



# A Specialised National Reporting System of Adverse Reactions to Dental Materials

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## INTRODUCTION

Materials for dental use grow in number and complexity. Dental materials are classified as medical devices according to the European Medical Devices Directive (93/42/EEC). The associated general vigilance reporting procedure is aimed at the manufacturer and the appropriate national Competent Authority and is not designed to record subtle adverse reactions seen with the wide-spread use of dental materials.

## MATERIAL AND METHOD

A "Dental Biomaterials Adverse Reaction Unit" was initiated by the Norwegian Board of Health in 1992, and began its activities in 1993. One of the main purposes was to obtain experience with regard to nationwide reporting of adverse reactions (side effects) seen with all types of dental biomaterials. The procedure is based on spontaneous voluntary reporting from dentists, physicians and dental hygienists.

Norway has a population of about 4.5 million with nearly 3900 dentists in private and public dental health service.

Reporting forms are published regularly in the Norwegian Dental Journal, and can be obtained over the Internet as well via mail, if requested.

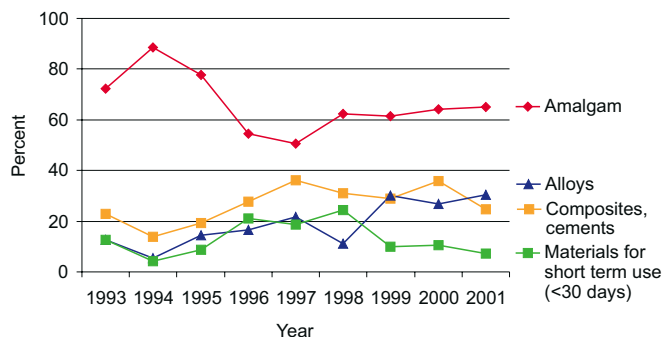
The reports are evaluated by the Unit. Some of the patients involved are referred for clinical examination at the Unit. Thus, some of the reported reactions can be validated.

## RESULTS

From 1993 to the end of 2001 a total of 1074 reports were received at an average reporting rate of about 100 per year during the last 6 years. The proportion of reports involving dental amalgam has decreased from a peak of 89% of the reports in 1994 and has remained on the 60% level since. Reactions to direct non-amalgam filling materials have not increased in proportion to the increased use of such materials in the last decade. Reactions associated with fixed prostheses have increased over the registration period (Figure 1).

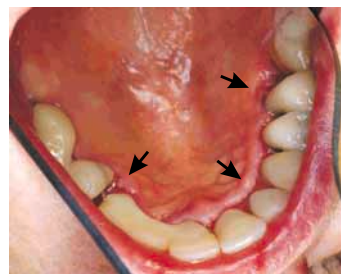
Three cases with suspected adverse reactions to dental biomaterials are presented (Case 1-3).

**Figure 1**  
The percentage of types of materials involved in adverse reaction reports (per year)

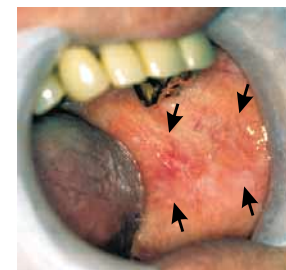


## CASES

The cases below demonstrate that it might be difficult to establish a certain causal relationship with specific exposure to components of dental biomaterials. The association were evaluated as likely/probable for all cases presented below (Case 1-3).



**CASE 1**  
Gingival reactions after exposure to acrylate-based cement used as a permanent luting cement for ceramic restorations. A patch test to dental materials (Dental Screening DS 1000, Chemotechnique Diagnostics) showed positive reactions (at day 7) to acrylates (ethyleneglycol dimethacrylate and 2-hydroxyethyl methacrylate, HEMA).



**CASE 2**  
Oral lichenoid contact reaction to gold following treatment with a fixed gold bridge. The patient showed facial dermatitis and oral lichenoid reactions. The patient was patch test positive to gold (goldsodiumthiosulfate). After replacement of all the patient's gold-containing restorations with titanium/ceramic restorations the lesions cleared.



**CASE 3**  
A widespread reaction in the mucosa associated with the insertion of a temporary crown made from autopolymerising acrylic. The reaction occurred about 1 day after insertion, and cleared after 3-4 days after removal. The patient tolerated the temporary cement (non-eugenol type).

## DISCUSSION

A national reporting procedure can be implemented and is used by practitioners. However, it is complicated to make causality assessments between the reaction and the suspected dental product. Several types of materials are usually involved in one type of treatment, e.g. prosthetic restorations, and the offending substance cannot be easily identified. Moreover, many products are placed on the market without detailed compositional information, making causality assessment difficult in case of e.g. allergic reactions.

It is our opinion that the reporting systems based solely on the recommended procedures affiliated with the Medical Devices Directive (vigilance system) is not fully adequate in order to establish a research-based knowledge about adverse reaction with the widespread dental materials. Post-marketing evaluation of dental materials in the form of a specialized reporting procedure can detect changes in adverse reaction patterns and serve as a signal-generating tool. The monitoring of adverse reactions could benefit from international collaboration creating a larger reporting base.

(For information on adverse reaction reporting: <http://www.uib.no/ood/advrep/MAIN-Advrep.html>)