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A follow-up study of patients with subjective symptoms related to dental materials

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Abstract – *Objectives:* The extent to which substances released from dental materials cause adverse health effects and whether removal of dental materials results in improvement of health is a matter of dispute. The aim of the study was to investigate changes in the intensity of subjective symptoms after replacement of dental materials in patients referred for adverse reactions related to dental materials, and to compare the profiles of symptoms with those found in the general population. *Methods:* Information was obtained from 142 patients referred to the Dental Biomaterials Adverse Reaction Unit in Bergen, Norway. At the time of examination, all patients completed a questionnaire regarding a range of subjective symptoms. A follow-up questionnaire was sent to all patients $1\frac{1}{2}$ to $2\frac{1}{2}$ years later. Similar questionnaires were sent to a reference group of 800 persons drawn from the general population. *Results:* The follow-up questionnaires were completed and returned by 84 patients, and 441 persons in the reference group. The patient group presented higher symptom indices than the reference group ($P < 0.001$). Generally, there was some decrease in the intensity of different symptoms in patients who had replaced dental materials. The decrease was evident regarding intraoral symptoms ($P = 0.022$) and total symptom index ($P = 0.041$). The group of patients who had replaced materials still had significantly higher symptom indices than those of the reference group. Patients who had not replaced dental materials did not present any reduction in symptom indices. *Conclusion:* The pattern of symptoms was similar for the groups investigated. At the group level, the intensity of local and some general subjective symptoms was reduced after replacement of the materials, but not to the level found in the general population.

Key words: adverse reactions; dental materials; follow-up; replacement; subjective symptoms

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Dental treatment usually involves a wide range of materials, and dental biomaterials are among the most extensively used for incorporation in the body. It is well documented, both from *in vitro* and *in vivo* studies, that substances are released from dental restorations (1–9). To what extent the released substances cause adverse health effects remains a matter of dispute (10–20).

A national Dental Biomaterials Adverse Reaction Unit was established in Norway in 1993 (21, 22). The Unit is funded by the Ministry of Health and located at the University of Bergen. The Unit examines patients referred from dentists and physicians for possible adverse reactions to dental materials. The Unit is also responsible for the national reporting system for adverse effects related to dental materials (22).

Patients referred for health problems related to dental materials comprise a heterogeneous group and many of these patients had multiple subjective symptoms associated with several organ systems (13, 23–26). Fatigue, muscle and joint pain, dizziness and headache are among the most common complaints. Patients also report local intraoral symptoms including burning sensations, taste disturbances and dry mouth (21, 23, 27, 28). If patients with suspected adverse reactions to dental materials experience improvement of health after

replacement of dental materials is a matter of debate (29–33).

The aim of the present study was to investigate if patients who had their dental materials replaced after the examination at the Dental Biomaterials Adverse Reaction Unit, experience improvement of health and reduction of the intensity of subjective symptoms, and compare the results with patients who had not replaced dental materials and a comparable group from the general population.

Materials and methods

Information obtained at the examination at the Dental Biomaterials Adverse Reaction Unit

From February 1999 to July 2001, a total of 142 patients (mean age 49.3 years) with reported adverse reactions related to dental materials were examined at the Dental Biomaterials Adverse Reaction Unit in Bergen, Norway.

The group of patients was heterogeneous, presenting symptoms which ranged from specific dental problems to multiple general symptoms. The majority of the patients was referred to the Unit because of general subjective symptoms.

At the day of examination, the patients were asked to complete a questionnaire regarding current subjective symptoms. The patients were asked to indicate the intensity of intraoral symptoms (six items), orofacial symptoms (five items) and general symptoms (12 items) (Fig. 2) on horizontal scales. Each scale was marked from 0 to 10 where 0 indicated no symptoms at all, and 10 indicated extremely severe symptoms. Symptom indices were calculated by adding the scores for intraoral, orofacial and general symptoms (30). Internal consistency, estimated by Cronbach's alpha, for these sub-scales were 0.78, 0.77, and 0.87 respectively.

Follow-up questionnaire

During September 2000 to July 2003, a follow-up questionnaire was sent to all 142 patients who had been examined at the Dental Biomaterials Adverse Reaction Unit from February 1999 to July 2001. The follow-up questionnaire was mailed between $1\frac{1}{2}$ and $2\frac{1}{2}$ years after the examination at the Unit.

