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National Reporting of Adverse Reactions to Dental Materials. The Norwegian Registry

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INTRODUCTION

There are scarce data on the frequency and severity of adverse reactions associated with dental materials. Since dental materials grow in number and complexity, there appears to be a need for a registry for adverse reactions as reported by practitioners. Moreover, the public is becoming more concerned about such reactions.

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 in the field of adverse reaction reporting concerning all types of dental biomaterials.

METHOD AND MATERIAL

The adverse reactions are to be reported by a dentist or a physician using a specially designed form (see the poster's right hand side). The procedure is based on spontaneous and voluntary reporting.

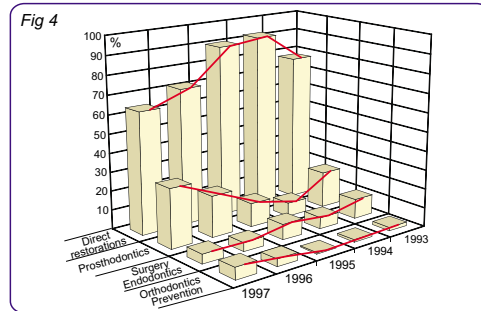
By the end of 1997, 674 reports were received. (Norway has a population of 4.3 million, and there are 3800 dentists).

The basic information to be reported concern general patient data, the reaction(s) in question - classified as subjective or objective symptoms and findings. The location of the reaction(s) is divided into local, oro-facial and/or general ones. The relevant dental procedures as well as the materials involved should be stated.

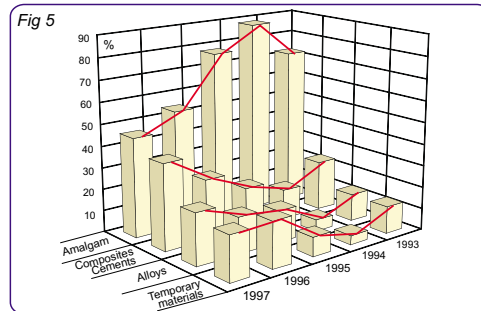
RESULTS

The number of women involved in adverse reactions was about twice that of men. The most common age-group was 40-49 years. 82% of the reports were submitted by dentists, the remainder from physicians.

Fillings and associated procedures account for the highest proportion of treatments being reported, but the proportion of reports concerning prosthodontic treatment has increased over the years since 1994. (Fig. 4)



Concerning materials, the relative number of reports involving dental amalgam has decreased from a peak of 89% of the reports in 1994 to 46% in 1997. Reactions related to "non-amalgam" direct filling materials have increased from 14% in 1994 to nearly 40% in 1997. (Fig. 5)



Reactions associated with dental amalgam are of a more subjective nature than reactions to other dental biomaterials. Furthermore, the onset of amalgam related reactions of subjective nature was usually noted after a long time (several months to years) following the insertion of amalgam (Table 1).

Table 1: Subjective symptoms only and time of onset

Material	Reactions involving subjective symptoms only (% of reports)	Reactions noted within 1 week or at first visit (% of reports)
Amalgam	53%	21%
Alloys	35%	31%
Composites	34%	45%
Cements	34%	45%
Temporary materials	12%	96%

The most common objective reactions reported were those seen intra-orally (Table 2). About half of the intra-oral reactions were reported as "lichenoid" patches which were topographically related to fillings, mostly amalgam (Fig. 1).

Generalized subjective symptoms (Table 2) are most often linked to the presence or earlier exposure to dental amalgam. The most common symptoms were tiredness, memory disturbances, headache, and muscle and joint pain. Frequently, there were multiple symptoms of this kind in the same patient.

Table 2: Localization and type of reaction

Localization	Objective findings (% of reports)	Subjective symptoms (% of reports)
Intra-oral reactions	36%	69%
Extra-oral reactions, lip and face	17%	40%
Reactions elsewhere	14%	75%
General reactions	14%	75%

Regarding the opinion on the association between the reaction and the material, the patients were generally more convinced that an association existed than the dentist or physician.

The form used for reporting adverse reactions (side effects) from dental materials

NOTIFICATION OF ADVERSE REACTIONS RELATED TO DENTAL MATERIALS

Background: Reporting on this form is part of the duty to conduct a register on adverse effects of dental materials. The form is filled in according to the professional judgement of the dentist, physician or other professional. The form records reactions from dental materials associated with dental materials. Even if there are doubts regarding the grade and type of reaction, or regarding the relationship to dental materials, the form is filled in and sent on. One form for each patient participation shall be used. It is also important that possible adverse reactions to materials that occur in dental procedures during their work are reported in the relevant sections. Name and address of the reporter: City, Zip code, City/Place.

Data regarding patient: The reporter's own identification of the patient (no name or personal code number): Doctor: Female Male Age: _____ years General diseases: Present use of medicine, specify: Allergic hypersensitivity (drug, polymer, metal): specify if possible.

Reaction of patient: Objective findings (The reaction is observed): None Reaction intraoral: Intraoral symptoms: Burning sensation Pain, tenderness Taste changes Dry mouth Increased salivation Swollen gingiva Lichenoid patches Stomatitis Pain, tenderness Swollen gingiva Stomatitis Dry mouth Increased salivation Swollen gingiva Lichenoid patches Stomatitis Pain, tenderness Taste changes Dry mouth Increased salivation Swollen gingiva Lichenoid patches Stomatitis Pain, tenderness Taste changes Dry mouth Increased salivation Swollen gingiva Lichenoid patches Stomatitis Pain, tenderness Taste changes Dry mouth Increased salivation Swollen gingiva Lichenoid patches Stomatitis Pain, tenderness Taste changes Dry mouth Increased salivation Swollen gingiva Lichenoid patches Stomatitis Pain, tenderness Taste changes Dry mouth Increased salivation Swollen gingiva Lichenoid patches Stomatitis Pain, tenderness Taste changes Dry mouth Increased salivation Swollen gingiva Lichenoid patches Stomatitis 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