Does Smear Layer Removal Influence Root Canal Therapy Outcome? A Systematic Review

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Objective*: The aim of this systematic review was to determine whether the smear layer (SL) removal procedure influences the outcome of root canal treatment.* ***Study design:*** *We performed a search on Pubmed, Scopus, ISI Web of Science, Cochrane Library, Lilacs and SIGLE. We included randomized controlled clinical trials (RCT), with clinical and radiographic outcomes, conducted on subjects who had undergone root canal therapy. The protocol differed only in the SL removal or maintenance procedure. We evaluated the papers for risk of bias according to the Cochrane assessment tool.* ***Results****: A total of 1,983 articles were found, after removal of duplicates, 892 remained. We included two studies in this review. One study revealed a low risk of bias and a high success rate for the SL removal group compared to the non SL removal group (P = 0.04), while the other study had a high risk of bias and found no difference between the SL removal and non SL removal groups (P = 1.00).* ***Conclusion:*** *We concluded that the SL removal for root canal treatment of primary teeth with initial clinical signs and symptoms or pulpal necrotic status, could benefit the outcome, although further RCT should be performed to achieve evidence.*

Key-words: smear layer, endodontics, root canal therapy, root canal irrigants.

INTRODUCTION

The mechanical preparation of root canals, shaping and cleaning, with instrumentation produces an amorphous, irregular surface layer[1], which was initially called "smeared layer"[2] that covers the canal walls. The smear layer consists of two layers, a superficial layer that is 1-2µm thick and a deeper portion inside the dentinal tubules that reaches 40µm in depth and seems to be loosely adhered to the dentinal tubules. This layer contains inorganic (dentin debris) and organic components such as necrotic pulpal tissues, remnants of odontoblastic processes and microorganisms.[3]

Recent research advocates smear layer removal for root canal therapy, in order to improve the fluid-tight seal of the system[4], decrease the amount of bacteria in the root canal[5], facilitate root canal disinfection and adapt the canal surface for better filling material adherence[6,7], as well as having better long-term treatment outcomes.[8] The existing knowledge base on the smear layer role on root canal therapy indicates the removal.[7] Many studies have evaluated the efficiency of different root canal irrigant solutions[9,10] and techniques associated to irrigants[1,11] on smear layer removal. Although *in vitro* studies have been conducted evaluating the efficiency of smear layer removal methods and smear layer presence related to filling or restorative materials, there is a lack of clinical data on root canal treatment outcomes associated to smear layer removal.[7]

Therefore this systematic review of the literature was performed to answer the following focused question: "Does smear layer removal influence root canal therapy outcome?"

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MATERIALS AND METHOD

We performed this systematic review according to Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement for reporting systematic reviews that evaluate health care interventions.[12] We registered this review at PROSPERO – International prospective register of systematic review under the number CRD42013004100.

Eligibility Criteria

According to the PICO criteria (Table 1) we included in this review clinically controlled and randomized controlled trials conducted on subjects that undergone root canal therapy with a protocol that differed only in the smear layer removal or maintenance procedure. The included studies evaluated both clinically and radiographically effects of smear layer removal on treatment outcome with a follow-up of at least 6 months. There were no restrictions regarding age, gender, ethnicity, tooth type or initial pulpal diagnostic condition. Also we applied no limits regarding language or year of publication.

The exclusion criteria were applied to the publication type. We excluded: case reports, review articles, editorials, opinions, technique articles, surveys, guidelines, commentary articles, animal and *in vitro* studies.

Table 1. Outlines the populations, interventions, comparisons, and outcomes (PICO format).

