg) and tocopherol (500 IU) act synergistically as potent antifibrotic agents and may be used as a prophylactic medication to prevent ORN after tooth extractions in patients with head and neck cancer. [16] Therefore, this systematic review aimed to determine whether the PENTO protocol effectively.

Material and methods

Protocol and registration

This systematic review protocol was registered at the International Prospective Register of Systematic Reviews as CRD42022321603 (https://www.crd.york.ac.uk/prospero/display_record.php?RecordID = 321603).

Eligibility criteria

Inclusion criteria

The inclusion criteria were as follows: population: patients diagnosed with head and neck cancer undergoing tooth extraction after receiving head and neck radiotherapy; intervention: pentoxifylline and tocopherol prophylaxis before tooth extraction; comparison: the control group comprised patients with tooth extraction without pentoxifylline and tocopherol prophylaxis; outcome: ORN development after tooth extraction; and study design: all study designs were included, except for case reports with <10 cases. No language restriction was applied, and no time limit was set.

Exclusion criteria

We excluded reviews, editorials, letters, personal opinions, book chapters, and conference abstracts; experimental in vitro or in vivo studies; and studies that did not describe the postoperative outcome.

Study selection—Information sources.

Studies were identified through a search in the following electronic databases: PubMed, SCOPUS, LILACS, EMBASE, Web of Science, and Cochrane, with an additional gray literature search in Google Scholar and ProQuest. All searches were completed by August 27, 2022. A manual search was conducted across the reference lists of the included articles for other pertinent studies that might not have appeared in the search

Search strategy.

The search strategy is detailed in Supplementary Appendix S1.

Selection process.

Two reviewers independently screened articles by reading the title and abstract of the entire list and excluded articles that did not fulfill the eligibility criteria. The same 2 reviewers independently read the full text of all the articles, screening them to identify the eligible articles. No disagreements were found, and a third reviewer was not necessary. All primary reasons for exclusions were registered. Duplicate references were removed using a reference manager (Mendeley Desktop, Elsevier, New York, NY, USA).

Data collection process.

One author extracted data from each included study. A second author reviewed the extracted data to confirm their accuracy. Qualitative and quantitative data were tabulated and processed in Microsoft Excel (Microsoft, Inc., Redmond, WA, USA).

Data items.

The development of ORN, according to the Notani classification,[17] after tooth extraction was the primary outcome of this systematic review.

Other data analyzed included the number of patients, age, sex, time of medication, side effect of medication, site of the primary tumor, radiotherapy system, number and indication of tooth extraction, site of jaw extraction, type of healing, other medications, and risk for ORN.

Risk of bias within studies.

The Joanna Briggs Institute Critical Appraisal Checklist for Case Series[18] was used to evaluate the quality of the included studies. The scoring was discussed among the authors, with the studies categorized as high when the study analysis score was <49%, moderate when the analysis score was between 50 and 69%, and low when the analysis of the study score was >70%.

Results

In phase 1, 642 articles were found in the selected databases. After the removal of duplicates (n = 120), 522 articles remained. The titles and abstracts of the studies were read for initial screening. After confirming the eligibility criteria, 6 studies were selected for full-text reading. No articles from the Google Scholar or Pro-Quest search were included in the review. A full reading of the articles selected in phase 1 was performed. This method led to the exclusion of 2 studies, 1 for being a conference abstract[19] and another for not describing the postoperative outcome.[20] The remaining 4 articles were included in the final analyses. A flow-chart of the selection method is shown in Figure 1.

Study characteristics

Characteristics of the trial designs and settings.

Four case series studies were selected for the review. No randomized clinical trials or observational studies were found in the search strategy. Two studies were conducted in the United Kingdom,[13,14] 1 in Italy,[15] and another in India.[12] All the studies were written in English, and articles were published between 2016[13] and 2022.[14,15]

Risk of bias

All 4 studies were submitted to The Joanna Briggs Institute Critical Appraisal Checklist for Case Series.[18] Two studies[14,15] had a low risk of bias. One study[13] had a moderate risk of bias, and another[12] had a high risk of bias. Further information concerning the risk of bias assessment is summarized in Figure 2 and Table I.

Characteristics of the participants.

Four hundred forty cases were analyzed; among these, 52 patients reported by Samani et al.[14] did not use the PENTO protocol, and Lombardi et al.[15] reported a patient undergoing implant surgery. Three hundred eighty-seven patients received head and neck radiotherapy and had their teeth extracted while on PENTO prophylaxis. Patel et al.[13] included 6 patients who had not taken complete prophylaxis, 2 patients who took pentoxifylline alone, and 4 who took tocopherol alone. Samani et al.[14] included 19 patients who had not taken medication by the predetermined time. The detail of demographic data are listed in Table II.

The mean age ranged between 55[13] and 66.5[15] years. Aggarwal et al.[12] did not report the age of the patients. Among the patients, 300 were men and 140 were women. External beam radiotherapy was the most common delivery system, Patel et al.[13] and Aggarwal et al.[12] reported rates higher than 92.7%. However, Samani et al.[14] reported rates of 58.4%. Lombardi et al.[15] did not report the system of radiotherapy used. Samani et al.[14] included patients who received doses >40 Gy. Lombardi et al.[15] reported the radiation dose only in 12/29 patients; 4 cases received <60 Gy, and 8 cases received 60 Gy or more. Aggarwal et al.[12] and Patel et al.[13] did not report the radiation dose.

Different criteria were used to classify the risk of tooth extraction for the development of ORN: (a) by the direction of radiotherapy[13,12]; (b) based on the tooth position, radiation protocol, and radiation dose[14]; or (c) based on age, chemotherapy, type of intervention, and oral hygiene.[15] Teeth at high risk of ORN were extracted in >50% of cases in the studies by Aggarwal et al.[12] and Patel et al.[13] and in <23% of cases in the study by Samani et al.14 The risk of tooth extraction for the development of ORN was not reported in the study by Lombardi et al.[15]

Characteristics of the PENTO protocol.

The dose of pentoxifylline used was 400 mg twice daily in all the studies.[12-15] However, the tocopherol dose used varied between 1000 IU[12-14] and 800 IU[15] per day. Aggarwal et al.[12] and Patel et al.[13] recommended a protocol of ideally 4 weeks preoperatively and postoperatively until the socket healed. However, for these studies, the time of medication was longer than the preconized protocol. The preoperative medication time in these studies was 11 to 12[12] weeks preoperatively and 14[12,13] weeks postoperatively. Samani et al.[14] advocated a minimum of 1 week before dental extraction and continuation for a minimum of 1 month, ideally for 3 months postoperatively. Lombardi et al.[15] recommended the protocol of 1 week preoperatively and 8 weeks postoperatively. The details of the PENTO protocol are listed in Table III.

Side effects of prophylaxis.

Adverse side effects occurred between 4.8%[14] and 9.1%[12] of the patients who received prophylaxis with pentoxifylline and tocopherol. Aggarwal et al.[12] reported 10 patients (10/110, 9.09%) with nausea, headache, and gastric irritation. No information about the

symptom's treatment or prophylaxis discontinuation was provided. Patel et al.[13] reported 6 patients (6/82, 7.32%) with side effects but did not specify what they were. Because of side effects, 2 patients took pentoxifylline alone, and 4 took tocopherol alone. Samani et al.[14] reported side effects in 8 patients (8/167, 4.79%). No information about the symptoms, treatment, or prophylaxis discontinuation was provided. Lombardi et al.[15] excluded 2 patients because of side effects, mainly nausea, diarrhea, dizziness, and asthenia, and the medication was discontinued. The details of the PENTO protocol are listed in Table III.

