



# Caution and Causation: Lessons From the Delicate Story of Dental Amalgam

**David Williams**

There is a long running debate about whether or not dental amalgams represent a serious health hazard because of the mercury they contain. A scientific opinion produced for the European Commission has recommended a solution to the conundrum and provides some lessons for other medical device related causation issues.

## The issues

A silver mercury paste was developed in France for dental use as long ago as the 1820s and a similar substance was introduced into commercial dental practice in the United States a decade later. One hundred and seventy five years later we are still arguing about the effectiveness and safety of this so-called dental amalgam. The amalgam conundrum is extremely obvious to see, but has been equally difficult to resolve. On the one side, we have the profound materials science problem of creating a substance that can be inserted in a fluid-like state into a cavity in a tooth, where it sets in a short period of time to produce a strong, hard and durable replacement for dentine and enamel. There are extremely few materials that can do this. Mercury, being liquid at ambient temperatures, is able to form an alloy with silver and achieve this goal. This is the metallurgical basis of the dental amalgam, which has been used in many millions of patients worldwide as a highly effective dental restorative material. On the other side, we have a profound public health concern. Some forms of mercury are toxic and there are known toxicological hazards to humans associated with certain mercury exposure conditions. The question arises, therefore, of whether or not we

should solve the problem of dental decay by inserting a potentially lethal substance into the tooth cavity.

The debate over this question has been taking place for more than a century. The seriousness of this debate has been raised by threats of legal action by groups of patients who claim that some or all of their illnesses are caused by the amalgams they have had in their mouths since early childhood. There are also environmental concerns. The levels of mercury being used for general industrial and commercial goods has been decreasing because of toxicological hazards and the availability of alternative materials so that dentistry is now one of the few remaining practices in which mercury is still being used.

Because of these concerns, the European Commission has considered the questions raised by the continued use of dental amalgam and an Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on this subject has been published.<sup>1</sup> The production of this Opinion has been an interesting exercise in balancing the concepts of the precautionary principle, which states that the absence of scientific certainty shall not be used as a reason to postpone measures where there is a risk of serious harm to public health or the environment, with the concepts of epidemiology, which →



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Professor Williams retired from the University of Liverpool, after 40 years, at the end of 2007. He retains the position of Emeritus Professor there and now has a series of professorial appointments in North Carolina, USA; Sydney, Australia; Cape Town, South Africa; and in China. He offers consulting services from his company Morgan & Masterson, based in Brussels, Belgium. He is Editor-in-Chief of Biomaterials, the leading journal in the biomaterials field. He is Scientific Director of STEPS, the European Commission Framework VI Programme on a Systems Approach to Tissue Engineering Products and Processes.



- espouse some rules on the determination of scientific certainty with respect to causation.

### Principles of causation

Let us start with the issues of causation. The amalgam question is not the only medical device matter where claims of biomaterials related harm have arisen. The well known silicone gel breast implant fiasco of a decade ago serves to highlight the dangers of forming conclusions about causation without the necessary evidence. The claims that silicones were the cause of a variety of conditions, especially with auto-immunity and the development of scleroderma, lupus and rheumatoid arthritis, which were without any mechanistic basis to start with, were shown to be false following numerous epidemiological studies. These studies actually revealed that individuals with breast implants were slightly less likely to develop these conditions. Similar difficulties arise with the claims that medical devices fabricated from poly(vinyl chloride) containing plasticisers cause harm to patients. When individuals are exposed to a wide variety of substances on a daily basis, through the air they breathe, the food they ingest or the medical products with which they are treated, we must be extremely cautious in blaming one exposure entity for the development of a disease, where it is known that the disease has complex and multiple aetiologies.

The problems of identifying causes of disease have been at the centre of epidemiological debates for many years and current practice is based on the Bradford Hill Criteria of Causation published in 1965.<sup>2</sup> The main features of these criteria are the paramount need to establish a temporal relationship between exposure and outcome, the strength of any effect or association determined statistically, the evidence of a dose-response relationship, the plausibility and specificity of any association, and the coherence of any putative association with existing knowledge. It became obvious with respect to dental amalgam that some of these questions are difficult to analyse, for example, because of the uncertainty over the exposure of individuals to mercury derived from amalgams compared with their exposure to mercury from other sources.