PICO format	
Population	Subjects submitted to root canal therapy
Intervention/Exposition	Smear layer removal
Comparison	Non smear layer removal
Outcome	Radiographic and clinical success with at least 6 months follow-up
Null hypothesis	The smear layer removal does not improve the root canal treatment outcome

Information Source

We conducted electronic searches up to May 2013, and an updating up to December 2015 Search strategy using the following electronic bibliography databases: PubMed, Scopus, ISI Web of Science, Cochrane Library, Lilacs, and SIGLE (System of Information on Grey Literature in Europe). The searches were complemented by manually screening the references of the selected articles to find any that did not appear in the database search.

Search Strategy

The search process was performed independently by two review authors (AVBP and MR) under the guidance of a librarian (DMF). MesH (Medical Subject Headings) Terms and keywords were identified on the Health Science Descriptors site and in the published papers. The search strategy included appropriate changes in the terms and followed the syntax rules of each database (Table 2). We applied no filters or limits in the searches. We read the title and, when needed, title and abstract of selected studies and evaluated them for the identification of eligible studies. Papers appearing in more than one database search were considered only once. Any differences between the two reviewers were solved by consensus with the help of a third senior reviewer (LCM).

During the search process, we identified the researchers using the eTBlast, a text-similarity based search engine, as a response for the query "influence of smear layer removal on root canal treatment outcome, considering both radiographic and clinical aspects", applying the "Find Expert" tool. We sent out by email a letter to researchers asking for ongoing or unpublished preliminary results of clinical studies concerning the query.

We read the selected articles (Figure 1) for quality assessment control of bias and data extraction. We assessed independently the full texts of the studies for eligibility, and we filled a form to guarantee eligibility according to the PICO criteria (Table 1). In case of doubt, we summarized and discussed the reasons in the consensus meetings.

Methodological Risk Of Bias Assessment

We evaluated each selected study for inner methodological risk of bias according to The Cochrane Collaboration's common scheme for bias: selection, performance, attrition, detection, and reporting bias.[13] We filled in a form designed for assessing risk of bias evaluation, with the comments to support the results. According to The Cochrane Handbook version 5.1.0, assessments considered the risk of material bias, those with sufficient magnitude to cause a notable impact on the results and conclusions of the trials, as the most important. Therefore, we considered the selection, performance and attrition bias, as the material bias for the selected studies in accordance to the proposed eligibility criteria. Also the key domains associated to these biases were: sequence generation and allocation concealment, blinding of participants and personnel, other potential threats to validity and incomplete outcome data. According to the "Possible approach for summary assessment of risk of bias for each important outcome (across domains) within and across studies", the criteria for High risk of bias was High risk found in one or more key domains and Low risk of bias when Low risk was considered in all key domains and Unclear risk indicating either lack of information or uncertainty over the potential for bias.

Data extraction included: paper reference, allocation sequence generation, study design type, sample size and description, number of groups, smear layer protocol, canal root filling material used, follow-up time and intervals, clinical and radiographic criteria of success and results (success rate) (Table 3).

RESULTS

We exported all the articles (1,433) found to End Note Web software® in database groups (484 from Pubmed, 544 from Scopus, 310 from Web of Science, 75 from Cochrane Library, 20 from Lilacs). We removed the duplicates by the Find Duplicates tool, after which 707 papers remained. Another check revealed some duplicates and we used a selecting delete tool of the same software to remove all duplicates, leaving 682 papers. Then the selected studies from the database groups consisted of 30 papers from Pubmed, 341 from Scopus, 290 from Web of Science, 13 from Cochrane Library and 8 from Lilacs. Based on the exclusion criteria, we excluded: 9 case reports, 2 clinical update articles; 6 letters, notes and abstracts; 20 review papers; 1 web-based survey article; 2 electronically mailed survey papers; 3 randomized clinical trials with different purposes; 5 clinical trials with different purposes, 1 clinical trial without clinical and radiographic follow-up, only with microbiological evaluation; and 631 *in vitro* studies (Figure 1). No ongoing or unpublished studies

