

# Changes in health over time in patients with symptoms allegedly caused by their dental restorative materials

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Abstract - Objectives: In Sweden, many patients with symptoms allegedly caused by their dental materials have exchanged their restorations, but the effects of the exchange have been insufficiently investigated. Therefore, the aim of the study was to describe the change in health over time for these patients and the hypothesis was that the patients could be divided based on their symptoms and that the ability to recover differs between these groups. Furthermore, we also examined if other factors such as replacement of dental restorative materials and follow-up time had any impact on the perceived health status. Methods: A questionnaire was sent to 614 patients who had been referred to the School of Dentistry, Umeå, Sweden, with symptoms allegedly caused by dental restorative materials. The response rate was 55%. Results: The risk of having any further complaints was higher for patients with complex symptoms (P = 0.03) and these patients had exchanged their restorations to a significantly larger extent than the others (P = 0.03). The remaining complaints was more frequent among men (P = 0.02). Exchange of dental restorative materials had no significant impact on the ability to recover completely. However, the patients who had exchanged their restorations completely perceived a significantly larger alleviation of their symptoms than the others (P < 0.01), although the frequency of most of the symptoms had increased. Conclusions: Patients with complex symptoms had a more unfavorable long-term prognosis concerning persistent complaints than those with localized symptoms only. Furthermore, the results indicate that the patients might experience health improvements after removal of their dental restorative materials. The reason for this improvement, however, is unclear. Further analyses regarding other possible explanations than the 'odontological/ medical' are needed.

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Key words: dental materials; follow-up study; long-term prognosis; subgroups

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For almost two centuries, the safety of dental filling materials has been debated off and on. In the beginning, the debate was focused on dental amalgam only, and in Sweden a debate started in the early 1980s concerning possible health effects of the electrochemical corrosion occurring within and between alloys in the oral cavity (1–4).

With time, the interest has shifted from electrochemical corrosion to the release of mercury from amalgam restorations and its possible effects on general health. Based on available scientific literature, international state-of-the-art meetings (5) and national and international expert groups (6, 7) have come to similar conclusions, i.e. that there is no scientific evidence that mercury released from dental amalgam present a significant health hazard to the general population, although a small number of patients might experience allergic responses to components released from amalgam. However, some researchers have come to different conclusions (8, 9).

The group of patients with symptoms allegedly caused by dental materials has been described in the scientific literature by several authors during the last two decades (10–13). These patients often report a various number of both localized and general symptoms, such as burning mouth, dry mouth, temporomandibular joint problems, back problems, sleeping problems and nausea. Psychologically, these patients have been reported to differ from the reference population (14, 15).

Despite the lack of scientific evidence of a connection between dental materials and general health, there are still a considerable number of patients – who seek help from both dentists and physicians – convinced that their disease and/or symptoms are caused by dental materials such as dental amalgam, gold, titanium and polymers. Some of these patients also claim that exposure to electricity, visual display units and bad indoor air quality exacerbates their problems (16–18).

In reports by the Swedish National Social Insurance Board (19, 20), it has been shown that the cost for the dental insurance system concerning the exchange of dental restorative materials because of adverse reactions in a population of 9 million have been relatively high. A number of patients, 4000 during 1993 and 2500 during 1995, got their dental materials exchanged at an average cost per patient for the insurance system of 2000 and 2500 US\$, respectively. It is reasonable to assume that a substantially larger number of people either exchanged all or a part of their dental restorations without applying for support from the dental insurance system. Despite that the exchange has costed both the individual and the society large amounts, the effects of the exchange has been insufficiently investigated.

However, the few studies published on the effect of removal of amalgam restorations on the general health have mainly been carried out in Scandinavia (21, 22), the results have been inconclusive. After the replacement of amalgam, some patients have experienced an improvement in health, some unchanged and some even impaired health. Because of methodological reasons, the results of these studies are difficult to compare. Even though many patients claim that removal of dental amalgam has resulted in improved health, the causes of these improvements have not been satisfactory clarified. Our 15-year clinical experience with the patients referred to the Department of Oral Diagnosis (School of Dentistry, Umeå, Sweden), with symptoms allegedly caused by dental restorative materials and 6-year experience in the Swedish National Board of Health and Welfares Register of Side Effects of Dental Materials, is that patients with many symptoms are less likely to recover than patients with few and localized symptoms. This is also supported by the results of a study on perceived hypersensitivity to electricity and skin symptoms related to the use of visual display terminals (23).

