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SYSTEMATIC REVIEW

Microbial Contamination Comparison Between Cotton Pellet and Polytetrafluoroethylene Tape Endodontic Spacers: A Systematic Review

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ABSTRACT

This systematic review compares polytetrafluoroethylene tape and cotton pellet when used as endodontic spacers underneath provisional restorations. The review followed the PRISMA guidelines and was registered in the PROSPERO database (CRD42020176555). Studies that compared the microbial contamination between polytetrafluoroethylene tape and cotton pellet, when used as spacers, were included. Literature searches of Pubmed, Embase, EBSCOHost Dentistry & Oral Sciences Source, Scopus, and Open Grey databases were conducted from their inception until May 2020 for studies in English or other Latin script languages. Hand searching of reference lists was performed. Three laboratory and three clinical studies were included. The risk of bias of the component studies varied widely. Results from the laboratory studies showed higher bacterial counts for cotton pellets. Results from the clinical studies showed that polytetrafluoroethylene tape was associated with a significantly lower incidence of microbial contamination. Findings were consistent throughout the studies, though the evidence available is scarce and heterogeneous. Polytetrafluoroethylene tape was associated with less microbial contamination when compared with cotton pellets as endodontic spacers and therefore appears to be a more suitable material for the purpose.

Keywords: Dental filling, endodontics, root canal therapy, temporary, temporary dental filling

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HIGHLIGHTS

- PTFE tape was associated with reduced contamination levels when compared with cotton pellets as endodontic spacer.
- Further clinical studies of adequate quality are required to better understand the role of endodontic spacers.
- This review provides the clinician with useful information to make evidence-based decisions on the most effective endodontic spacer.

INTRODUCTION

Provisional restorations are required when a multiple visit approach is chosen or required by the clinical situation, and are placed within an endodontic access cavity when a definitive coronal restoration is to be provided at a subsequent appointment (1). Endodontic provisional restorations aim to prevent contamination of the root canal space, maintain function and aesthetics (1, 2). In addition to the provisional restoration per se, a "spacer" or "barrier material" placed apically to the restoration is recommended to prevent unwanted materials entering and blocking the canal space (3). Further reasons to advocate the use of a spacer are its ease of removal, which reduces the time required to access the root canal system, and reduced risk of tooth damage during removal of the temporary material (3, 4).

Commonly used endodontic spacers include cotton pellets and polytetrafluoroethylene (PTFE) tape (4, 5). Desirable qualities of spacer materials include the ease of handling, cost-effectiveness, ease of placement and removal, visibility, autoclavability, inert and inorganic nature, ability to take up limited volume and to support the provisional restoration (3, 6, 7).

Cotton pellets have been widely used as an endodontic spacer, as reported in a survey (4). Although the use of cotton pellets fulfils the aims of spacer materials, it also has some disadvantages. It may reduce the thickness of the overlying provisional restoration, which should ideally measure between 3.0 and 4.0 mm, and may compromise the ability of the provisional restoration to prevent marginal penetration (2). Due to its yielding nature, a cotton pellet may allow displacement of the overlying restorative material during masticatory loading and thereby compromise its stability (2). Furthermore, the cotton fibres may adhere to the cavity walls, affecting the marginal integrity of the provisional restoration, and act as a wick by drawing fluids from the oral cavity (2).

PTFE tape is a versatile material that has been increasingly used for various purposes in dentistry (3). It is an inert, non-biodegradable, non-fibrous polymer and has been considered a suitable alternative spacer material with the potential to overcome the disadvantages of using cotton pellets (6, 8, 9). Its inorganic nature reduces the potential for it to act as a wick, and its non-spongy nature better supports the provisional restoration (7).

Cotton pellets and PTFE tape have been used extensively in endodontics. Hence, the clinician may be unclear regarding the selection of the best spacer. To address this gap in knowledge, this systematic review was undertaken. The results of this review provide the clinician with useful information to make evidence-based decisions on the most effective endodontic spacer by comparing the contamination associated with PTFE tape or cotton pellets.