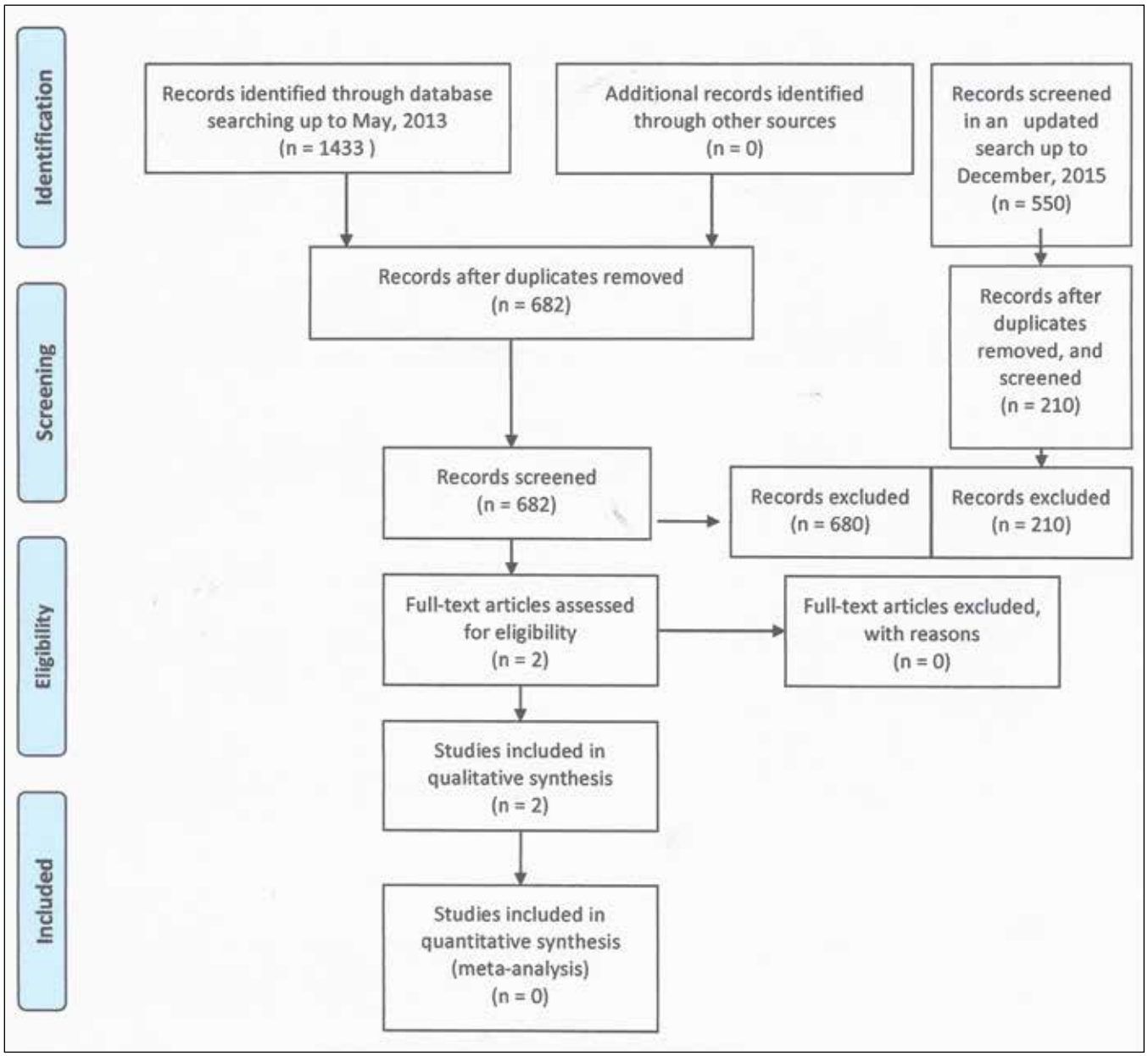
Table 2. Electronic database and search strategy