Therefore, the hypothesis of the present study is that patients with symptoms allegedly caused by dental materials can be divided into subgroups based on their symptoms and that the ability to recover differs between the groups. Patients with local symptoms only have a better chance to recover than those with a wide variety of general symptoms. Furthermore, the aim was to test whether gender, age, follow-up time and replacement of dental restorative materials had any impact on the perceived health and reported symptoms. This study is the first part of a project investigating the prognostic factors of patients with symptoms allegedly caused by their dental materials.

## Material and methods

#### Study population

The study population consisted of consecutive patients referred by dentists/physicians to the Department of Oral Diagnosis, School of Dentistry in Umeå, during 1991–1998 for an examination of symptoms allegedly caused by dental materials. A total of 751 patients had been examined during the period but initially, 137 patients were excluded because of reasons such as missing dental records, no dental examination, confirmed medical diagnosis that explained the symptoms and patients who had deceased between the first examination (baseline) and the follow-up (Table 1).

The inclusion criteria for participating in the study for the remaining patients were that they, at baseline, should have stated that they believed that their dental restorative materials caused their symptoms, or that they had oral lesions that the referring dentist/physician suspected to be caused by the patients' dental materials.

Data from the patients' case books comprised, among others, gender, age, date of first visit,

	Total	Women	Men	P-value
Total number of patients examined (n)	751	538	213	
Inclusion criteria not fulfilled ( <i>n</i> )	137	98	39	
Study population				
Baseline ( <i>n</i> )	614	436	178	
Mean age (range)	49.5 (19-86)	50.2 (21-86)	47.9 (19–77)	
Responders (n)	334	243	91	
Mean age (range)	51.3 (19-86)	52.1 (23-86)	49.4 (19–76)	
Nonresponders ( <i>n</i> )	280	193	87	
Mean age (range)	47.3 (21-81)	47.9 (21-81)	46.2 (24–77)	
Study population (follow-up)				
Responders ( <i>n</i> )	334	243	91	
Mean age (range)	56.5 (23-89)	57.3 (31-89)	54.6 (23-80)	
Responders stratified by symptoms				
Oral lesions only <sup>a</sup> $(n)$	33	21	12	0.22
Mean age (range)	61.0 (33-80)	63.1 (47-76)	57.3 (33-80)	
Local symptoms only ( <i>n</i> )	83	63	20	0.46
Mean age (range)	60.7 (29-83)	61.4 (34-83)	58.6 (29–79)	
Local + general symptoms $(n)$	164	126	38	0.10
Mean age (range)	55.3 (30-89)	55.6 (31-89)	54.3 (30-70)	
General symptoms only ( <i>n</i> )	54	33	21	0.04
Mean age (range)	51.1 (23-85)	51.9 (31-85)	49.9 (23–73)	
Dropout analysis (telephone interview) ( <i>n</i> )	46	32	14	
Mean age (range)	50.9 (32–76)	51.6 (22–78)	49.2 (29–64)	

Table 1. Characteristi	s of the study	population (	P =	0.05)
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<sup>a</sup>As a part of the patients had oral lesions only without symptoms (n = 33), they were excluded from the analysis of change of symptoms at follow-up.

occupation, employment situation, sick leave, symptoms and evoking factors for the symptoms. The classification of the patients in subgroups according to symptoms (Table 1) was performed by two dentists (AT, LM) from the baseline information in the dental records. The relative distribution between the subgroups 'oral lesions only', 'local symptoms only' and 'local and general symptoms', were not significantly different between the women and men. Patients with 'general symptoms only', however, were significantly more frequent among men.

#### Questionnaire

Questionnaires were mailed to 614 patients and 334 (55.0%) were returned (Table 1). Forty-five patients returned more or less incomplete questionnaires together with a personal letter. Data collection lasted from June to October 2000. The questionnaire was based on a version previously used in a project on health effects of Electricity and Visual Display Units (23) and in the Office Illness Project in Northern Sweden (24). The questionnaire contained questions on, among others, civil status, present health, medical and odontological treatment and other measures taken for the problems referred for. Furthermore, consequences of the problems, precipitating factors, current employment situation, and questions concerning feelings, self-image and coping ability were included. The sociological and psychological issues were evaluated with Structure Analysis of Social Behavior (SASB), Coping Resources Inventory (CRI) and Symptom Check List 90 (SCL-90). Results from sociological and personality assessments will be reported in a future paper where other possible explanations to the patients' symptoms than the 'odontological/medical' will be discussed.

