

Re: Information on Non-Mercury Alternatives to Dental Amalgam

Dear Executive Secretary Stankiewicz:

Because the non-mercury alternatives are available, technically feasible, economically feasible, and offer environmental and health benefits, the World Alliance for Mercury-Free Dentistry supports the accelerated worldwide transition to dentistry without mercury

We invite the Minamata Secretariat to consider the evidence summarized below and detailed in the accompanying scientific literature review.

Mercury-free dental fillings are available

A variety of mercury-free dental fillings, including composites and glass ionomers, are widely available today. As a result, a growing number of countries – including countries with people at high caries risk, lower-income people, and other people with a diverse array of circumstances – have already made significant progress in phasing down and phasing out amalgam use. For example:

- ***Countries that are phasing out amalgam use:*** Czech Republic¹, Denmark², Finland³, Ireland⁴, Japan⁵, Moldova⁶, Nepal⁷, Netherlands⁸, New Caledonia (independent French territory)⁹, Norway¹⁰, Philippines¹¹, Slovakia¹², Sweden¹³, and Suriname¹⁴ have phased out amalgam use, announced plans for phasing out amalgam use, or use de minimis amounts of amalgam.
- ***Countries that are ending amalgam use in children:*** Denmark¹⁵, the European Union¹⁶, Mauritius¹⁷, Nepal¹⁸, Philippines¹⁹, Tanzania²⁰, Sweden²¹, and Vietnam²² have ended or are ending amalgam use in children specifically. (Several of these countries are also ending amalgam use in pregnant women, women of childbearing age, or breastfeeding mothers.)
- ***Countries that are ending amalgam use in programs:*** As called for in provision (vi) and (vii) of Annex A-II, which highlights the key role of programs in the transition to mercury-free dentistry, Bangladesh's armed forces²³, Indonesia's national health insurance²⁴, and Mongolia's ban on amalgam procurement²⁵ have ended amalgam use via these government programs. The Cameroon Baptist Convention hospital system's network of dental clinics – which provided oral care to approximately 47,000 in 2016 – phased out amalgam use more than a decade ago.²⁶

This widespread progress is possible because high quality mercury-free alternatives to dental amalgam are available today.

Mercury-free dental fillings are technically feasible

Mercury-free dental fillings are technically feasible – and *superior* to dental amalgam:

- ***Mercury-free fillings are long lasting:*** Recent studies show that composites last as long as – and even longer than – amalgam.^{27,28,29,30,31,32,33} Government scientific panels have agreed; as the European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) explains, “some recent studies from the Netherlands, Sweden and Denmark showed very good long-term clinical effectiveness for posterior resin composite restorations with equal and better longevity than for amalgam.”³⁴ Between the irrelevancy of filling longevity in short-lived milk teeth³⁵ and amalgam’s higher failure rates in these teeth^{36,37}, using amalgam instead of mercury-free fillings in children can longer be justified.
- ***Mercury-free fillings facilitate future repairs:*** Studies clearly show that it is easier to repair a composite than an amalgam, which can increase longevity of the filling, increase longevity of the tooth, and reduce costs.^{38,39,40}
- ***Mercury-free fillings are user-friendly:*** Mercury-free fillings are also user-friendly for dentists. As a result, studies show there is only a negligible difference, if any, between amalgam and composite when it comes to the treatment time spent by the dentist^{41,42,43,44,45}, which confirms that mercury-free fillings should not entail additional labor costs. Despite scientific studies, some dentists might still claim a minor difference in the time it takes to place mercury-free fillings and amalgam. But any difference may be accounted for by tooth structure that has already been damaged by amalgam. As explained in the BIOIS report, “the time required for a composite to replace a previous amalgam restoration is higher than for replacing a composite filling: a cavity originally prepared to receive an amalgam filling is typically larger and distinguished by various angles that would never be prepared for a composite, rendering the placement of a composite more difficult and time-consuming than it would otherwise have been.”⁴⁶

Mercury-free dental fillings are economically feasible

Mercury-free dental fillings are economically feasible – and more accessible in lower-income areas without electricity.

- ***The technical superiority of mercury-free alternatives eliminates cost differences:*** Because composite fillings can last as long – or even longer – than amalgam, a European Commission report concluded, “Given the results of recent studies comparing the longevity of different materials, in the present study it is considered that the longevity of Hg-free fillings is no longer a factor with significant effect on the overall cost difference between dental amalgam and composite or glass ionomer restorations.”⁴⁷ Because it is easier to repair composite, mercury-free fillings can be repaired more economically than amalgam can be repaired or replaced. Because there is only a negligible difference, if any, between amalgam and composite when it comes to the treatment time spent by the dentist, mercury-free fillings should not entail additional labor costs.
- ***Mercury-free filling techniques can be less expensive and more accessible:*** Atraumatic restorative treatment (ART) is a low-cost technique that relies on glass ionomer for the filling material and uses only hand instruments to place the filling. While not appropriate for all cavities, studies have shown that when it is appropriate this mercury-free technique is less expensive than dental amalgam, especially for children (who tend to have smaller caries).⁴⁸ As a Pan American Health Organization report explains, “The costs of employing the PRAT approach for dental caries treatment, including retreatment, are roughly half the cost of amalgam without retreatment.”⁴⁹ Because this technique does not require electricity, it also makes mercury-free fillings more accessible than amalgam (which often requires two visits to place and polish properly and specialized equipment like amalgamators and separators).

- ***Mercury-free fillings eliminate the high environmental costs of dental mercury that governments (not dentists) must bear:*** Studies have concluded that after environmental costs are factored in, dental amalgam is more expensive than mercury-free fillings.^{50,51} Amalgam separators cannot eliminate the environmental costs of amalgam because this technology does not address all routes by which dental mercury enters the environment, it is costly to enforce separator laws, and many countries do not have the infrastructure to collect, transport, and store amalgam waste. But use of mercury-free alternatives would eliminate the costs of dental mercury.

Mercury-free dental fillings offer environmental and health benefits


In addition to their technical and economic advantages, mercury-free dental fillings offer important environmental and health benefits even beyond eliminating the many risks of mercury exposure, including:

- ***Mercury-free fillings preserve tooth structure:*** Researchers and governments – as well as many dentists and dental authorities – have agreed that preparation for amalgam placement results in a greater loss of healthy tooth tissue than placement of mercury-free fillings. As a result, amalgam preparation and amalgam placement weaken tooth structure. Conversely, mercury-free fillings preserve tooth structure, which can increase the longevity of the tooth itself – and save the patient the additional costs of more extensive restorative dental treatment in the future.^{52,53,54,55,56,57,58,59,60,61,62}
- ***Mercury-free fillings can help prevent future caries:*** Studies show mercury-free fillings can help prevent costly caries in the future. Glass ionomers release fluoride that can help prevent caries^{63,64} and composites placement can incorporate preventive measures like the sealing of adjacent pits and fissures.⁶⁵
- ***Studies show that mercury-free fillings are safe for health and the environment:*** One of the health and environmental benefits of mercury-free fillings is that there is no evidence of harm. The mercury-free alternatives to dental amalgam have been studied for more than half a century.⁶⁶ During that time, studies and government health authorities have repeatedly conducted risk assessments that confirm mercury-free dental fillings are safe.^{67,68,69,70,71,72,73,74,75,76,77}

Conclusion

First, the evidence clearly demonstrates that non-mercury alternatives are available, technically feasible, economically feasible, and offer environmental and health benefits. Second, with the increasing costs of mercury and silver, the increasing evidence of mercury's risks, and the increasingly heavy burden that amalgam waste and pollution puts on governments, the infeasibility and disadvantages of amalgam become clearer each year.

