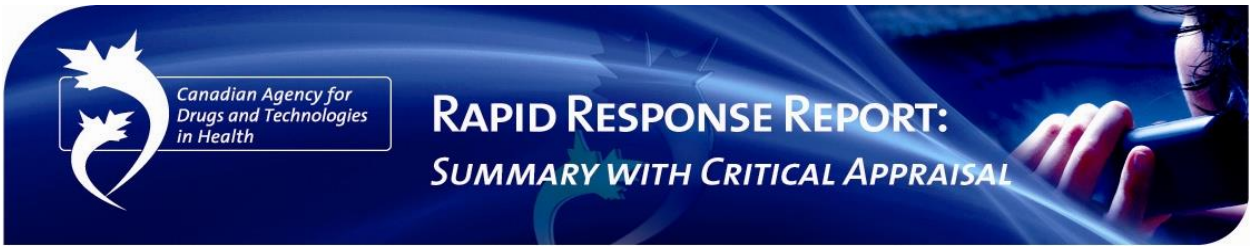

TITLE: Composite Resin Filling Materials: A Review of Safety, Cost-Effectiveness and Guidelines – An Update

DATE: 15 October 2015

CONTEXT AND POLICY ISSUES

Dental caries is a major public health problem in most industrialized countries, affecting 60-90% of school children and the majority of adults.[1] It is a localized, progressive demineralization of the hard tissues of the crown and root surfaces of teeth.[2] Whereas very early dental caries lesions can be managed preventively to reverse the disease process, all more advanced and cavitated carious lesions must be restored by excavating the carious tissue and replacing it with an appropriate dental filling material, mainly composite resins and silver amalgam.

Composite resins are tooth-colored restorative materials. They are being increasingly used instead of silver amalgam, most probably due to their higher esthetic value and the increasing concerns about amalgam safety.[3] However, some factors prevent the full adoption of composite materials as an alternative to amalgams. First, the clinical longevity of amalgam fillings is thought to be superior to that of composites.[4,5] Second, the use and handling proprieties of composite resins are operator sensitive, and in the absence of ideal conditions and equipment, may result in more secondary caries around restored teeth and the need for more frequent replacement and repair of restorations.[4] The increased cariogenicity of composite materials, in contrast to amalgam, can also be explained by the lack of antibacterial properties and their association with a favorable environment for cariogenic and pathogenic bacterial growth.[6,7]

The higher price of composite filling is another factor that may potentially limit its use instead of amalgam. Finally, recent safety concerns have been reported relative to the exposure to bisphenol A (BPA) from dental composite.[8] BPA is a component of many plastic products; it is a potent endocrine disruptor that can mimic the effect of the female hormone estrogen.[9] A review of the literature about the harms from BPA products suggested that BPA might be implicated in some allergic reactions.[10]

In 2012, CADTH has published a Rapid Response report examining the comparative safety, clinical effectiveness and cost-effectiveness of amalgam and composite.[5] The main findings of the review provided strong evidence of amalgam safety when used in children 6 to 10 years old,

and showed that there was limited information to evaluate the evidence of potential harms caused by composite resin. There was a suggestive evidence of longer longevity of dental amalgams than composites, and that the long-term costs of both fillings suggest a relative cheaper price of amalgam material.

The purpose of this report is to provide an update on the clinical safety and cost effectiveness of composite filling materials; evidence-based clinical guidelines will also be reviewed in this report.

RESEARCH QUESTIONS

1. What is the clinical evidence regarding the safety of composite resin when used as filling material on permanent teeth?

2. What is the cost-effectiveness of composite resin when used as filling material on permanent teeth?

3. What are the evidence-based guidelines regarding indications for the use of composite resin as filling material on permanent teeth?

KEY FINDINGS

One systematic review, one non-randomized study, and one clinical guideline were reviewed. No relevant cost-effectiveness studies were identified in the literature search. Available evidence is of low to moderate quality, and it showed that composite resin restorations, compared with amalgam, were associated with lower survival rates, and higher rates of secondary caries and endodontic complications. Potential systemic adverse events were not evaluated in the included studies. The American Academy of Pediatric Dentistry recommended the use composite or amalgam for class I and class II restorations on permanent teeth.