A test was carried out to determine whether the patients could be divided into subgroups based on their symptoms and their ability to recover. Furthermore, age, gender and impact of time elapsed between baseline and follow-up (follow-up time) and possible effects of a replacement of dental restorative materials on the perceived health and reported symptoms were analyzed. Five subgroups were created for the tests based on follow-up time; 0-2, 3-4, 5-6, 7-8 and  $\geq 9$  years.

As it was of great interest to determine whether our patients had significantly more symptoms than the general population, an adult control population consisting of 2154 individuals was used. This was a random sample of the Swedish population, age 18–64 years, selected in 1998 by the public authority Statistics Sweden, Stockholm on commission of

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the authors (25). The data were collected in order to be used as a reference to studies on the environmental syndromes: 'hypersensitivity to electricity and visual display units', 'sick-building syndromes', and the present study. The study was approved by the Ethics Committee of Umeå University, Umeå, Sweden.

#### Statistical methods

Comparisons between proportions were made using chi-square or Fisher's exact test. Mantel– Haenszel extension test was used to test for trend. When comparing symptoms between baseline and follow-up and symptoms between the study population at follow-up and the reference population, the significance level was set to 0.01 because of multiple comparisons. However, in all other comparisons, the level was set to 0.05. When analyzing the association between multiple independent variables and the outcome variable, odds ratio and 95% confidence interval were calculated using logistic regression. The variables were tested using both univariate and multivariate logistic regression models in SPSS version 11.

## Results

#### Dropout analysis

A total of 280 persons (45%) did not return a completed questionnaire. At the time of the baseline investigation, the mean age among nonresponders was 4 years lesser than that of the response group, whereas the distribution according to gender was similar as for the response group. The distribution of general and local symptoms were similar between the responders and dropouts, except for vertigo, which was overrepresented in the dropout group -20.7% compared with 13.7\% in the response group (P = 0.02). Among the responders, 15.6% (n = 51) had lichenoid reactions (44 verified by PAD (Pathological Anatomical Diagnosis) and seven by clinical diagnosis), while the corresponding figure for the dropout group was 8.6% (n = 24, P = 0.01).

The dropout group was also subdivided into four subgroups, 'oral lesions only', 'local symptoms only', 'local and general symptoms' and 'general symptoms only'. The groups were further divided regarding gender and time for follow-up ('early visits', i.e. before 1995 and 'late visits' from 1995). From the 16 sub-groups formed, every sixth patient was contacted for a telephone interview. A total of 46 patients were interviewed and the most common reason for not responding was dissatisfaction with the questionnaire, especially with the psychological questions.

The telephone interviewed dropouts perceived worse health status and well being in comparison with the response group. Their complaints, causing the baseline investigation, were still present to a higher degree, whereas sick leave and retirement because of medical reasons were less common in this group than among the responders. Of the patients interviewed, 30.1% experienced no change regarding reported problems compared to 19.1% in the response group.

#### Some characteristics at baseline

The following baseline data were compiled from the patients' medical casebook. Oral lichenoid reactions and lingua geographica were found in 15.6 and 6.9% of the patients, respectively. A large proportion of intra oral findings (46.7%) was classified as 'other lesions' and included linea alba, impression in tongue and cheek, Fordyce spots and amalgam tattoos. Among the patients, 10.2% reported previous problems with asthma, 16.1% reported problems with allergic rhinitis, and 25.4% reported problems with atopic dermatitis. Only a few patients related their symptoms to sick building syndrome (2.7%), visual display terminals (2.7%) and hypersensitivity to electricity (5.1%). Most of them were women.

## *Change of symptoms between baseline and follow-up*

The distribution of symptoms at baseline and follow-up is listed in Table 2.

#### Oral symptoms

Some of the oral symptoms decreased from baseline to follow-up. Burning mouth among women had decreased significantly, while the decrease among men did not reach significance (P = 0.02). Taste disorder was reduced by 58–68%, i.e. significant for both women and men. Stiffness/numbness increased significantly for women by a factor of 4.5.

