

Concise Review

Alternative Direct Restorative Materials for Dental Amalgam: A Concise Review Based on an FDI Policy Statement

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ABSTRACT

Dental restorative procedures remain a cornerstone of dental practice, and for many decades, dental amalgam was the most frequently employed material. However, its use is declining, mainly driven by its poor aesthetics and by the development of tooth-coloured adhesive materials. Furthermore, the Minamata Convention agreed on a phase-down on the use of dental amalgam. This concise review is based on a FDI Policy Statement which provides guidance on the selection of direct restorative materials as alternatives to amalgam. The Policy Statement was informed by current literature, identified mainly from PubMed and the internet. Ultimately, dental, oral, and patient factors should be considered when choosing the best material for each individual case. Dental factors include the dentition, tooth type, and cavity class and extension; oral aspects comprise caries risk profiles and related risk factors; and patient-related aspects include systemic risks/medical conditions such as allergies towards certain materials as well as compliance. Special protective measures (eg, a no-touch technique, blue light protection) are required when handling resin-based materials, and copious water spray is recommended when adjusting or removing restorative materials. Cost and reimbursement policies may need to be considered when amalgam alternatives are used, and the material recommendation requires the informed consent of the patient. There is no single material which can replace amalgam in all applications; different materials are needed for different situations. The policy statement recommends using a patient-centred rather than purely a material-centred approach. Further research is needed to improve overall material properties, the clinical performance, the impact on the environment, and cost-effectiveness of all alternative materials.

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Introduction

Dental restorative procedures remain a cornerstone of dental practice. Daily, millions of dental restorations are placed worldwide because of the persistently high burden of cavitated dental caries in both primary and permanent teeth. Despite preventive efforts being widely implemented in many health care systems, untreated caries in permanent teeth affected 2.5 billion people in 2019; untreated caries in deciduous teeth affected 573 million children.¹ Whilst non-restorative strategies can arrest early dental caries, many

caries lesions progress to cavitation and require restorative intervention to reinstate cleansability, form, and function of teeth. Moreover, many restorative procedures are the result of failed restorations; restoration replacement accounts for more than half of the restorations placed by dental practitioners.²

For more than a century, dental amalgam was the most frequently employed material to restore dental cavities, especially in posterior teeth. Recognised advantages of this material were its comparatively high longevity, low technique sensitivity, and a favorable cost-benefit ratio.^{3,4} Although amalgam has been demonstrated to show acceptable health risk,^{5,6} its use is declining worldwide, mainly driven by its poor aesthetics⁷ compared to tooth-coloured and adhesive materials that have been developed and tested. Furthermore, the Minamata Convention, signed in 2013 and entered into force in 2017, aims to reduce mercury emissions into the environment. For dental amalgam, a general phase-down of its use was agreed upon.⁸ The Conference of Parties (COP), a regular follow-up conference designed to decide on further measures related to the Minamata Convention, ruled on more stringent provisions in 2022 (COP 4), namely to not allow the use of

- Mercury in bulk form by dental practitioners
- Dental amalgam for the dental treatment of (1) deciduous teeth, (2) patients younger than 15 years, and (3) pregnant and breastfeeding persons, except when considered necessary by the dental practitioner based on the needs of the patient⁹

In this context, several meta-analyses and other reviews have addressed the question of which restorative material could possibly be used as an alternative to amalgam or to even to replace amalgam. It became evident that the clinical outcome of a particular restorative therapy does not only depend on a specific material, but other aspects must be considered when choosing the best material for each individual case.^{10,11} In 2023, FDI adopted a Policy Statement providing guidance on factors to be considered when choosing direct restorative materials as alternatives to amalgam (<https://fdiworlddental.org/alternative-direct-restorative-materials-dental-amalgam>). The present piece presents this Policy Statement and provides background information and some more in-depth discussion around issues of dental amalgam alternatives relevant to dental practitioners, patients, and policymakers.

Available materials

In recent years, many different tooth-coloured materials have been developed and marketed. They can be classified into the following groups.