Sincerely,



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Attachment – Scientific Literature Review

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- ⁶³ Mickenautsch S, Yengopal V. *Absence of carious lesions at margins of glass-ionomer cement and amalgam restorations: An update of systematic review evidence*. BMC Research Notes. 2011;4:58. <https://bmcresnotes.biomedcentral.com/articles/10.1186/1756-0500-4-58>
- ⁶⁴ Mandari GJ, Mandari GJ, Frencken JE, Frencken JE, van't Hof MA, van't Hof MA: *Six-Year Success Rates of Occlusal Amalgam and Glass-Ionomer Restorations Placed Using Three Minimal Intervention Approaches*. Caries Res 2003;37:246-253, <http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowAbstract&ProduktNr=224219&Ausgabe=229216&ArtikelNr=70866> (abstract)
- ⁶⁵ Lynch et. al., *Managing the phase-down of amalgam: part I. Educational and training issues*, British Dental Journal (Aug. 2013).
- ⁶⁶ Jack L Ferracane, *Resin composite--state of the art*, DENTAL MATERIALS, Vol.27, issue 1, p.29-38 (Jan. 2011), <http://www.ppgoufma.br/uploads/files/Dental%20materials%20official%20publication%20of%20the%20Academy%20of%20Dental%20Materials%202010%20FerracaneResin%20composite-State%20of%20the%20art.pdf>:
- ⁶⁷ European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), *Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users* (29 April 2015), http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf, pp.73,74
- ⁶⁸ European Commission Scientific Committee on Emerging and Newly Identified Health Risks. *Opinion on the safety of the use of bisphenol A in medical devices* (2015), https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_040.pdf, pp. 10, 15-16, 30, 44
- ⁶⁹ Scientific Committee on Health and Environmental Risks (SCHER), *Opinion on the Environmental Risks and Indirect Health Effects of Mercury from Dental Amalgam* (2014): http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_165.pdf, p5
- SCHER (2014): http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_165.pdf
- ⁷⁰ Health Care Research Collaborative of the University of Illinois at Chicago School of Public Health, the Healthier Hospitals Initiative, and Health Care Without Harm, *Mercury in Dental Amalgam and Resin-Based Alternatives: A Comparative Health Risk Evaluation* (June 2012), https://www.wfpha.org/tl_files/images/Newsletter%202012/July/Res%20Colab%20Amalgam%20Risk%20Final.pdf.6
- ⁷¹ Chen & Suh, *Bisphenol A in Dental Materials: A Review*, JSM Dent 1:1004 (2013), <http://www.jsimedcentral.com/Dentistry/Articles/dentistry-1-1004.pdf>
- ⁷² Yin et. al., *Associations of blood mercury, inorganic mercury, methylmercury and bisphenol A with dental surface restorations in the U.S. population*, NHANES 2003–2004 and 2010–2012, Ecotoxicity and Environmental Safety (2016), <https://www.ncbi.nlm.nih.gov/pubmed/27639196>
- ⁷³ Berge, T.L.L., Lygre, G.B., Lie, S.A. et al. *Polymer-based dental filling materials placed during pregnancy and risk to the fetus*. BMC Oral Health 18, 144 (2018). <https://doi.org/10.1186/s12903-018-0608-1>, <https://link.springer.com/article/10.1186/s12903-018-0608-1>
- ⁷⁴ European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids, *Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs*, <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.3978>, p.54
- ⁷⁵ BIO Intelligence Service (2012), *Study on the potential for reducing mercury pollution from dental amalgam and batteries*, Final report prepared for the European Commission-DG ENV, <http://bookshop.europa.eu/en/study-on-the-potential-for-reducing-mercury-pollution-from-dental-amalgam-and-batteries-pbKH3013440/>, p.78-79
- ⁷⁶ KEMI, Bisfenol A (2/11), http://www.kemi.se/Documents/Publikationer/Trycksaker/Rapporter/Rapport2_11_BisfenolA.pdf, page 9
- ⁷⁷ Joint FAO/WHO Expert Meeting to Review Toxicological and Health Aspects of Bisphenol A, Summary Report (2010), http://www.who.int/foodsafety/chem/chemicals/BPA_Summary2010.pdf



Scientific Literature Review:

The Availability, Technical and Economic Feasibility, and Environmental and Health Benefits of Mercury-Free Dental Fillings

A. Availability of Mercury-Free Dental Fillings

A variety of mercury-free dental fillings, like composites and glass ionomers, are widely available today. As a result, a growing number of countries – including countries with people at high caries risk, lower-income people, and other people with a diverse array of circumstances – have already made significant progress in phasing down and phasing out amalgam use. For example:

- **Bangladesh:** The Bangladeshi armed forces have taken steps that would limit procurement of amalgam, which would effectively phase down its use. The Bangladesh Army Dental Corps ended new procurement of dental amalgam in January 2018, a decision that circulated to all forces including the army, navy, air force and Border Guards Bangladesh (BGB) – about 1.5 million persons under treatment.¹
- **Cameroon:** The Cameroon Baptist Convention hospital system’s network of dental clinics – which provided oral care to approximately 47,000 in 2016 – phased out amalgam use more than a decade ago.²
- **Denmark:** Since 1999 the use of dental amalgam in frontal teeth and children’s milk teeth has been banned in Denmark.³ Denmark now uses dental amalgam for only 1.7% of all dental fillings.⁴
- **European Union:** The European Union banned amalgam use in children under age 15, pregnant women, and breastfeeding mothers as of July 1, 2018 with narrow exceptions: “From 1 July 2018, dental amalgam shall not be used for dental treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.”⁵
- **Finland:** Since 1994, Finland has had national recommendations that amalgam should not be used in restorations. The use of amalgam was significantly reduced after these

recommendations were issued. In 2012, amalgam use was estimated at 3% of dental restorations in Finland with a current annual use of 150 kg of mercury.⁶ By 2019, amalgam accounted for “considerably less than 1%” of all restorative materials used in Finland.⁷ In 2019, Finland announced its plans to phase out amalgam use.⁸

- **France:** New Caledonia, in France, no longer uses dental amalgam.⁹
- **Hungary:** In Hungary, the 2008 national inspectorate of dentists’ recommendation on dental restoration materials does not advise using dental amalgam in new dental restorations.¹⁰
- **Japan:** Amalgam was used in approximately 11% of all dental restorations in the 1980s, declining to less than 4% in the 1990s. In 2010 only 20 kg of mercury were used in dentistry.¹¹
- **Mauritius:** A decade ago, the Ministry of Health and Quality of Life made the decision to phase out the use of amalgam for pregnant women and children under 10 years old. Since then, there has been a significant reduction in the number of school children receiving amalgam fillings.¹²
- **Mongolia:** Mongolia has taken steps to limit procurement of amalgam. On 11 January 2011 a joint order of the Minister of Health and General Director of the National Emergency Management Agency of Mongolia stated that it had been ordered: “To ban further procurement of the mercury containing thermometer, sphygmomanometer and dental amalgam, beginning January 15, 2011 and to authorize directors of the corresponding organizations and city and provincial health care departments and managers of all level health care organizations to take measures to reduce the use of mercury containing medical equipment and replace them with mercury-free alternatives.”¹³
- **Nepal:** In 2019, Nepal announced that it is phasing out dental amalgam use in two steps. As explained by Nepal’s Ministry of Health and Population, it has made the decision to implement a “Complete ban the use of mercury dental amalgam in pregnant and breast feeding women and children below 15 years.” It then phases out amalgam on a timetable.¹⁴
- **Netherlands:** The average use of amalgam in the 2000s was around 7% of all dental restorative fillings, dropping to less than 1% by 2011.¹⁵
- **Norway:** In 2008 amalgam use was banned with a three year transition period, which has since expired.¹⁶
- **Philippines:** In 2020, the Philippines Department of Health signed an administrative order that phases out dental amalgam in the Philippines in three years. Furthermore, it immediately bans amalgam use in pregnant women, children under the age of 14, breastfeeding mothers, and persons with compromised renal and immune systems.¹⁷
- **Sweden:** By 2012, Sweden phased out amalgam use.¹⁸

- **Tanzania:** Tanzania’s Ministry of Health, Community Development, Gender, Elderly and Children has adopted guidelines that will end amalgam use for children and for women of childbearing age.¹⁹
- **Vietnam:** In 2019, the Ministry of Health’s Health Service Administration Department advised dental offices to stop using amalgam for children under 15, pregnant women, and lactating women by 1 April 2019. It further called for a roadmap to stop using amalgam in dentistry.²⁰

This widespread progress is possible because high quality mercury-free alternatives to dental amalgam are available today.