#### General symptoms

The frequency of a number of symptoms increased significantly between baseline and follow-up. Fatigue increased significantly among women by a factor of 1.4, difficulties in concentrating increased with a factor of 1.8 for women and 3.0

	Women ( $n =$	243)		Men $(n = 91)$			
	Baseline (%)	Follow-up (%)	<i>P</i> -value	Baseline (%)	Follow-up (%)	<i>P</i> -value	
Oral symptoms							
Burning mouth	55.5	20.1	< 0.01	36.3	19.5	0.02	
Dry mouth	26.7	26.2	0.90	20.9	13.1	0.17	
Increased salivation	1.6	4.6	0.07	3.3	6.2	0.40	
Taste disorder	33.7	14.3	< 0.01	34.1	11.0	< 0.01	
TMJ pain	17.3	15.5	0.60	13.2	15.7	0.64	
Stiffness/numbness	2.5	11.3	< 0.01	3.3	9.9	0.08	
General symptoms							
Fatigue	30.9	44.4	< 0.01	33.0	37.3	0.55	
Headache	27.2	20.1	0.08	24.2	14.3	0.10	
Nausea	2.1	4.4	0.16	6.6	8.8	0.60	
Anxiety	13.6	8.9	0.12	16.5	14.6	0.74	
Depression	8.2	7.6	0.81	8.8	12.2	0.46	
Sleeping problems	15.6	21.7	0.09	12.1	20.2	0.14	
Neurological symptoms							
Vertigo	16.0	13.9	0.52	7.7	9.6	0.65	
Diff. Concentrating	12.8	22.5	< 0.01	7.7	23.2	< 0.01	
Eye symptoms							
Eye irritation	7.8	21.0	< 0.01	6.6	17.6	0.024	
Dry eyes	4.9	20.0	< 0.01	5.5	9.6	0.30	
Respiratory symptoms							
Nasal symptoms	9.1	18.9	< 0.01	5.5	17.9	< 0.01	
Cough	1.6	8.2	< 0.01	1.1	5.0	0.19	
Hoarseness	2.1	16.0	< 0.01	2.2	11.0	0.02	
Lump in the throat	2.9	13.2	< 0.01	2.2	9.6	0.05	
Skin symptoms							
Dry facial skin	3.7	23.4	< 0.01	-	11.1	< 0.01	
Facial erythema	2.9	21.2	< 0.01	1.1	11.1	< 0.01	
Facial sensory symptoms	1.2	15.9	< 0.01	2.2	9.9	0.05	
Body itch	1.6	9.4	< 0.01	1.1	7.3	0.05	
Circulatory symptoms							
Palpitation	7.0	10.1	0.23	5.5	8.5	0.43	
Chest pain	1.2	6.4	< 0.01	1.1	8.4	0.03	
Breathlessness	-	14.6	< 0.01	0.8	20.5	< 0.01	
Cold hands and feet	0.8	27.2	< 0.01	1.1	21.4	< 0.01	
Muscular and joint problems	5						
Pain from muscles	38.3	35.6	0.60	36.3	20.5	0.022	
Pain from joints	44.9	36.2	0.06	44.0	23.2	< 0.01	

Table 2. Self-reported symptoms at baseline compared with follow-up stratified by gender (valid percent)

for men, and eye irritation increased by a factor 2.7 for both women and men, but the increase did not reach significance for men (P = 0.02). Dry eyes increased by a factor of 4.1 for women. Among the respiratory symptoms, nasal symptoms, cough, hoarseness, and lump in the throat increased significantly for women by the factors 2.1, 5.1, 7.6, and 4.6, respectively. However, the only respiratory problem that increased significantly for men was nasal symptoms, which increased by a factor 3.2.

Regarding skin problems, dry facial skin, facial erythema, facial sensory symptoms and body itch increased significantly for women by the factors 6.3, 7.3, 13.3 and 5.9, respectively. For men, facial erythema increased significantly by a factor 10.0

and dry facial skin was not reported by any men at baseline but by 11.1% at follow-up.

Concerning circulatory problems such as cold hands and feet increased by a factor of 34.0 for women and 19.4 for men, breathlessness with a factor 25.6 for men and was not reported by any women at baseline, but by 14.6% at follow-up. Chest pain increased by a factor 5.3 for women. However, pain from joints for men was the only general symptom that decreased significantly between baseline and follow-up, and it was reduced by almost half.

#### Actions taken because of complaints

After the baseline investigation, many patients had sought medical and/or other types of treatment. It

was a marked difference between the women and men regarding the type of care. Treatment by physicians at healthcare centers was reported by 51.5% of the women and 34.8% of the men (P = 0.02). Examinations by dermatologists were reported by 34.6% of the women and 17.2% of the men (P = 0.002). Complementary therapies had been undergone by 24.7% of the women and 10.1%of the men (P = 0.003).

Among the patients, 76.8% had carried out partial or total replacement of the dental restorative material believed to cause their symptoms (Table 3). There was no significant difference between women and men, even though the figures were slightly higher for women. Replacement was more common among patients with complex symptoms compared with those with oral lesions and local symptoms only (P = 0.03).