Antibiotics.

Antibiotics were used in all the studies, although their frequency varied. Antibiotics were used preoperatively in approximately 36% of patients by Patel et al.[13] and Aggarwal et al.[12] Samani et al.[14] and Lombardi et al.[15] did not report the preoperative use of antibiotics. In the postoperative period, the use of antibiotics ranged from 44.8%[15] to 100%.[14]

The first-choice antibiotic for all the studies was amoxicillin, with clindamycin[15] or metronidazole[14] being administered to those allergic to penicillin. Most patients received amoxicillin alone; however, the association of amoxicillin with metronidazole was used in 36% of patients by Patel et al.[13] and 54.5% by Aggarwal et al.[12] The details of the antibiotics are listed in Table IV.

Characteristics of the interventions and results.

Aggarwal et al.[12] realized 450 tooth extractions: 290 in the mandible and 160 in the maxilla. No description of the flap status or type of healing was made. The author did not report the time between radiotherapy and tooth extraction. Aggarwal et al.[12] reported only the ORN rate by the patient; 2 ORNs occurred in 110 patients (1.82%). The author did not report the ORN risk by teeth.

Patel et al.[13] realized 390 tooth extractions: 232 in the mandible and 158 in the maxilla. Sixty-six patients had their surgery performed without a flap, and 55 patients were healed by primary closure. Teeth were extracted with a mean time of 95 months after radiotherapy. Patel et al.[13] reported ORN rates for different demographic data. Osteoradionecrosis occurred in 1 of 82 patients (1.22%). By tooth-level analysis, the ORN rate was 0.26% (1/390). The only ORN case occurred after the extraction of a maxillary tooth that healed by second intention in a high-risk patient.

Samani et al.[14] divided patients into 3 groups. All patients in the full and partial compliance groups followed a prophylactic regimen with pentoxifylline and tocopherol. Extractions were performed 775, 104, and 200 times in groups that achieved full compliance with the prophylactic regimen, partial compliance, and control, respectively. Teeth were extracted with a median time of 48 months after radiotherapy. In the full compliance plus partial compliance groups, most teeth were extracted without flap surgery (82%) and healed by primary intention (45.8%). In the full compliance group, ORN occurred in 5 of 148 patients (3.38%), or 8 teeth after 775 tooth extractions (1.03%). In the partial compliance group, ORN occurred in 1 of 19 patients (5.26%) or in 2 teeth after 104 tooth extractions (1.92%). Comparison of the full compliance group with the control group revealed a significant reduction in ORN at both the patient level (3.4% vs 11.5%; P <.03) and tooth level (1.0% vs 3.5%; P < .01).

Lombardi et al.[15] performed 71 surgical procedures (single or multiple dental extractions). One hundred fifty-two dental extractions were performed. Sixty-four surgical extractions required raising the mucoperiosteal flap, whereas 82 were simple dental extractions. Eighty-two extractions occurred in the mandible and 70 in the maxilla. Teeth were extracted with a mean time of 42 months after radiotherapy. Osteoradionecrosis developed in 3 of 28 patients (10.71%), and ORN developed in 4 of 71 procedures (5.63%). The details of each surgical procedure are listed in Table IV.

A total of 1871 teeth were extracted across the included studies. However, only 2 studies reported the rate of ORN per tooth,[13,14] yielding a total of 0.9% (11/1269). Lombardi et al.[15] reported the ORN rate per procedure at 5.6% (4/71). Combined analyses of the studies revealed that the rate of ORN per patient using the PENTO protocol was 3.1% (12/387).[12-15]

Characteristics of the outcomes.

Only Samani et al.[14] used a well-known scale to classify the severity of ORN. In this study, 8 patients were affected by Notani I ORN, 1 patient by Notani II ORN, and 2 patients by Notani III ORN. For 1 patient, the classification was not mentioned. The authors did not correlate the Notani classification with the prophylactic PENTO group (control, full compliance, and partial compliance).

Discussion

The present systematic review aimed to determine whether a prophylactic protocol using a combination of pentoxifylline and tocopherol before dental extractions in patients with cancer irradiated in the head and neck would prevent or decrease the incidence of ORN.

The incidence of ORN is quite variable in the literature. Systematic reviews report incidences of ORN between 3.7%[10] and 7.1%[11] after tooth extraction in irradiated patients, depending on the adjuvant therapy used.[9-11] Pooled analysis of the studies revealed an incidence of ORN per patient of 3.1%,[12-15] lower than the total incidence of ORN and lower than the incidence of ORN with HBO use. Table V summarizes the incidences of ORN with different therapies after tooth extraction. Among the studies included in the present systematic review, Lombardi et al.[15] had the highest rate of ORN, 10.7%, probably due to the shorter preoperative PENTO time (1 week), a lower dose of tocopherol (800 IU), and fewer postoperative antibiotic prescriptions (48%).

Few side effects were observed, with a rate ranging from 4.8%[14] to 9.1%,[12] favoring the use of this drug protocol. The side effects were not severe. The most common included nausea, headache, diarrhea, dizziness, asthenia, and gastric irritation.[15,12] Samani et al.[14] did not report the specific symptoms and cited them as "well-recognized side effects". Patel et al.[13] did not report the side effects. Patients with side effects (n = 2) had PENTO discontinuation and were excluded from the study of Lombardi et al.[15] Patel et al.[13] did not exclude patients due to side effects, although 2 patients took pentoxifylline alone and 4 took tocopherol alone. Samani et al.[14] included patients who did not fulfill the PENTO protocol in the "partial compliance group"; however, they did not explain the cause of inclusion in this group. Aggarwal et al.[12] did not report data concerning side effect treatment or discontinuation.

The proposed drug protocol evaluated in the present study is easily accessible and accepted by the patient, with few side effects, but presents contraindications. Pentoxifylline was contraindicated in pregnant or breast-feeding patients, patients with a history of cerebral hemorrhage, extensive retinal hemorrhage, acute myocardial infarction, severe cardiac arrhythmias, impaired renal function, impaired liver function, or those with metastatic disease.[14] The main advantage of the proposed drug protocol with pentoxifylline and tocopherol is that the drugs are easily accessible. The HBO protocol requires a hyperbaric chamber, a highly complex device available in a few centers, making it difficult for the population to have broad access. In addition, the proposed protocol is expensive, requiring 20 preoperative and 10 postoperative sessions, with 90 minutes for each session, 5 to 6 days a week.[3] In total, 45 hours in a hyperbaric chamber are needed to perform the protocol. Park et al.[21] reported an additional cost of 16,500 New Zealand dollars of HBO to treat ORN.

The present systematic review has significant limitations. Selection bias is present in that only 2 studies report the radiotherapy dose administered to the head and neck region.[14,15] In addition, a discrepancy exists between the studies regarding the type of radiotherapy used. External beam radiotherapy was used in more than 92% of patients in the Patel et al.[13] and Aggarwal et al.[12] studies and 65% in the Samani et al.[14] study. Another problem identified is the discrepancy in how the type of extraction and healing is reported: related to the number of patients[13] or the number of extractions.[14,15] This discrepancy makes comparisons difficult. One study did not report these data.[12] Antibiotics were used postoperatively, ranging from 44.8%[15] to 100%.[14] Differences in antibiotic rates may influence the risk of developing ORN.