MATERIALS AND METHODS

The current review was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, (10) and was registered in the PROSPERO database (CRD42020176555).

Research question

The research question was framed based on PICOS format: Does PTFE tape (I) reduce the microbial contamination (O) when used as endodontic spacer compared to cotton pellets (C) in human teeth provisionally restored during root canal treatment (P) from laboratory and clinical studies (S)?

Literature search process

Initially, PubMed was explored for a screening of search terms pertinent to the research question using sentinel studies as a reference. Two independent reviewers (AIM and SCL) performed a comprehensive literature search in electronic databases (PubMed, Embase, EBSCOHost Dentistry & Oral Sciences Source, and Scopus) by using the following search strategy: ((((((polytetrafluoroethylene) OR PTFE) OR Teflon) OR cotton) OR spacer)) AND ((((“microbial leakage”) OR microbiologic) OR “root canal”) OR endodontic) until May 2020. A grey literature search was performed in the Open Grey database. The reference lists of included studies were searched to identify any relevant studies. Additionally, Google Scholar was hand searched with the strategy described above and search fields limited to “in the title of the article”. A final search was completed on 12th May 2020. Search results were imported into a computerized database and duplicate records were removed. Based on selection criteria, two reviewers (AIM and SCL) independently screened titles and abstracts, followed by a full-text reading.

Inclusion criteria

- Laboratory and clinical studies conducted in human teeth comparing the microbial contamination between PTFE tape and cotton pellet when placed underneath provisional restorations in the pulp chamber or root canal.
- Studies published in English and other Latin script languages.

Exclusion criteria

- Studies that used artificial teeth, animal teeth or artificial blocks.
- Studies that evaluated either PTFE tape or cotton pellet only or evaluated other barriers or if a medicament was used within the pulp chamber space.
- Reviews or editorials.

Data extraction

The data extraction form was developed with the following items: surname of the first author, year of publication, tooth selection, groups and sample size, preparation of teeth, experimental set-up, follow-up/recalls, outcomes measured, and main results. Two reviewers (AIM, SCL) independently extracted the data. Authors of the included studies were contacted for clarification and requested to provide further information as required.

Quality of laboratory studies

Two authors (AIM, WNH) independently assessed the quality of included studies and any points of disagreement were resolved by a third author (GRF), a trained Joanna Briggs Institute (JBI) reviewer. The quality of non-randomized studies was appraised using the JBI Critical Appraisal Checklist for Quasi-Experimental Studies (non-randomized experimental studies) (11) and the quality of randomized laboratory studies was appraised using a customized version of Checklist for Randomized Controlled Trials (11). For the latter checklist, four criteria were deemed irrelevant and removed (Was allocation to treatment groups concealed? Were participants blind to treatment assignment? Were those delivering treatment blind to treatment assignment? Were outcomes assessors blind to treatment assignment?) (12). Under each item, the included studies were scored ‘1’ when adequately reported and ‘0’ when inadequately reported or information was missing. The included studies were categorized into high (1-3), moderate (4-6) or low (7–9) risk of bias. Reliability scores for the checklists were analyzed for agreement between the two independent reviewers by Cohen’s kappa coefficient (13).

Quality of randomized clinical trials

Two authors (AIM, WNH) independently assessed the quality of included trials and any points of disagreement were resolved by a third author (GRF). The Cochrane risk of bias tool for randomized trials (RoB 2.0) (14) was used to appraise the quality of clinical trials. A ‘low risk’ of bias score was given when all

domains in the assessment were found to be of low risk. When one of the domains was found to have either some concerns or high risk of bias, a score of 'some concerns' or 'high risk' was provided respectively.

Data synthesis

Following tabulation, a narrative synthesis was used to draw conclusions.