B. Technical Feasibility of Mercury-Free Dental Fillings

Mercury-free dental fillings are technically feasible, and technically superior, to dental amalgam. Below are examples of studies showing that mercury-free fillings are long-lasting, easier to repair, and user-friendly – all factors that contribute to their technical superiority.

B.1. Mercury-free fillings are long lasting

Recent studies show that composites last as long as amalgam and governmental bodies agree, leaving no cost difference due to durability. For example:

- *Palotie, U., Eronen, A.K., Vehkalahti, K. & Vehkalahti, M.M. 2017, Longevity of 2- and 3-surface restorations in posterior teeth of 25- to 30-year-olds attending public dental Service—A 13-year observation. Journal of Dentistry 62, 13-17, https://helda.helsinki.fi/bitstream/handle/10138/297784/1_s2.0_S0300571217301227_main.pdf?sequence=1&isAllowed=y*
The researchers, following a total of 5542 two- and three-surface posterior composite and amalgam restorations from 2002 to 2015, concluded that “Longevity of posterior composite multisurface restoration is comparable to amalgam longevity.”²¹
- *Vieira AR, Silva MB, Souza KKA, Filho AVA, Rosenblatt A and Modesto A (2017) A Pragmatic Study Shows Failure of Dental Composite Fillings Is Genetically Determined: A Contribution to the Discussion on Dental Amalgams. Front. Med. 4:186. <https://doi.org/10.3389/fmed.2017.00186>.*
“Composite resins for posterior tooth restorations have become a viable alternative to dental amalgam....Our data also show that direct composite resins perform similarly (and maybe slightly better) to amalgam in posterior teeth up to 5 years and are suitable substitutes for their metallic counterparts, making it feasible to completely replace amalgam in dentistry. The justification of using amalgam due to its lower costs alone in contrast to the potential of eliminating an environmental hazard has become harder to

support now that direct composite resins can perform at acceptable levels. Our data come from a large clinic where dentists working are in the beginning of their professional careers. Also, the population treated has some of the worst oral health and overall health indicators in the country (26). The statistically significant lower failure rate of posterior composite resin versus amalgam restorations with 5 years follow-up in our study, despite the fact that direct composite resins are more technique sensitive than amalgam, further suggest that the first can replace the latter.”²²

- *Owen, Benjamin D., et al. Placement and replacement rates of amalgam and composite restorations on posterior teeth in a military population. U.S. Army Medical Department Journal, July-Sept. 2017, p. 88+, <https://europepmc.org/article/med/28853125>*
In this retrospective cross-sectional study of data from 600 randomly selected military patient dental records, “No significant difference was found between composite and amalgam restorations.”²³
- *McCracken MS, Gordan VV, Litaker MS, et al. A 24-month evaluation of amalgam and resin-based composite restorations: Findings from the National Dental Practice-Based Research Network. J Am Dent Assoc. 2013;144(6):583-593, <https://europepmc.org/article/MED/23729455#free-full-text>*
“In this study, the choice of using amalgam or resin-based composite had no meaningful impact on restoration longevity....The early failure rate of direct restorations in this study was 6.6% after an average follow-up of 24 months. There was no evident difference between amalgam and resin-based composite materials.”
- *Heintze, S.D. & Rousson, V. 2012, Clinical effectiveness of direct class II restorations - a meta-analysis, The journal of adhesive dentistry, vol. 14, no. 5, pp. 407-431, https://www.researchgate.net/profile/Siegward_Heintze/publication/232321585_Clinical_Effectiveness_of_Direct_Class_II_Restorations_-_A_Meta-Analysis/links/554a2ea60cf29752ee7c03ba/Clinical-Effectiveness-of-Direct-Class-II-Restorations-A-Meta-Analysis.pdf*
“Data from the last 10 to 20 years indicate that – as far as the longevity is concerned – there is no significant difference between posterior composite resin and amalgam restorations in controlled clinical trials at universities.”²⁴
- *N.J.M. Opdam, E.M. Bronkhorst, B.A.C. Loomans, and M.-C.D.N.J.M. Huysmana, 12-Year Survival of Composite vs. Amalgam Restorations, Journal of Dental Research (October 2010), Vol. 89, 10: pp. 1063-1067, <http://jdr.sagepub.com/content/89/10/1063.abstract>:*
Opdam et. al. (2010) shows that composite lasts as long as amalgam – and actually has a higher overall survival rate. According to a 2010 study over the course of 12 years, “Large composite restorations showed a higher survival in the combined population and in the low-risk group.”²⁵
- *Opdam NJ, Bronkhorst EM, Roeters JM, Loomans BA. A retrospective clinical study on longevity of posterior composite and amalgam restorations. Dent Mater 2007;23(1):2-8, <http://www.ncbi.nlm.nih.gov/pubmed/16417916>:*
Opdam et. al. (2007) did a study comparing amalgam and composite longevity that concluded “Life tables calculated from the data reveal a survival for composite resin of

91.7% at 5 years and 82.2% at 10 years. For amalgam the survival is 89.6% at 5 years and 79.2% at 10 years. Cox-regression analysis resulted in a significant effect of the amount of restored surfaces on the survival of the restorations. No significant effect of operator, material as well as combination of material and operator was found...In the investigated general practice, two dentists obtained comparable longevity for amalgam and composite resin restorations.”²⁶

- *European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users (29 April 2015), http://ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_o_046.pdf, pp.8,10,77:*
The European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) acknowledges that “the quality and durability of alternative materials have improved...The SCENIHR concludes that dental restorative treatment can be adequately ensured by amalgam and alternative types of restorative material. The longevity of restorations of alternative materials in posterior teeth has improved with the continuing development of these materials and the practitioner’s familiarity with effective placement techniques....some recent studies from the Netherlands, Sweden and Denmark showed very good long-term clinical effectiveness for posterior resin composite restorations with equal and better longevity than for amalgam.”²⁷
- *BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, http://ec.europa.eu/environment/chemicals/mercury/pdf/Final_report_11.07.12.pdf, p.69:*
The European Commission’s BIOIS report concluded, “Given the results of recent studies comparing the longevity of different materials, in the present study it is considered that the longevity of Hg-free fillings is no longer a factor with significant effect on the overall cost difference between dental amalgam and composite or glass ionomer restorations.”²⁸
- *World Health Organization, Future Use of Materials for Dental Restoration (2011), http://www.who.int/oral_health/publications/dental_material_2011.pdf, p.11:*
According to this World Health Organization report, “recent data suggest that RBCs [resin-based composites] perform equally well” as amalgam.”²⁹

Studies show that mercury-free alternatives fail less often than amalgams in children’s teeth, which makes them less expensive than amalgam for children:

- *Reinhard Hickel et al., Longevity of occlusally-stressed restorations in posterior primary teeth, AMERICAN JOURNAL OF DENTISTRY, Vol. 18, No. 3, June 2005, <http://www.amjdent.com/Archive/2005/Hickel%20-%20June%202005.pdf> (See Figure 1 and Table 11).*

This study showed that amalgam failure rates are higher in children than in adults. Additionally, the failure rate for amalgam in children is higher than the failure rate for the

major mercury-free fillings in children. “Annual failure rates in stress-bearing cavities of primary molars were determined to be: 0-14% for stainless steel crowns, 0- 35.3% for amalgam restorations, 0-25.8% for glass-ionomer restorations, 2-29.1% for atraumatic restorative treatments, 0-15% for composite restorations, and 0-11 for compomer restorations. Main reasons for failure were secondary caries, marginal deficiencies, fracture, and wear.” As seen in the below table from the study, amalgam has a mean annual failure rate of 7.6% in children’s primary teeth. This high 7.6% failure rate contrasts with 5.9% for composite and 3.3% for compomer, and with only 4.2% for resin-modified glass ionomer.³⁰

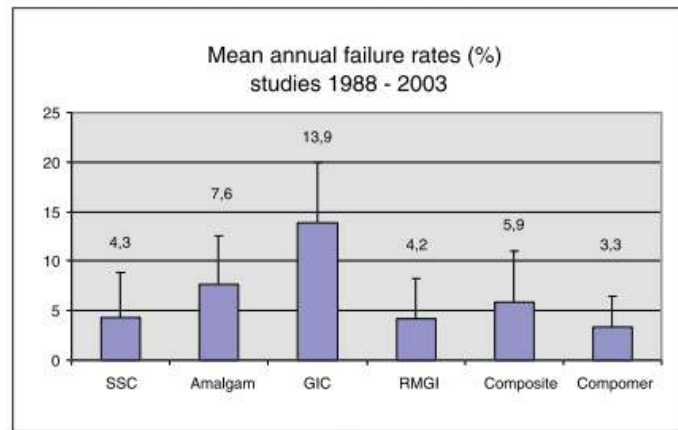


Figure. Mean annual failure rates of different types of restorations in primary molars.