Most of the authors consider that the diagnosis of ORN requires exposed bone in the oral cavity for a period longer than 3 months.[22] If the time of exposed bone is not considered, other processes can be misdiagnosed as ORN (e.g., alveolitis or delayed healing). Only Lombardi et al.[15] specified the time necessary to classify ORN, which is 3 months. Moreover, the time between radiotherapy and tooth extraction varies among studies; this fact can influence the risk for ORN. Aggarwal et al.[12] did not report clear ORN data. In the abstract, the authors report 2 patients with ORN; only 1 patient with ORN was cited in the results. This study obtained the worst result in the risk of bias analysis. For the present study, we considered that 2 patients had ORN in the study by Aggarwal et al.[12]

The included studies have different methods, and insufficient evidence exists to promote using the PENTO protocol. Prospective studies with a similar method are needed to indicate the use of these drugs to promote the prevention of ORN in irradiated patients who require tooth extraction.

Disclosure

None.

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Fig. 1- Preferred Reporting Items for Systematic reviews and Meta-Analyses flowchart.

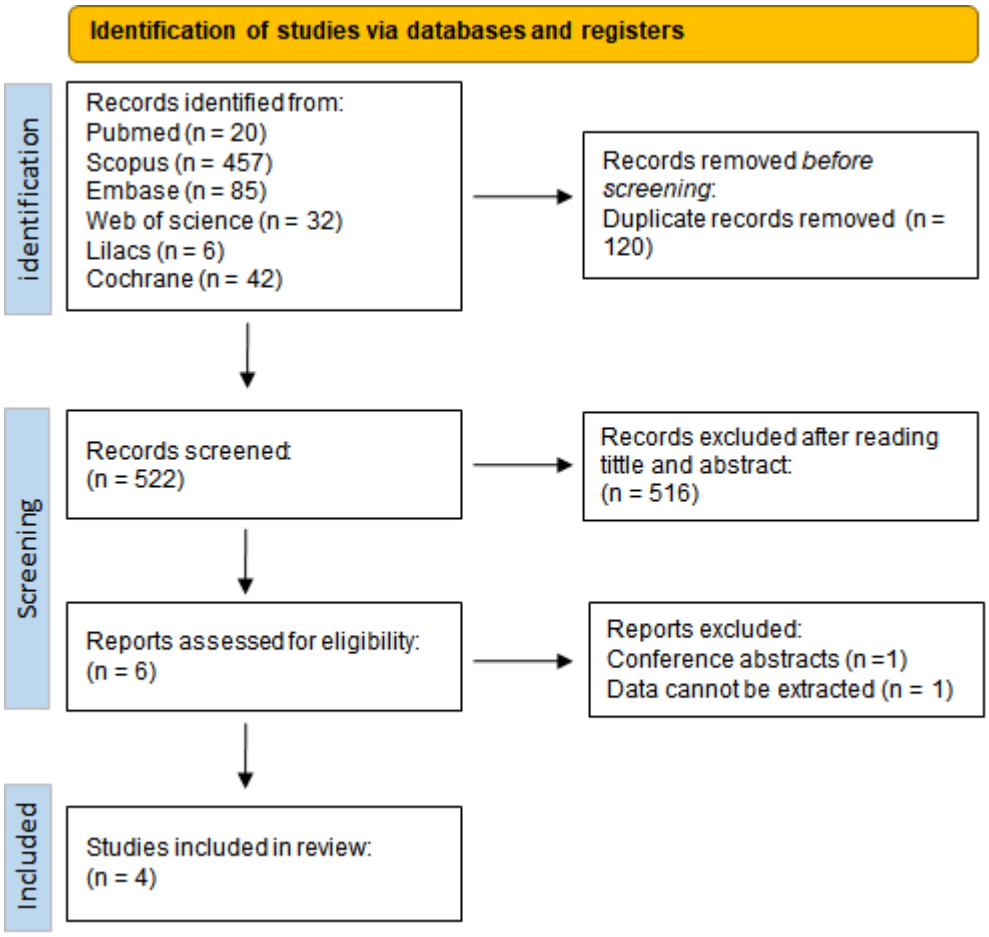

Fig. 2 - Risk of bias assessment of included studies.

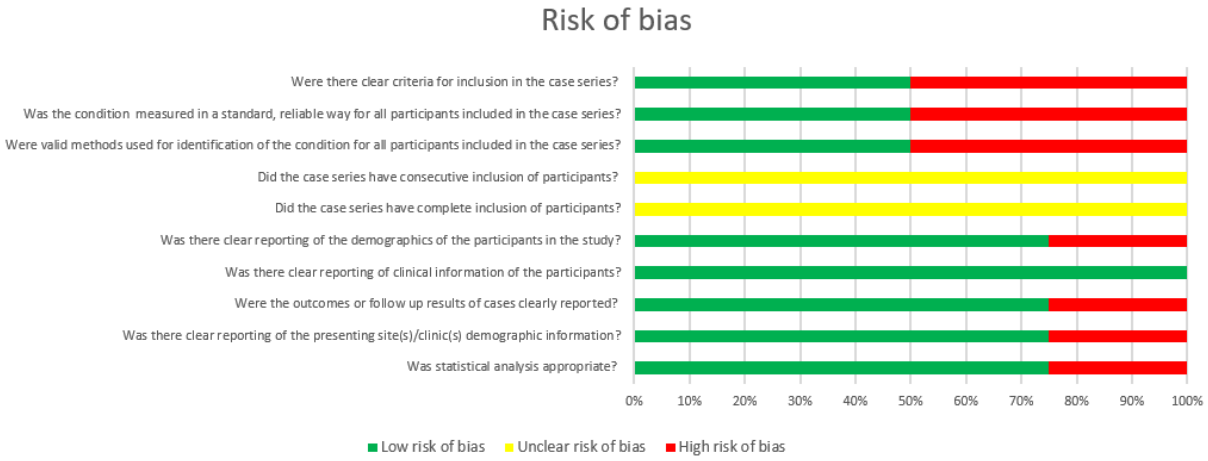

Table 1 - Risk of bias.

	Aggarwal et al. (2017)12	**Patel et al. (2016)13**	**Samani et al. (2022)14**	**Lombardi et al. (2022)15**
Were there clear criteria for inclusion in the case series?	N	N	Y	Y
Was the condition measured in a standard, reliable way for all participants included in the case series?	N	N	Y	Y
Were valid methods used for identification of the condition for all participants included in the case series?	N	N	Y	Y
Did the case series have consecutive inclusion of participants?	U	U	U	U
Did the case series have complete inclusion of participants?	U	U	U	U
Was there clear reporting of the demographics of the participants in the study?	N	Y	Y	Y
Was there clear reporting of clinical information of the participants?	Y	Y	Y	Y
Were the outcomes or follow up results of cases clearly reported?	N	Y	Y	Y
Was there clear reporting of the presenting site(s)/clinic(s) demographic information?	N	Y	Y	Y
Was statistical analysis appropriate?	N	Y	Y	Y

Y – yes, N – no, U - unclear

Table 2 - Demographic data.