Database	Search strategy		
Pubmed	# 1 Smear layer	#2 Root Canal Therapy [mh] OR Root Canal Therapy [tiab] OR Root Canal Preparation [mh] OR Root Canal Preparation [tiab] OR Pulpectomy [mh] OR Pulpectomy [tiab] OR Endodontics [mh] OR Endodontic* [tiab] OR Dental Pulp Cavity [mh] OR Dental Pulp Cavit* [tiab]	#3 Root Canal Irrigants [mh] OR Root Canal Irrigants [tiab] OR Irrigants [tiab] OR Chelating Agents [mh] OR Chelating Agents [tiab] OR Sodium Hypochlorite [mh] OR Sodium Hypochlorite [tiab] OR Edetic Acid [mh] OR Edetic Acid [tiab] OR EDTA [mh] OR EDTA [tiab] OR Ethylenediaminetetraacetic acid [mh] OR Ethylenediaminetetraacetic acid [tiab] OR Citric Acid [mh] OR Citric Acid [tiab] OR Hydrogen Peroxide [mh] OR Hydrogen Peroxide [tiab] OR Tetracycline [mh] OR Tetracycline [tiab] OR Maleates [mh] OR Maleates [tiab] OR Chlorhexidine [mh] OR Chlorhexidine [tiab] OR Metronidazole [mh] OR Metronidazole [tiab]
	#1 AND #2 AND #3		
Scopus	#1 “smear layer”	#2 “Root Canal Therapy” OR “Root Canal Preparation” OR “Pulpectomy” OR “Endodontic*” OR “Dental Pulp Cavit*”	#3 “Root Canal Irrigants” OR “Irrigants” OR “Chelating Agents” OR “Sodium Hypochlorite” OR “Edetic Acid” OR “EDTA” OR “Ethylenediaminetetraacetic acid” OR “Citric Acid” OR “Hydrogen Peroxide” OR “Tetracycline” OR “Maleates” OR “Chlorhexidine” OR “Metronidazole”
	#1 AND #2 AND #3		
Web of Science	TS = (smear layer) OR TI = (smear layer)	TS = (Root Canal Therapy OR Root Canal Preparation OR Pulpectomy OR Endodontic OR Endodontics OR Dental Pulp Cavity) OR TI = (Root Canal Therapy OR Root Canal Preparation OR Pulpectomy OR Endodontic OR Endodontics OR Dental Pulp Cavity)	TS = (Root Canal Irrigants OR Canal irrigants, root OR Chelating Agents OR Sodium Hypochlorite OR Edetic Acid OR EDTA OR Ethylenediaminetetraacetic acid OR Citric Acid OR Hydrogen Peroxide OR Tetracycline OR Maleates OR Chlorhexidine OR Metronidazole) OR TI = (Root Canal Irrigants OR Canal irrigants, root OR Irrigants, canal root OR Irrigants OR Chelating Agents OR Sodium Hypochlorite OR Edetic Acid OR EDTA OR Ethylenediaminetetraacetic acid OR Citric Acid OR Hydrogen Peroxide OR Tetracycline OR Maleates OR Chlorhexidine OR Metronidazole)
	#1 AND #2 AND #3		
Cochrane Library	smear layer	Root Canal Therapy OR Root Canal Preparation OR Pulpectomy OR Endodontic OR Dental Pulp Cavity	Root Canal Irrigants OR Canal irrigants, root OR Irrigants, canal root OR Irrigants OR Chelating Agents OR Sodium Hypochlorite OR Edetic Acid OR EDTA OR Ethylenediaminetetraacetic acid OR Citric Acid OR Hydrogen Peroxide OR Tetracycline OR Maleates OR Chlorhexidine OR Metronidazole
	#1 AND #2 AND #3		
Lilacs	(smear layer) AND (Root Canal Therapy OR Root Canal Preparation OR Pulpectomy OR Endodontic OR Dental Pulp Cavity) AND (Root Canal Irrigants OR Irrigants OR Chelating Agents OR Sodium Hypochlorite OR Edetic Acid OR EDTA OR Ethylenediaminetetraacetic acid OR Citric Acid OR Hydrogen Peroxide OR Tetracycline OR Maleates OR Chlorhexidine OR Metronidazole)		
SIGLE	#1 Abstract: “smear layer”	#2 Abstract: “Root Canal Therapy” OR “Root Canal Preparation” OR “Pulpectomy” OR “Endodontic” OR “Dental Pulp Cavity”	#3 Abstract: “Root Canal Irrigants” OR “Canal irrigants, root” OR “Irrigants, canal root” OR “Irrigants” OR “Chelating Agents” OR “Sodium Hypochlorite” OR “Edetic Acid” OR “EDTA” OR “Ethylenediaminetetraacetic acid” OR “Citric Acid” OR “Hydrogen Peroxide” OR “Tetracycline” OR “Maleates” OR “Chlorhexidine” OR “Metronidazole
	#1 AND #2 AND #3		