METHODS

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between May 1, 2012 and September 11, 2015.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for

inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients (of any age) requiring fillings on permanent teeth
Intervention	Composite resin filling materials
Comparator	Q1 and 2: Amalgam or glass ionomer cement filling materials Q3: No comparator required
Outcomes	Q1: Safety outcomes (e.g., post-placement pain, tooth sensitivity, risk of failure, secondary caries, restoration fracture, neurobehavioral function, renal outcomes, psychosocial function, physical development) Q2: Cost-effectiveness outcomes Q3: Evidence-based guidelines regarding patient indications for composite resin fillings
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials and non-randomized studies, economic evaluations and evidence-based clinical guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1 or if they were duplicate reports of the same outcomes from the same trials. Studies which were included in 2012 CADTH report[11] and systematic reviews that exclusively included these studies were also excluded. Additionally, clinical trials were excluded if they did not directly compare resin-composite filling materials with amalgam-based or glass ionomer dental fillings. Studies evaluating filling materials on patients with mixed dentition were excluded if they did not report the results for the permanent dentition separately (or as subgroup analysis).

Critical Appraisal of Individual Studies

The included systematic reviews were critically appraised using AMSTAR checklist;[12] randomized and non-randomized studies were critically appraised using Downs and Black tool,[13] and guidelines were assessed with the AGREE II instrument.[14] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 327 citations were identified in the literature search and one additional citation was identified in the grey literature. Following screening of titles and abstracts, 309 citations were excluded and 19 potentially relevant reports were retrieved for full-text review. Of these potentially relevant articles, 16 publications were excluded for various reasons, while three publications met the inclusion criteria and were included in this report. Appendix 1 describes the PRISMA flowchart of the study selection.

Summary of Study Characteristics

A detailed summary of included studies is provided in Appendix 2.

Clinical evidence regarding the safety of composite resin when used as filling material on permanent teeth

Dawson et al. published a systematic review in 2015 evaluating the effect of direct composite resin dental restorations on pulpal status.[15] The authors included ten studies published between 1995 and 2010, five of which were uncontrolled studies. Four studies compared composite direct fillings with amalgam, and one study compared direct composite with indirect composite (inlay). The review was based on more than 3613 patients with 7649 restorations, of which 4945 restorations were composite resin-based. All included studies were conducted on vital teeth at baseline. Restored cavities varied from one surface (class I) to multi-surface cavities (three-surface class II or four-surface class IV). The authors were interested in evaluating endodontic complications such as pulpal sensitivity and apical periodontitis.

In 2012, Kopperud et al. published an evaluation of the survival time of class II restorations placed in 11 Norwegian public dental clinics.[16] The authors retrieved data about restorations placed by 27 dentists during the period between 2001 and 2004. After an average follow-up of 4.6 years, patients were called for an assessment visit. Of the originally treated patients, 1873 patients and 4030 restorations were included in the analysis. The original number of treated patients was not reported, but the authors reported that 27.2% of the original restorations could not be followed-up because patients did not attend the recall examinations. Placed restorations were mainly resin composite fillings (81.5%), compomer fillings (i.e., hybrid of composite and glass ionomer) (12.7%), amalgam (184), and glass ionomers (1.2%). The main outcome was failure of restoration and reason of failure.

Cost-effectiveness of composite resin when used as filling material on permanent teeth Outcomes

No relevant cost-effectiveness studies were identified in the literature search.

Evidence-based guidelines regarding indications for the use of composite resin as filling material on permanent teeth

In 2014, the American Academy of Pediatric Dentistry (AAPD) issued the only guideline identified in the literature search.[17] The objective of this guideline was to provide dentists with recommendations with regard to restorative dentistry; recommendations included treatment timing and the appropriate materials and techniques appropriate for children and adolescents. The authors relied on 35 systematic reviews and meta-analyses and 62 randomized controlled trials. The authors did not report any grading for the recommendations; the strength of evidence however, was classified based on the type of studies reporting it: "***Strong evidence*** *– based on well executed randomized control trials, meta-analyses, or systematic reviews;* ***Evidence in favor*** *– based on weaker evidence from clinical trials;* ***Expert opinion*** *– based on retrospective trials, case reports, in vitro studies and opinions from clinical researchers;* ***Evidence against*** *– based on randomized control trials, meta-analysis, systematic reviews."* (page 241).

Summary of Critical Appraisal

Detailed description of individual study critical appraisal is provided in Appendix 3.