RESULTS

Search strategy

The results of the literature search process are presented in Figure 1. The initial search in electronic databases resulted in a total of 1237 articles. The hand search resulted in 19 additional articles. After the removal of duplicates, the search strategy yielded a total of 525 articles. Title and abstract screening identified 516 articles for exclusion. The most frequent reason for exclusion was not fulfilling inclusion criteria. Six articles were selected for full-text retrieval. Three laboratory studies (6, 9, 15) and three clinical studies (7, 16, 17) fulfilled the inclusion criteria and were included in the review. Due to heterogeneity among the included studies, quantitative synthesis was not performed.

Study characteristics

i) Laboratory studies (Table 1)

Among the three laboratory studies, sample sizes ranged from 5 to 20 teeth. One study included two negative control groups, one for each spacer material (6). One study included both positive and negative control groups (9). One study had no positive or negative control groups (15). Only one study described a rationale for their sample sizes (9). The period of evaluation ranged from 7 to 30 days. All studies described a rationale for the period of evaluation. One was based on recommendations for intracanal medicament efficacy, whereas the remaining two were based on previous recommendations for provisional restorative materials (6, 15). All studies used Cavit or Cavit G (3M ESPE, Seefeld, Germany) with minimum thickness ranging from 3.5 to 4 mm. Two studies described a rationale for the thickness and choice of provisional material used (6, 15). Outcomes measured included colony-forming unit counts, (6, 15) the occurrence of broth turbidity, (6, 9) and quantitative real-time polymerase chain reaction to assess bacterial counts (9).

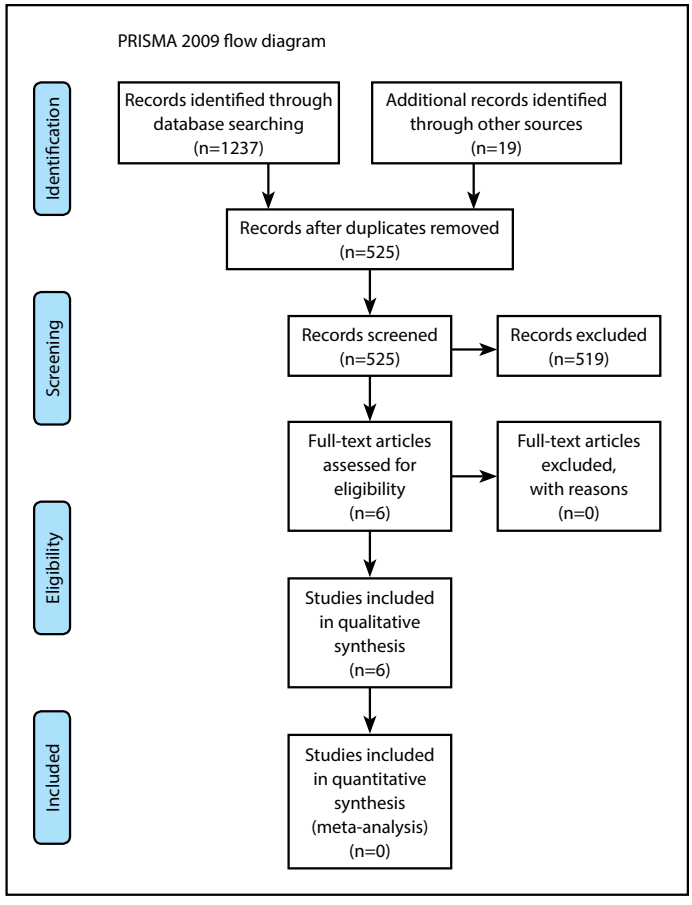

Figure 1. PRISMA flow chart showing the results of the search process

ii) Clinical studies (Table 2)

Among the three clinical studies, sample sizes ranged from 17 to 24 patients. The period of evaluation ranged from 1 to 4 weeks. Two studies used primary teeth (16, 17). All studies described a rationale for the period of evaluation. One was based on recommendations for intracanal medicament efficacy, (7) whereas the remaining two were based on previous recommendations for provisional restorative materials (16, 17). All three studies used colony-forming unit counts as their outcome measure (7, 16, 17). In addition, Prabhakar et al. (16) evaluated the occurrence of broth turbidity.