Resin-based materials set exclusively by polymerisation. These are the classic (incrementally placed) resin composites but also bulk fill materials which allow for an increased polymerisation depth of up to 4 to 5 mm. Polymerisation can be initiated by light, chemical (2 component materials), or both. These materials are used with an

adhesion technique. More recently, self-adhesive resin composites have been marketed which do not require separate treatment steps to promote adhesion to dental hard tissue. Polymerisation initiation by light requires blue light-emitting curing units used with appropriate patient and operator protections.¹²

Glass ionomer cements (also named polyalkenoate cements) set exclusively by an acid-base reaction. They develop a chemical bond to dental hard tissues; pretreatment of dental hard tissues with polyacrylic acid may improve adhesion. Materials with low and high viscosity are available. Recent developments (termed glass hybrids by some manufacturers) involve glass particles of different size and are supposed to come with improved physical properties. Coverage of glass ionomers with resin-based materials has also been proposed to improve their acid- and wear-resistance and aesthetics.

Resin materials combined with components of glass ionomer cements are available, with examples including compomers (polyacid-modified composites) mainly setting by polymerisation and resin-modified glass ionomer cements setting through polymerisation and acid-base reactions. Generally, the more the material relies on polymerisation, the more it is used together with an adhesive system.

Recently, a new group of tooth-coloured restorative materials has been marketed which are mainly based on resin chemistry but have additional properties, often the release of certain ions such as fluoride, calcium, and hydroxide ions. This ion release is claimed to have a positive effect on secondary caries.

All these alternatives have a range of physical and chemical properties that influence their application and longevity. It should be kept in mind that the final properties of the restoration strongly depend on the handling procedure and environmental factors (see below).

Considerations for choosing alternatives

A wide range of factors have been identified that affect clinical success of direct restorations. These factors, jointly, were demonstrated to override material properties when it comes to their impact on restoration longevity.^{10,11,13,14} Overall, dental practitioners should assess these factors systematically and comprehensively, considering them when choosing direct amalgam alternative materials. Here, we distinguish amongst factors on dental, oral, and patient levels.

Dental-level factors

Tooth type

Two clinical studies have directly compared amalgam and resin-based composite materials in children aged 6 to 12 years including *primary teeth*.^{15,16} Both studies showed a significantly higher failure rate of resin-based materials compared to amalgam, especially in cavities involving 3 or more surfaces. However, it should be considered that primary teeth have a limited life-span in the mouth¹⁷ and a retrospective practice-based study reported 5-year cumulative survival rates of 43% for resin-based composite and 49% for compomer restorations, respectively.¹⁸ This means that for those materials,

on average, each restoration will be replaced once during the lifetime of a primary tooth, with differences between amalgam and resin-based materials likely being clinically irrelevant, especially compared to permanent teeth. This was one reason that the Scientific Committee of the EU (SCENIHR) found amalgam not to be the first choice for restoring cavities in primary teeth,⁶ which is in line with the abovementioned decision of Minamata COP 4 regarding primary teeth.⁹ Rather, resin-based materials including compomers and resin modified glass ionomers or stainless-steel crowns are recommended.¹⁷ Also, glass ionomer cements have been shown suitable, particularly for Class I cavities (see below).

Size and location of the planned restoration

For *permanent teeth*, data from Finland on mainly resin composite restorations have shown longer median survival times and lower failure rates for premolars compared to molars and for 2-surface compared to 3-surface restorations.¹⁹ This indicates that the occlusal load and the size of the cavity have an influence on the longevity of a restoration, whilst this impact differs for different amalgam alternatives,^{10,11,19} as will be delineated in more detail below.

Class I cavities

There is general agreement that in Class I cavities the longevity of alternative materials including glass ionomer cements, resin composites, and combination materials is like that of amalgam. Mechanical limitations such as reduced flexural strength of glass ionomer cements²⁰ are not of prime clinical relevance in such cases. However, glass ionomer cements and combination materials may show increased (erosive) wear (see below). The placement of high-viscosity glass ionomers in the atraumatic restorative technique shows an acceptable performance for Class I cavities,²¹ whilst for Class II cavities data are equivocal.

