Patients' choice of dental treatment following examination at a specialty unit for adverse reactions to dental materials

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The Dental Biomaterials Adverse Reaction Unit in Bergen, Norway, is a national unit for the examination of patients with suspected adverse reactions to dental materials. The aim of this study was to investigate whether patients with suspected adverse reactions to dental materials experienced improvement in health after dental restorations had been replaced, and whether they had acted according to the recommendations of the Unit. A questionnaire was sent to 358 patients who had been examined at the Unit 18 months to 7 years earlier. Of the 207 patients who completed the questionnaire, 85 had had restorative materials replaced with other types of materials. A majority had had amalgam fillings replaced. After replacement, 51 patients reported an improvement in health. Twelve patients reported that they felt worse after replacement. The Unit recommended replacement of materials in 31 patients, of whom 24 followed the recommendation. Among 176 patients who were not given specific recommendations as to replacement of dental materials, 67 had had their restorations replaced, and 40 had started to have them replaced. It appears that the examination at the Dental Biomaterials Adverse Reaction Unit is one of several inputs that influence a person's decision to replace dental materials. □ *Adverse reactions; dental materials; follow-up study; improvement of health; replacing dental materials*

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There is concern in the population about health effects related to dental restorative materials (1), although the incidence of adverse reactions is considered to be low (2–4). In response to the question about amalgam safety, several reports have been presented by national and international health organizations and authorities (5–7).

A national Dental Biomaterials Adverse Reaction Unit was established in Norway in 1993, its purpose being to offer consultative services to patients referred for suspected adverse reactions to dental materials. Dental treatment is not performed by the Unit, but by the patient's own local dentist. Funded by the Norwegian Ministry of Health and Social Affairs and located at the University of Bergen, the Unit also runs a national reporting system for adverse reactions to dental biomaterials (8).

Patients with suspected adverse reactions often complain about general symptoms, including pain from muscles and joints, fatigue, dizziness, headache, memory and concentration problems, anxiety, restlessness, and depression (9–13). Intraoral lichenoid reactions are the most common objective reactions (14–17). In addition to objective signs of reactions, the patients have a number of intraoral subjective symptoms (18, 19).

Some studies report that patients who have had their amalgam restorations replaced may experience reduced symptoms and improved health (20–22).

The aim of the present study was to investigate whether patients examined at the Dental Biomaterials Adverse Reaction Unit acted according to the recommendations given by the Unit, and if patients who had had dental materials replaced experienced any change in health.

Materials and methods

Examination at the dental material adverse reaction unit

During the period 1993–99 a total of 368 patients (106 M and 262 F) with assumed adverse reactions to dental materials underwent an oral, orofacial, and medical examination at the Dental Biomaterials Adverse Reaction Unit in Bergen, Norway. The patients had different complaints ascribed to dental restorative materials. The nature of the reactions determined whether the local dentist or physician requested an evaluation by the Unit. The majority of patients were referred to the Unit because of general subjective symptoms. Some patients also had intraoral objective findings.

Before the examination, the patients completed a questionnaire concerning their health situation, as well as demographic information. Additional information from their own dentist and physician were obtained, along with laboratory test results. Patients with suspected contact allergy to dental materials were referred to a dermatologist, and most of these were patch-tested. The clinical examination procedures at the Unit have been reported previously (10, 14).

Based on the examination at the Unit, the relationship between the patients' health problems and exposure to dental materials was assessed. Patients with intraoral contact lesions were recommended to have the relevant dental materials in contact with the lesion replaced. Patients who had lesions not only directly in contact with the dental material, and additionally a clinical relevant positive patch test, were recommended to have all the

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Table 1. Data obtained at time of examination of patients ($n = 358$) who received follow-up questionnaires as a function of response status

	Answered the questionnaire			Did not answer the questionnaire		
	Women ($n = 148$)	Men ($n = 59$)	Total ($n = 207$)	Women ($n = 108$)	Men ($n = 43$)	Total ($n = 151$)
Mean age, years (min-max)	48	47	48 (17–73)	46	44	45 (8–85)
No. of patients referred for reactions allegedly related to amalgam restorations	122	52	174 (84%)	86	38	124 (82%)
No. of patients with non-amalgam material reactions	26	7	33 (16%)	22	5	27 (18%)
No. of patients with general subjective complaints	138	55	193 (93%)	101	40	141 (93%)
No. of patients with objective intraoral findings at the examination	58	15	73 (35%)	26	9	35 (23%)

dental materials replaced that contained the substances causing reactions (10).