The questionnaire included questions about whether dental materials had been replaced because of suspected adverse reactions and the type of material. They were also asked to indicate the intensity of different intraoral, orofacial and general subjective symptoms on the same type of scales as used during the examination at the Unit. In addition, a question on the patient's self-assessed change in health situation after the examination at the Unit was included, using the following alternatives: 'worse', 'no change', 'do not know', 'somewhat better', 'much better', 'completely well'. The first three were alternatives coded 'do not feel better' and the following three were coded 'feel better'.

The study was approved by the Regional Committee for Medical Research Ethics in western Norway, and only one reminder was allowed.

Reference group

During spring 2004, questionnaires with the same questions regarding subjective health as included in the follow-up questionnaire, was sent to 800 persons from the general population to create a reference group. The reference group was sampled from the general population in Norway, and the sampling was performed by Statistic Norway. The sampling strategy used was designed to generate a reference group similar to the patient group regarding age, gender, and place of residence.

Statistical analyses

Independent-sample *t*-test was used to test differences between groups. Paired-sample *t*-test was used to analyze differences in symptom scores at the time of examination and at the follow-up. Chi-square test was used to evaluate distribution of categorical data.

Results

The follow-up questionnaire was completed and returned by 84 of the total of 142 patients, and the overall response rate was 59% (Fig. 1).

From the reference group, answers from 441 persons were received, giving a response rate of 55%. The reference group was similar to the patient group regarding age, gender distribution and education. The patient group who completed the questionnaire ($n = 84$) was, on average, older than the group that did not respond (Table 1).

There was no significant difference in the response rate between women and men in the patient group (chi-square; $P = 0.207$), and the intraoral, orofacial, general and total symptom indices, from the examination at the Unit, were similar by response status (Table 1).

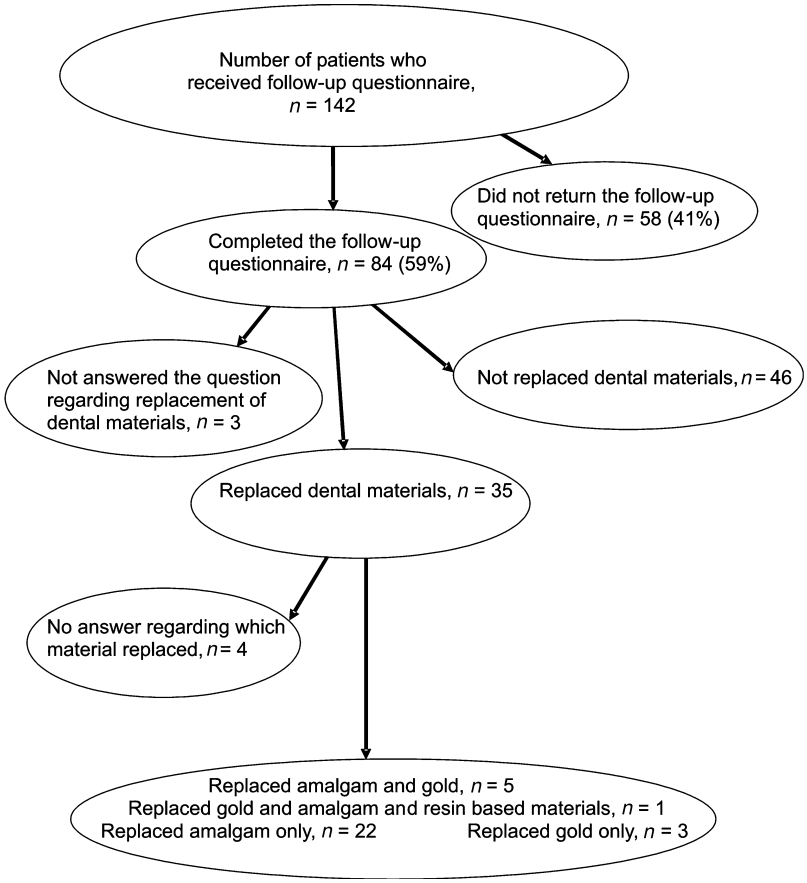

Fig. 1. Flow chart showing number of patients included in the study, and the final groups available for analyses.