- *Barr-Agholme M, Oden A, Dahllof G, Modeer T. A two-year clinical study of light-cured composite and amalgam restorations in primary molars. Dent Mater 1991; 7: 230-233*
As explained in the abstract, “We selected children (n = 43) with an average age of 6.4 yr exhibiting proximal caries lesions in primary molars distributed on both left and right sides. In each child, one amalgam and one composite side were randomly chosen, resulting in 64 fillings for composite and 55 for amalgam. After a two-year period, significantly (p < 0.05) more composite fillings (88%) were clinically classified as satisfactory compared with amalgam fillings (68%). No significant relationship was found between the success rate of proximal fillings and the caries activity of the individuals. The results indicate that composite can be used successfully as a class II filling material in primary molars in children.”³¹

Governmental bodies agree that children’s primary teeth fall out before any restoration is likely to fail, meaning filling longevity is not a cost factor under any circumstances when it comes to young children’s teeth:

- *World Health Organization, Future Use of Materials for Dental Restoration (2011), http://www.who.int/oral_health/publications/dental_material_2011.pdf, p.35:*
As the World Health Organization explains in *Future Use of Materials for Dental Restoration*, “Alternative restorative materials of sufficient quality are available for use in the deciduous dentition of children.”³²

- *BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, http://ec.europa.eu/environment/chemicals/mercury/pdf/Final_report_11.07.12.pdf, p.69:* The European Commission's BIOIS report elaborated that "With regard to young children, longevity of the restoration is not a relevant concern since baby teeth will fall out long before the restoration fails."³³
- *Scottish Dental Clinical Effectiveness Programme, Restricting the Use of Dental Amalgam in Specific Patient Groups (June 2018), <http://www.sdcep.org.uk/wp-content/uploads/2018/06/SDCEP-Dental-Amalgam-Implementation-Advice.pdf>, pp.8, 12* "There are no indications for the use of dental amalgam in primary teeth. Alternative approaches and materials are widely used and include selective caries removal, fluoride varnish, sealants, preformed crowns, resin composites and glass ionomer restorative materials....For the treatment of primary teeth, while the same issues of cooperation or moisture control might apply for an individual patient, the availability of other treatment options, such as preformed metal crowns, and the likely longevity of the tooth to be treated make it more difficult to justify the use of dental amalgam. Consequently, the working group considered that there are no indications for the use of dental amalgam in primary teeth."³⁴

B.2. Mercury-free fillings facilitate future repairs

Recent studies clearly show that it is easier to repair a composite than an amalgam, which can increase longevity of the filling, longevity of the tooth, and reduce costs. For example:

- *JJM Roeters, ACC Shortall, and NJM Opdam, Can a single composite resin serve all purposes?, BRITISH DENTAL JOURNAL 199, 73 - 79 (2005), <http://www.nature.com/bdj/journal/v199/n2/full/4812520a.html>:* Roeters *et. al.* found that "when composite resin restorations fail on the long term, there is no need to replace them completely as they can be repaired. By doing this the 'tooth countdown' repeat restorative cycle is halted."³⁵
- *Christopher D. Lynch, Kevin B. Frazier, Robert J. McConnell, Igor R. Blum and Nairn H.F. Wilson, Minimally invasive management of dental caries: Contemporary teaching of posterior resin-based composite placement in U.S. and Canadian dental schools, J Am Dent Assoc 2011; 142; 612-620, <http://jada.ada.org/content/142/6/612.abstract>:* Lynch *et. al.* concludes that "predictable techniques exist for the refurbishment or repair of resin-based composite restorations that exhibit signs of deterioration, staining or marginal degradation. Such minimally invasive approaches permit localized repair, thereby avoiding the consequences of total restoration replacement, including an inevitable increase in the depth and width of the cavity preparation and an unnecessary challenge to the viability of the pulp-dentin complex. These tooth-friendly features of resin based composites make them preferable to amalgam, which has provided an invaluable service but which, we believe, now should be considered outdated for use in operative dentistry."³⁶

- *Niek J.M. Opdam, Longevity of repaired restorations: A practice based study, Journal of Dentistry 40 (2012) 829 – 835, https://www.researchgate.net/profile/Niek_Opdam/publication/228441700_Longevity_of_repaired_restorations_A_practice_based_study/links/0c96052766a325245a000000.pdf: Opdam et. al. found that composite can be repaired more successfully than amalgam, explaining that “The annual failure rate (AFR) after 4 years for repairs of amalgam restoration was 9.3%, while the AFR of repaired composite restorations was 5.7%. The log-rank test revealed a significant superior performance of repairs of composite restorations (p = 0.001)... The results of the study as shown in Fig. 4 and the log-rank test indicating high significance suggest that a composite restoration can be repaired more successfully than an amalgam restoration.” The reason was that “In the present study it was found that repaired restorations in case of tooth fracture, which is a common failure type among large amalgam restorations, have a worse prognosis than repaired restorations due to recurrent caries, which is more common among the composite resin restorations investigated. This is likely to explain as a repaired restoration in case of e.g. a cusp fracture (Fig. 2) will be subjected to the same forces that caused the same cusp fracture, leading to a second fracture soon. On the other hand, a secondary caries lesion in a large composite resin restoration that is repaired with a local box-type restoration (Fig. 3) is likely to survive longer due to the fact that a new secondary caries lesion needs at least three years to develop to a size making a new operative intervention necessary. Moreover, preventive measures taken may cause the demise of caries activity in the patient preventing new secondary caries lesions to develop.”³⁷*

B.3. Mercury-free fillings are user-friendly

Mercury-free fillings are also user-friendly for dentists. As a result, studies show there is only a negligible difference, if any, between amalgam and composite when it comes to the treatment time spent by the dentist, which confirms that mercury-free fillings should not entail additional labor costs. For example:

- *BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, pp.67, 199:* According to the BIOIS report prepared for the European Commission, “it has been shown that the time needed to carry out a Hg-free [mercury-free] restoration has reduced significantly as dentists have gained more experience in the handling of Hg-free materials, so that there is currently no (or minor) time difference to perform Hg-free restorations compared to amalgam.”³⁸ The BIOIS report went on to describe a Swedish study on placement times: “The Dental Service Organisation of the county of Orebro has provided an assessment made in 2007, when amalgam was to some extent still an option relevant for comparison. The assessment clearly shows that the time required to make composite fillings is merely a few minutes longer than for similar amalgam fillings, with time difference of less than 10 percent for all three categories of treatments (one surface, several surfaces and crown)...the Swedish Environment Ministry received a signed statement from the Swedish Dental and Pharmaceutical Benefits Agency (TLV) that is responsible for the

Swedish subsidy scheme covering dental care. According to the statement, in preparation of the new dental care reform that went into effect 1 July 2008 in Sweden, TLV gathered extensive information (e.g. on time studies) from several Swedish Dental Service Organisations (among them Orebro county). TLV states that the information in time and resources use, in different types of dental treatments, showed great similarities between dental care providers in Sweden, i.e. that there are only minimal differences in time use assessments on dental treatments reported from various parts of Sweden. This means that the assessment (on time use difference between amalgam and alternative fillings) made by Orebro County that is referred to above can clearly be said to well represent the situation on the national scale in Sweden. Based on the information above, the Swedish Environment Ministry reported that it is confident that dental restorations with Hg-free dental materials, if they are at all taking longer time, only require minimal extra time when performed by dental staff with regular experience in the field.”³⁹