## Change of symptoms in connection with the replacement of dental restorations

About half of the patients reported that they had experienced some kind of negative reaction in connection with the replacement. The most common reactions were fatigue and pain from muscles. Among women, headache and nausea also appeared frequently in connection with the replacement.

Relief from symptoms was reported by 14.0% of the patients in connection with the replacement of dental restorations. There was a significant difference between women and men regarding the perceived alleviation in connection with replacement, with 42.9% for men and 63.7% for women (P = 0.006). Among the men, 36.5% reported 'no effect' after the replacement, whereas the corresponding figure for women was 19.0%. No information was available on additional interventions that the patients had been subjected to.

#### Characteristics at follow-up

Of the 334 patients, 72.8% were women and 27.2% men and the mean age at follow-up for men was 54.6 years (range 23–80) and 57.3 years (range 31–89) for women (Table 1). Regarding follow-up time, no significant difference between women and men was found. Most of the patients (63.1%) had a follow-up time between 3 and 6 years and the average follow-up time was 5.2 years.

According to the questionnaire, nearly all symptoms were more prevalent among women than men, of which dry eyes, dry facial skin, facial erythema and dry mouth were significantly more prevalent (P < 0.05). Symptoms in joints and muscles were the other symptoms that appeared more frequently among women, while general symptoms like fatigue and sleeping problems were more equally distributed. Oral symptoms were more prevalent in women, except for burning mouth, which was evenly distributed between women and men. Among the men, heavy-headedness, nausea and pain from chest were more prevalent.

There was a difference between women and men regarding perceived alleviation of symptoms, where women reported a larger perceived alleviation of symptoms than men (Table 3). However, the difference was only significant for symptoms 'remaining to a limited extent', where the proportion of women was almost 60% larger than that of men. Almost a fifth of the patients stated that their complaints had disappeared, i.e. a total relief of symptoms. However, there was no significant difference regarding total relief of symptoms between patients who had exchanged their dental restorative materials, either completely or partly, and those who had not replaced any of their dental restorations.

Table 3.	Replacement	of	number	of	dental	restorations,	and	perceived	health	at	the	time	of	follow-up	stratified	d for
gender (v	valid percent)	(P	= 0.05)					-						_		

	Total		Women	L	Men		
	%	п	%	п	%	п	<i>P</i> -value
Complete replacement of restorations	40.6	121	42.1	90	36.9	26	0.42
Partial replacement of restorations	36.2	108	36.4	78	35.7	25	0.90
No replacement of restorations	23.2	69	21.5	46	27.4	22	0.28
Reactions after replacement	52.0	119	54.2	91	45.9	28	0.27
No reactions after replacement	48.0	110	45.8	77	54.1	33	0.27
Complaints at follow-up							
Unchanged	19.1	62	17.5	41	23.3	21	0.23
Almost unchanged	25.1	81	22.6	53	31.1	28	0.12
Remained to a limited extent	37.3	121	41.5	97	26.7	24	0.02
Disappeared	18.5	60	18.4	43	18.9	17	0.92

In order to analyze the prognosis in different selected subgroups (gender, age, symptoms, follow-up time and replacement of restorations) logistic regression was applied (Table 4). Regarding gender, men had a significantly higher risk than women of having unchanged or almost unchanged complaints. Furthermore, this risk was significantly higher for patients with 'local and general symptoms' in comparison with the other subgroups divided by symptoms.

Regarding exchange of dental restorations, patients with a partial replacement of restorations or no replacement of restorations showed a significantly higher risk of having unchanged or almost unchanged complaints at follow-up compared with patients who had replaced all their restorations. However, when the risk of having any kind of remaining complaints was analyzed, no significant differences could be found within the subgroups (Table 4). Furthermore, the followup time, stratified in five groups and the age did not have any significant impact on the alleviation of symptoms.

After adjustments of the variable 'subgroups by symptoms' for gender, the risk of having unchanged or almost unchanged complaints at follow-up were higher among men than women in the subgroups – 'local and general symptoms' odds ratio (OR) 3.25 [95% confidence interval (CI) 1.02–10.30] and 'general symptoms only', OR 2.68 (95% CI 1.03–7.02). Furthermore, the prevalence of symptoms in the present patient group was significantly higher (P < 0.01) than for the adult control population (Table 5).