Class II cavities

A Class II (occlusal/approximal) cavity comprises—in contrast to Class I—a large group of different clinical situations ranging from small 2-surface cavities in premolars to large 3- up to 5-surface cavities in molars, often with deep subgingival extensions of the approximal cavity floor. These variables must be considered when choosing a suitable material.

The larger extension of the material from the occlusal to the approximal area requires adequate mechanical properties, such as flexural strength, to avoid bulk fractures. According to ISO 4049, the flexural strength of composites should be at least 80 MPa to minimise the risk of fractures. A recent study on mechanical properties—including flexural strength parameters—showed significantly lower values for glass ionomers, including their more recent generations, the glass hybrids (33 MPa compared to a resin composite with 115 MPa).²⁰ Clinical data, however, have found this material class to display similar results in Class II cavities as resin-based composites.²² Similarly, another study reported positive clinical results after 5 years in “small Class II cavities.”²³ However, data remain ambiguous, with another clinical study finding conventional resin composites more successful in Class II cavities.²⁴ The discussed positive results were mainly achieved with one specific (glass hybrid) product, which may

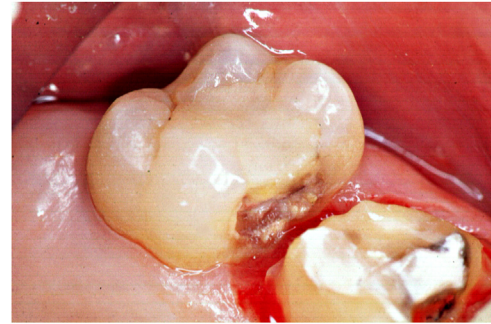


Fig – A secondary caries lesion adjacent to a restoration. It is not always clear whether the lesion developed due to the defective restoration or due to the high caries risk of the patient. Both the patient-related factors as well as those related to the restorative material must be taken into consideration when selecting an alternative to amalgam.

not be representative for the whole glass ionomer material group. A recent meta-analysis showed that compomer and glass ionomer restorations demonstrated considerable shortcomings and had a significantly shorter longevity than resin-based composites.²⁵

(Erosive) tooth wear

A further aspect to be considered in this context is (erosive) wear. Glass ionomer cements are especially prone to surface corrosion when exposed to acids like 1.23% acidulated phosphate fluoride gel and citric acid at pH 2.6. Thus, low pH within a biofilm may affect the surface of a glass ionomer cement restoration.^{26,27} Additionally, mechanical wear due to mastication may lead to a more rapid loss of anatomic form compared to resin composites.^{25,28} These aspects are main reasons for the idea of covering glass ionomers with a resin-based coating.²⁹

Subgingival extension of the approximal cavity floor

Another special aspect of Class II cavities is the extension of the cavity floor into the gingival sulcus. This generates challenges to adequate moisture control, which may be especially a problem for moisture/contamination sensitive materials such as dental adhesives required for resin composites.³⁰ Furthermore, accessibility may be restricted, which challenges placement of the matrix band and obtaining sufficient light-curing,³¹ increasing the risk for microleakage³² and secondary caries (Figure). Notably, laboratory studies found more biofilm formation on resin-based materials compared to amalgam, which may contribute to increased secondary caries³³ around resin composites and influence the health of the neighbouring periodontal tissues. Subgingival restorations in general lead to a greater accumulation of biofilm, local inflammation, and clinical attachment loss.³⁴ Another study reported that resin composite restorations may have negative effects on the quantity and quality of subgingival biofilm.³⁵ Therefore, special techniques have been described, such as the open sandwich technique, to overcome the problems.³⁰

However, such techniques add to the treatment time and have shown mixed results.²⁶