- *F.H.J. Hendriks et. al., Cost Benefit Analysis of Direct Posterior Restorations. Community Dent Oral Epidemiol 1985 13. (5) 256-259, <http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0528.1985.tb00448.x/abstract>: Hendriks et. al. found that even four decades ago in the 1980s, when dentists were not as well trained in composite use, “The treatment time for amalgam restorations is equal to the treatment time of composite restorations.” Furthermore, the researchers asserted that the time for placing composite was only going to get faster as dentists gained more experience with them: “It should be stressed, however, that the application of posterior composite restorations was put into practice for the first time, whereas amalgam restorations were routine for operators. It is likely, therefore, that the treatment time for composite Class I and Class II restorations might further be improved.”⁴⁰*
- *Da Mata et. al., Cost-effectiveness of ART restorations in elderly adults: A randomized clinical trial, Centre for Policy Studies, University College Cork, National University of Ireland, <https://www.ucc.ie/en/media/academic/centreforpolycystudies/CPSWP13-006-daMataC,AllenPF,CroninM,OMahonyD,MckennaG,WoodsNCost-effectivenessofARTRestorationsinElderlyAdults.pdf>, pp. 5-6-,8, 10:* A study conducted in Ireland found that glass ionomer fillings can be completed more quickly than either amalgam or composite: “In order to estimate costs for treating patients with either ART [with a glass ionomer] or CT [conventional technique; i.e. with amalgam or composite] technique, the procedure for placement of restorations was timed using a stopwatch. The stopwatch was started when the patient had his mouth open and the dentist was about to start the restorative intervention and stopped when the chair was brought back to a neutral position and the patient allowed to rinse their mouth if desired. It could be estimated so, the average time to place an ART or a conventional restoration... The average time of procedures was 13 minutes for ART and 18 for conventional restorations. It was estimated then that 32 restorations could be performed using the ART technique per day and 23 conventional restorations...”⁴¹

- *S. Mickenautsch, I. Munshi, & E.S. Grossman, Comparative cost of ART and conventional treatment within a dental school clinic, JOURNAL OF MINIMUM INTERVENTION IN DENTISTRY (2009), <http://www.miseeq.com/e-2-2-8.pdf>*

A 2009 study found that glass ionomers could be placed more quickly: “Duration of procedure for one amalgam and one composite restoration is estimated as an average of 22 minutes; ART restorations [with glass ionomer] are estimated to take 19.8 minutes.”⁴²

- *Jackson, R. D. 2016. “Class II Composite Resin Restorations: Faster, Easier, Predictable.” *British Dental Journal* 221 (10): 623–31. <https://doi.org/10.1038/sj.bdj.2016.856>, <https://www.pinkband.com/wp-content/uploads/2018/02/BDJ.pdf>*

“The development of innovative sectional matrix systems and simplified universal adhesives, with or without selective etch, along with the advent of bulk fill composites, would seem to be a significant turning point in posterior direct restorative dentistry. This combination creates a streamlined, straight forward, faster, more efficient and economical placement technique with less effort than previous methods. Practicing dentists have always desired a less labour intensive clinical protocol for placing posterior composite resin restorations – one that was as easy and timely as amalgam. It appears it has finally arrived.”⁴³

Despite scientific studies, some dentists might still claim a minor difference in the time it takes to place mercury-free fillings and amalgam. But any difference may be accounted for by tooth structure that has already been damaged by amalgam. For example:

- *BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, http://ec.europa.eu/environment/chemicals/mercury/pdf/Final_report_11.07.12.pdf, pp.67-68*

As explained in the BIOIS report, “the time required for a composite to replace a previous amalgam restoration is higher than for replacing a composite filling: a cavity originally prepared to receive an amalgam filling is typically larger and distinguished by various angles that would never be prepared for a composite, rendering the placement of a composite more difficult and time-consuming than it would otherwise have been.”⁴⁴

C. Economic Feasibility of Mercury-Free Dental Fillings

The technical superiority of dental amalgam eliminates any cost difference. Because composite fillings can last as long – or even longer – than amalgam, a European Commission report concluded, “Given the results of recent studies comparing the longevity of different materials, in the present study it is considered that the longevity of Hg-free fillings is no longer a factor with significant effect on the overall cost difference between dental amalgam and composite or glass ionomer restorations.”⁴⁵

Because it is easier to repair composite, mercury-free fillings can be repaired more economically than amalgam can be repaired or replaced. Because there is only a negligible difference, if any, between amalgam and composite when it comes to the treatment time spent by the dentist, mercury-free fillings

should not entail additional labor costs. Additionally, below are examples of studies showing that mercury-free fillings facilitate techniques that can be less expensive (and more accessible) and eliminate the environmental costs of dental mercury – even more factors that contribute to their economic feasibility.

C.1. Mercury-free filling techniques can be less expensive and more accessible

Atraumatic restorative treatment (ART) is a low-cost technique that relies on glass ionomer for the filling material and uses only hand instruments to place the filling. Studies have shown that this mercury-free technique can be less expensive and more accessible than dental amalgam, especially for children. For example:

- *Pan American Health Organization, Oral Health of Low Income Children: Procedures for Atraumatic Restorative Treatment (PRAT) (2006), http://new.paho.org/hq/dmdocuments/2009/OH_top_PT_low06.pdf*
“The findings from the PRAT [procedures for atraumatic restorative treatment] study clearly demonstrate the cost-effectiveness of the ART technique in a variety of settings in the Region in comparison with the cost-effectiveness of the Amalgam technique in the same settings...the cost savings that can be achieved are substantial...The costs of employing the PRAT approach for dental caries treatment, including retreatment, are roughly half the cost of amalgam without retreatment.”⁴⁶
- *S. Mickenautsch, I. Munshi, & E.S. Grossman, Comparative cost of ART and conventional treatment within a dental school clinic, JOURNAL OF MINIMUM INTERVENTION IN DENTISTRY (2009), <http://www.miseeq.com/e-2-2-8.pdf>*
“ART is also a cost-effective means of oral health care within a modern dental clinic. The ART approach can be undertaken at approximately 50% of the capital costs of conventional restorative dentistry.”⁴⁷
- *Regia Luzia Zanata, Ticiane Cestari Fagundes, Maria Cristina Carvalho de Almendra Freitas, José Roberto Pereira Lauris and Maria Fidela de Lima Navarro, Ten-year survival of ART restorations in permanent posterior teeth, CLINICAL ORAL INVESTIGATIONS, Volume 15, Number 2, 265-271 (2010), <http://www.springerlink.com/content/w208655418q560g0/>*
“The survival rates observed, especially for single-surface restorations, confirm the potential of the ART approach for restoring and saving posterior permanent teeth. The technique was effective after 10 years of clinical service.”⁴⁸

C.2. Mercury-free fillings eliminate environmental costs of dental mercury

Use of mercury-free alternatives would eliminate the costs of dental mercury. Studies have concluded that after environmental costs are factored in, dental amalgam is more expensive than mercury-free fillings. For example:

- *Lars D. Hylander & Michael E. Goodsite, Environmental Costs of Mercury Pollution, Science of the Total Environment 368 (2006) 352-370, <http://www.aikencolon.com/assets/images/pdfs/Nikro/MercuryVacuum/STOTENbestpaper.pdf>:*
Hylander *et. al.* (2006) observes that “amalgam fillings are considered to be economic while they de facto are more expensive than most, possibly all, other fillings when including environmental costs” and goes on to explain the environmental consequences of amalgam. It explains that “Amalgam fillings not replaced before death will cause emissions to air, soil, and water upon cremation or burial.”⁴⁹
- *Concorde East/West, The Real Cost of Dental Mercury (March 2012), http://www.zeromercury.org/index.php?option=com_phocadownload&view=file&id=158%3Athe-real-cost-of-dental-mercury&Itemid=70, pp.3-4:*
Concorde East/West (2012) found that after taking into account the environmental costs, an amalgam filling costs up to \$87 more than a composite filling.⁵⁰

D. Environmental and Health Benefits of Mercury-Free Dental Fillings

In addition to their technical and economic advantages, mercury-free dental fillings offer important environmental and health benefits. Beyond eliminating the many risks of dental mercury, mercury-free fillings also preserve more healthy tooth structure and can help prevent future dental caries – all while not posing any known risks of their own.