Risk of bias assessment

The assessed quality of component studies is shown in Figures 2, 3, 4. The inter-examiner strength of agreement for the quality of laboratory studies was 'perfect' (inter-rater agreement k=1). Among the three laboratory studies, one was deemed to have an overall 'low' risk of bias (9) One study was deemed to have a 'moderate' risk of bias arising from differences in treatment between groups, lack of appropriate statistical analyses, pre-intervention measurements, and an appropriate control group (15). One study was deemed to have a 'moderate' risk of bias arising from differences between groups at baseline, lack of true randomization and appropriate statistical analyses, and limitations in trial design (6). Of the three clinical studies, all studies were deemed to have an overall 'high risk' of bias, arising from lack of detail regarding their randomization process and allocation concealment (7, 16, 17). The corresponding authors of four studies (7, 15-17) were contacted for clarifications necessary to the assessment of risk of bias, with no replies.

Narrative synthesis

Results from the laboratory studies were overall consistent, showing higher bacterial counts and more positive samples for cotton pellets compared with PTFE tape. However, some inconsistencies were evident when comparing different recall times assessed in the component studies. No study reported higher contamination levels for PTFE at any recall or experimental set-up.

Results from the clinical studies were consistent and generally suggested that PTFE tape was associated with a significantly lower incidence of microbial contamination and positive cultures.

TABLE 1. Summary of the main characteristics of the included laboratory studies

Authors	Tooth selection	Groups (sample size)	Preparation method	Experimental setup	Follow-up/ Recall period	Outcomes measured	Main results	Risk of bias
Paranjpe et al. 2012 (6)	Molars	Cotton pellet negative control (3) PTFE negative control (3) Cotton pellet (10) PTFE (10)	Access shape and design not specified, minimum depth of 4 mm. Two cotton pellets per tooth (size-one). PTFE tape (2.5 inches in length). Both materials were sterilized prior to use. Provisional restoration with minimum 4 mm Cavit.	Experimental groups: crowns immersed in broth inoculated with *Streptococcus gordonii*. Cotton pellet/PTFE spacers were collected and samples were collected from access cavities after retrieval of spacer.	7 days	Presence of colonies for indication of *S. gordonii* contamination of the spacer. Broth turbidity for indication of *S. gordonii* contamination of the access cavity.	"Presence of colonies from spacer material in: 9 of 10 cotton pellet samples; 1 of 10 PTFE samples; 0 of 3 control samples; Contamination of access cavities indicated by broth turbidity in: 9 of 10 cotton pellet samples; 0 of 10 PTFE samples".	Moderate
Alkadi & Alsalleeh 2019 (9)	Single-rooted premolars	Cotton pellet (20) PTFE (20) Positive control (6) Negative control (6)	Crowns sectioned to produce flat occlusal surfaces. Oval occlusal access – 2.5 mm width, 3 mm length, 5.5 mm depth. Cotton pellets (size-four). PTFE tape (2 cm in length) made into pellets using a resin mold of a size-four cotton pellet. Both materials were sterilized prior to use. Provisional restoration with 3.5 mm Cavit.	Experimental setup: dual-chamber microbial leakage model (upper chamber inoculated with *Enterococcus faecalis*). Occurrence of turbidity in lower chambers was monitored. Quantitative real-time polymerase chain reaction analysis of bacterial counts on liquid samples from lower chambers at day 7 and day 30.	7, 14, 21, 30 days	Occurrence of broth turbidity; qPCR.	"By broth turbidity: No significant difference between experimental groups (cotton pellet and PTFE tape) at 7 and 14 days. Significantly higher positive samples with cotton pellet at 21 and 30 days; 14 out of 20 cotton pellet samples were positive, while only 7 out of 19 PTFE samples were positive. By qPCR: Significantly higher *E. faecalis* counts in cotton pellet samples compared to PTFE at 7 days. Higher *E. faecalis* counts in cotton pellet samples compared to PTFE at 30 days (not significant). A significant increase in the number of bacterial cells in intra-group comparisons between 7 days and 30 days".	Low
Shetty et al. 2019 (10)	Mandibular premolars	Cotton pellet (5) PTFE (5)	Access shape and design not specified. Cotton pellet.PTFE tape (2 inches in length) standardized. Both materials were sterilized prior to use. Provisional restoration with minimum 3.5-4 mm Cavit.	Experimental setup: Crowns exposed to nutrient broth, inoculated with Staphylococcus aureus. Bacterial samples were collected from access cavities.	7 days	CFU counts.	"Access cavities with cotton as a spacer presented with higher CFUs than PTFE".	Moderate