Pulp reactions

Although resin-based materials are cytotoxic and cause an intracellular redox imbalance,^{36,37} in shallow and medium cavities—just as with amalgam—they do not cause significant adverse pulp reactions if bacterial penetration is prohibited.³⁸ Data for the use of resin-based materials in deep cavities are controversial.³⁸ For pulp exposures, which are sometimes difficult to diagnose (eg, if the tooth is anaesthetised with decreased blood flow), pulp inflammation has been described after application of resin-based materials including adhesives.^{38,39} Furthermore, monomers eluted from resin-based materials are genotoxic due to their ability to cause a redox imbalance,⁴⁰ and consequently, intracellular adaptive mechanisms to compensate this effect are initiated.⁴¹ This causes cellular stress and inhibits biomineralisation, potentially preventing dentin bridge formation.⁴² Although glass ionomer cements are mainly considered to have low cytotoxicity, they nevertheless elicit a pulp reaction in direct contact with the exposed pulp, probably due to incomplete setting when in contact with a wet surface (pulp tissue).³⁸ Resin-free tricalcium silicate formulations do not provoke major inflammation and induce dentin bridge formation.⁴³

Presence of endodontic treatment

It is well established that the success of conventional root canal treatment requires proper restorative treatment of the tooth. These teeth may exhibit large amounts of hard tooth substance loss or cracks. Also, bacterial penetration through coronal leakage should be prevented,⁴⁴ which may be a problem especially in large cavities.⁴⁴ Especially in these situations, indirect restoration should be considered as preferred to all direct filling techniques.⁴⁴ When restored directly, higher fracture rates are found for teeth restored with glass ionomers than composites.⁴⁵

Oral-level factors

Caries risk

Secondary caries is often identified as a major cause of resin-based restoration failure.^{7,11,15,16,27,46} Monomers, such as triethylene glycol dimethacrylate (TEGDMA) or hydroxyethyl methacrylate (HEMA), which are released from some resin composites, have been shown to enhance bacterial biomass.²⁷ Therefore, the consideration of an individual's caries risk is highly relevant when choosing amalgam alternatives. The dental practitioner should assess a patient's oral hygiene, dietary factors, fluoride intake, saliva flow, and medical conditions before placing a restoration and should aim to modify them advantageously during active and supportive care. Adequate oral hygiene and a diet avoiding high carbohydrate consumption are the cornerstones to (secondary) caries prevention,⁴⁷ which becomes especially relevant when using resin composite materials. Overall, restorative treatment using amalgam alternatives must be integrated into a management concept focussing on prevention. Notably, glass ionomer restorations are less prone to secondary caries,^{27,48} probably due to their fluoride release, whilst the clinical

relevance of this release for adjacent tissue or teeth may be limited.⁴⁹

Special risk groups

Some patient groups are less able to cooperate during dental treatment and to perform adequate oral hygiene themselves, such as *patients with disabilities*.⁵⁰ The caries rate in this patient group is heterogeneous and depends on the disability and the level of care provided. The number of untreated caries lesions has been reported to be significantly higher in individuals with disabilities than in the general population,⁵⁰ particularly in those with intellectual disabilities.⁵¹ Here, treatment strategies need to be adapted accordingly to include an intensive prevention program and special assistance. Materials which are prone to bacterial accumulation may not be the first choice, and glass ionomers, potentially placed in the ART technique, may be an alternative to amalgam. However, more high-quality clinical evidence is needed.⁵²

Inconsistent with the general population, *elderly patients* experience consistent or even increased caries rates.^{11,53} Possible reasons may be a reduced ability to perform adequate oral hygiene and exposed root surfaces due to periodontal diseases, factors that significantly increase the risk for secondary caries.^{53,54} Reduced salivary flow due to age per se or due to multiple medications common in the geriatric population add to the high risk of (secondary) caries.^{55,56} Also, complicated procedures that require longer treatment times and the protection of the operative field against contamination, things common for virtually all alternative materials and especially for resin composites,⁵⁷ are difficult to execute.

Postradiation patients often experienced a strongly reduced or totally lacking salivary flow rate that contributes to increased caries rates.⁵⁸ In such patients, alternative materials such as resin composites with a comparatively high biofilm accumulation²⁷ may further enhance the high risk of failure due to secondary caries in such patients. Generally, clinical evidence for longevity of amalgam alternatives for special risk groups is sparse.