D.1. Mercury-free fillings preserve tooth structure

For many years now, researchers and governments – as well as many dentists and dental authorities – have agreed that preparation for amalgam placement results in a greater loss of healthy tooth tissue than placement of mercury-free fillings. As a result, amalgam preparation and amalgam placement weaken tooth structure. Conversely, mercury-free fillings preserve tooth structure, which can increase the longevity of the tooth itself – and save the patient the additional costs of more extensive restorative dental treatment in the future. For example:

- *I. A. Mjor and A. Jokstad, Five-year study of Class II restorations in permanent teeth using amalgam, glass polyalkenoate (ionomer) cermet and resin-based composite materials, J. Dent. 1993; 21: 338-343, <http://www.jokstad.net/1993%20JDent%205year%20Mjor.pdf>*
“The mean intercuspatal width of the preparations was 5.6 ± 0.7 mm and a proximal circumference width of 12.5 ± 1.2 mm. However, the cavity preparation dimensions varied with the restorative material used. A one-way analysis of variance identified significantly larger cavity preparations for the amalgam compared to the cermet and resin composite restorations (Fig. 1).”⁵¹

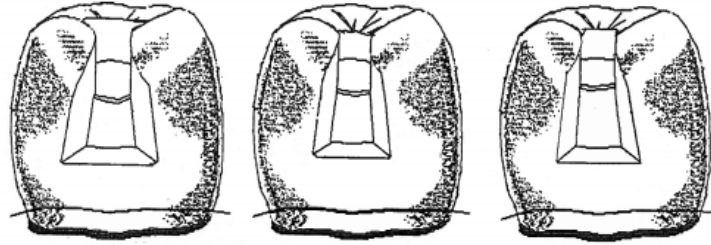


Fig. 1. Illustration of the average size of the cavity preparations for amalgam (left), cermet (middle) and resin composite restorations (right). The average size of the cavities prepared for amalgam were significantly larger than for the other materials, while the cavities for the cermet material were the smallest of the three.

- Walls AW, Murray JJ, McCabe JF. *The management of occlusal caries in permanent molars. A clinical trial comparing a minimal composite restoration with an occlusal amalgam restoration.* Br Dent J 1988; 164: 288–292, https://www.researchgate.net/publication/20879918_The_management_of_occlusal_caries_in_permanent_molars_A_5-year_clinical_trial_comparing_a_minimal_composite_with_an_amalgam_restoration/download,pp.363,366.

“Amalgam restorations occupied, on average, 25% of the occlusal surface of the tooth, while minimal composite restorations occupied 5%. ‘Pit’ amalgam restorations in the mesial portion of the occlusal surface of upper first and second molars occupied 15% of the tooth surface....Minimal composite restorations involved much less of the occlusal tooth surface (5%) than with a contiguous amalgam restoration in a permanent molar (25%) or a pit restoration in the mesial portion of the occlusal surface of an upper first or second molar (15%). This is a reflection of two factors. First, the cavities for the minimal composite restorations were not extended into deep, stained fissures adjacent to the carious lesion (these were sealed with sealant material), whereas the amalgam restorations were extended into the stained fissure pattern. Secondly, in ten cases, the amalgam control replaced an existing amalgam restoration whose size was outside the control of the investigation. The reduction in the amount of natural tooth tissue removed in the more conservative cavity preparation can only be beneficial to the patient in the future, when fresh cavity preparation may be necessary due to recurrent or approximal decay. Minimal composite restorations compare well with amalgam restorations after 5 years. There was no significant difference between the median survival times of amalgam (61 · 5 [1 · 6] months) and composite (63 · 3 [1 · 4] months) restorations. This parity of minimal composite restorations to amalgam restorations was achieved with significantly less destruction of tooth tissue.”⁵²

- Donovan TE, *Longevity of the tooth/restoration complex: a review* Journal of the California Dental Association [01 Feb 2006, 34(2):122-128], <https://europepmc.org/abstract/med/16724467>; https://www.cda.org/Portals/0/journal/journal_022006.pdf

“One critical factor when determining a prospective prognosis for any given tooth is the amount of remaining tooth structure. The words ‘preservation of tooth structure’ which are

uttered in almost all lectures related to tooth preparations, are critical to establishing a positive long-term prognosis. The amount of tooth structure removed from a tooth when preparing a porcelain laminate veneer is much less than when preparing a full crown. Thus, the long-term prognosis for the veneered tooth is substantially better than that for the crowned tooth. The advent of predictable adhesion to tooth structure has allowed clinicians the ability to practice minimally invasive dentistry, and thus preserve tooth structure and concomitantly improve the long-term prognosis of the tooth/ restoration complex. A preventive resin restoration in a mandibular first molar is more conservative than a minimal silver amalgam restoration improving the long-term prognosis for the tooth (Figure 6). A mesial slot preparation restored with adhesives and composite resin is more conservative than a Class II MO silver amalgam restoration, and cuspal flexibility is reduced with the slot preparation, thereby reducing the likelihood of cusp fracture over time (Figures 7 and 8)... The amount of remaining tooth structure plays a major role in determining the prognosis. Minimally invasive adhesive restorative dentistry can assist in the preservation of tooth structure.”⁵³

- JJM Roeters, ACC Shortall, and NJM Opdam, Can a single composite resin serve all purposes?, BRITISH DENTAL JOURNAL 199, 73 - 79 (2005), <http://www.nature.com/bdj/journal/v199/n2/full/4812520a.html> (emphasis added)*

Roeters *et. al.* found that “Longevity should not be the only way to look at a restorative material though this has always been the case with dental amalgam. Using dental amalgam the cavity preparation needed to be adjusted to meet the requirements of the material. Instead of this *one should question in what way the tooth can be preserved as long as possible.* Composite resin, glass ionomer cements and compomers do not require the more traditional preparation required for amalgam and adhesive restorative materials and techniques can be adjusted to all kinds of cavity shapes. As a consequence much less sound tooth tissue will be sacrificed. An *in vivo* study showed that when primary caries lesions in the occlusal surfaces of first molars were restored with amalgam the surface occupied by the restoration was five times larger than when a composite resin was used. This means that a composite restoration can be replaced several times before the same amount of tooth material as with amalgam is lost. However, when composite resin restorations fail on the long term, there is no need to replace them completely as they can be repaired.”⁵⁴
- Christopher D. Lynch, Kevin B. Frazier, Robert J. McConnell, Igor R. Blum and Nairn H.F. Wilson, Minimally invasive management of dental caries: Contemporary teaching of posterior resin-based composite placement in U.S. and Canadian dental schools, J AM DENTA Assoc 2011; 142; 612-620, <http://jada.ada.org/content/142/6/612.abstract>:*

Lynch *et. al.*, note that “some significant disadvantages are associated with amalgam that are not encountered with resin based composite. These include...strict preparation requirements for depth and mechanical retention; and its nonadhesive nature.”⁵⁵
- Andre V. Ritter, DDS, MS, Clinical Techniques: A Review of Posterior Composites, ADA Professional Product Review (Oct. 2011), p.3*

“Composites offer many advantages over traditional restorative materials and techniques used in posterior teeth. They can be placed in ultra-conservative preparations. Unlike amalgam, composites present minimal mechanical requirements relative to depth and width of tooth preparation, allowing the clinician to limit the preparation to access and

eliminate diseased tooth structure and/or failed restoration, remove grossly unsupported enamel, and establish a convenient form for the restoration. Consequently, the strength of the tooth is better preserved by reduced loss of sound tooth structure. Composites are also compatible with the concept of minimal intervention dentistry. The proper intracoronal use of a resin-based composite with an adhesive technique can replace some of the tooth strength lost due to caries, fracture, or tooth preparation.”⁵⁶

