Policy Statement:

Dental Amalgam and Resin-Based Composites: Environmental and Health Impacts

Association of State and Territorial Dental Directors

Adopted: August 14, 2023

Summary

Use of restorative dental materials is conventional to replace damaged tooth structure, allowing people to maintain oral health and function. Direct restorative materials, defined as those that in most cases are accomplished in a single dental visit, are predominately mercury-containing dental amalgam ("silver fillings") and resin-based composites ("white" or "plastic fillings"). Dental amalgam has been used for hundreds of years. Resin based composites (RBCs) have been in use for about 50 years, with newer generations of the materials being developed in the last few decades. The 2013 Minamata Convention on Mercury resulted in a global treaty (entered into force August 16, 2017) and meetings of U.S. and international dental public health experts and policymakers concerning the phase down of dental amalgam to protect human health and the environment from adverse effects of mercury. (See below and in Appendix, #1).

Mercury components of scrap dental amalgam are concerning because of build-up in waterways as well as other environmental impacts that have implications for human health via the immune system, brain, heart, kidneys, and lungs. In the U.S., mitigation strategies such as amalgam separators are required in dental offices to prevent mercury pollution from amalgam. Resin-based composites (RBCs) offer an alternative to dental amalgam, but concerns also exist about their potential for toxic environmental and adverse human health effects. Mitigation strategies are not yet in place for RBCs in the U.S. Awareness of amalgam environmental risk has been found to be greater than the awareness of RBC environmental risk.

The Association of State and Territorial Dental Directors, the American Dental Association, and the American Academy of Pediatric Dentistry support continued judicious use of amalgam as a low-cost, high-longevity restorative product that is safe for the majority of patients, with discretionary alternative material use by dental practitioners for high-risk populations (e.g., young children, pregnant or nursing persons, individuals with neurological or kidney dysfunction, or with sensitivities to certain metals). ASTDD promotes strategies for primary prevention of dental caries such as dietary counseling and treatments to remineralize dental enamel; secondary prevention of caries that incorporates minimally invasive dentistry materials and therapies; and comprehensive dental care to decrease the prevalence

and severity of dental caries, thus reducing the need for dental restorative materials along with correspondingly appropriate dental office waste management. Development of alternative biomimetic materials (synthetic materials with natural properties) for restoration or prevention has potential for dental caries management and a reduced environmental footprint as part of efforts for sustainable and equitable oral healthcare.

Problem

Dental caries is a common chronic disease in the United States.[1,2] Treatment of lesions from dental caries ("cavities") is often removal of damaged tooth tissue and replacement with dental fillings, typically dental amalgam or resin-based composites (RBCs). The use of these restorative materials has potential impacts on environmental health and human health via the immune system, brain, heart, kidneys, and lungs.

Dental Amalgam

Dental amalgam, which is classified as a medical device, is a filling material with several constituent metals, including liquid mercury, tin, silver, and copper.[3] Scientific reviews and consensus statements over many years have supported the safety and effectiveness of dental amalgam as a tooth restorative material, but its widespread use has decreased due to esthetic concerns about its metallic appearance and evolving concerns surrounding environmental impacts of mercury.[4] The focus on reduction of use of dental amalgam in the United States intensified at about the time of the 2013 Minamata Convention on Mercury that resulted in a global treaty (entered into force August 16, 2017), which led to meetings of dental public health experts and policymakers concerning the phase-down of dental amalgam to protect human health and the environment from adverse effects of mercury.[5]

The Minamata Convention Elements for Parties concerning dental amalgam are contained in Annex A (Part II) of the Convention. The overarching intent of this global treaty is to ban the use of mercury with the treaty subject to monitoring of its implementation and proposal of amendments by its Parties. Dental amalgam is among products recommended for phase down, versus phase out, with the provisions that "shall take into account the Party's domestic circumstances and relevant international guidance…" as well as to have the Parties take at least two from a list of nine measures such as a focus on caries prevention. The Parties are to include two or more measures for phase down, starting with setting national objectives aiming at dental caries prevention and health promotion. The full list of measures is included in the Appendix (#1).