Bruxism and tooth wear patients aggravate the mechanical demands made on restorative materials and demonstrate increased failure due to fracture. Material fracture properties should be reflected upon accordingly when choosing a material.¹¹

To compensate for some alternative materials' propensity to accumulate biofilm and thus to be prone to secondary caries, so-called bioactive materials have been marketed. In 2022, the FDI adopted a Policy Statement that had an accompanying publication,⁵⁹ where the prerequisites for a truly bioactive restorative material were delineated. So far, the clinical evidence for any claims of "true" bioactivity remains low; data for the effects of any bioactive materials in the abovementioned special risk groups are even more scarce.

Patient-level factors

A major concern for restorative materials at the patient level is their biocompatibility; for amalgam, this has been a topic of discussion over many years. Adverse reactions have been claimed by patients for virtually all restorative materials.⁶⁰ However, the incidence of such reactions for all materials

and the whole population is estimated to be <0.3%, with most of these being allergic or local reactions.⁶ Notably, the frequency of such effects in dental professionals is much higher and mainly related to latex and resin monomers.^{6,61,62} For glass ionomer cements, no such adverse reactions have been verified so far.

Allergies

Several allergy cases (mainly type IV [prolonged, cell-mediated] reactions) in the presence of resin-based materials have been reported for dental professionals but also patients.³⁸ Mainly HEMA and TEGDMA but also bisphenol A-glycidyl methacrylate (bis-GMA) have been identified as responsible allergens.^{38,62} Generally, a “no-touch technique” intended to preclude direct contact when handling these materials is recommended for dental professionals.⁶³

Nanoparticles

Nanoparticles (size 1 to 100 nm) are released during grinding/polishing and removal of restorative materials, even if the material itself does not inherently contain such particles.^{64,65} This has been especially analysed for resin-based materials. The main exposure routes are inhalation and swallowing. Risk assessment based on the estimated exposure scenario showed that the risk for both patients and dental professionals is acceptable. However, protective measures such as the use of masks and water coolants with high volume suction are recommended.^{64,65}

Endocrine disruptors

Bisphenol A is considered an endocrine disruptor, which acts like an estrogen, binding on relevant cell receptors.⁶⁶ It is not added directly into dental resin materials but may be released as an impurity from materials based on bis-GMA or similar monomers (especially bis-DMA).⁶⁷⁻⁶⁹ Measurements of released BPA revealed concentrations 2500 times below the limit established by the European Union in 2015 (5 µg/kg body weight).⁶⁷ However, in 2023, the European Food Safety Authority (EFSA) reduced this limit by a factor of 20,000.⁷⁰ This decision has been challenged by the European Medicines Agency (EMA), but no final decision has been made as of this writing. Such a reduction in safety thresholds will affect the risk assessment of these resin-based materials. In addition to BPA, other substances in resin composites, such as the photostabiliser HMBP and photoinitiator DMPA, exert estrogenic activity to some degree.⁷¹

Environment

As was stated above, the Minamata Convention addressed adverse effects of mercury for the environment, which then indirectly may affect human health. In this context, amalgam has been regulated.^{8,9} When considering alternative materials, possible effects on the environment should also be considered. In 2015, the European Commission Scientific Committee on Health and Environmental Risks (SCHER) commented on the possible environmental impact of resin monomers and found it reasonable to assume that the ecological risk is low. However, it is the opinion of the SCHER that, at present, there is no scientific evidence supporting these statements, and more research on alternative materials is recommended.⁷²

Leachable molecules from resin composites may also reach the environment through wastewater. BPA was detected after leaching different resin composite disks in water.^{67,73,74} Agonistic estrogenic activity was also found for the photostabiliser HMBP and photoinitiator DMPA.⁷¹ Leachates from resin composites showed significant agonistic estrogenic activity.⁷¹ Whilst Reidelbach et al⁷⁵ did not find estrogenic activity for dust from resin composites, they demonstrated bactericidal and cytotoxic effects of such dusts released into wastewater.