Table 5. Symptoms at follow-up in comparison with a Swedish reference population (valid percent)

Follow-up (%) <sup>a</sup> (%) <sup>b</sup> (n = 2154)P-valueOral symptoms Burning mouth19.90.4<0.01Dry mouth22.44.7<0.01General symptoms7<0.01Fatigue42.529.3<0.01Heavy-headiness19.38.6<0.01Headache18.59.7<0.01Nausea5.61.4<0.01Neurological symptoms7Vertigo12.72.8<0.01Difficulties in22.7Concentrating7Eye symptoms7Eye symptoms18.912.1Circulatory symptoms18.912.1Nasal symptoms18.912.1Cough7.43.7<0.01Lump in the throat12.22.8<0.01Skin symptoms8Dry facial skin20.112.6<0.01Facial erythema18.54.5<0.01Facial sensory14.22.7<0.01Symptoms894.1<0.01Circulatory symptoms89Body itch8.94.1<0.01Facial sensory14.22.7<0.01symptoms8Dry facial sensory14.22.7<0.01Facial sensory14.22.7<0.01Facial sensory14.22.7 <th></th> <th>Total</th> <th></th> <th></th>		Total		
(n = 334) (n = 2154) P-value Oral symptoms Burning mouth 19.9 0.4 <0.01 Dry mouth 22.4 4.7 <0.01 General symptoms Fatigue 42.5 29.3 <0.01 Heavy-headiness 19.3 8.6 <0.01 Headache 18.5 9.7 <0.01 Nausea 5.6 1.4 <0.01 Neurological symptoms Vertigo 12.7 2.8 <0.01 Difficulties in 22.7 6.6 <0.01 concentrating Eye symptoms Eye irritation 20.1 6.5 <0.01 Dry eyes 17.2 6.4 <0.01 Circulatory symptoms Nasal symptoms 18.9 12.1 <0.01 Hoarseness 14.6 4.7 <0.01 Cough 7.4 3.7 <0.01 Lump in the throat 12.2 2.8 <0.01 Skin symptoms Dry facial skin 20.1 12.6 <0.01 Facial erythema 18.5 4.5 <0.01 Facial sensory 14.2 2.7 <0.01 Suppress Body itch 8.9 4.1 <0.01 Circulatory symptoms Irregular heartbeats 7.9 1.8 <0.01 Palpitation 9.7 1.6 <0.01 Chest pain 7.0 1.3 <0.01 Breathlessness 16.2 3.4 <0.01 Cold hands and feet 25.6 18.2 <0.01		Follow-up (%) <sup>a</sup>	Population (%) <sup>b</sup>	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $		(n = 334)	(n = 2154)	P-value
Burning mouth19.9 $0.4$ <0.01Dry mouth22.44.7<0.01	Oral symptoms			
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Burning mouth	19.9	0.4	< 0.01
General symptomsFatigue $42.5$ $29.3$ <0.01	Dry mouth	22.4	4.7	< 0.01
Fatigue $42.5$ $29.3$ $<0.01$ Heavy-headiness $19.3$ $8.6$ $<0.01$ Headache $18.5$ $9.7$ $<0.01$ Nausea $5.6$ $1.4$ $<0.01$ Neurological symptoms $vertigo$ $12.7$ $2.8$ $<0.01$ Difficulties in $22.7$ $6.6$ $<0.01$ concentrating $vertigo$ $22.7$ $6.6$ $<0.01$ Concentrating $vertigo$ $22.7$ $6.4$ $<0.01$ Difficulties in $20.1$ $6.5$ $<0.01$ Dry eyes $17.2$ $6.4$ $<0.01$ Circulatory symptoms $8.9$ $12.1$ $<0.01$ Hoarseness $14.6$ $4.7$ $<0.01$ Cough $7.4$ $3.7$ $<0.01$ Lump in the throat $12.2$ $2.8$ $<0.01$ Skin symptoms $verthema$ $18.5$ $4.5$ $<0.01$ Facial erythema $18.5$ $4.5$ $<0.01$ Facial sensory $14.2$ $2.7$ $<0.01$ symptoms $verthema$ $8.9$ $4.1$ $<0.01$ Circulatory symptoms $verthema$ $verthema$ $verthema$ Body itch $8.9$ $4.1$ $<0.01$ Circulatory symptoms $verthema$ $verthema$ $verthema$ Irregular heartbeats $7.9$ $1.8$ $<0.01$ Palpitation $9.7$ $1.6$ $<0.01$ Chest pain $7.0$ $1.3$ $<0.01$ Breathlessness $16.2$ $3.4$ $<0.01$	General symptoms			