Clinical evidence regarding the safety of composite resin when used as filling material on permanent teeth

Dawson et al.[15] searched two major databases for their systematic review, PubMed and Cochrane, but they did not explicitly report that the search and study selection was conducted in duplicate. The authors evaluated the quality of the included studies, and they concluded that the overall quality was low. The reason for this evaluation was due to lack of clear criteria for measuring the outcome, the examination procedure for the collected teeth, and patient selection. Furthermore, five included studies were uncontrolled; therefore, results from these studies could not be used to draw comparative safety conclusions. The authors did not report the follow-up duration in each included study or a justification for not reporting it. The rate of endodontic complications (main outcome) considerably varied across studies; however, the authors did not discuss or provide any possible explanation for this heterogeneity.

The study by Kopperud et al.[16] included a relatively large number of patients and restorations. The patient population represented a wide range of socio-economic spectrum; this is of particular importance because of the association between risk of caries and the socio-economic status. Therefore, findings from this study were likely generalizable to other jurisdictions that have similar health care systems. However, the study was not a randomized trial, and several factors could affect the choice of filling materials such as patient's preference or lesion severity; these factors might affect the outcome as well. The authors reported that 27.2% of the original restorations could not be followed-up because patients did not attend the recall examinations. The authors did not attempt to evaluate the distribution of these missing values across the different filling materials or other baseline characteristics. Furthermore, 458 compomer restorations were excluded from the analysis (90% of all compomer restorations) because they were placed by one dentist. This exclusion was not based on a scientific justification.

Evidence-based guidelines regarding indications for the use of composite resin as filling material on permanent teeth

The authors of the AAPD guidelines conducted a systematic literature search with clear criteria for evidence selection.[17] These guidelines were limited by the fact that it was not clear how the quality of the included studies were evaluated. As well, the authors did not report the methods used to develop the recommendations or to validate the guidelines; however, the authors did not report the strength of evidence for all of the produced recommendations. The authors relied mainly on the efficacy of each restorative material; however, safety of these materials apparently was not considered.

Summary of Findings

Clinical evidence regarding the safety of composite resin when used as filling material on permanent teeth

Dawson et al.[15] reported that, in the controlled studies, composite was associated with 258/3128 (8.2%) cases of endodontic complications relative to 154/2543 (6.1%) cases for amalgam; the authors did not conduct any statistical analysis to evaluate the difference between the two

groups. The authors could not provide a conclusion due to lack of scientific evidence manifested by low quality studies.

Kopperud et al.[16] reported that, after an average follow-up of 4.6 years, amalgam was associated with a statistically significantly lower failure rate than composite (7% vs. 12%, *P* = 0.02). Secondary caries was reported at higher rates with composite restorations (9%) compared with amalgam (5%). The authors concluded that the choice of restorative material affects its survival. They also showed that the risk of failure, in composite restorations, was higher in medium/deep cavities compared with shallow cavities.

Evidence-based guidelines regarding indications for the use of composite resin as filling material on permanent teeth

The AAPD guidelines reported that there was strong evidence that composite resins could be used successfully for Class I and II restorations placed in permanent teeth. This recommendation did not consider the comparative efficacy, safety, and cost-effectiveness of amalgam or other restorative materials.

Limitations

None of the included studies explicitly evaluated the safety of composite resin dental materials, and safety assessment was a secondary outcome. Even when safety was considered, local adverse events such as recurrent caries and restoration failure were reported; none of these studies evaluated systemic adverse events potentially caused by dental filling materials.

None of the included studies were conducted in Canada; variation in population socio-economic status, water fluoridation policy, and provision of oral health care may vary from one jurisdiction to another. Therefore, findings from included studies might not be directly applicable to the Canadian setting.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

The objective of this review was to provide an update of the clinical safety and cost-effectiveness of composite resin dental fillings. The review also reviewed evidence-based clinical guidelines on the use of these filling materials. A systematic review, one non-randomized study, and one clinical guideline were included. No cost-effectiveness studies were identified in the reviewed literature.