Dental office wastewater can add mercury to the environment, and is mitigated through Environmental Protection Agency (EPA) regulations via Dental Rule (40 CFR Part 441). This rule requires dischargers of wastewater containing dental amalgam into publicly owned treatment works (e.g., municipal sewage systems) to provide for the removal of dental amalgam solids from all amalgam process wastewater as of July 2020. Previously, dental amalgam build-up in sedimentary form in municipal water systems was seen at rates approaching five tons per year in the U.S.[6] For its 2021 progress report on phasing down the use of dental amalgam, the World Health Organization (WHO) found that 84% of their participating countries still use dental amalgam, with two regions at 100% (Eastern Mediterranean Region and South-east Asia Region) and the lowest region at 64% for AMR (Region of the Americas).[5] The U.S. continues to use dental amalgam. A review of U.S. commercial claims data between 2010 and 2020 for children ages 3-12 years indicated that the percentage of restorations using amalgam decreased over time from a high of 26.9% in 2010 for the next 10 years, with the overall decrease varying through the decade to a low of 9.4% in 2020. Pediatric dentists were less likely to use amalgam than general dentists, but the decrease varied by patient age and family income.[7]

In numerous reviews and white papers, dental amalgam has not been shown to create clinically detectable adverse health effects for patients or providers; in other words, it is safe for the majority of patients.[8] Dental amalgam's advantages have included that it is long lasting, relatively inexpensive, and applicable in treatment of large cavities due to ease of use and superior strength.[9,10,11] The World Dental Federation (FDI), as the international dental observer to the Minamata Convention, recognizes that dental amalgam for many parts of the world is the only viable restorative choice due to challenges in use and placement (i.e., clinical, economic or practical) and cost of alternative materials.[12,13]

The U.S. Food and Drug Administration (FDA) provided an Update Statement on September 24, 2020, resulting from the November 13-14, 2019 meeting of its Immunology Devices Panel of the Medical Devices Advisory Committee, noting that "while the majority of evidence suggests exposure to mercury vapor from dental amalgam fillings doesn't lead to harmful health effects for most people, there may be some effects in people with certain health issues such as those who are hypersensitive to mercury." The update provides recommendations for dental amalgam to be avoided in high-risk populations (i.e., children, especially younger than age six years; people who are pregnant or nursing; individuals with neurological impairment or kidney dysfunction or who are sensitive to mercury, silver, copper, tin, or zinc).[14] (See Appendix, #3)

Resin-Based Composites (RBCs)

RBCs are the most commonly used direct restoration alternative to amalgam. Some authors note that RBCs' components are known to have cytotoxic (i.e., a substance or process that can damage cells or cause them to die), genotoxic, proinflammatory, and mutagenic effects and potential for local, systemic, and allergic reactions.[15,9] The state of the evidence for human and environmental impact is weak because of attributes that make RBCs difficult to study.[9,16,17] RBCs' advantage is that they offer patients a restorative option that is similar to the appearance of natural teeth.

RBCs' environmental impact in contrast to amalgam associated mercury has not been evaluated conclusively.[9,17] Recent emerging assessments provide additional concern for RBCs when including the high environmental impact from RBC processing and packaging materials.[17]

While RBCs do not contain mercury, they contain complex chemical components that can break down into monomer components. (A monomer is a molecule that can react with other monomer molecules to form a larger polymer chain or three-dimensional network.)[15] Some monomers pose a cytotoxic threat.[15]

One potential byproduct, bisphenol A (BPA), is known to have estrogen-mimicking qualities that affect wildlife and pose concerns to human health.[18] Other byproducts, such as Bis-GMA are known to be toxic to aquatic life.[19,16] In addition, these products have micro- and nano-particles that can build up and may pose environmental threats.[20]

RBCs pose a pollution risk[9] thought to result largely from degradation of these products with concerns for eluted (removed by a solvent) monomers and microparticles.[21,16,17] These particles are produced in processing, wear and removal of restorations and may become embedded into tissue such as the lungs if inhaled.[22,23] Due to the variety in chemical specification and lack of manufacturer data, a definitive statement is not available yet on the human and environmental health impacts of these materials.[9,16,17]

Ongoing Considerations

As a Party to the Minamata Convention and in conjunction with FDA recommendations, the U.S. is phasing down use of dental amalgam and enforcing mitigation of its waste. However, a broad understanding of environmental effects of RBCs is still evolving. A changing awareness of the environmental impacts of dental restorative materials suggests the importance of maintaining a contextual consideration of the judicious use of dental amalgam and a need for increasing knowledge about the effects of all dental direct restorative materials on human and environmental health, for developing clinical and policy recommendations and program planning. In addition, a mixed methods study from the United Kingdom suggests that "policies geared towards a complete ban on amalgam need to carefully consider their likely impact on widening oral health inequalities... data suggest that a complete phase out is not currently feasible unless appropriate measures are in place to ensure cheaper, long-lasting and easy to use alternatives are available and can be readily adopted by primary care oral health providers."[24]