Table 1. Data from the examination for patients who answered the follow-up questionnaire and for patients who did not answer the questionnaire

	Answered the questionnaire ($n = 84$; 57 F, 27 M)	Not answered the questionnaire ($n = 58$; 45 F, 13 M)	*P*-value
Age (years)	51.6 (11.7) ($n = 84$)	46.0 (13.1) ($n = 58$)	0.008
Education (years)	11.4 (3.0) ($n = 81$)	11.3 (3.0) ($n = 55$)	0.898
Mean intraoral symptom index[a]	14.9 (13.5) ($n = 78$)	14.1 (10.8) ($n = 57$)	0.727
Mean orofacial symptom index[b]	11.4 (10.8) ($n = 78$)	10.5 (10.4) ($n = 57$)	0.654
Mean general symptom index[c]	41.0 (23.0) ($n = 78$)	42.4 (22.5) ($n = 57$)	0.728
Mean total symptom index[d]	67.2 (38.6) ($n = 78$)	67.0 (36.1) ($n = 57$)	0.975

Group mean values with standard deviations within parantheses for age, education and mean symptom indices at examination. Females (F) and males (M) analyzed together. *P*-values from *t*-test of differences between groups.
[a]6 items; [b]5 items; [c]12 items; [d]23 items.

The patient group ($n = 84$) presented higher intraoral, orofacial and general symptom indices than the reference group, and these differences were statistically significant (*t*-test; $P < 0.001$). When analyzing the difference between the various symptoms, the patient group had significantly higher symptom score of each symptom except for cardiovascular symptoms where both groups reported low symptom intensity.

Of the patients who answered the questionnaire, 35 of 84 (42%) had replaced dental restorations related to the symptoms. Replacement was recommended in patients with confirmed allergy to substances in dental materials or patients with contact lesions adjacent to dental materials (21, 30). Twelve of the 84 patients were recommended by the Unit to replace dental materials, and 11 of them had done so. Ten of the patients who followed the recommendation had confirmed allergy to substances in dental materials and one had a lichenoid contact lesion related to a dental restoration. One patient had confirmed allergy to mercury and had started, but not finished replacement of amalgam fillings. The group of patients who had replaced

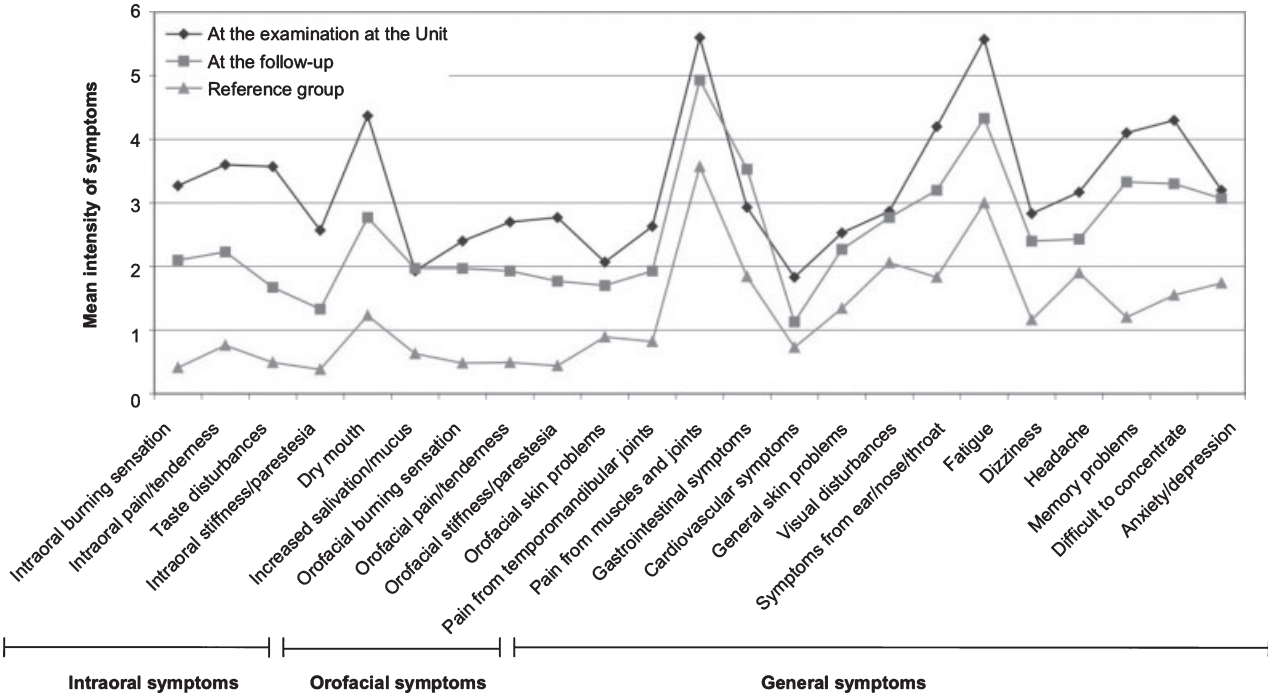

Fig. 2. Mean intensity of different intraoral, orofacial and general symptoms in patients who had replaced dental materials ($n = 35$) before and after replacement, compared with intensity of symptoms in the reference group ($n = 441$).