were added to the search. We exported all the papers recovered in the updated search (n=550) (December/2015) and removed the duplicates. Therefore, 210 articles remained: 98 papers from Pubmed, 36 from Scopus, 72 from Web of Science, 0 from Cochrane Library and 4 from Lilacs. Since none of them met the inclusion criteria, no other study was considered eligible for this review. Finally, we retrieved two randomized controlled trials as potentially eligible and we included them in this review. The main characteristics of the two studies are compiled in Table 3.

The results for the study conducted on both anterior and posterior teeth[8] revealed a higher success rate for the SL removal group (91.2%) compared to the non-SL removal group (70%) (P = 0.04). However for the anterior teeth paired split-mouth study[14] there was no statistically significant difference between the SL removal group (82.3%) and the non-SL removal group (88.2%) (P = 1.00). According to Barcelos *et. al.* [8] the influence of smear layer removal on secondary variables were evaluated and a significant difference was found regarding the initial pulpal status of selected teeth, as pulpal necrotic teeth revealed a success rate of 95.8% for the SL removal group and 71.4% for the non-SL removal group (P=0.02). When initial clinical signs and symptoms were present, the symptomatic teeth revealed a success rate of 93.8% for the SL removal group and 54.5% for the non-SL removal group (P=0.02).[8] And when there was initial periapical radiolucency, the evaluated teeth revealed a success rate of 94.1% for the SL removal group and 66.7% for the non-SL removal group (P=0.04).[8] However no such correlation was made in the Tannure *et al* [14] study. For the statistical analysis, data were grouped according to the treatment to which each tooth was randomly assigned (intention-to-treat analysis), regardless if any patient deviation from the protocol occurred.[8] Two

Figure 1: Study selection flow diagram



teeth were excluded from the analysis, after 36 months, because one patient failed to attend his follow-up appointments.[14]

Based on the inner methodological risk of bias evaluation, we considered the studies to be Low risk of bias8 and High risk of bias.[14] In the former study[8] Low risk of bias results were achieved for all domains. In the latter study[14] the key domains, sequence generation and allocation concealment, blinding of participants and personnel, other potential threats to validity and incomplete outcome data were considered High risk of bias. Additional information obtained from these authors[14] concerning the details of the randomization process and allocation concealment, and also the small sample size, supported the finding of High risk of bias for this study. The final methodological risk of bias results and interpretation are summarized in Table 4.