Follow-up questionnaire

A questionnaire regarding the type of dental treatment given by their local dentist after the examination at the Unit was sent to 358 patients (102 M and 256 F) during 2000 and 2001. The patients had been examined at the Unit from 18 months to 7 years previously. Ten patients could not be reached because of unknown address.

The patients were asked if they had had dental restorations replaced due to suspected adverse reactions and, if so, which type of material was replaced. Information about their self-assessed current health condition was requested, and the patients were asked to classify alterations in their health.

The patients were asked to indicate the degree of various subjective symptoms on horizontal scales (0 = no symptoms, 10 = extremely severe symptoms). From these scales, we created two symptom indices by calculating the sum of the scores for local symptoms (11 items) and the scores for general symptoms (12 items). Reliability of the two scales was assessed by Cronbach's alpha (0.86 and 0.88, respectively).

The study was approved by the Regional Committee for Medical Research Ethics in Western Norway.

Statistical analyses

An independent sample t test and the chi-square test were used to test differences between groups. The Kruskal-Wallis test and the Mann-Whitney U-test were used where ordinal data were included.

Results

Responses were received from 218 of the patients (61%). Eleven explicitly stated that they did not want to answer the questionnaire. Some of these patients said that the association between health problems and dental materials had become irrelevant because other conditions causing the symptoms had been diagnosed. One patient claimed that she was disappointed with the consultation at the Unit and therefore did not want to participate. This left 207 responses (58%) for analysis.

Persons who answered the questionnaire tended to be older than those who did not answer (t test; $P = 0.031$). Those who submitted the questionnaire had more intraoral findings than those who did not respond (chi-square; $P = 0.014$) (Table 1).

The response rate for patients recommended to have dental materials replaced was higher than that of patients who had not been given this advice (76% versus 56%; Table 2; chi-square; $P = 0.037$).

Patients with a positive patch test, but without clinical signs of contact allergy, were recommended to avoid dental materials containing the relevant components in future dental treatment. Completed questionnaires were received from 50% of these patients (Table 2).

Of the 207 patients who completed the questionnaire, 85 had had all restorations assumed to be related to the reactions replaced. A majority had had amalgam restorations replaced (Table 3). Of the patients who had started to have dental restorations replaced, the majority were in the process of having amalgam restorations replaced (Table 3).

A large number of patients (105) had consulted several types of complementary medicine. Homeopathy (51 patients) and acupuncture (62 patients) were the most common types of treatment sought.

Table 2. Recommendations given following the examination by response status

Recommendations given	Answered questionnaire ($n = 207$)	Did not answer questionnaire ($n = 151$)	Total ($n = 358$)
Replaced dental materials	31	10	41
Avoid specific materials in future dental treatment according to postive patch test	21	21	42
No recommendations for replacement of dental materials	155	120	275

Table 3. Number of patients who had started to have dental restorations replaced and number of patients who had had all restorations related to adverse reactions replaced

	Replacement of restorations started ($n = 46$)		All restorations replaced ($n = 85$)	
Materials	*n*	%	*n*	%
Amalgam	39	85	63	74
Amalgam and gold	1	2	10	12
Amalgam and resin-based materials	2	4	1	1
Amalgam, gold and resin-based materials	0	0	1	1
Gold	0	0	8	9
Resin-based materials	3	7	2	2
Resin-based materials and gold	1	2	0	0

After having had dental restorative materials replaced, 60% of the patients (51 of 85) indicated an improvement in health, compared with 28% who had not had dental materials replaced (chi-square; $P < 0.001$).

After replacement of the dental material that was allegedly causing the reactions, 6 patients (1 M and 5 F) gave the response 'completely well'. Three of those had had amalgam fillings replaced and three had had gold restorations replaced (Table 4). Patients who had gold restorations replaced and reported 'completely well' all patch-tested positive to gold, whereas the three patients who had had amalgam replaced had no reactions to amalgam components in the patch test.

Thirty-one patients reported feeling 'much better' after having the material associated with the reaction replaced. The majority had had amalgam restorations replaced. However, 12 patients reported 'worse' after replacement (Table 4).