Heavy-headiness19.38.6<0.01Headache18.59.7<0.01	Fatigue	42.5	29.3	< 0.01
Headache18.59.7<0.01Nausea5.61.4<0.01	Heavy-headiness	19.3	8.6	< 0.01
Nausea $5.6$ $1.4$ $<0.01$ Neurological symptoms $12.7$ $2.8$ $<0.01$ Difficulties in $22.7$ $6.6$ $<0.01$ concentrating $Eye$ symptoms $Eye$ symptoms $Eye irritation20.16.5<0.01Dry eyes17.26.4<0.01Circulatory symptoms<0.01Hoarseness14.64.7<0.01Cough7.43.7<0.01Lump in the throat12.22.8<0.01Skin symptomsDry facial skin20.112.6<0.01Facial erythema18.54.5<0.01Facial sensory14.22.7<0.01symptomsBody itch8.94.1<0.01Circulatory symptomsIrregular heartbeats7.91.8<0.01Palpitation9.71.6<0.01Chest pain7.01.3<0.01Breathlessness16.23.4<0.01$	Headache	18.5	9.7	< 0.01
Neurological symptoms         Vertigo       12.7       2.8       <0.01         Difficulties in       22.7       6.6       <0.01	Nausea	5.6	1.4	< 0.01
Vertigo12.72.8<0.01Difficulties in22.76.6<0.01	Neurological symptoms	5		
$\begin{array}{c cccc} \text{Difficulties in} & 22.7 & 6.6 & <0.01 \\ \text{concentrating} \\ \text{Eye symptoms} \\ \text{Eye irritation} & 20.1 & 6.5 & <0.01 \\ \text{Dry eyes} & 17.2 & 6.4 & <0.01 \\ \text{Circulatory symptoms} \\ \text{Nasal symptoms} & 18.9 & 12.1 & <0.01 \\ \text{Hoarseness} & 14.6 & 4.7 & <0.01 \\ \text{Cough} & 7.4 & 3.7 & <0.01 \\ \text{Lump in the throat} & 12.2 & 2.8 & <0.01 \\ \text{Skin symptoms} \\ \text{Dry facial skin} & 20.1 & 12.6 & <0.01 \\ \text{Facial erythema} & 18.5 & 4.5 & <0.01 \\ \text{Facial sensory} & 14.2 & 2.7 & <0.01 \\ \text{Facial sensory} & 14.2 & 2.7 & <0.01 \\ \text{Symptoms} \\ \text{Body itch} & 8.9 & 4.1 & <0.01 \\ \text{Circulatory symptoms} \\ \text{Irregular heartbeats} & 7.9 & 1.8 & <0.01 \\ \text{Palpitation} & 9.7 & 1.6 & <0.01 \\ \text{Chest pain} & 7.0 & 1.3 & <0.01 \\ \text{Breathlessness} & 16.2 & 3.4 & <0.01 \\ \text{Cold hands and feet} & 25.6 & 18.2 & <0.01 \\ \end{array}$	Vertigo	12.7	2.8	< 0.01
concentratingEye symptomsEye irritation20.1 $6.5$ $<0.01$ Dry eyes $17.2$ $6.4$ $<0.01$ Circulatory symptoms $18.9$ $12.1$ $<0.01$ Hoarseness $14.6$ $4.7$ $<0.01$ Cough $7.4$ $3.7$ $<0.01$ Lump in the throat $12.2$ $2.8$ $<0.01$ Skin symptoms $20.1$ $12.6$ $<0.01$ Facial erythema $18.5$ $4.5$ $<0.01$ Facial sensory $14.2$ $2.7$ $<0.01$ symptoms $s$ $s$ $<0.01$ Circulatory symptoms $s$ $<0.01$ Circulatory symptoms $s$ $<0.01$ Circulatory symptoms $<0.01$ $<0.01$ Circulatory symptoms $<0.01$ $<0.01$ Dregular heartbeats $7.9$ $1.8$ $<0.01$ Chest pain $7.0$ $1.3$ $<0.01$ Breathlessness $16.2$ $3.4$ $<0.01$	Difficulties in	22.7	6.6	< 0.01
Eye symptomsEye irritation20.1 $6.5$ <0.01	concentrating			