### The claims of amalgam related disease

There have been claims of causation with respect to a variety of systemic conditions, particularly neurological and psychological/psychiatric effects, including, Alzheimer's, Parkinson Disease, multiple sclerosis and kidney disease. Elemental mercury does have a specific toxicological profile and the presence of amalgam restorations in an individual is likely to lead to raised blood and urine mercury levels. However, these raised levels are lower than those necessary to cause adverse effects in general, and the available clinical and epidemiological evidence does not support any causal link between mercury and any of the diseases that have been suggested as being associated with dental amalgam. This takes into account the possibilities of effects within

the urinary, neurological, reproductive and immune systems and also associations with psychological conditions. The most recent studies involving assessments in children and pregnant and lactating women have failed to find any association between the use of amalgam and neuro-psychological development in children. Parenthetically we should note that there is evidence of a low incidence of local manifestations of allergy to dental amalgam, which may be resolved by removal of a filling, but these are not considered further here.

### The solution

The detailed analysis in the SCENIHR Opinion makes it clear that, using the criteria for causation mentioned above, there is no unequivocal evidence to support any claims of causation with respect to amalgams and systemic disease. To some people this may not seem good enough to avoid the precautionary principle, but let us consider the options. For a scientific committee to advise an organisation such as the European Commission that, although no evidence of causation exists, it is prudent to believe that amalgams could cause systemic disease and therefore this use should be prohibited, would create significant legal and social dilemmas; it would create precedents for other causation claims with respect to medical devices and lay the basis for malpractice and product liability litigation actions. Yet, it is clear that just because there is no evidence of harm does not mean that no harm exists and it would be a huge mistake to ignore a potential problem if other solutions are available.

At the same time as investigating amalgam, SCENIHR was asked to consider the risks related to the alternative dental filling materials. For the past 40 years there have been alternative materials, mostly resin based composites, but also some ceramic based cements that can be used for certain types of dental restoration. In reality, there is even less evidence about the biological safety of these materials, with much less data on exposure levels, but significant in vitro data concerning the genotoxicity of some components. Nevertheless these materials have been gaining popularity at an increasing rate, not so much because of the toxicological concerns associated with amalgam but because of two important clinical factors. First, they actually look like teeth rather than having the metallic amalgam appearance, which is a hugely important matter in aesthetic dentistry. Second, and even more importantly, most of the materials are, directly or indirectly, adhesive to tooth substance, which amalgam is not. This means that far less of a tooth has to be removed during the placement of this type of restoration; the dentist no longer has to drill away much of the tooth simply to prepare a retentive cavity for the amalgam.

These two factors alone are so attractive to dentists and patients that in most parts of Europe, the use of amalgam is in serious decline; indeed in some dental schools the use of amalgam is no longer taught. This, therefore, is a classic



case of a problem going away by itself. There is no need for a ban on amalgam, with all of the legal and philosophical consequences that would ensue.

The decreased clinical use of amalgams will ensure, quite rapidly, that increasingly less mercury will get into our teeth and issues of causation become moot. There is just one final point to clear up and that is the question of whether or not individuals with amalgams who develop a serious medical condition such as multiple sclerosis should have the fillings removed. There is no evidence that removal will be of any benefit and it is well known that the mercury levels in individuals is transiently increased during removal, but this has to be an individual choice taken by the patient in consultation with their dentist and physician.

Questions of causation can be difficult to resolve, especially where vast numbers of patients or individuals are involved, and where spurious liability consequences can arise from poorly constructed arguments and decisions. In some cases, a little common sense can go a long way.

#### Author's note

The author was the Chairman and Rapporteur of the SCENIHR Opinion on dental amalgam. The Opinion itself does not represent the position of the European Commission, but the advice given to it by a scientific committee.

The additional views presented in this article are the sole responsibility of the author.

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