Awareness of dental amalgam's environmental impact via mercury is seen as considerably higher than awareness of RBC environmental impact.[25,26] A recent report (2022) of U.S. dental students found that while they are supportive of environmental sustainability, they are not very knowledgeable about implementation of sustainable practices in dentistry.[27] The development of biomimetic approaches (synthetic materials with natural properties) in place of traditional direct restorations for comprehensive everyday use is a current focus of research.[28] Bioactive materials (those used for repair (and regeneration) of or other interaction with adjacent tissues or an interaction with bacteria/biofilm on or next to restorative materials) also show promise; the FDI published a policy statement early in 2023 to reinforce appropriate use of the term.[29]

Methods

Mitigation strategies for amalgam waste have been recommended for years as best practices by the California Dental Association and the American Dental Association (ADA).[30,31,32] The use of dental amalgam separators for reducing mercury contributions to municipal water systems in the U.S. is mandatory.[33] (see Appendix, #2.)

Dental amalgam usage has continued to be supported and affirmed by major organizations, including the ADA and the American Academy of Pediatric Dentistry (AAPD).[34,35] While some countries have entirely phased out dental amalgam,[5] it is still used in the U.S., although with geographic and demographic variations.[4] In its 2023 systematic review and meta-analysis *Direct Materials for Restoring Caries Lesions*, the ADA Council on Scientific Affairs concluded that there was "limited evidence to support clinically important differences between the direct restorative materials assessed. Larger studies with longer follow-up periods are needed to assess the long-term effectiveness of direct restorative materials with higher certainty".[36] However, in June 2023, the ADA released a new clinical practice guideline on restorative treatments for caries lesions "that suggests more conservative approaches to removing carious tissue may decrease the risk of adverse effects."[37] (See Appendix, #4.)

To aid in future understanding of environmental health risks attributable to clinical dental activities and contributions to environmental pollution, dental professional school curricula as well as ongoing continuing dental education should be implemented to address the issues of uses and choices of direct restorative materials. [25.26,27,38]

Dental amalgam's mercury risk can be managed through the use of amalgam separators, filtration, and recycling in dental clinical settings. Research suggests that RBCs' pollution can be mitigated with catalytic carbon filters or additional types of filter traps,[17,25] in addition to ongoing training of dental practitioners and assurance of complete cure of monomers during placement.[21] Alternatively, new material design may limit the ecologically harmful components of resin composites, such as removing the Bis-GMA component of RBCs.[22,23] Due to the "newness" of RBCs and a variety in composition, further scientific research to understand the risks of environmental contamination from long-term use of these materials should be conducted.[21,17]

Dental amalgam and RBCs are not the only ways for dental providers to treat and manage dental caries. Treatment of small lesions with chemical therapeutics such as silver diamine fluoride (SDF) and others, as well as atraumatic restorative techniques (ART), offer minimally invasive treatment options for patients and providers that have good success in managing chronic dental disease.[39] Regenerative, bioactive, or biomimetic materials may offer an alternative to traditional restorative interventions and environmental hazards associated with such therapies, thus negating the need to decide between dental amalgam and RBCs.[28] As in the Minamata Convention on Mercury, a suggested measure is to increase efforts in dental caries prevention and health promotion to minimize the need for dental restorations.

Both dental amalgam and RBCs have constituent materials that contribute to environmental pollution, which in turn impacts human health. Dental amalgam's mercury contamination can be limited through mitigation strategies, but corresponding strategies are not yet common for RBCs. ASTDD, ADA[34], and AAPD[35] support continued judicious use of dental amalgam as a low-cost, high-longevity restorative material for patients, while also recognizing the judicious use of RBCs as a more technique sensitive but often esthetically preferred material.