CFU: Colony-forming units, PTFE: Polytetrafluoroethylene, qPCR: Quantitative real-time polymerase chain reaction, Cavit: 3M ESPE, Seefeld, Germany

TABLE 2. Summary of the main characteristics of the included clinical studies

Authors	Tooth selection	Groups (sample size)	Preparation method	Experimental setup	Follow-up period	Outcomes measured	Main results	Risk of bias
Olsson et al. 2017 (7)	First and second molars	Cotton pellet (24) PTFE (24)	Access shape and design not specified. Cotton pellet (size-two) PTFE tape (2.5 inches in length). Both materials were sterile. Provisional restoration with 3-4 mm Cavit.	Bacterial sample collected from pulp chamber before delivery of a spacer. Bacterial sample collected from pulp chamber after retrieval of spacer.	2-4 weeks	CFU counts; Intra-group comparisons of log CFU counts in 2-week versus 4-week samples.	"Positive for microbial growth with statistically significant difference (P<0.05) in: 15 of 24 cotton pellet samples, 2 of 24 PTFE samples. No significant differences (P>0.05) in the intra-group comparisons of 2-week recall versus 4-week recall".	High
Prabhakar et al. 2018 (11)	Mandibular second primary molars	Cotton pellet (17) PTFE (17)	Access shape and design not specified. Cotton pellets. PTFE tape (2.5 inches in length). Both materials were sterilized prior to use. Provisional restoration with 3 mm Cavit G.	Bacterial samples collected from access cavity before delivery of a spacer. Spacers collected after 7 days. Bacterial samples collected from inner surfaces of access cavity.	1 week and after 1 week	CFU counts.	"At 1 week Significant increase (P<0.05) in colony count (from zero) on both the cotton spacer and access cavity, indicating contamination in 15 of 17 samples. Significant difference (P<0.05) in colony counts on the cotton and access cavity No significant increase (P>0.05) in colony count on PTFE spacer or access cavity, indicating contamination in 2 of 17 samples. No significant difference (P>0.05) in colony counts on the PTFE tape and access cavity. After 1 week Significant difference (P<0.05) in colony counts on cotton pellet and PTFE spacers, with PTFE tape showing less microbial contamination. Significant difference (P<0.05) in colony counts from access cavity of cotton pellet and PTFE samples, with PTFE tape showing lower microbial numbers in the access cavity".	High
Khatab & Abdelhafez 2020 (12)	Bilateral primary molars	Cotton pellet (20) PTFE (20)	Access shape and design not specified. Cotton pellets PTFE tape (6 cm) Both materials were sterile. Provisional restoration with 3.5 mm Cavit G.	Bacterial samples collected from access cavity before delivery of a spacer. Spacers collected after 1 week. Bacterial samples collected from inner surfaces of access cavity.	1 week	CFU counts.	'Significant increase (P<0.05) in colony counts (from zero) from both the spacer and access cavity after 1 week from the cotton pellet group. No significant differences (P<0.05) in colony counts between baseline samples and access cavity samples after 1 week from the PTFE group. Minimal microbial contamination with PTFE spacer after 1 week (P<0.05). Significant difference (P<0.05) in colony counts on cotton pellet and PTFE spacers after 1 week, with PTFE tape showing less microbial contamination".	High