When compared to amalgam, composite resin restorations were associated with lower survival rates, and higher rates of secondary caries and endodontic complications. These results were in line with the findings of 2012 CADTH review that reported suggestive evidence of longer longevity of dental amalgams than composites.[5] However, the included studies in this review did not evaluate the potential systemic adverse events caused by composite filling materials or other materials. Two RCTs were included in the 2012 review;[5] in these studies neurobehavioral, renal, and immunological outcomes were evaluated before and four to six years after teeth restorations; it was reported that these outcomes did not differ between children whom teeth were restored with composite or amalgam.

American Academy of Pediatric Dentistry provided similar recommendations for both amalgam and composite indicating their efficacy (based on their individual longevity) in restoring class I and class II in permanent teeth. These recommendations did not account for the comparative safety, efficacy or cost-effectiveness of the two materials.

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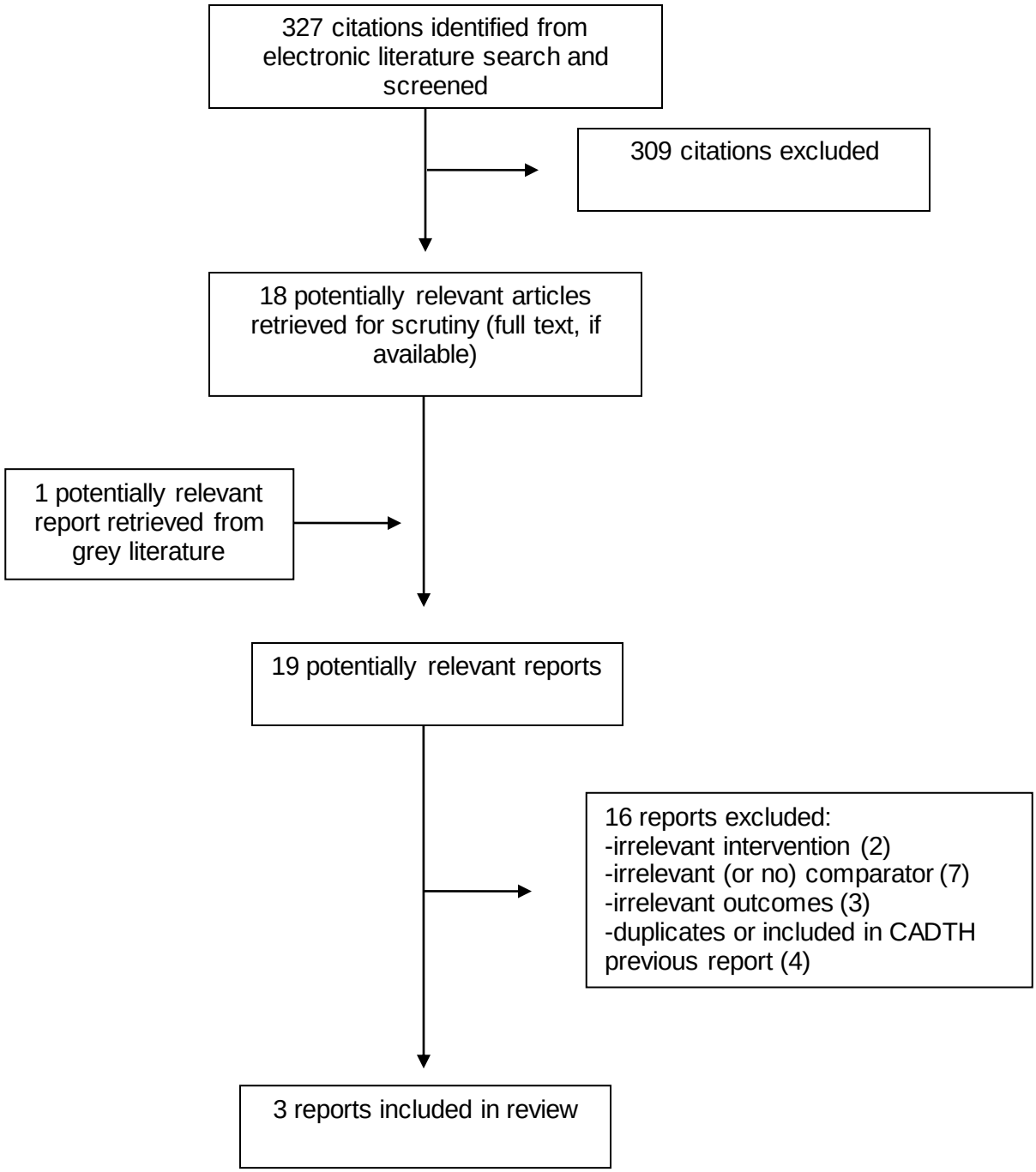
APPENDIX 1: SELECTION OF INCLUDED STUDIES