	Total of patients (%)	**Age mean (range)**	**Tumor site**	**Radiotherapy system**	**Chemotherapy**	**ORN risk by patient**	**ORN risk by teeth**
Aggarwal et al. (2017)[12]	110; male: 70 (63.6%) female: 40 (36.4%)	not reported	oropharynx: 36 (32.7%) oral cavity: 26 (23.6%) hypopharynx: 17 (15.4%) nasopharynx: 14 (12.7%) other sites: 17 (15.4%)	EBRT: 102 (97.72%) IMRT: 8 (7.2%)	44 (40%)	high: 38 (34.5%) moderate: 32 (29.1%) low: 40 (36.4%)	high: 248 (55.1%) moderate: 104 (23.1%) low: 98 (21.8%)
Patel et al. (2016)[13]	82; male: 58 (70.7%) female: 24 (29.3%)	55 years (17–83)	oropharynx: 25 (30.5%) oral cavity: 20 (24.4%) hypopharynx: 14 (17.1%) nasopharynx: 10 (12.2%) other sites: 13 (15.8%)	EBRT: 76 (92.68%) IMRT: 6 (7.32%)	31 (37.8%)	high: 30 (36.6%) moderate: 18 (22%) low: 34 (41.5%)	high: 197 (50.5%) moderate: 101 (25.9%) low: 92 (23.6%)
Samani et al. (2022)*[14]	219; male: 154 (70.3%) female: 65 (29.7%)	60 years (24-93)	oropharynx: 79 (36.1%) oral cavity: 47 (21.5%) hypopharynx/larynx: 36 (16.4%) nasopharynx: 15 (6,8%) other sites: 42 (19.2%)	EBRT: 128 (58.4%) IMRT: 91 (41.6%)	107 (48.8%)	not reported	high: 237 (22%) low: 842 (78%)
Lombardi et al. (2022)#[15]	29; male: 18 (62%) female: 11 (38%)	66.5 years (35– 89)	oral cavity: 17 (58.7%) pharynx 4 (13.8%) larynx 3 (10.4%) thyroid 2 (6.9%) nose 1 (3.4%) cervical area 1 (3.4%) submandibular area 1 (3.4%)	not reported	13 (44.8%)	high: 7 (24.1%) moderate: 13 (44.8%) low: 9 (31.1%)	not reported

ORN: osteoradionecrosis; EBRT: external beam radiotherapy; IMRT: intensity modulated radiotherapy; * including patients without PENTO protocol (n=52); # including patient with dental implant surgery (n=1)

Table 3 - Characteristic of PENTO protocol and side effects.

	Advocated	**Dosage**	**Accomplished**	**Side effect**	**Symptoms**
Aggarwal et al. (2017)[12]	Preoperatively: ideally 4 week Postperatively: until the socket had healed	Pentoxifylline 400 mg twice daily Tocopherol 1000 IU once daily	Preoperatively: 12 Postperatively: 14	10/110 (9.1%)	Nausea, headache, and gastric irritation
Patel et al. (2016)[13]	Preoperatively: ideally 4 week Postperatively: until the socket had healed	Pentoxifylline 400 mg twice daily Tocopherol 1000 IU once daily	Preoperatively: 11 Postperatively: 13.6	6/82 (7.3%)	Not reported
Samani et al. (2022)[14]	Preoperatively: minimum 1 week Postperatively: minimum 4, but ideally for 12 week	Pentoxifylline 400 mg twice daily Tocopherol 1000 IU once daily	Not reported	8/167 (4.8%)	Well recognized side efects
Lombardi et al. (2022)[15]	Preoperatively: 1 week Postperatively: 8 week	Pentoxifylline 400 mg twice daily Tocopherol 800 IU once daily	Not reported	2/32 (6.2%)*	Nausea, diarrhea, dizziness and asthenia

PENTO: pentoxifylline and tocopherol; *patients with side effects were excluded from study (n=2)

Table 4 - Surgical procedure data.

	Nunber of teeth	**Reason for dental extraction**	**Surgery type**	**Healing type**	**Antibiotics**
Aggarwal et al. (2017)[12]	450 Mandibular: 290 (64.4%) Maxillary: 160 (35.6%)	Apical periodontitis: 28 (25.5%) Periodontal disease: 20 (18.2%) Unrestorable caries: 12 (10.9%) Irreversible pulpitis: 8 (7.3%) radiation caries: 42 (38.2%)	Not reported	Not reported	Preoperatively: 40 (36.4%) Postoperatively : 70 (63.6%)
Patel et al. (2016)[13]	390 Mandibular: 232 (59.5%) Maxillary: 158 (40.5%)	Apical periodontitis: 20 (24.4%) Periodontal disease: 10 (12.2%) Unrestorable caries: 4 (4.9%) Radiation caries: 1 (1.2%) Irreversible pulpitis: 47 (57.3%)	Without a flap: 66 (80.5%) Mucoperiosteal flap: 16 (19.5%)	Closed primary: 55 (67.1%) Secondary intention: 27 (32.9%)	Preoperatively: 30 (36.6%) Postoperatively : 77 (93.0%)
Samani et al. (2022)[14]	879 Mandibular: 449 (51.1%) Maxillary: 430 (48.9%)	Directly impacting the alveolar bone: 286 (32.5%)* Not directly impacting the dentoalveolar bone: 593 (67.5%)*	Without a flap: 721 (82%)* Mucoperiosteal flap: 53 (6%)* Unknown: 105 (12%)*	Closed primary: 403 (45.8%)* Secondary intention: 340 (38.7%)* Unknown: 136 (15.5%)*	Preoperatively: not reported Postoperatively : 167 (100%)
Lombardi et al. (2022)[15]	152 Mandibular: 82 (53.9%) Maxillary: 60 (46.1%)	Not reported	Without a flap: 88 (57.9%)* Mucoperiosteal flap: 64 (42.1%)*	Closed primary: 152*	Preoperatively: not reported Postoperatively : 13 (44.8%)[#]

* teeth level data; # including patient with dental implant surgery (n=1)

Table 5 - Osteoradionecrosis rates.

	ORN by patient	**ORN by teeth**	**ORN by procedure**
Aggarwal et al. (2017)[12]	2/110 (1.8%)	not reported	not reported
Patel et al. (2016)[13]	1/82 (1.2%)	1/390 (0.3%)	not reported
Samani et al. (2022)[14]	6/167 (3.6%) Full prophylaxis: 5/148 (3.4%) Partial prophylaxis: 1/19 (5.3%)	10/879 (1.1%) Full prophylaxis: 8/775 (1%) Partial prophylaxis: 2/104 (1.9%)	not reported
Lombardi et al. (2022)[15]	3/28 (10.7%)	not reported	4/71 (5.6%)
Pooled analysis	12/387 (3.1%)	11/1269 (0.9%)	4/71 (5.6%)
	Adjuvant treatment	**Number of patient**	**Number of teeth**
Nabil et al. (2011)[10]	Total	57/828 (6.9%)	54/2766 (1.9%)
	HBO	6/160 (3.7%)	10/595 (1.7%)
	ATB	21/377 (5.6%)	42/1444 (2.9%)
Lajolo et al. (2021)[9]	All types	41/462 (5.8%)	Not reported
Fritz et al. (2010)[11]	Without HBO	(7.1%)	Not reported
	HBO	(4.1%)	
Preset systematic review	PENTO	12/387 (3.1%)	11/1269 (0.9%)

ORN: osteoradionecrosis; HBO: hyperbaric oxygen therapy ; ATB: antibiotic; PENTO: pentoxifylline and tocopherol protocol

MATERIAL SUPLEMENTAR DO ARTIGO

Supplementary Table 1 - Search strategies in the databases and grey literature.