DISCUSSION

The two studies retrieved for data extraction and risk of bias evaluation were conducted on pediatric patients. The clinical and radiographical success criteria used to evaluate the treatment outcome in both studies were similar and are commonly applied in pediatric pulpal therapy researches.[15-17] The clinical and radiographical success rate results obtained in the included studies were in agreement with the results of other studies involving pulpectomy in primary teeth with zinc oxide and eugenol (ZOE) as a canal filling material, with long-term follow-up: Mortazavi and Mesbahi[15] (78.5%), Ozalp *et al*[16] (100%) and Trairatvorakul and Chunlasikaiwan[17] (85%). Ozalp *et al* did not include teeth with initial pulp necrosis status.[16]

In the endodontic literature some factors like preoperative diagnosis, the ability to obtain infection control, root canal system morphology, procedural complications, and patients' signs and symptoms play an important role in the decision-making process of a 1- versus a 2-visit endodontic session with the use of an intracanal disinfecting medication.[18,19] The use of camphorated paramonochlorophenol as intracanal medication instead of calcium hydroxide and the two-visit regimen were justified by Barcelos *et al* [8] The calcium hydroxide alone is less effective than other medications against *Enterococcus faecalis* in necrotic primary teeth.[20] Also the authors reported that all treatments were performed with local anesthesia, without general anesthesia or conscious sedation, and a single-visit appointment would be hard for younger or uncooperative patients to stand, especially when treating the primary molars.[21] The single-visit regimen was applied in the treatment of primary anterior teeth.[14]

Table 3. Main characteristics of the randomized clinical trials included

Reference	Allocation Sequence generation	Study design	Sample Size and description	Number of groups	Smear layer protocol	Canal root Filling material	Follow-up Time and intervals	Follow-up: clinical criteria of success	Follow-up: radiographic criteria of success	Success rate (SL removal group)	Success rate (non-removal SL group)	*P* value
Tannure *et al.*,2011	Randomization by tooth	Split-mouth	32 primary maxillary incisors (14 centrals, 18 laterals) and 4 primary mandibular incisors (2 centrals, 2 laterals)	2	6% Citric acid	ZOE	*36 months*	Clinical signs and symptoms before treatment overcome within 2 weeks	Bone deposition within 6 months in previous radiolucent areas. No pathologic root resorption nor apical radiolucency	82.3%	88.2%	1.00
Barcelos *et al.*,2012	Randomization by patient	Randomized Controlled Clinical Trial	82 primary teeth. Maxillary incisors (25 centrals, 18 laterals). Maxillary (6 canines, 6 first molars, 8 second molars). Mandibular (8 first molars, 11 second molars)	2	6% Citric acid	ZOE	24 months	no signs or symptoms of infection, no pain, swelling, fistula, or sensitivity to percussion	evidence of a reduction in the size of previous radiolucent area no newly formed radiolucency in the cases without radiolucency	91.2%	70.0%	0.04

Regarding methodological inner evaluation of risk of bias, we considered the double blind randomized controlled trial performed by Barcelos *et al* [8] as Low risk of bias. Randomization was properly described and performed by a professor not involved in the research, by tossing a coin at the moment following the instrumentation phase of the pulpectomy procedure. Allocation concealment was guaranteed as participants and investigators enrolling participants could not foresee the allocations. Tossing a coin at the end of the root canal preparation and disinfection protocol carried out the randomization. Performance bias was prevented as operators were blinded until the end of canal instrumentation, then group allocation was known for the smear layer removal solutions physicochemical characteristics. So incomplete blinding occurred, but the authors felt that it did not affect the study outcome. Patients were blinded during the whole treatment and follow-up period. Blinding the outcome assessment was performed as two assessors examined the teeth blind and independently. Attrition bias (Incomplete outcome data) was avoided; missing outcome data was balanced in both groups, through statistical approaches and showed similar reasons. Missing data was input using proper methods: a) the complete cases analysis, ignoring all with unknown outcomes, that showed no significant differences; and b) the extreme cases analysis, but no statistically significant differences were found when assuming that all patients in both groups with unknown outcome had either a good (success) or a poor (failure) outcome. Reporting bias (Selective reporting) was not observed in this study, as authors followed the CONSORT (Consolidated Standards of Reporting Trials) guidelines for reporting, and the pre-specified primary and secondary outcomes that were of interest of this review were reported properly. No other bias was detected.