CFU: Colony-forming units, PTFE: Polytetrafluoroethylene, Cavit and Cavit G: 3M ESPE, Seefeld, Germany

Figure 2. Possibility of bias assessment for non-randomized experimental studies

Author, year	Alkadi & Alsalleeh (2019)	Shetty et al. (2019)
Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	1	1
Were the participants included in any comparisons similar?	1	1
Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	1	0
Was there a control group?	1	0
Were there multiple measurements of the outcome both pre and post the intervention/ exposure?	0	0
Was follow up complete and if not, were differences between groups in terms of their follow up adequately described any analysed?	1	1
Were the outcomes of participants included in any comparisons measured in the same way?	1	1
Were outcomes measured in a reliable way?	1	1
Was appropriate statistical analysis used?	1	0

1/ green color means 'adequate'; 0/ red color means 'inadequate'

Figure 3. Possibility of bias assessment for a randomized experimental study

Author, year	Paranjpe et al. (2012)[6]
Was true randomization used for assignment of participants to treatment groups?	0
Were treatment groups similar at the baseline?	0
Were treatment groups treated identically other than the intervention of interest?	1
Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	1
Were participants analyzed in the groups to which they were randomized?	1
Were outcomes measured in the same way for treatment groups?	1
Were outcomes measured in a reliable way?	1
Was appropriate statistical analysis used?	0
Was the trial design appropriate, and any deviations from the standard RCT design (individual ramdomization, parallel groups) accounted for in the conduct and analysis of the trial?	0

1/ green color means 'adequate'; 0/ red color means 'inadequate'

Figure 4. Possibility of bias assessment for randomized clinical trials

Author, year	Prabhakar et al. (2018)[16]	Olsson et al. (2017)[7]	Khatab & Abdelhafez (2020)[17]
Bias arising from the ramdomization process	-	-	-
Bias due to deviations from intended interventions	+	+	+
Bias due to missing outcome data	+	+	+
Bias in measurement of the outcome	+	+	+
Bias in selection of the reported result	+	+	+
Overall bias	-	-	-

+ symbol/green color means 'low risk of bias', - symbol/red color means 'high risk of bias'

DISCUSSION

Selecting the appropriate endodontic spacer materials during root canal treatment is important and should be based on reliable evidence. The current review was performed with the inclusion of three laboratory and three clinical studies. Although two studies had comparable methodologies, (16, 17) a meta-analysis was not performed due to overall methodological heterogeneity and the limited clinical significance of the reported outcome measures (colony counts) from different studies. The role of microbial penetration during treatment in persistent infections is recognized in Endodontology, (18) and spacer contamination is a surrogate measure for pulpal cavity contamination.

The use of PTFE tape as a spacer is associated with less contamination compared with cotton pellets, though the evidence available is limited and heterogeneous. It is important to note that cotton pellets are not medically registered to be used into patients yet it is common practice to temporarily place them in the access cavity. PTFE tape is a material that has been recently introduced into dentistry and serves various applications (3). When considering the suitability of use clinically and to comply with regulatory bodies, the use of medical-grade PTFE such as Isotape (TDV Dental, Santa Catarina, Brazil), or similar, is advised. Due to the assessment of only two provisional materials (Cavit and Cavit G), the results of the present review may not be transferable to other materials. Additionally, Cavit has been reported to have superior hardness, dimensional stability and seal when compared with Cavit G, (2) which may affect the durability of the temporary filling and microbial contamination of the access cavity. Laboratory studies did not include loading which is likely to affect the marginal seal of provisional restorations (2). One of the laboratory studies used decoronated roots (9). Two clinical studies included primary molars (11, 12). As the furcation region of primary teeth show a higher prevalence of accessory canals, increased microbial contamination is anticipated in comparison to permanent teeth (19). The two component clinical studies, (7, 16) which included normal oral function and mastication, also reported contamination more commonly when cotton pellets were used. Only one study reported that the PTFE tape used was standardized with a resin mold to a size similar to the cotton pellets used, as any variability in thickness of the spacer may have influenced the outcomes. Further variables that may influence the outcomes include the number and size of cotton pellets, the size, location and design of the access cavity, remaining hard tissue and cavity walls, existing restorations, and occlusion.