Database	Search strategy (Search date: August 26, 2022)	Results
PubMed	(pentoxifylline[MeSH Terms] OR pentoxifylline OR oxpentifylline OR trental OR pentoxil OR torental OR agapurin OR “BL-191” OR “BL 191” OR BL191 OR tocopherols[MeSH Terms] OR tocopherols OR tocopherol OR tocovital OR UnoVit OR “Vitamin E” OR vitazell OR detulin OR “E-ferol” OR “E-mulsin” OR “E mulsin” OR “E-Vicotrat” OR “E Vicotrat” OR ecoro OR embial OR evion OR ephynal OR eplonat OR Eusovit OR “Dal-E” OR “Dal E” OR Abortosan OR “Aquasol E” OR “Bio E” OR Biosan OR Lasar OR Bioweyxin OR Davitamon OR Dermorelle OR Spondyvit OR Tocolion OR Tocopa OR Tocopharm OR Vibolex OR “Vita-E” OR “Vita E” OR VitaE OR “Unique E”) AND ("tooth extraction"[MeSH Terms] OR "tooth extraction" OR "tooth extractions" OR "teeth extraction" OR "teeth extractions" OR "tooth removal" OR "teeth removal" OR "dental removal" OR "dental extraction" OR "dental extractions" OR "dental status" OR "dental treatment" OR "dental management" OR "dental procedures")	20
Scopus	TITLE-ABS-KEY (pentoxifylline OR oxpentifylline OR trental OR pentoxil OR torental OR agapurin OR “BL-191” OR “BL 191” OR BL191 OR tocopherols OR tocopherol OR tocovital OR UnoVit OR “Vitamin E” OR vitazell OR detulin OR “E-ferol” OR “E-mulsin” OR “E mulsin” OR “E-Vicotrat” OR “E Vicotrat” OR ecoro OR embial OR evion OR ephynal OR eplonat OR Eusovit OR “Dal-E” OR “Dal E” OR Abortosan OR “Aquasol E” OR “Bio E” OR Biosan OR Lasar OR Bioweyxin OR Davitamon OR Dermorelle OR Spondyvit OR Tocolion OR Tocopa OR Tocopharm OR Vibolex OR “Vita-E” OR “Vita E” OR VitaE OR “Unique E”) AND TITLE-ABS-KEY ("tooth extraction" OR "tooth extractions" OR "teeth extraction" OR "teeth extractions" OR "tooth removal" OR "teeth removal" OR "dental removal" OR "dental extraction" OR "dental extractions" OR "dental status" OR "dental treatment" OR "dental management" OR "dental procedures")	457
Embase	('pentoxifylline'/de OR 'oxpentifylline'/de OR 'trental'/de OR 'pentoxil'/de OR 'torental'/de OR 'agapurin'/de OR 'bl-191'/de OR 'bl 191'/de OR 'bl191'/de OR 'tocopherols'/de OR 'tocopherol'/de OR 'tocovital'/de OR unovit OR 'vitamin e'/de OR vitazell OR 'detulin'/de OR 'e-ferol'/de OR 'e-mulsin' OR 'e mulsin' OR 'e-vicotrat'/de OR 'e vicotrat'/de OR ecoro OR embial OR 'evion'/de OR 'ephynal'/de OR 'eplonat'/de OR eusovit OR 'dal-e' OR 'dal e' OR abortosan OR 'aquasol e'/de OR 'bio e' OR biosan OR lasar OR bioweyxin OR davitamon OR 'dermorelle'/de OR 'spondyvit'/de OR tocolion OR tocopa OR tocopharm OR vibolex OR 'vita-e' OR 'vita e' OR vitae OR 'unique e') AND ('tooth extraction'/de OR 'tooth extractions' OR 'teeth extraction'/de OR 'teeth extractions' OR 'tooth removal'/de OR 'teeth removal' OR 'dental removal' OR 'dental extraction'/de OR 'dental	85

	extractions'/de OR 'dental status' OR 'dental treatment'/de OR 'dental management' OR 'dental procedures')	
Web of Science	TS=(pentoxifylline OR oxpentifylline OR trental OR pentoxil OR torental OR agapurin OR “BL-191” OR “BL 191” OR BL191 OR tocopherols OR tocopherol OR tocovital OR UnoVit OR “Vitamin E” OR vitazell OR detulin OR “E-ferol” OR “E-mulsin” OR “E mulsin” OR “E-Vicotrat” OR “E Vicotrat” OR ecoro OR embial OR evion OR ephynal OR eplonat OR Eusovit OR “Dal-E” OR “Dal E” OR Abortosan OR “Aquasol E” OR “Bio E” OR Biosan OR Lasar OR Bioweyxin OR Davitamon OR Dermorelle OR Spondyvit OR Tocolion OR Tocopa OR Tocopharm OR Vibolex OR “Vita-E” OR “Vita E” OR VitaE OR “Unique E”) AND TS=("tooth extraction" OR "tooth extractions" OR "teeth extraction" OR "teeth extractions" OR "tooth removal" OR "teeth removal" OR "dental removal" OR "dental extraction" OR "dental extractions" OR "dental status" OR "dental treatment" OR "dental management" OR "dental procedures")	32
LILACS	(pentoxifylline OR pentoxifilina OR tocoferóis OR tocoferoles OR tocopherol) AND (“tooth extraction” OR “extração dentária” OR “extracción dental”)	6
Cochrane Library	(pentoxifylline OR oxpentifylline OR trental OR pentoxil OR torental OR agapurin OR “BL-191” OR “BL 191” OR BL191 OR tocopherols OR tocopherol OR tocovital OR UnoVit OR “Vitamin E” OR vitazell OR detulin OR “E-ferol” OR “E-mulsin” OR “E mulsin” OR “E-Vicotrat” OR “E Vicotrat” OR ecoro OR embial OR evion OR ephynal OR eplonat OR Eusovit OR “Dal-E” OR “Dal E” OR Abortosan OR “Aquasol E” OR “Bio E” OR Biosan OR Lasar OR Bioweyxin OR Davitamon OR Dermorelle OR Spondyvit OR Tocolion OR Tocopa OR Tocopharm OR Vibolex OR “Vita-E” OR “Vita E” OR VitaE OR “Unique E”) AND ("tooth extraction" OR "tooth extractions" OR "teeth extraction" OR "teeth extractions" OR "tooth removal" OR "teeth removal" OR "dental removal" OR "dental extraction" OR "dental extractions" OR "dental status" OR "dental treatment" OR "dental management" OR "dental procedures")	42
Grey Literature		
Google Scholar	First 100 more relevant hits. No patents and no citations. (pentoxifylline OR tocoferol) AND (“tooth” OR teeth” OR dental)	100
ProQuest	TI,AB(pentoxifylline OR oxpentifylline OR trental OR pentoxil OR torental OR agapurin OR “BL-191” OR “BL 191” OR BL191 OR tocopherols OR tocopherol OR tocovital OR UnoVit OR “Vitamin E” OR vitazell OR detulin OR “E-ferol” OR “E-mulsin” OR “E mulsin” OR “E-Vicotrat” OR “E Vicotrat” OR ecoro OR embial OR evion OR ephynal OR eplonat OR Eusovit OR “Dal-E” OR “Dal E” OR Abortosan OR “Aquasol E” OR “Bio E” OR Biosan OR Lasar OR Bioweyxin OR Davitamon OR Dermorelle OR Spondyvit OR Tocolion OR Tocopa OR Tocopharm OR Vibolex OR “Vita-E” OR “Vita E” OR VitaE OR “Unique E”) AND TI,AB("tooth extraction" OR "tooth extractions" OR "teeth extraction" OR "teeth extractions" OR "tooth removal" OR "teeth removal" OR "dental removal" OR "dental extraction" OR "dental extractions" OR "dental status" OR "dental treatment" OR "dental management" OR "dental procedures")	6

Supplementary Table 2 - Excluded articles in alphabetically ordered and reasons for exclusion.