APPENDIX 2: CHARACTERISTICS OF INCLUDED PUBLICATIONS

Table A1: Characteristics of Included Systematic Reviews			
Study Objectives	**Study & Population Characteristics**	**Intervention & Comparator(s)**	**Clinical Outcomes, Length of Follow-Up**
Dawson et al. 2015,[15] Sweden. Systematic Review			
To evaluate the effect of direct composite resins restorations on pulpal status.	**Studies:** 10 studies published between 1995 and 2010 were included. Five studies were uncontrolled. **Patients:** - a total of > 3613 patients were included (one study did not report the number of patients) **Restored teeth/ dental cavities:** - a total of 7649 restorations (4945 composite restorations) - one study included class I to IV cavities - one study included class II cavities only - three studies included class I and II - five studies included multiple-surface cavities (without determining cavity class)	**Intervention:** Composite resins direct fillings **Comparators:** None: 5 studies Amalgam fillings: 4 studies Composite inlay (indirect) restoration: 1 study	"*endodontic complications such as pulpal sensitivity, apical periodontitis or root filling following coronal restoration*". (page 628)

Table A2: Characteristics of Included Randomized Controlled Trials			
Study Objectives and design	**Patient Characteristics**	**Intervention and Comparator(s)**	**Clinical Outcomes**
Kopperud et al. 2012,[16] Norway. Non-randomized controlled study			
To evaluate the survival time of Class II restorations Analysis of data from 11 public dental clinics. The average follow-up was 4.6 years between 2001 and 2004.	**Patients** - A total of 1873 patients - mean age was 15.3 years - 962 male and 911 female patients **Teeth/ restorations** A total of 4030 restorations were placed in class II cavities - primary caries = 3735 (92.7%); of these 3080 (76.5%) were considered as level 3 severity (of 5)	Resin composite filling materials: 3286 (81.5%) restorations Compomer filling material: 510 (12.7%) restorations; 92.5% of these fillings were placed by one dentist Amalgam: 184 (4.6%) restorations Glass-ionomer cement: 50 (1.2%) restorations A total of 27 dentists participated in providing these restorations	Failure of restoration, and reason of failure. Outcomes were assessed during a recall visit conducted for the purpose of this study

Table A3: Characteristics of Included Guideline					
Objectives		**Methodology**			
Intended users/ Target population	**Major Outcomes Considered**	**Evidence collection, Selection and Synthesis**	**Evidence Quality and Strength**	**Recommendations development and Evaluation**	**Guideline Validation**
American Academy of Pediatric Dentistry 2014.[17] USA					
Practitioners who provide restorative dentistry for children and adolescents	Clinical efficacy	Electronic and hand searches, for studies published between 1995 and 2013. The authors included MA/SR (N = 35) and RCTs (N = 62).	Methods used for the assessment of evidence quality were not described **Strong evidence:** well-executed RCTs, MA, or SR; **Evidence in favor**: Weaker evidence from clinical trials; **Expert opinion**: retrospective trials	No reported	Not reported

APPENDIX 3: CRITICAL APPRAISAL OF INCLUDED PUBLICATIONS

Table A4: Strengths and Limitations of the Systematic Review

Strengths	Limitations
Dawson et al. 2015,[15] Sweden. Systematic Review	
• Two databases were searched for relevant literature; however, it was not explicitly reported that literature screening and selection was done in duplicate • Quality of the included studies was evaluated	• The quality of the included studies was rated as "low level". The reason for this rating according to the authors was due to lack of criteria for measuring the outcome, the examination procedure for the collected teeth and patient selection. • The follow-up duration for each included study was not reported. • The authors did not use appropriate analysis methods to compare between composite fillings and amalgam. • The rates of endodontic complications considerably varied across studies; however, the authors did not discuss or provide any possible explanation for this heterogeneity.