We evaluated the split-mouth study performed by Tannure *et al* [14], as High risk according to the Cochrane's risk of bias tool. The randomization and allocation concealment processes presented some failures, the first tooth operated on was assigned for one irrigation group by tossing a coin, but the exact moment of randomization was not described and the operator performed the randomization. Concerning the risk of performance bias, the study was considered High risk because the participants and the single operator were not blinded during treatment. Detection bias was avoided as outcome assessors were blinded. The attrition bias risk was evaluated as Low risk as there was no missing data. Also the reporting domain was considered as Low risk of bias, as the authors provided results compatible to their pre-specified primary objectives. And although the sample size and pre-calculation sample size do not constitute a domain in the Cochrane's tool, the small sample size and the absence of a sample size calculation were included in the section of other bias, as it could possibly compromise the external validity of the reported results.

Table 4. Summary assessment of the risk of bias for an outcome within a study

Reference	Risk of bias	Interpretation	Within a study
Tannure *et al*., 2011.	High risk of bias	Plausible bias that weakens confidence in the results	High risk of bias for 2 key domains.
Barcelos *et al*., 2012.	Low risk of bias.	Plausible bias unlikely to seriously alter the results.	Low risk of bias for all key domains.

According to Shahravan *et al* (2007) in a systematic review and meta-analysis, the smear layer removal improved fluid-tight seal of root canal system of permanent teeth.[4] Although a recent *in vitro* study that evaluated the effect of smear layer on the penetration of bacteria along different root canal fillings and their sealing abilities in primary teeth showed that the ZOE groups' results were not affected by the smear layer treatment.[22] These results were in accordance with those clinical and radiographic findings of Tannure *et al* study.[14]

The aim of this study was to systematically review the literature concerning the influence of smear layer removal on root canal treatment outcome, considering both radiographic and clinical aspects. In the search process we applied no limits concerning permanent or primary dentitions, but we found only clinical trials performed on primary teeth. The complex morphology of the root canal system of posterior primary teeth, the rhyzolysis process, and the close relationship of the developing permanent teeth buds to the primary teeth apices difficult the elimination of remaining microbiota and tissues in infected teeth by mechanical preparation alone.[21] Trairatvorakul & Chunlasikaiwan[17] reported that all the failed primary teeth in the clinically controlled randomized trial conducted by them, presented pre-existing infection. The smear layer removal would benefit the cleaning and disinfecting procedure, as the opened dentinal tubules possibly allow the antimicrobial irrigants and medication penetration.[23] Moreover, the chelating agents produce a clean root surface for further obturation.[6,24] According to Hariharan *et al*[25] 6% citric acid presented the best efficacy for smear layer removal in primary teeth root canal systems without affecting the normal structures of dentinal tubules. However, neither the British Society of Paediatric Dentistry (2006)[26], nor the American Academy of Pediatric Dentistry (AAPD) guidelines on pulp therapy for primary teeth[27] recently revised (2014-2015), include on the recommendations, the smear layer removal for root canal treatment of primary teeth.

The smear layer removal has become an accepted and disseminated practice in endodontics.[24] Violich and Chandler (2010) concluded that the found data indicated the smear layer removal for a more thorough cleaning and disinfection of root canals and better filling materials adaptation, although there were no clinical trials to support this.[6] Thus, these authors suggested that further investigation should be performed to determine the role of smear layer in root canal treatment outcome. We observed that the pediatric dentists researchers started attending this demand.

In the light of the findings[28] in this systematic review, and within the limitation of too few studies included, we can say that the smear layer removal procedure could benefit the root treatment outcome for primary teeth with initial clinical signs and symptoms or pulpal necrotic status. However, further randomized controlled clinical trials with a similar design could be performed on primary and permanent teeth, to achieve evidence.

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