ASTDD promotes prevention efforts, including dietary counseling, motivational interviewing, minimally invasive care in dentistry, and the provision of comprehensive dental care, as well as appropriate waste management strategies. Clinical decision making and cost decisions must be weighed on an individual basis between patient and provider when considering direct restorative materials. Use of ART or SDF may provide future directions for modern dentistry that can arrest the progression of dental decay, preserve tooth structure and function, and leave a smaller ecological footprint in efforts for sustainable and equitable oral healthcare.[21,25]

Policy Statement ASTDD supports the judicious use and a phase down of dental amalgam as well as the judicious use of resin-based composites (RBCs), while promoting appropriate mitigation of associated wastes to avoid adverse environmental and health impacts. ASTDD encourages ongoing and new research aimed at decreasing these impacts and developing new dental caries arresting therapies and restorative materials. ASTDD also emphasizes the importance of preventing tooth decay, of engaging in interdisciplinary efforts and strategies such as education and early intervention, and of emerging strategies that incorporate minimally invasive dentistry to reduce environmental burdens from direct restorative dental materials as part of efforts for sustainable and equitable oral healthcare.

The ASTDD Dental Public Health Policy Committee is pleased to acknowledge
Lydia J. DeJonge, DDS, MS, MPH, and
Linda M. Kaste, DDS, MS, PhD University of Illinois Chicago, College of Dentistry
for their efforts in drafting this paper.

The development of this document was supported by Cooperative Agreement 5 NU58DP006573-05-00 from the Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

Appendix:

1. The **Minamata Convention Elements for Parties** concerning dental amalgam are contained in Annex A, Part II of the Convention. The overarching intent of this global treaty is to ban the use of mercury with the treaty subject to monitoring of its implementation and proposal of amendments by its Parties. Dental amalgam is among products recommended for phase down, versus phase out, with the provisions that "shall take into account the Party's domestic circumstances and relevant international guidance…" as well as to have the Parties take at least two from a list of nine measures such as a focus on caries prevention. The Parties are to include two or more of these measures for phase down are listed below:

    (i) Setting national objectives aiming at dental caries prevention and health promotion, thereby

minimizing the need for dental restoration;
(ii) Setting national objectives aiming at minimizing its use;
(iii) Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration;
(iv) Promoting research and development of quality mercury-free materials for dental restoration;
(v) Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices;
(vi) Discouraging insurance policies and programmes that favour dental amalgam use over mercury-free dental restoration;
(vii) Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration;
(viii) Restricting the use of dental amalgam to its encapsulated form;
(ix) Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

2. In the U.S., implementation of the Minamata Convention follows from the State Department representation as a Party with their delegation to oversight by the **Environmental Protection Agency**. For dentistry within the U.S., the use of protective measures such as amalgam recycling and separators in dental settings became mandatory as of a 2017 ruling from the EPA. (Dental Rule (40 CFR Part 441)[33]

3. The U.S. **Food and Drug Administration**) has periodically reviewed the classification of dental amalgam as a medical device, such as in 2009 with the Class II Special Controls guidance; and subsequent resources, such as regulation documents, literature reviews, a Safety Communication issued in 2020 and resources for consumers.[8,14]

4. On June 26, 2023, the **American Dental Association** released a new clinical practice guideline on restorative treatments for caries lesions "that suggests more conservative approaches to removing carious tissue may decrease the risk of adverse effects." The guideline notes:

   "... potential adverse effects (AEs) for patients and the reported environmental harms of mercury have raised concerns, questioning the acceptability of amalgam. Although there is insufficient evidence to support the hypothesis that amalgam increases the risk of AEs compared with any other restorative materials, national and international stakeholders have questioned the use of amalgam in general and in vulnerable populations specifically." It adds, "environmental concerns beyond the confines of dentistry influenced the acceptability factor for direct restorative materials. It is important to emphasize that prioritizing an intervention does not equate to a recommendation against another."

Additional information
The Minamata Convention is the most significant agreement, but others may be of interest:

- **Other international agreements and treaties** exist that are similar for their constructs and potential for impact on the dental profession. Two major focus areas are:

(1) The Stockholm Convention, which entered into force on May 17, 2004, and is directed at protection of human health and environment from the effects of persistent organic pollutants (POPs). "The United States signed the Stockholm Convention in 2001, but has yet to ratify because we currently lack the authority to implement all of its provisions. The United States participates as an observer in the meetings of the parties and in technical working groups."[40]

"The most commonly encountered POPs are organochlorine pesticides, such as DDT, industrial chemicals, polychlorinated biphenyls (PCBs) as well as unintentional by-products of many industrial processes, especially polychlorinated dibenzo-p-dioxins (PCDD) and dibenzofurans (PCDF), commonly known as dioxins."[41]

(2) "Turning off the Tap: How the world can end plastic pollution and create a circular economy" is the title of the May 2023 United Nations Environment Programme report that "examines the economic and business models needed to address the impacts of the plastics economy."[42]

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