

Problem

The U.S. Food and Drug Administration (FDA) has periodically reviewed the classification of dental amalgam and dental mercury as medical devices.^{1,2} Medical devices are classified “based on the level of control necessary to assure the safety and effectiveness of the device”.³ Recent scientific reviews and consensus statements continue to support the safety and effectiveness of dental amalgam as a tooth restoration material.^{4,5,6,7} Despite these conclusions, public concerns about the general safety of amalgam persist.

By age 11, approximately 40 percent of U.S. children have experienced tooth decay in their primary teeth and almost 23 percent have untreated decay in these teeth.⁸ Over 90 percent of U.S. adults have experienced tooth decay.³ The prevalence of untreated decay is highest in certain groups of adults, including those without a high school education (45% of adults), and people with incomes less than 100 percent of the federal poverty level (44% of adults).⁸ Treatment of dental decay, especially in public health settings, is facilitated by the availability of restorative materials that are safe and cost-effective.

Methods

Numerous studies have reviewed recent developments in the scientific community about dental amalgam, including research that examines its use in children, long term effects in individuals, and comparisons with alternative materials.

Two major reviews of scientific literature related to dental amalgam have been conducted by the Life Sciences Research Office (LSRO)⁹ and the American Dental Association (ADA).¹⁰ The LSRO review examined peer-reviewed scientific publications from 1996 through 2003. The ADA updated the LSRO report with publications from 2004 through May, 2008. The LSRO concluded that recent studies “did not reveal sufficient evidence to support a causal relationship between dental amalgam restorations and human health problems” other than rare instances of allergic reaction.⁹ The ADA’s review added that several studies published after 2003 provide further support for this conclusion, including ones that support the safety of amalgam in young children.¹⁰

The LSRO report and the ADA update identify areas where there are gaps in knowledge about amalgam safety – especially in specific groups of people such as pregnant or nursing women, infants, and developing fetuses. Well-designed studies of the effects of low-dose exposure to mercury through amalgam restorations in these populations would help address existing safety concerns.

Recent studies include two major clinical trials: the Casa Pia study of dental amalgams in children¹¹ and the New England Children's Amalgam Trial (NECAT).¹² These were the first randomized clinical trials to follow young children for extended periods of time (5-7 years) and monitor them for any adverse effects related to amalgam or non-amalgam restorations. Neurological, psychological, and physical characteristics were assessed repeatedly throughout both studies. No adverse health effects were found to be associated with either amalgam or non-amalgam restorations in children.^{13,14,15,16,17,18} The studies did find that children with amalgam restorations had higher urinary mercury levels, but did not find this to be associated with any health problems.^{19,20}

A recent study of U.S. military veterans examined the possible relationship between long term, low dose exposure to mercury vapor from amalgams and clinical symptoms.²¹ No clinical symptoms were found to be associated with amalgam restorations. The authors did find a significant association between an abnormal sensitivity to vibration and amalgam exposure. This finding was not associated with any clinical findings or symptoms, and the relationship was not consistent among different groups in the study.

The Casa Pia study and the NECAT study, along with other recent studies, provide information about the durability and longevity of amalgam and composite or compomer restorations. These recent studies show amalgam restorations generally last longer before needing replacement and require fewer repairs than composite restorations.^{22,23,24,25,26} However, reported differences between amalgam and composite restorations are mixed, especially regarding the development of secondary (recurrent) caries.^{22,23} In general, size of the restoration plays a role in longevity: extensive amalgam restorations tend to perform better than extensive composite restorations, especially in patients with high caries risk. In addition to better longevity, amalgam restorations cost less than composites²⁷ and are less technique sensitive.

The U.S. Environmental Protection Agency (EPA) and the ADA have encouraged dentists to minimize the environmental impact associated with amalgam use.^{28,29} "Best management practices" are described and include the use of amalgam separators and amalgam recycling in dental offices. Amalgam separators are expected to become mandatory in U.S. dental offices by 2012.²⁹

Recent clinical trials and scientific reviews have found no evidence that dental amalgams contribute to adverse health effects in the general population. Allergies to the components of amalgam are rare and can be medically managed by dental professionals when they occur. When compared to existing alternative materials, dental amalgam is a cost-effective option for dental restorations. Research gaps have been identified and progress continues to be made to address areas of concern.

Policy Statement

The Association of State and Territorial Dental Directors (ASTDD) supports and endorses the use of dental amalgam as a restorative material with proper disposal of waste amalgam.

- ¹ U.S. Food and Drug Administration. Advisory Panel to Review Dental Amalgam. Food and Drug Administration Web site. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm215061.htm>. Published June 10, 2010. Accessed July 26, 2010.
- ² U.S. Food and Drug Administration. Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073311.htm>. Published July 28, 2009. Accessed September 7, 2010.
- ³ FDA Device Classification. FDA Web site. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>. Accessed September 7, 2010.
- ⁴ European Commission, SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks). The safety of dental amalgam and alternative dental restoration materials for patients and users. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_016.pdf. Published May 2008. Accessed September 7, 2010.
- ⁵ FDI World Dental Federation. FDI Policy Statement: Safety of Dental Amalgam. October 2007. <http://www.fdiworldental.org/sites/default/files/statements/English/Safety-of-dental-amalgam-2007.pdf>. Accessed September 2, 2010.
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- ¹⁶ Bellinger DC, Trachtenberg F, Daniel D, Zhang A, Tavares M, McKinlay S. A dose-effect analysis of children's exposure to dental amalgam and neuropsychological function: The New England Children's Amalgam Trial. *J Am Dent Assoc.* 2007;138(9):1210-1216.
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²⁷ American Dental Association. *Dental Practice: 2009 Survey of Dental Fees*. Chicago, IL: American Dental Association Survey Center; 2009.

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²⁹ U.S. Environmental Protection Agency. EPA will propose rule to protect waterways by reducing mercury from dental offices - Existing technology is available to capture dental mercury. <http://yosemite.epa.gov/opa/admpress.nsf/e77fdd4f5afd88a3852576b3005a604f/a640db2ebad201cd852577ab00634848!OpenDocument>. Published September 27, 2010. Accessed September 30, 2010.