- *Joseph B. Dennison, DDS, MS & James C. Hamilton, DDS, Treatment Decisions and Conservation of Tooth Structure, Dent Clin N Am 49 (2005) 825–845, https://www.researchgate.net/profile/James_Hamilton10/publication/7612380_Treatment_Decisions_and_Conservation_of_Tooth_Structure/links/5b3f92ada6fdcc85060366af/Treatment-Decisions-and-Conservation-of-Tooth-Structure.pdf*

“Minimally invasive dentistry, sometimes referred to as “microdentistry,” is a logical extension of conservation of tooth structure. With the advent of resin-based composites [10] and acid-etching of enamel [11], smaller preparations minimize the destruction of tooth structure required to provide amalgam the necessary bulk for strength.... The potential benefits of conserving tooth structure by delaying intervention or minimizing the operative procedure, if intervention is required, have already been alluded to as prolonging the life cycle of a tooth. The direct benefits are fourfold: (1) the opportunity for recurrent caries to develop along a restoration margin is minimized, (2) the incidence of early restoration failure is reduced, (3) the incidence of tooth fracture related to weakened cusps resulting from larger restorations is decreased, and (4) pulpal vitality is retained throughout life.”⁵⁷

- *NJM Opdam, R Frankenberger, and P Magne (2016) From 'Direct Versus Indirect' Toward an Integrated Restorative Concept in the Posterior Dentition. Operative Dentistry: September 2016, Vol. 41, No. S7, pp. S27-S34, https://www.researchgate.net/profile/Pascal_Magne/publication/296055458_From_'Direct_Versus_Indirect'_Toward_an_Integrated_Restorative_Concept_in_the_Posterior_Dentition/links/572b6f1a08ae057b0a0951fa/From-Direct-Versus-Indirect-Toward-an-Integrated-Restorative-Concept-in-the-Posterior-Dentition.pdf*

This article explains the importance of preserving more natural tooth structure: “For too long, the longevity of the restoration itself has been the focus of the attention. Today, it appears that it is more important to preserve the underlying tooth and the functioning of the dentition as a whole. In a good restorative concept, it is important to keep open future options for restorations as the present available restoration will fail in the future and will need replacement, repair, or adjustment. This is the essence of the biomimetics approach, in which the aim is not to create the strongest restoration but rather a restoration that is compatible with the mechanical, biologic, and optical properties of underlying tissues.” The article also notes that “it can be concluded that longevity data are no longer a justification for making a choice between direct and indirect restorations and between resin composite, metal, or ceramic materials.”⁵⁸

- *Norway Directorate for Health and Social Affairs, A National Clinical Guideline for the Use of Dental Filling Materials: Information for Dental Health Care Personnel, pp. 6, 8, 15:*

This list of guidelines includes “Dental tissue-conserving techniques shall always be chosen when dental filling therapy is necessary.” As explained later in the document, “When a

dental filling must be placed, it is important to choose a tissue conserving technique, that is a technique that involves minimal removal of dental tissue (1). Glass ionomer cements and composites bind themselves to dental tissue. These require less removal of tooth tissue than amalgam to gain retention.... In the assessment leading to the following recommendation, it is emphasized that in a lifetime perspective it is favourable to preserve as much dental tissues as possible. This will save teeth in the long run, and presumably save expense on complicated restorations later in life.... Dental tissue-conserving techniques shall always be chosen when dental filling therapy is necessary.... In Norway it is mainly the patient that must bear the additional costs. However, in the long run, and in a lifetime perspective, it may be less expensive for some patients. Tissue-conserving techniques and adhesive filling materials may lower the risk of dentine fracture, and thus save the patient for complex and costly dental restorations (42).”⁵⁹

- *European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users (29 April 2015), http://ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_o_046.pdf, p.42, 69:*

The European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) explains that “It is with respect to their aesthetics and non-adhesive character, which means that larger cavities have to be prepared, often with excessive tooth tissue removal, that amalgams may be seen to be inferior to the alternatives...”⁶⁰ SCENIHR explains that mercury-free dental fillings “have facilitated a radical change in the concepts of restorative dentistry through the introduction of more minimally invasive techniques and the associated retention of more tooth substance when treating caries.”⁶¹
- *BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, http://ec.europa.eu/environment/chemicals/mercury/pdf/Final_report_11.07.12.pdf, p.77:*

The 2012 European Commission-commissioned BIOIS report found that “dental amalgam placement tends to weaken the overall tooth structure (due to the significant amount of healthy tooth tissue that has to be removed).”⁶²
- *World Health Organization, Future Use of Materials for Dental Restoration (2011), http://www.who.int/oral_health/publications/dental_material_2011.pdf, pp.16, 27, 29*

The World Health Organization (WHO) states that “Adhesive resin materials [like composite] allow for less tooth destruction and, as a result, a longer survival of the tooth itself. Funding agencies should take the initiative and encourage the replacement of amalgam as the material of choice for posterior teeth with adhesive systems.”⁶³ The WHO adds “It may be more important to examine tooth survival and to preserve tooth structure than filling survival...Preservation of the tooth in a functional state should be taken into consideration rather than retention of the material used for restoration; this is in line with goals for oral health suggested by WHO.”⁶⁴
- *UNEP, Lessons from Countries Phasing Down Dental Amalgam Use (2016), <https://wedocs.unep.org/bitstream/handle/20.500.11822/11624/Dental.Amalgam.10mar2016.pages.WEB.pdf?sequence=1&isAllowed=y>, p.24*

This UNEP report emphasizes the “importance of minimally invasive dentistry”, citing the Norwegian guideline that explained how amalgam “requires the removal of more healthy tooth tissue than mercury-free fillings.”⁶⁵

D.2. Mercury-free fillings can help prevent future caries

Studies show mercury-free fillings can help prevent costly caries in the future. For example:

- *Mickenautsch S, Yengopal V. Absence of carious lesions at margins of glass-ionomer cement and amalgam restorations: An update of systematic review evidence. BMC Research Notes. 2011;4:58, <https://bmcreresnotes.biomedcentral.com/articles/10.1186/1756-0500-4-58>*
“The overall results of the computed datasets suggest that GIC [glass ionomer cement] has a higher caries-preventive effect than amalgam for restorations in permanent teeth.”⁶⁶
- *Mandari GJ, Mandari GJ, Frencken JE, Frencken JE, van't Hof MA, van't Hof MA: Six-Year Success Rates of Occlusal Amalgam and Glass-Ionomer Restorations Placed Using Three Minimal Intervention Approaches. Caries Res 2003;37:246-253, <http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowAbstract&ProduktNr=224219&Ausgabe=229216&ArtikelNr=70866> (abstract):*
Glass ionomers release fluoride, which can help prevent caries. Mandari et. al. found that “Secondary caries was observed for 2% of glass-ionomer and for 10% of amalgam restorations. This difference was statistically significant (p = 0.001). The ART approach using glass-ionomer performed equally well as conventional restorative approaches using electrically driven equipment and amalgam for treating dentinal lesions in occlusal surfaces after 6 years.”⁶⁷
- *Lynch et. al., Managing the phase-down of amalgam: part I. Educational and training issues, British Dental Journal (Aug. 2013):*
Lynch et. al. notes that composites placement can also incorporate preventive measures, including sealing of adjacent pits and fissures.⁶⁸

D.3. Studies show that mercury-free fillings are safe for health and the environment

One of the health and environmental benefits of mercury-free fillings is that there is no evidence of harm. The mercury-free alternatives to dental amalgam have been studied for more than half a century.⁶⁹ During that time, as seen in the examples below, studies and government health authorities have repeatedly confirmed that mercury-free dental fillings are safe.