Author and tittle	Reason
Abarno, S., Gehrke, A. F., Dedavid, B. A. & Gehrke, S. A. Stress distribution around dental implants, generated by six different ceramic materials for unitary restoration: An experimental photoelastic study. Dent. Med. Probl. 58, 453–461 (2021).	tittle and abstract
Abbas, B. A., Marzouk, E. S. & Zaher, A. R. Treatment of various degrees of white spot lesions using resin infiltration—in vitro study. Prog. Orthod. 19, (2018).	tittle and abstract
Abboud, W. A. et al. Restricted mouth opening in head and neck cancer: etiology, prevention, and treatment. JCO Oncol. Pract. 16, 643–653 (2020).	tittle and abstract
Abdalkadeer, H. K. et al. Influence of the coca-cola drinks on the overall color of glazed or polished porcelain veneers fabricated from different materials and thicknesses: An In Vitro study. J. Contemp. Dent. Pract. 21, 56–61 (2020).	tittle and abstract
Aboushelib, M. N. & Elsafi, M. H. Survival of resin infiltrated ceramics under influence of fatigue. Dent. Mater. 32, 529–534 (2016).	tittle and abstract
Abtahi, S., Alikhasi, M., & Siadat, H. (2022). Biomechanical behavior of endocrown restorations with different cavity design and CAD-CAM materials under a static and vertical load: A finite element analysis. Journal of Prosthetic Dentistry, 127(4), 600.e1-600.e8. https://doi.org/10.1016/j.prosdent.2021.11.027	tittle and abstract
Acar, D. H. & Kalyoncuoğlu, E. The fracture strength of endocrowns manufactured from different hybrid blocks under axial and lateral forces. Clin. Oral Investig. 25, 1889–1897 (2021).	tittle and abstract
Addison, O., Cao, X., Sunnar, P. & Fleming, G. J. P. Machining variability impacts on the strength of a 'chair-side' CAD-CAM ceramic. Dent. Mater. 28, 880–887 (2012).	tittle and abstract
Ahmed, Y. T., Almutairi, F. A., Alomran, S. A., Alkhayatt, N. M., Alsulaiman, S. A., Alohali, S. Y., & Alhamdi, A. A. (2022). Dehydration Time Effect on Tooth Color Measurement: An In Vitro Study. European Journal of Dentistry. https://doi.org/10.1055/s-0041-1741377	tittle and abstract
Ahmet, S. O., Egilmez, F., Ergun, G. & Cekic-Nagas, I. Surface treatment effects on bond strength of CAD/CAM fabricated posts to root canal dentin. Am. J. Dent. 32, 113–117 (2019).	tittle and abstract
Aka, B. & Celik, E. U. Evaluation of the Efficacy and Color Stability of Two Different At-Home Bleaching Systems on Teeth of Different Shades: A Randomized Controlled Clinical Trial. J. Esthet. Restor. Dent. 29, 325–338 (2017).	tittle and abstract
Al-Aali, K. A. et al. Influence of milling systems and marginal configurations on the fit of yttrium stabilized tetragonal zirconia polycrystals (Y-TZP)' copings. J. Appl. Biomater. Funct. Mater. 18, (2020).	tittle and abstract
Al-Akhali, M., Chaar, M. S., Elsayed, A., Samran, A. & Kern, M. Fracture resistance of ceramic and polymer-based occlusal veneer restorations. J. Mech. Behav. Biomed. Mater. 74, 245–250 (2017).	tittle and abstract
Al-Akhali, M., Kern, M., Elsayed, A., Samran, A. & Chaar, M. S. Influence of thermomechanical fatigue on the fracture strength of CAD-CAM-fabricated occlusal veneers. J. Prosthet. Dent. 121, 644–650 (2019).	tittle and abstract
Alamoush, R. A., Silikas, N., Salim, N. A., Al-Nasrawi, S. & Satterthwaite, J. D. Effect of the Composition of CAD/CAM Composite Blocks on Mechanical Properties. Biomed Res. Int. 2018, (2018).	tittle and abstract
Al-Ansari, A., Ellakany, P., Fouda, S., Al-Sheikh, R. & El Tantawi, M. Intention to seek esthetic dental treatment and the theory of planned behavior in Saudi dental students and the general population. J. Prosthet. Dent. 124, 774–779 (2020).	tittle and abstract
Albelasy, E., Hamama, H. H., Tsoi, J. K. H. & Mahmoud, S. H. Influence of material type, thickness and storage on fracture resistance of CAD/CAM occlusal veneers. J. Mech. Behav. Biomed. Mater. 119, (2021).	tittle and abstract

Alghazali, N. et al. The Effect of Try-In Paste and Resin Cement Shade on Colour Properties of Dental Veneers. Eur. J. Prosthodont. Restor. Dent. 26, 144–151 (2018).	tittle and abstract
AlGhazali, N., Burnside, G., Smith, R. W., Preston, A. J. & Jarad, F. D. Performance assessment of Vita Easy Shade spectrophotometer on colour measurement of aesthetic dental materials. Eur. J. Prosthodont. Restor. Dent. 19, 168–174 (2011).	tittle and abstract
Almeida-Júnior, A. A., Longhini, D., Domingues, N. B., Santos, C. & Adabo, G. L. Effects of extreme cooling methods on mechanical properties and shear bond strength of bilayered porcelain/3Y-TZP specimens. J. Dent. 41, 356–362 (2013).	tittle and abstract
Alnasser, M. et al. Effect of acidic pH on surface roughness of esthetic dental materials. J. Prosthet. Dent. 122, 567.e1-567.e8 (2019).	tittle and abstract
Al-Omiri, M. K., Abul Hassan, R. S., AlZarea, B. K. & Lynch, E. Improved tooth bleaching combining ozone and hydrogen peroxide - A blinded study. J. Dent. 46, 30–35 (2016).	tittle and abstract
Al-Omiri, M. K., Hassan, R. S. A., Alzarea, B. K. & Lynch, E. Comparison of dental bleaching effects of ozone and hydrogen peroxide: An ex vivo study. Am. J. Dent. 29, 251–254 (2016).	tittle and abstract
AL-Omiri, M. K., Hassan, R. S. A., AlZarea, B. K. & Lynch, E. Effects of combining ozone and hydrogren peroxide on tooth bleaching: A clinical study. J. Dent. 53, 88–93 (2016).	tittle and abstract
AL-Omiri, M. K., Lamfon, H. A., Al Nazeh, A. A., Kielbassa, A. M. & Lynch, E. Randomized clinical trial on the comparison of bleaching outcomes using either ozone or hydrogen peroxide. Quintessence Int. (Berl). 49, 625–634 (2018).	tittle and abstract
Alrejaye, N., Pober, R. & Giordano, R. Torsional strength of computer-aided design/computer-aided manufacturing-fabricated esthetic orthodontic brackets. Angle Orthod. 87, 125–130 (2017).	tittle and abstract
Alsadon, O., Wood, D., Patrick, D. & Pollington, S. Fatigue behavior and damage modes of high performance poly-ether-ketone-ketone PEKK bilayered crowns. J. Mech. Behav. Biomed. Mater. 110, (2020).	tittle and abstract
Alsaleh, S., Labban, M., Alhariri, M. & Tashkandi, E. Evaluation of self shade matching ability of dental students using visual and instrumental means. J. Dent. 40, (2012).	tittle and abstract
Al-Tarakemah, Y. & Darvell, B. W. On the permanence of tooth bleaching. Dent. Mater. 32, 1281–1288 (2016).	tittle and abstract
Altshuler, G. et al. Peroxide dental bleaching via laser microchannels and tooth color measurements. J. Biomed. Opt. 21, (2016).	tittle and abstract
AL-Turki, L. et al. Repair bond strength of dental computer-aided design/computer-aided manufactured ceramics after different surface treatments. J. Esthet. Restor. Dent. 32, 726–733 (2020).	tittle and abstract
Alves, D. M. et al. Fatigue performance of adhesively luted glass or polycrystalline CAD-CAM monolithic crowns. J. Prosthet. Dent. (2020) doi:10.1016/j.prosdent.2020.03.032.	tittle and abstract
Al-Wahadni, A., Shahin, A. & Kurtz, K. S. Veneered Zirconia-Based Restorations Fracture Resistance Analysis. J. Prosthodont. 27, 651–658 (2018).	tittle and abstract
Amorim, A. A., de Arruda, C. N. F., Vivanco, R. G., Bikker, F. & de Pires-de-Souza, F. C. P. Effect of phytosphingosine on staining resistance and microhardness of tooth enamel. J. Esthet. Restor. Dent. 33, 294–302 (2021).	tittle and abstract
Analoui, M., Papkosta, E., Cochran, M. & Matis, B. Designing visually optimal shade guides. J. Prosthet. Dent. 92, 371–376 (2004).	tittle and abstract
Anderson, J. G. & Hennet, P. Management of Severe Oral Inflammatory Conditions in Dogs and Cats. Vet. Clin. North Am. - Small Anim. Pract. 52, 159–184 (2022).	tittle and abstract
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Angel, P. et al. Color stability, psychosocial impact, and effect on self-perception of esthetics of tooth whitening using low-concentration (6%) hydrogen peroxide. Quintessence Int. (Berl). 49, 557–566 (2018).	tittle and abstract