Apparently, leachates from alternative materials containing resin monomers can reach the environment and *in vitro* studies have demonstrated several biological effects. However, the clinical relevance of these data is still to be determined.

Reimbursement system

Specific alternative materials come with different material costs and requirements during placement. Generally, most restorations using amalgam alternatives are more expensive than those using,^{76,77} which is why amalgam remains popular in many settings with limited oral health resources. More important than the material costs are the costs associated with placing different materials.⁷⁶ Whilst manufacturers have sought to ease the complexity of placement techniques, some require a multistep process, which is a technique that is sensitive and relies on appropriate equipment and treatment conditions. Local regulations and insurance reimbursement policies reflect the associated costs and the preference of policymakers.⁷⁸

Informed consent

As the group of amalgam alternative materials is rather heterogeneous and as its indication strongly depends on several parameters as listed above, it is of utmost importance to inform the patient properly and to respond to the patient's expectations and demands towards a material.⁴⁶ Information provided should include the advantages and disadvantages of specific materials, reflecting on the determined caries and overall risk and the lesion-specific aspects described above.⁴⁶ This is the basis for joint decision-making between patient and dental practitioner in the specific clinical setting and taking legal regulations into account.⁴⁶ The FDI Policy Statement on alternative materials may be used as a template for communication with the patient.

Further basic and clinical research

Despite a history of multiple decades of research in developing and testing amalgam alternatives, progress has been incremental, focusing on things such as simplifying steps when placing resin composites (eg, 1-step self-etch adhesives and bulk fill technologies). Other approaches aimed to reduce resin shrinkage^{79,80} or improve the physicochemical properties of glass ionomer cements. These are interesting approaches, but overall, the clinical evidence supporting the impact of these efforts remains limited.

More importantly, these steps have not led to any one of these materials being a fully universal amalgam replacement; the described limitations of each material class remain,

although they are partially mitigated, and impact the individual clinical indication. Further basic and clinical research is needed to improve overall material properties and to demonstrate their clinical performance (particularly in real-world settings and for special risk groups).¹¹ Greater understanding of the wider impact of using these materials in terms of implementation and oral health economics is needed.

Conclusions

It has become apparent that, currently, there is no single material which can replace amalgam in all applications. Therefore, a range of materials are needed, with different materials being indicated for different situations. In their Policy Statement, FDI recommends:

- Using a patient-centred approach instead of a purely material-centred approach when selecting a restorative material, taking individual and material factors into consideration, including:
 - o Location and size of the planned restoration, as these impact the required physical and biological properties of the material;
 - o Caries risk of the individual as ion-/fluoride-releasing materials may be preferred in high-risk individuals;
 - o Systemic risk and medical conditions including allergies as alternative materials (specifically resin-containing ones) may induce allergic reactions;
 - o Protection of the provider by use of a no-touch technique when handling resin-based materials, as well as relevant physical, chemical, and biological personal protective measures including protection against blue light emitted from curing devices;
 - o Use of copious water spray when adjusting or removing restorative materials for sufficient cooling and to mitigate the presence of nanoparticles;
 - o Cost and reimbursement policies for placing different materials in different countries;
 - o Patients' expectations and demands as the material of choice should be the result of shared decision-making;
 - o Informed consent for using a specific material should be sought.
- Further research is needed to improve overall material properties and, eventually, their clinical performance and cost-effectiveness.
- Oral health professionals are encouraged to remain up-to-date as research continues.

Conflict of interest

F. Schwendicke is lecturing for GC, 3M, DMG, and Dentsply Sirona on various dental materials mentioned in this text. All other authors declare no conflict of interest.

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Author contributions

G. Schmalz, R. Hickel, R.B. Price, and J.A. Platt contributed to conception, design, and data acquisition and interpretation and drafted and critically revised manuscript. G. Schmalz and F. Schwendicke contributed equally to this work. All authors gave final approval and agree to be accountable for all aspects of the work.

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