Table 2. Mean symptom indices for patients with data both from the examination and from the follow-up questionnaire and data from the reference group

	Replaced dental materials (30 pairs)[a]			Not replaced dental materials (44 pairs)[b]			
	At the examination at the Unit	At the follow-up	*P*-value	At the examination at the Unit	At the follow-up	*P*-value	Reference group
Mean intraoral symptom index	19.3 (14.0)	12.1 (11.5)	0.022	10.6 (10.9)	11.3 (10.7)	0.617	3.8 (6.9)
Mean orofacial symptom index	12.6 (10.9)	9.3 (10.7)	0.136	10.2 (10.4)	8.3 (8.1)	0.184	3.2 (5.8)
Mean general symptom index	43.1 (23.1)	36.7 (25.6)	0.180	37.6 (21.8)	38.1 (22.5)	0.858	21.4 (17.3)
Mean total symptom index	75.0 (37.8)	58.1 (39.6)	0.041	58.4 (35.1)	57.7 (35.6)	0.879	28.3 (26.1)

Mean symptom index, standard deviations and *P*-values for paired sample *t*-test for intraoral, orofacial and general symptoms in patients who had replaced dental materials and patients who had not.
[a]Five patients had missing values; [b]two patients had missing values.

dental materials because of recommendations from the Unit, reported larger reduction of intraoral symptom intensity (mean reduction 21.7) compared with those who had replaced dental materials without recommendation from the Unit (mean reduction 3.7). The difference was statistically significant (*t*-test; $P = 0.004$).

The majority of the patients had replaced amalgam fillings [28 of 35 (80%)]. Nine patients had replaced gold restorations or gold in combination with amalgam (Fig. 1).

A small decrease in the intensity of different symptoms, except for gastrointestinal symptoms, was seen in patients who had replaced dental materials. The decrease was statistically significant for intraoral symptom scores, including 'taste disturbances' ($P = 0.010$), 'dry mouth' ($P = 0.034$), and 'stiffness/paresthesia' ($P = 0.050$) (Fig. 2). In addition there was a significant difference in intraoral symptom index ($P = 0.022$) and total symptom index ($P = 0.041$) after replacement of dental materials (Table 2).

After replacement, the intensity of each intraoral and orofacial symptom was still significantly higher than that for the reference group, except for orofacial skin problems where both groups reported low symptom intensity. Regarding intensity of the general symptoms, the differences between