Studies confirm that mercury-free fillings are safe for health and the environment. For example:

- *European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users (29 April 2015),*
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_o_046.pdf,
 pp.73,74:
 “Alternative materials have now been in clinical use for more than thirty years, initially in anterior teeth and later also for restorations in posterior teeth. This clinical use has revealed little evidence of clinically significant adverse events....There is no evidence that infants or children are at risk of adverse effects arising from the use of alternatives to dental amalgam.”⁷⁰
- *European Commission Scientific Committee on Emerging and Newly Identified Health Risks. Opinion on the safety of the use of bisphenol A in medical devices (2015),*
https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenih_r_o_040.pdf, pp. 10, 15-16, 30, 44
 “For dental materials, the leakage is limited to resins composed of Bis-DMA (Bisphenol A dimethylacrylate) which has an ester linkage that can be hydrolysed to BPA, whereas the ether linkage in Bis-GMA (Bisphenol A glycidyl methacrylate) was found to be stable.... For the placing of dental composite resin restorations, measurements have shown that the release of BPA mainly occurs during the few hours directly after application while the BPA level is back to pretreatment levels at 24 hours.... The estimated highest BPA exposures for different scenarios were: 6) 2 to 12 ng/kg b.w./day due to long-term contact with dental materials, far below the exposure to BPA via food (EFSA 2013, EFSA 2015).... The oral long-term exposure via dental material is far below the recently determined oral t-TDI of 4 µg/kg b.w./day (EFSA 2015) and pose negligible risk for human health.... Recent reports from different authorities addressing the risk assessment of BPA from various sources, especially food contact materials, have to some extent also addressed dental materials. The general conclusion is that the contribution from dental materials to the total exposure is low (Beronius and Hanberg, 2011; FAO/WHO, 2011; Environment Canada/Health Canada 2008;EC 2010b; US NTP-CERHR, 2008; EFSA, 2013).”⁷¹
- *Scientific Committee on Health and Environmental Risks (SCHER), Opinion on the Environmental Risks and Indirect Health Effects of Mercury from Dental Amalgam (2014):*
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_165.pdf, p5:
 “For the environment, considering the probably low level of emissions and the relatively low toxicity of the chemicals involved, it is reasonable to assume that the ecological risk is low.”⁷²
- *Health Care Research Collaborative of the University of Illinois at Chicago School of Public Health, the Healthier Hospitals Initiative, and Health Care Without Harm, Mercury in Dental Amalgam and Resin-Based Alternatives: A Comparative Health Risk Evaluation (June 2012),*
https://www.wfpha.org/tl_files/images/Newsletter%202012/July/Res%20Colab%20Amalgam%20Risk%20Final.pdf, p.6:
 The 2012 report *Mercury in Dental Amalgam and Resin-Based Alternatives: A Comparative Health Risk Evaluation* explains, “other than individual allergies to components of one or

another composite, there is no current evidence of significant personal or environmental toxicity.”⁷³

- *Chen & Suh, Bisphenol A in Dental Materials: A Review, JSM Dent 1:1004 (2013), <http://www.jscimedcentral.com/Dentistry/Articles/dentistry-1-1004.pdf>:*
The researchers conclude that “Modern dental materials contain BPA-derivatives, not pure BPA. There are two types of BPA-derivatives: ones that cannot be hydrolyzed into BPA, such as BisGMA and BisEMA, and others that can be hydrolyzed into BPA in saliva, such as BisDMA and polycarbonate.... On the basis of the huge benefits of resin-based dental materials and negligible BPA-release after resin application, we recommend continuing application of resin-based dental materials.”⁷⁴
- *Yin et. al., Associations of blood mercury, inorganic mercury, methylmercury and bisphenol A with dental surface restorations in the U.S. population, NHANES 2003–2004 and 2010–2012, Ecotoxicity and Environmental Safety (2016), <https://www.ncbi.nlm.nih.gov/pubmed/27639196>*
Using NHANES data from 14,703 subjects, the researchers concluded that “no association between the dental fillings and urinary BPA was found.”⁷⁵
- *Berge, T.L.L., Lygre, G.B., Lie, S.A. et al. Polymer-based dental filling materials placed during pregnancy and risk to the foetus. BMC Oral Health 18, 144 (2018). <https://doi.org/10.1186/s12903-018-0608-1>, <https://link.springer.com/article/10.1186/s12903-018-0608-1>*
In this study, which included more than 90,000 pregnancies, “women who had white fillings placed during pregnancy had no increased risk for adverse birth outcomes compared with women who did not consult a dentist during pregnancy. Thus, our findings do not support the hypothesis of an association between placement of polymer-based fillings during pregnancy and adverse birth outcomes.”⁷⁶

Government authorities agree that mercury-free fillings are safe for health and the environment. For example:

- *European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes, Flavours and Processing Aids, Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs, <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.3978>, p.54*
“Dental materials that are commonly used in dental surgery both for children and adults, as dental fillers (adults) or as fissure sealants (children) were not found to be a source of chronic exposure [to BPA] either (see Section 4.3.3).”⁷⁷
- *BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV, <http://bookshop.europa.eu/en/study-on-the-potential-for-reducing-mercury-pollution-from-dental-amalgam-and-batteries-pbKH3013440/>, pp.78-79:*

“It should be noted that composite resins are widely available without BPA. In fact, according to the American Dental Association, BPA is rarely an ingredient in these Hg-free alternatives...In June 2012, the Swedish National Board of Health and Welfare released a report on BPA in dental materials. The report concludes that there may be traces of BPA in dental materials even if not stated in the product information, since it is not compulsory to report low levels of BPA if not intentionally added. However, in such materials, the BPA concentrations are so low that even if the fillings would totally disintegrate in a four-year period, the levels of exposure to BPA would remain far below the EU limit for BPA intake.”⁷⁸

- *KEMI, Bisfenol A (2/11)*,
http://www.kemi.se/Documents/Publikationer/Trycksaker/Rapporter/Rapport2_11_BisfenolA.pdf, page 9:
“Risk assessments of BPA have so far generally concluded that exposure from dental materials does not contribute significantly to total exposure...”⁷⁹
- *Joint FAO/WHO Expert Meeting to Review Toxicological and Health Aspects of Bisphenol A, Summary Report (2010)*,
http://www.who.int/foodsafety/chem/chemicals/BPA_Summary2010.pdf
“BPA levels in saliva from dental materials were low. The Expert Meeting determined that there was no need to collect additional data on BPA levels from dental materials, as exposure is short term and unlikely to contribute substantially to chronic exposure.”⁸⁰

¹ UN Environmental Programme, *Promoting Dental Amalgam Phase-Down Measures Under the Minamata Convention and Other Initiatives, For “Especially Women, Children and, Through Them, Future Generations”, Workshop Report (2018)*, <https://mercuryfreedentistry.files.wordpress.com/2018/06/workshop-report.pdf>, pp.29-29.

² UN Environmental Programme, *Promoting Dental Amalgam Phase-Down Measures Under the Minamata Convention and Other Initiatives, For “Especially Women, Children and, Through Them, Future Generations”, Workshop Report (2018)*, <https://mercuryfreedentistry.files.wordpress.com/2018/06/workshop-report.pdf>, p.20.

³ UNEP, *Lessons from Countries Phasing Down Dental Amalgam Use (2016)*, <https://wedocs.unep.org/bitstream/handle/20.500.11822/11624/Dental.Amalgam.10mar2016.pages.WEB.pdf>; Mercury Policy Project Report to the United Nations Environment Program Chemicals Branch Division of Technology, Industry and Economics (UNEP) on “Phasing Down Dental Amalgam: Country Case Studies”; Project Account Number: MC/4030-09-04-2204, December 30, 2012.

⁴ Ministry of Environment and Food of Denmark, *Overview of Danish legislation and actions in connection with the phasing out of dental amalgam*, <https://circabc.europa.eu/ui/group/19e66753-84ca-4e4e-a4a1-73befb368fc2/library/67c149f5-c04a-4310-a828-42f0fdf78e71/details>

⁵ Regulation (EU) 2017/852, <https://op.europa.eu/en/publication-detail/-/publication/687ef0ed-4045-11e7-a9b0-01aa75ed71a1/language-en>

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