Aravinth, H., Don, K. R. & Dinesh, S. P. S. Osteoradionecrosis of mandible - A review. Drug Invent. Today 11, 108–117 (2019).	tittle and abstract
Arslan, M. & Tosun, İ. Fracture load and microcrack comparison of crowns manufactured from tooth-shaped and traditional blocks. Microsc. Res. Tech. 84, 111–118 (2021).	tittle and abstract
Ataol, A. S. & Ergun, G. Effects of surface treatments on repair bond strength of a new CAD/CAM ZLS glass ceramic and two different types of CAD/CAM ceramics. J. Oral Sci. 60, 201–211 (2018).	tittle and abstract
Auschill, T. M., Savio, T. S.-D., Hellwig, E. & Arweiler, N. B. Randomized clinical trial of the efficacy, tolerability, and long-term color stability of two bleaching techniques: 18-month follow-up. Quintessence Int. (Berl). 43, 683–694 (2012).	tittle and abstract
Awad, D., Stawarczyk, B., Liebermann, A. & Ilie, N. Translucency of esthetic dental restorative CAD/CAM materials and composite resins with respect to thickness and surface roughness. J. Prosthet. Dent. 113, 534–540 (2015).	tittle and abstract
Awad, M. M. et al. Effect of universal adhesives on microtensile bond strength to hybrid ceramic. BMC Oral Health 19, (2019).	tittle and abstract
Awada, A. & Nathanson, D. Mechanical properties of resin-ceramic CAD/CAM restorative materials Presented at the American Association of Dental Research/Canadian Association of Dental Research Annual Meeting, Charlotte, NC, March 2014. J. Prosthet. Dent. 114, 587–593 (2015).	tittle and abstract
Babaier, R. S., Aldeeb, M. S., Silikas, N., & Watts, D. C. (2022). Is the radiopacity of CAD/CAM aesthetic materials sufficient? Dental Materials, 38(6), 1072–1081. https://doi.org/10.1016/j.dental.2022.04.025	tittle and abstract
Bagan, J. V., Scully, C., Zapater, E., Basterra, J. & Bagan, L. Osteoradionecrosis of the jaws. Clin. Rev. Bone Miner. Metab. 9, 47–53 (2011).	tittle and abstract
Bagegni, A., Spies, B. C., Kern, M., Hazard, D. & Kohal, R. The influence of prosthetic crown height and implant-abutment connection design selection on the long-term implant-abutment stability: A laboratory study. J. Mech. Behav. Biomed. Mater. 113, (2021).	tittle and abstract
Bajkin, B. & Rajic, N. Dental extractions in anticoagulated patients-comparison of local haemostatic modalities with and without suturing. J. Thromb. Haemost. 9 CC-Oral Health, 578-579 (2011).	tittle and abstract
Baliga, M., Chakraborty, S., Kumari, T., Tusharbhai, D. M. & Sarkar, S. Is there a role for PRF with simvastatin in stage I osteoradionecrosis? Oral Oncol. 87, 177–178 (2018).	tittle and abstract
Bansal, M. et al. Impact of different antioxidants on the bond strength of resinbased composite on bleached enamel-an in vitro study. J. Contemp. Dent. Pract. 20, 64–70 (2019).	tittle and abstract
Bartoňová, M., Dostálová, T., Peterka, M., Kozák, J. & Müllerová, Ž. Long-term stability of prosthetic treatment of oronasal and oroantral communications. Acta Chir. Plast. 47, 85–91 (2005).	tittle and abstract
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Baser, U., Gamsiz-Isik, H., Cifcibasi, E. & Yalcin, F. Plasma and salivary total antioxidant capacity in healthy controls compared with aggressive and chronic periodontitis patients. Saudi Med. J. 36, 856–861 (2015).	tittle and abstract
Basting, R. T., Amaral, F. L. B., França, F. M. G. & Flório, F. M. Clinical comparative study of the effectiveness of and tooth sensitivity to 10% and 20% carbamide peroxide home-use and 35% and 38% hydrogen peroxide in-office bleaching materials containing desensitizing agents. Oper. Dent. 37, 464–473 (2012).	tittle and abstract
Bałlar, S., Çolak, H. & Hamidi, M. M. Evaluation of novel microabrasion paste as a dental bleaching material and effects on enamel surface. J. Esthet. Restor. Dent. 27, 258–266 (2015).	tittle and abstract
Baumann, M. A. & Schifferdecker, B. Color determination in dental ceramics . Schweizer Monatsschrift fur Zahnmedizin = Rev. Mens. suisse d"odonto-stomatologie = Riv. Mens. Svizz. di Odontol. e Stomatol. / SSO 104, 423–429 (1994).	tittle and abstract