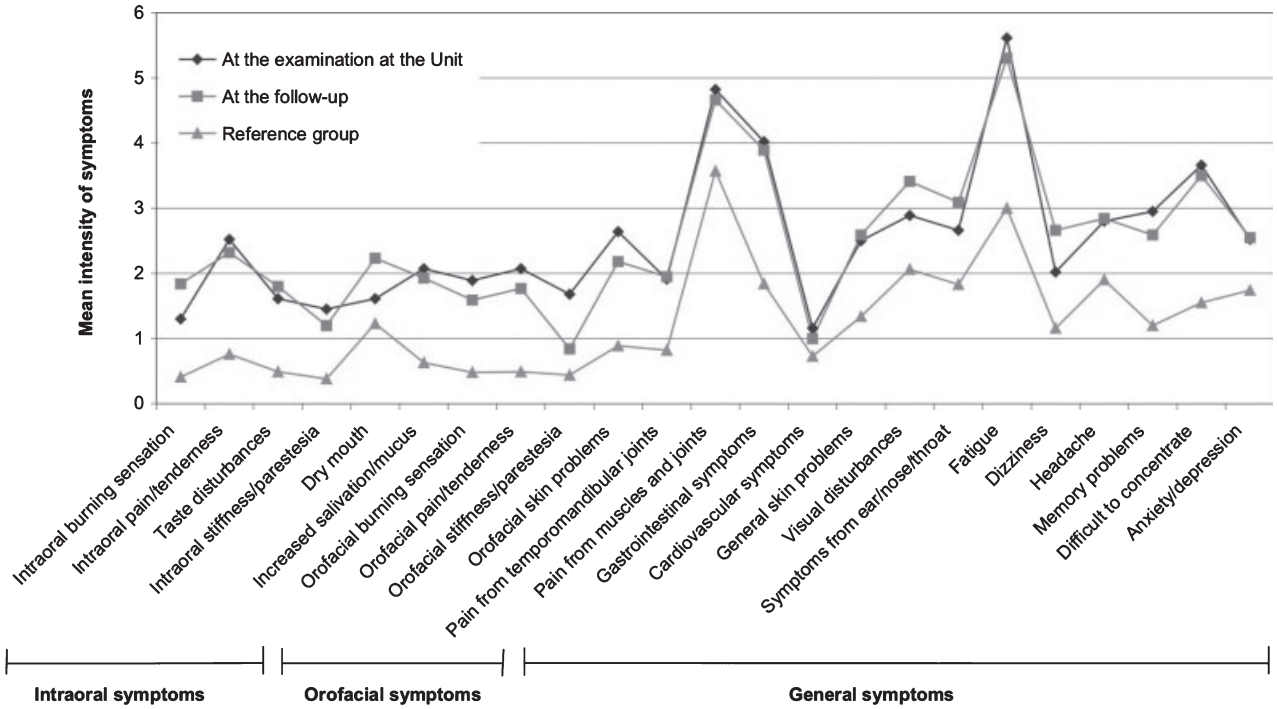

Fig. 3. Mean intensity of intraoral, orofacial and general symptoms in patients who had not replaced dental materials ($n = 46$) at the examination and at follow-up, compared with intensity of symptoms in the reference group ($n = 441$).

patients who had replaced dental materials and the reference group were statistically significant for the majority of the symptoms, except for cardiovascular symptoms, skin problems, visual disturbances, headache and anxiety/depression.

Neither the intraoral, orofacial nor the general symptom indices reached the level of the reference group (Table 2), and the differences in symptom indices between patients and reference group were all statistically significant ($P < 0.001$). A small decrease in intensity of intraoral, orofacial and general symptoms was also found in patients who had replaced amalgam fillings only ($n = 22$). However, the decrease was not statistically significant.

In patients who had not replaced dental materials ($n = 46$) no statistically significant differences of the intensity of different intraoral, orofacial or general symptoms was observed, except orofacial stiffness/paresthesia ($P = 0.036$) (Fig. 3). These patients did not show reduction in intraoral, orofacial, general or total symptom indices (Table 2).

In patients who had replaced dental materials, the mean reduction in intraoral, orofacial, general and total symptom intensities (score at examination minus score at follow-up) was larger than that for patients who had not replaced dental materials. However, the difference was statistically significant for intraoral symptom intensity (t-test; $P = 0.022$) (Table 3).

Patients who had replaced dental materials were more likely to assess their current health situation as better than those who had not replaced dental materials (chi-square test; $P = 0.001$). There was no association between the patients' assessment of overall health ('feel better' versus 'do not feel better') and reduction in intraoral, orofacial, general or total symptom intensities.

Discussion

This study describes subjective health complaints of 84 patients referred for examination of adverse reactions related to dental materials. The data were based on responses from persons who answered a follow-up questionnaire 18 months to $2\frac{1}{2}$ years after examination at a specialty unit for dental biomaterial adverse reactions.

Subjective complaints to dental materials can be local symptoms in the mouth or face. A number of patients also presented several general complaints including pain from muscles and joints, fatigue and memory problems (16, 21–23).

Subjective health complaints are common in the normal population. A study of the Norwegian population by Ihlebæk et al. (34) reported that 96% had at least one type of complaints during the last 30 days. A similar result is reported in a

Table 3. Mean reduction (score at examination minus score at follow-up) and standard deviations for intraoral, orofacial, general and total symptom intensities in patients who had replaced dental materials and in patients who had not replaced dental materials

	Replaced dental materials (30 patients)[a]		Not replaced dental materials (44 patients)[b]		
	Mean difference	SD	Mean difference	SD	*P*-value
Reduction in intraoral symptom intensity[c]	7.2	16.4	−0.8	9.9	0.022
Reduction in orofacial symptom intensity[d]	3.3	11.7	1.8	9.1	0.556
Reduction in general symptom intensity[e]	6.4	25.6	−0.5	16.6	0.202
Reduction in total symptom intensity[f]	16.9	43.3	0.6	27.6	0.075

A positive mean difference indicates a reduction of symptom intensity, and a negative mean difference indicates increase of symptom intensity.
[a]Five patients had missing values; [b]two patients had missing values.
[c]6 items; [d]5 items; [e]12 items; [f]23 items.

study including people from Norway, Sweden, Denmark, and Finland (35). However, there are differences in both prevalence and degree of complaints (34).

