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.

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...
The claims of amalgam related disease
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 organ-
isation 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 com-
ponents. 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.

References

David Williams
Morgan & Masterson, Avenue de la Forêt 103, Brussels 1000
Belgium, tel. +32 4 7597 0556
e-mail: peggy@morgan-masterson.com
www.morgan-masterson.com

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