Eighteen patients had had dental materials replaced according to recommendations from the Unit and 50% of them reported different degrees of improved health (Table 5). However, of the 67 patients who had not been given this recommendation, 63% reported improvement in health.

There were significant differences between groups regarding age, local and general symptom indices related to the patients' experience of health at the follow-up (Table 5). There was no association between the patients' perception of health at the follow-up and the Unit's recommendation whether or not to replace dental materials, period of time since the restorative materials were replaced, or if the patients had patch-tested positive to dental materials (Table 5). Significant differences in the local and general symptom indices were found between the group of patients who reported 'much better' or 'completely well' after replacement of dental materials and the group that reported 'worse' (Mann-Whitney, $P = 0.035$ and $P < 0.001$).

Of the patients who were advised to replace dental materials, 77% acted according to the recommendations (Table 6). For 176 patients the Unit found no indications to recommend replacement of the dental material. Nevertheless, 61% of these patients had, or had started having, their restorations replaced (Table 6).

Discussion

This study describes the self-assessed health situation of 207 patients who answered a follow-up questionnaire regarding their health situation 18 months to 7 years after examination at a dental biomaterials adverse reaction unit. Adverse reactions or side effects to dental materials usually do not comprise clear-cut diagnoses with a straightforward causal relationship. The complaints range from general ill-health without an obvious causal relation, to specific and confined objective reactions which are topographically related to the presence of a dental material.

At the time the patients received the follow-up questionnaire, the question about health problems related to dental materials could have been considered irrelevant for some patients because other diseases had been

Table 4. Number of patients who had had various dental materials replaced and alterations in health situation at the follow-up ($n = 85$)

	Response category							
Material replaced	Worse	No change	Somewhat better	Much better	Completely well	Do not know	No answer	Total
Amalgam	11	9	11	23	3	2	4	63
Amalgam and gold	0	2	1	4	0	1	2	10
Amalgam and resin-based materials	0	0	0	1	0	0	0	1
Amalgam, gold, resin-based materials	0	0	0	1	0	0	0	1
Gold	1	0	1	1	3	1	1	8
Resin-based materials	0	0	1	1	0	0	0	2

Table 5. Summary of results for patients ($n = 85$) who had had dental materials replaced related to self-assessed health. Results from the examination at the Unit: Mean age, number of patients with positive patch test to substances in dental materials, number of patients with objective intraoral findings, with general subjective complaints and number of patients recommended by the Unit to have dental materials replaced. Information in the follow-up questionnaire: Mean number of years since replacement of the suspected dental material (data for 77 patients), mean local symptom index (data for 83 patients), mean general symptom index ($n = 84$ patients), and number of patients who had received complementary medical treatments

	Response category							
	Worse	No change	Somewhat better	Much better	Completely well	Do not know	No answer[a]	Total
Women/men	7/5	7/4	10/4	24/7	5/1	3/1	6/1	62/23
At the time of the examination:								
Mean age in years[b]	50	56	43	45	50	54	51	48
Positive patch test	4	4	7	14	4	2	4	39
Gold	1	0	1	4	3	2	3	14
Mercury	1	2	2	3	0	0	0	8
Other materials	2	2	4	7	1	0	1	17
Objective intraoral findings	6	2	5	16	2	2	1	34
General subjective complaints	12	10	13	29	5	4	6	79
Advised to replace materials	2	3	3	4	2	3	1	18
At the follow-up:								
Replaced dental materials	12	11	14	31	6	4	7	85
Mean number of years since replacement (s)[c]	3.6 (3.1)	2.3 (1.8)	3.6 (3.5)	3.8 (3.3)	5.5 (2.4)	1.1 (0.6)	3.9 (4.4)	3.5 (3.2)
Mean local symptom index[d] (s)[e]	29.5 (21.9)	21.4 (26.0)	34.8 (25.4)	17.9 (17.5)	4.2 (6.7)	19.5 (5.7)	20.3 (22.9)	22.1 (21.3)
Mean general symptom index[f] (s)[g]	65.3 (28.8)	30.5 (22.1)	49.6 (29.4)	29.5 (22.0)	19.8 (12.3)	34.0 (6.2)	38.7 (16.2)	38.5 (26.3)
Received alternative medicine	8	7	9	12	3	2	6	47

s = Standard deviation.
[a] Did not answer question pertaining to health situation.
Kruskal-Wallis test was used to test differences across subgroups regarding age, number of years since replacement of dental materials, local and general symptom index. [b]$P = 0.028$. [c]Not significant. [d]Maximum possible score = 110. [e]$P = 0.027$.
[f]Maximum possible score = 120. [g]$P = 0.003$.