Beech, N., Robinson, S., Porceddu, S. & Batstone, M. Dental management of patients irradiated for head and neck cancer. Aust. Dent. J. 59, 20–28 (2014).	tittle and abstract
Belli, R. et al. Thermal-induced residual stresses affect the lifetime of zirconia-veneer crowns. Dent. Mater. 29, 181–190 (2013).	tittle and abstract
Belli, R., Geinzer, E., Muschweck, A., Petschelt, A. & Lohbauer, U. Mechanical fatigue degradation of ceramics versus resin composites for dental restorations. Dent. Mater. 30, 424–432 (2014).	tittle and abstract
Bergantiños, F., Amariles, P., Ríos, J. & Estrada, J. Patient prioritization based on clinical risk analysis and its referral to different levels of pharmaceutical care. pilot test. Vitae 22, S158–S161 (2015).	tittle and abstract
Bernardon, J. K., Ferrari, P., Baratieri, L. N. & Rauber, G. B. Comparison of treatment time versus patient satisfaction in at-home and in-office tooth bleaching therapy. J. Prosthet. Dent. 114, 826–830 (2015).	tittle and abstract
Bersezio, C. et al. Color regression and maintenance effect of intracoronal whitening on the quality of life: RCT—A one-year follow-up study. Oper. Dent. 44, 24–33 (2019).	tittle and abstract
Bersezio, C. et al. Does the Use of a ‘“walking bleaching”’ technique increase bone resorption markers? Oper. Dent. 43, 250–260 (2018).	tittle and abstract
Bersezio, C. et al. Effectiveness of dental bleaching with 37.5% and 6% hydrogen peroxide and its effect on quality of life. Oper. Dent. 44, 146–155 (2019).	tittle and abstract
Bersezio, C. et al. Evaluation of the effectiveness in teeth whitening of a single session with 6% hydrogen peroxide Laser/LED system. Photodiagnosis Photodyn. Ther. 36, (2021).	tittle and abstract
Bersezio, C. et al. Inflammatory markers IL-1β and RANK-L assessment after non-vital bleaching: A 3-month follow-up. J. Esthet. Restor. Dent. 32, 119–126 (2020).	tittle and abstract
Bersezio, C. et al. Six-month follow-up of the effect of nonvital bleaching on IL-1b and RANK-L: A randomized clinical trial. Oper. Dent. 44, 581–588 (2019).	tittle and abstract
Bersezio, C. et al. Teeth whitening with 6% hydrogen peroxide and its impact on quality of life: 2 years of follow-up. Odontology 107, 118–125 (2019).	tittle and abstract
Bhuvaneswari, P. Antioxidants in oral healthcare. J. Pharm. Sci. Res. 6, 206–209 (2014).	tittle and abstract
Bizhang, M., Domin, J., Danesh, G. & Zimmer, S. Effectiveness of a new non-hydrogen peroxide bleaching agent after single use - A double-blind placebo-controlled short-term study. J. Appl. Oral Sci. 25, 575–584 (2017).	tittle and abstract
Blasi, A., Blasi, I., Henarejos-Domingo, V., Castellano, V., Blasi, J. I., & Blasi, G. (2022). The PGO concept: Prosthetically guided orthodontics concept. Journal of Esthetic and Restorative Dentistry, 34(5), 750–758. https://doi.org/10.1111/jerd.12825	tittle and abstract
Block, M. S. & Gross, B. D. Epidermolysis bullosa dystrophica recessive: Oral surgery and anesthetic considerations. J. Oral Maxillofac. Surg. 40, 753–758 (1982).	tittle and abstract
Bocci, V. The case for oxygen-ozonetherapy. Int. J. Ozone Ther. 6, 58–64 (2007).	tittle and abstract
Borba, M. et al. Effect of different aging methods on the mechanical behavior of multi-layered ceramic structures. Dent. Mater. 32, 1536–1542 (2016).	tittle and abstract
Borba, M. et al. Flexural strength and failure modes of layered ceramic structures. Dent. Mater. 27, 1259–1266 (2011).	tittle and abstract
Borba, M., Cesar, P. F., Griggs, J. A. & Della Bona, Á. Adaptation of all-ceramic fixed partial dentures. Dent. Mater. 27, 1119–1126 (2011).	tittle and abstract
Borba, M., Cesar, P. F., Griggs, J. A. & Della Bona, Á. Step-stress analysis for predicting dental ceramic reliability. Dent. Mater. 29, 913–918 (2013).	tittle and abstract
Borba, M., Duan, Y., Griggs, J. A., Cesar, P. F. & Della Bona, Á. Effect of ceramic infrastructure on the failure behavior and stress distribution of fixed partial dentures. Dent. Mater. 31, 413–422 (2015).	tittle and abstract

Borges, B. C. D. et al. Efficacy of a novel at-home bleaching technique with carbamide peroxides modified by cpp-acp and its effect on the microhardness of bleached enamel. Oper. Dent. 36, 521–528 (2011).	tittle and abstract
Bortolatto, J. F. et al. A novel approach for in-office tooth bleaching with 6 % H2O2/TiO_N and LED/laser system—a controlled, triple-blinded, randomized clinical trial. Lasers Med. Sci. 31, 437–444 (2016).	tittle and abstract
Bortolatto, J. F. et al. Does a toothpaste containing blue covarine have any effect on bleached teeth? An in vitro, randomized and blinded study. Braz. Oral Res. 30, 1–7 (2016).	tittle and abstract
Bötel, F., Zimmermann, T., Sütel, M., Müller, W.-D. & Schwitalla, A. D. Influence of different low-pressure plasma process parameters on shear bond strength between veneering composites and PEEK materials. Dent. Mater. 34, e246–e254 (2018).	tittle and abstract
Boyd, L. D. & Lampi, K. J. Importance of nutrition for optimum health of the periodontium. J. Contemp. Dent. Pract. 2, 23–36 (2001).	tittle and abstract
Breik, O., Tocaciu, S., Briggs, K., Saief, S. T. & Richardson, S. Is there a role for pentoxifylline and tocopherol in the management of advanced osteoradionecrosis of the jaws with pathological fractures? Case reports and review of the literature. Int. J. Oral Maxillofac. Surg. 48, 1022–1027 (2019).	tittle and abstract
Brugnare, A. P. et al. Clinical Evaluation of In-Office Dental Bleaching Using a Violet Light-Emitted Diode. Photobiomodulation, Photomedicine, Laser Surg. 38, 98–104 (2020).	tittle and abstract
Burey, A. et al. Assessment of the effect of experimental bleaching agent with nano-bioactive material on postoperative sensitivity: A randomized, triple blind clinical trial. J. Esthet. Restor. Dent. 33, 764–774 (2021).	tittle and abstract
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3 CONCLUSÃO

- Os estudos primários incluídos na revisão sistemática e que foram analisados como base dessa dissertação são heterogêneos impactando diretamente na compreensão dos desfechos clínicos analisados e dificultando a comparação entre os estudos;
- A taxa total de ORN encontrada no estudo foi de 3,1%, sendo inferior às taxas encontradas após exodontia em estudos clínicos baseados em protocolos profiláticos de outra natureza como oxigenioterapia hiperbárica (3,7%) ou antibioticoterapia (5,6%);
- O protocolo PENTO é seguro e apresenta poucos efeitos adversos que foram mitigados rapidamente com a interrupção da medicação nos estudos incluídos;
- Com base na evidência encontrada, não é possível afirmar que a profilaxia com o protocolo PENTO antes da extração dentária previne a ORN.

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ANEXO 1 - Comprovante de publicação do artigo

Alan Roger Santos-Silva <alanroge@unicamp.br>

Acceptance of your submission TRIPLEO-D-22-01230R2

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Journal: Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology

Dear Dr. Santos-Silva,

I am pleased to inform you that your manuscript, "Can the prophylactic use of pentoxifylline and tocopherol prior to dental extractions prevent osteoradionecrosis? A systematic review.," which you recently submitted to Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology has been carefully reviewed and has been accepted for publication.

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