Table A2: Strengths and Limitations of the non-Randomized Controlled Study

Strengths	Limitations
Kopperud et al. 2012,[16] Norway. Non-randomized controlled study	
• The study included a relatively large number of patients and restorations • The study was based on restorations placed by several dentists, and the included patients represented a wide range of socio-economic spectrum	• The study was not randomized, and therefore, other factors such as patient's/dentist's preferences or lesion severity could play role in the selection of filling material. Such factors might affect/bias the comparison between the evaluated materials. • It was reported that 27.2% of the original restorations could not be followed-up because patients did not attend the recall examinations. The authors did not attempt to evaluate the distribution of these missing values across the different filling materials or other baseline characteristics. This evaluation would help to understand the reasons behind the missing data. • The authors excluded 458 compomer restorations (90% of all composmer restorations) because they were placed by one dentist. This exclusion was not based on a scientific justification.

Table A3: Strengths and Limitations of Guidelines	
Strengths	**Limitations**
American Academy of Pediatric Dentistry 2014.[17] USA	
• The authors used a systematic method for literature search.	• Methods used to evaluate the included studies were not described • The authors did not report methods, if any was used, to develop the recommendations and to validate the guidelines. For example, it was not clear if the recommendations underwent external review prior to publication. Furthermore, it was not clear if views from patient and public groups were sought. • Process for future updates was not specified. • Safety data discussed relative to amalgam, but safety of composite and other restorative materials was not discussed. • Relevant competing interests of guideline development group were not reported.

APPENDIX 4: MAIN STUDY FINDINGS AND AUTHOR'S CONCLUSIONS

Table A7: Summary of Findings of Included Studies

<table>
<tr><th colspan="4">Main Study Findings</th><th>Author's Conclusions/ Reviewer's Comments</th></tr>
<tr><td colspan="5">Dawson et al. 2015,[15] Sweden. Systematic Review</td></tr>
<tr><td>Outcome</td><td>Comparaison</td><td># studies</td><td>Number of restorations with outcome/ total number of restorations (%)</td><td rowspan="5">Author's Conclusions:
The authors could not provide a conclusion due to lack of scientific evidence manifested by low quality studies. Therefore, the study was not able to answer the question of whether a tooth with a vital pulp restored with composite resin is at greater risk of pulpal complications than one restored with other materials.</td></tr>
<tr><td rowspan="2">Endodontic complications</td><td>Composite vs amalgam</td><td>4</td><td>258/ 3128 (8.2%) vs. 154/ 2543 (6.1%)</td></tr>
<tr><td>Composite vs inlay</td><td>1</td><td>None reported</td></tr>
<tr><td rowspan="2">Composite alone</td><td>5</td><td>12/ 1761 (0.7%)</td></tr>
<tr><td>None endodontic failure</td><td>1</td><td>85/ 703 (12.1%)</td></tr>
<tr><td colspan="5">Kopperud et al. 2012,[16] Norway. Non-randomized controlled study</td></tr>
<tr><td>Outcome</td><td>Comparison</td><td># of restorations</td><td>Effect size (95% CI) ; P-value</td><td rowspan="3">Author's Conclusions:
The authors concluded that the choice of restorative material affect its survival. They also showed that composite longevity was significantly greater in older patients and in those with a low caries and missing teeth scores. Furthermore, they reported that the risk of failure, in composite restorations, was higher in medium/deep cavities compared with shallow cavities.</td></tr>
<tr><td>Failure</td><td>Amalgam vs. composite</td><td>13/184 vs. 407/3286</td><td>Not reported; P = 0.02 indicating superior survival of amalgam</td></tr>
<tr><td>Secondary caries</td><td>Amalgam vs. composite</td><td>9/184 vs. 301/3286</td><td>Not reported</td></tr>
<tr><td colspan="5">American Academy of Pediatric Dentistry 2014.[17] USA. Clinical Guidelines</td></tr>
<tr><td colspan="5">Recommendations related to composite resin restorative materials:
• "In primary molars, there is strong evidence that composite resins are successful when used in Class I restorations. For Class II lesions in primary teeth, there is one randomized controlled trial showing success of composite resin restorations for two years.
• In permanent molars, there is strong evidence indicated that composite resins can be used successfully for Class I and II restorations.
• Evidence from a meta-analysis shows enamel and dentin bonding agents decrease marginal staining and detectable margins for the different types of composites." (page 236)
Recommendations related to amalgam restorative materials:
"There is strong evidence that dental amalgam is efficacious in the restoration of Class I and Class II cavity restorations in primary and permanent teeth." (page 233)</td></tr>
</table>