Further alternatives are available for provisional restoration in endodontics. An alternative is the use of a "double seal" where two different layers are applied, aiming to compensate for the limitations of commercially-available materials (1, 2). The use of a spacer is still possible with the "double seal" approach, (1) given there is sufficient space.

The importance of providing an adequate provisional restoration should be reiterated (1). Provisional restorations are often placed following the removal of previous restorations and caries and enable assessment of restorability and the presence of cracks. They should be of sufficient thickness for mechanical strength and to prevent bacterial penetration (1). If a spacer is placed in proximity of potential sources of bacterial penetration, without an adequate thickness of provisional material, the ingress of micro-organisms may occur (2). Additionally, as none of the studies included within this review assessed the use of spacer materials in anterior teeth, (9) the results of the present review may not be transferrable to anterior teeth due to the variability in regards to pulp chamber volume. In cases of access cavities of limited volume, foregoing the use of a spacer will allow the placement of a thicker provisional material without the benefits a spacer (1, 2).

In the present review, the quality of all studies was appraised and categorized based on their risk of bias. Only one of the three laboratory studies revealed a 'low' risk of bias (9). Two studies revealed a 'moderate' risk of bias, (6, 15) as it was unclear if the spacer materials were standardized to a similar thickness and any variances in thickness could lead to variances in the provisional restorative material, affecting the overall seal rather than the spacer materials. There was no mention of statistical analysis in one study (6) and the absence of results derived from the statistical analysis in the second study (15). Four studies (6, 15, 16, 17) did not report an a priori sample size calculation, therefore results should be interpreted with caution (20). In one study, (6) there was no description of how random allocation of participants to treatment groups was carried out. Three clinical studies were deemed to have an overall 'high' risk of bias, due to the lack of concealment of allocation to groups (7, 16, 17). However, the methodological challenges in both the studies of masking interventions (cotton pellets and PFTE tape) during their placement are obvious. The materials differ in appearance and manipulation, which prevents their concealment from the operator.

The search strategy adopted in the present systematic review was extensive. Bias in the conduct of review was minimized by independent evaluation of study selection, data extraction and appraisal of the quality of studies by two reviewers, with disagreements resolved by a third experienced reviewer. Furthermore, the team included two trained JBI reviewers (WNH, GRF).

The current review was performed with a limited number of studies that showed methodological heterogeneity, including the use of culturing and molecular methods to detect infection. Unfortunately, missing or unclear information was not able to be clarified despite attempts to contact the authors.

Future high-quality studies that compare the effectiveness of spacer materials need to be conducted and should be reported based on the PRILE 2021 guidelines (20). Based on the results of laboratory studies, clinical studies can be conducted following the PRIRATE 2020, (21) or CONSORT guidelines (22). For studies assessing spacer materials in particular, complete reporting in regards to the thickness of the provisional restoration materials, tooth isolation, access cavity design and position, and dental occlusion, is crucial, as these are factors that could impact their outcomes. This will improve the validity and reliability of the manuscript and eventually help future authors to conduct the data extraction process in a subsequent systematic review.

CONCLUSION

PTFE tape was associated with less contamination when compared with cotton pellets as endodontic spacers, from limited and variable quality evidence. Furthermore, high-quality laboratory and clinical studies assessing the use of different spacers in association with alternative materials or the use of a "double-seal" for provisional restorations are required.

Disclosures

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