diagnosed after the examination at the Unit, and this may have influenced the responses and the response rate. In addition, the response rate is influenced by the fact that only one reminder, by letter, is allowed by the Committee for Medical Research Ethics in Norway. Suboptimal response rates are common in long-term questionnaire studies (22).

It could be speculated that patients who had received specific recommendations felt more positively towards to the Unit and therefore were more inclined to answer the questionnaire than those who had not been given such recommendations. However, the effect of this potential selection bias is not easily evaluated.

As expected, the persons reporting improvement of health had the lowest score of symptoms. Nevertheless, they still had a number of subjective symptoms. A study from Sweden has suggested that more than 70% of patients reported increased quality of life after having had all metallic materials replaced (21).

Lichtenberg (20) reported that removal of amalgam restorations or amalgam in combination with other metal restorations gave significant improvement of symptoms. These patients received additional 'detoxification' and diet recommendations. He suggested that the symptoms which were improved or eliminated are present in the general population, but undiagnosed. A recently published study (22) described reduced physical and mental symptom load compared to status prior to removal of amalgam restorations, but only to a level comparable with that reported by groups with known chronic medical disorders.

Age apparently plays a role in patients' change in health. It is considered likely that the occurrence of ill health

Table 6. Recommendations given following examination at the Unit for 207 patients

	Dental treatment since examination at the Unit				
Recommendations given by the Unit	Replaced all the suspected dental material ($n = 85$)	Started replacing the suspected dental material ($n = 46$)	Not replaced dental material ($n = 65$)	No answer ($n = 11$)	Total ($n = 207$)
Replace dental material	18	6	6	1	31
No recommendations to have dental restorations replaced	67	40	59	10	176

increases with increasing age, and that older patients would be more likely to have symptoms related to medical conditions. On the other hand, several other factors may influence patients' experience of health. It is well established that the differences could be associated with psychological factors (23–26). One study indicated that a majority of patients with health complaints related to dental amalgam frequently had mental disorders, including anxiety, depression, and somatization (27). However, this does not explain the fact that the majority of the patients in the present study reported that they felt better after having their amalgam restorations replaced. Interestingly, it has been reported that health improvement after removal of amalgam restorations was related to mercury excretion in urine prior to removal (13). It has also been suggested that the improvement may be due to a normal fluctuation over time among patients with severe symptoms (22).

Most of the patients recommended to have dental materials replaced actually did so. However, many had had dental materials replaced or had started the process of having them replaced without any recommendation from the Unit; these patients could have been so convinced that the suspected dental material was the reason behind their health problems and would therefore replace the material anyway. Other patients may not have been satisfied with the conclusion from the Unit and therefore consulted alternative medical practices and may have followed other advice about replacement of the dental restorations.

Not all patients followed the recommendations of the Unit to have dental materials replaced. Among the possible reasons is the notion that replacing dental materials is too expensive, or the health problems ascribed to dental materials had now become irrelevant because other diseases had been diagnosed since examination at the Unit, or the problem may simply have disappeared.

The majority of patients who had dental restorations replaced without recommendation from the Unit reported improvement in health. Their own decision to replace dental materials could have a positive effect on the experience of changes in health.

The importance of placebo effects in health improvement after amalgam removal has been discussed, and it is suggested that placebo may be an important factor (28). A recent study reported that placebo had no effect on objective symptoms, but could possibly give small effects on subjective symptoms (29).

It appears that the examination at the Dental Biomaterials Adverse Reaction Unit is one of several inputs that influenced the patients' decision to have dental materials replaced. Patients with subjective symptoms were inclined to replace materials, in most cases dental amalgam, independently of the Unit's evaluation. Patients with objective findings were more likely to act according to the recommendations issued by the Unit.

Further research should be directed at unexplained subjective health complaints to identify individuals who could be more sensitive than others to dental materials, and who may benefit from having dental materials replaced.

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