In our study, the reference group presented a similar profile of symptoms as the group of patients with complaints associated with reactions to dental materials. However, the intensity of the different symptoms was on a higher level in the patient group compared with the reference group.

A study by Malt et al. (16) showed that patients with symptoms associated with amalgam fillings reported significantly more physical symptoms in all parts of the body, similar to patients with multiple chemical sensitivity syndrome, and that the patients frequently had mental disorders.

In our study, the differences between patient group and reference group in intensity of symptoms were most obvious regarding intraoral and orofacial symptoms. This could be the reason why the patients also associated their general symptoms with reactions to dental materials. Patients with intraoral symptoms, including burning sensations, dry mouth, and taste disturbances frequently reported other complaints both from the oral cavity and from the rest of the body (28).

The response rate is lower than desirable and is assumed to be influenced by several different conditions. One reason could be that the problems associated with dental materials could have become irrelevant at the time of the follow-up because the symptoms had faded away or other diagnoses had given the explanation of the symptoms. Some studies reported that dropouts tend to be older and less educated than participants (36). It was also suggested that persons with positive health behaviors are more likely to respond to health-related surveys (37). However, in our study, the responders were older than the nonresponders and there were no differences in the number of years of education between responders and nonresponders. The symptom indices, summarizing different symptom items, for the two groups were not significantly different. Therefore, we assume that the dropouts would not influence the results regarding the patient group. Response rate at the follow-up may also be influenced by the fact that the Regional Committee for Medical Research Ethics in western Norway allows only one reminder. Similar follow-up studies also report sub-optimal response rates (31).

The response rate of the reference group was similar to the patient group. The groups were matched regarding age and gender when sampled, and we did not observe differences between responders in the patient group and the reference group. However, as suggested by Macera et al. (37) the individuals with most health problems may not respond to health-related surveys. This could have influenced the results from the reference group. However, the dropouts in our patient group could also have more health problems than the responders.

Most of the patients associated their symptoms to amalgam restorations. Lichtenberg (29) reported that removal of amalgam fillings gave significant improvement of general symptoms in 70% of the patients. Another study by Lindh et al. (33) suggested that more than 70% of the patients reported increased quality of life after having replaced metallic dental materials.

Nerdrum et al. (31) reported that patients who had their dental amalgam removed, reported reduced physical and mental symptom load after removal compared with the levels before removal. However, the symptom load 7 years after removal was on a higher level than the dental control group and corresponds to the level seen in chronic medical disorders. Data of intraoral and orofacial subjective symptoms were not included in the study.

Our study indicates that there was a reduction in overall symptom load after replacing dental materials in patients with subjective symptoms which they related to the materials, and that the main reduction was regarding intraoral and orofacial symptoms. We did not find any reduction of symptoms in patients who had not replaced dental materials. Thus, some patients may have perceived health benefits after replacing their dental materials. The reduction in intraoral symptom intensities was much larger in patients who were recommended by the Unit to replace dental materials, and this could indicate that the Unit's criteria for replacing dental materials were useful to recognize the patients who have health benefits because of replacing dental materials.

The patients who had their dental materials replaced presented higher intensity of intraoral symptoms at the examination at the Unit than those who had not. One could assume that the high intensity of intraoral symptoms could be the reason why these patients related both local and general symptoms to intraoral conditions, and therefore chose to replace the suspected dental material. Other studies have demonstrated that intraoral subjective symptoms in combination with objective findings are reduced following replacement of dental materials (38–42).

The reductions of the intensity of intraoral, orofacial, general and total symptoms were larger in the group of patients who had replaced dental materials compared with the group of patients who had not (Table 3). However, the variations in the reported reduction of intensities were considerable. The reduction of the intensities of symptoms was not associated with the patients self-assessment of overall health ('feel better' versus 'do not feel better') and thus, it does not seem that self-assessed general health is related to symptom intensity or reduction of symptom intensity. Self-assessed health may describe another entity than the load of different symptoms and other factors (e.g. coping) (43) may be of importance. The intensity of subjective health complaints varies, and there are no clear limit to indicate what is 'normal' complaints and what is 'illness'.

Conclusions

The profile of symptoms in patients with complaints related to dental materials was similar to the symptom profile in the general population. However, in the patient group the intensity of the different symptoms was on a higher level compared with a reference group.

At the group level, the intensity of local and general subjective symptoms was reduced after replacement of dental materials, but not to the level found in a comparable group in the general population.

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