



# Objective Intraoral Findings from Adverse Reaction Reports

## Gunvor Bentung LYGRE, Nils Roar GJERDET, Lars BJÖRKMAN

### Dental Biomaterials Adverse Reaction Unit, University of Bergen, Norway



#### INTRODUCTION

Dental materials may cause various adverse effects. Such reactions are considered rare, but some people might be sensitive to components of dental materials.

To monitor adverse reactions from dental biomaterials, a national reporting procedure was established in Norway in 1993, funded by the Ministry of Health and Social Affairs. It was coordinated by the Dental Biomaterials Adverse Reaction Unit at the University of Bergen. The aim of the present study was to compare the reported objective intraoral signs of reactions with findings during a dental and medical examination at the Adverse Reaction Unit.

#### MATERIAL AND METHOD

During 1993-1999 a total of 899 adverse reaction reports were received by the Dental Biomaterials Adverse Reaction Unit. The adverse reactions were reported by dentists and physicians using a reporting form. The procedure is based on voluntary, spontaneous reporting from health personnel. 253 of the patients (69 men and 184 women), with reported adverse reactions, were also referred and subsequently examined by dentists and physicians at the Dental Biomaterials Adverse Reaction Unit (Fig 1). All patients underwent an oral and orofacial examination including dental radiography and saliva sampling. All lesions were documented by photos. Based on the coordinated data, the sensitivity of the reporting system concerning the detection of intraoral signs of reactions could be estimated.

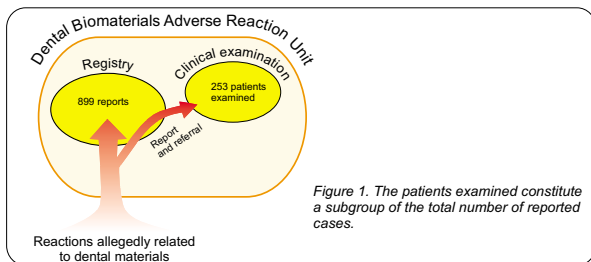


Figure 1. The patients examined constitute a subgroup of the total number of reported cases.

#### RESULTS

There were no major differences regarding sex and age between the total number of reported cases (n=899) and the group of patients who also were referred for clinical examination at the Unit (n=253). The reports involved about twice as many women as men and the median age was 47 years. Dentists in private practice were the most frequent reporters and also the most frequent referrers (Table 1).

Table 1. Distribution of reports and referrals from health personnel.

Reporter	All reports (n=899)	Referred patients (n=253)
Dentist - public	216 (24%)	56 (22%)
Dentist - private	548 (61%)	139 (55%)
Physician	99 (11%)	53 (21%)
Unspecified	36 (4%)	5 (2%)

The type of treatment associated with the reported adverse reactions was mainly fillings and related procedures. Amalgam was the most frequently involved material (Table 2).

Table 2. Number of patients with reactions allegedly related to different dental materials. Reports could involve more than one material.

Material	Reports (n=899)	Examined patients (n=253)
Amalgam	453 (50%)	213 (84%)
Metals, fixed dentures	88 (10%)	27 (11%)
Resin-based materials and cements	164 (18%)	9 (4%)
Materials for removable dentures	30 (3%)	6 (2%)
Endodontic materials	16 (2%)	4 (2%)
Unspecified materials	254 (28%)	19 (7%)
Others, incl. temporary materials	85 (9%)	5 (2%)

Lichenoid reactions in the oral mucosa were the most common finding in both the reports and at the examination at the Unit (Table 3).

Table 3. Number of intraoral objective findings in the subgroup of patients examined at the Adverse Reaction Unit (n=253). One patient could exhibit several objective findings.

Objective findings	Reported findings	Clinical examination
Lichenoid reaction	21	35
Erythema	16	32
Wounds/vesicles	11	23
Edema	6	8
Atrophy	0	4
Others	19	74
Total	73	176

During clinical examination at the Unit, a total of 102 objective intraoral findings were observed in 80 patients (Fig 2). 74 findings were classified as "others".



Figure 2. Signs of adverse reactions to dental materials. One patient could exhibit several objective findings.

Table 4. Number of patients at the clinical examination with different intraoral findings related to dental amalgam, fixed prosthesis and resin-based materials and cements. Each patient could be referred for alleged reactions to more than one material, and each patient could exhibit several intraoral signs of reaction.

Objective findings	Amalgam (213 patients)	Metals in fixed prostheses (27 patients)	Resin-based materials and cements (9 patients)
Lichenoid reaction	26	6	1
Wounds/vesicles	19	0	0
Erythema	20	7	1
Edema	6	3	0
Atrophy	2	1	0
Others	58	10	1
No intraoral findings	111	7	7

For 35 patients the findings stated in the reports were confirmed at the examination at the Unit. For another 45 patients objective intraoral signs of reactions were found by the Unit, but not reported. The reporting system, based on the clinical examination at the Unit, represent a sensitivity of 44% and a specificity of 94% with regard to the detection of intraoral signs of adverse reactions to dental materials. In 36 of 80 patients with objective findings the Unit assessed that there was a probable relationship between dental materials and the reactions.

#### DISCUSSION

The Norwegian Adverse Reaction Unit represents a system including both clinical functions as well as an adverse reaction registry concerning dental materials.

The coordinated activities make it possible to compare data from adverse reaction reports with clinical findings from examination of patients at the Unit. Thus there is a unique opportunity to evaluate the reports.

The presence of intraoral objective signs of reactions was confirmed in almost all cases at the clinical examination at the Unit. In a few cases no reactions were found by the Unit, which may be related to the elapsed time from reporting to examination. Consequently, reactions with only acute manifestations are not expected to be found during the examination at the Unit. In order to increase the sensitivity of adverse reaction reporting system, reporting forms could include more detailed guidance regarding conditions the practitioners should consider.

#### CONCLUSION

The adverse reaction reporting procedure is a valid tool for reporting intraoral signs of reactions related to dental materials. The reporting procedures could be refined.

#### ACKNOWLEDGEMENT

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