Eye irritation $20.1$ $6.5$ $<0.01$ Dry eyes $17.2$ $6.4$ $<0.01$ Circulatory symptoms $18.9$ $12.1$ $<0.01$ Hoarseness $14.6$ $4.7$ $<0.01$ Cough $7.4$ $3.7$ $<0.01$ Lump in the throat $12.2$ $2.8$ $<0.01$ Skin symptoms $0.1$ $12.6$ $<0.01$ Facial erythema $18.5$ $4.5$ $<0.01$ Facial erythema $18.5$ $4.5$ $<0.01$ Facial sensory $14.2$ $2.7$ $<0.01$ symptoms $S$ $S$ $<0.01$ Circulatory symptoms $S$ $<0.01$ Circulatory symptoms $S$ $<0.01$ Palpitation $9.7$ $1.6$ $<0.01$ Chest pain $7.0$ $1.3$ $<0.01$ Breathlessness $16.2$ $3.4$ $<0.01$ Cold hands and feet $25.6$ $18.2$ $<0.01$	Eye symptoms			
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Eye irritation	20.1	6.5	< 0.01
Circulatory symptomsNasal symptoms18.912.1<0.01	Dry eyes	17.2	6.4	< 0.01
Nasal symptoms $18.9$ $12.1$ $<0.01$ Hoarseness $14.6$ $4.7$ $<0.01$ Cough $7.4$ $3.7$ $<0.01$ Lump in the throat $12.2$ $2.8$ $<0.01$ Skin symptoms $0.01$ Dry facial skin $20.1$ $12.6$ $<0.01$ Facial erythema $18.5$ $4.5$ $<0.01$ Facial sensory $14.2$ $2.7$ $<0.01$ symptoms $<0.01$ Circulatory symptoms $<0.01$ Circulatory symptoms $1.8$ $<0.01$ Palpitation $9.7$ $1.6$ $<0.01$ Chest pain $7.0$ $1.3$ $<0.01$ Breathlessness $16.2$ $3.4$ $<0.01$ Cold hands and feet $25.6$ $18.2$ $<0.01$	Circulatory symptoms			
Hoarseness14.64.7<0.01Cough $7.4$ $3.7$ <0.01	Nasal symptoms	18.9	12.1	< 0.01
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Hoarseness	14.6	4.7	< 0.01
Lump in the throat $12.2$ $2.8$ $<0.01$ Skin symptomsDry facial skin $20.1$ $12.6$ $<0.01$ Facial erythema $18.5$ $4.5$ $<0.01$ Facial sensory $14.2$ $2.7$ $<0.01$ symptoms $Body itch8.94.1<0.01Circulatory symptomsIrregular heartbeats7.91.8<0.01Palpitation9.71.6<0.01Chest pain7.01.3<0.01Breathlessness16.23.4<0.01Cold hands and feet25.618.2<0.01$	Cough	7.4	3.7	< 0.01
$\begin{array}{c ccccc} {\rm Skin \ symptoms} & & & & \\ {\rm Dry \ facial \ skin} & 20.1 & 12.6 & <0.01 \\ {\rm Facial \ erythema} & 18.5 & 4.5 & <0.01 \\ {\rm Facial \ sensory} & 14.2 & 2.7 & <0.01 \\ {\rm symptoms} & & & \\ {\rm Body \ itch} & 8.9 & 4.1 & <0.01 \\ {\rm Circulatory \ symptoms} & & & \\ {\rm Irregular \ heartbeats} & 7.9 & 1.8 & <0.01 \\ {\rm Palpitation} & 9.7 & 1.6 & <0.01 \\ {\rm Chest \ pain} & 7.0 & 1.3 & <0.01 \\ {\rm Breathlessness} & 16.2 & 3.4 & <0.01 \\ {\rm Cold \ hands \ and \ feet \ 25.6 & 18.2 & <0.01 \\ \end{array}$	Lump in the throat	12.2	2.8	< 0.01
$\begin{array}{c cccccc} Dry \ facial \ skin & 20.1 & 12.6 & <0.01 \\ Facial \ erythema & 18.5 & 4.5 & <0.01 \\ Facial \ sensory & 14.2 & 2.7 & <0.01 \\ symptoms & & & \\ Body \ itch & 8.9 & 4.1 & <0.01 \\ Circulatory \ symptoms & & & \\ Irregular \ heartbeats & 7.9 & 1.8 & <0.01 \\ Palpitation & 9.7 & 1.6 & <0.01 \\ Chest \ pain & 7.0 & 1.3 & <0.01 \\ Breathlessness & 16.2 & 3.4 & <0.01 \\ Cold \ hands \ and \ feet \ 25.6 & 18.2 & <0.01 \\ \end{array}$	Skin symptoms			
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Dry facial skin	20.1	12.6	< 0.01
Facial sensory       14.2       2.7       <0.01	Facial erythema	18.5	4.5	< 0.01
symptoms Body itch 8.9 4.1 <0.01 Circulatory symptoms Irregular heartbeats 7.9 1.8 <0.01 Palpitation 9.7 1.6 <0.01 Chest pain 7.0 1.3 <0.01 Breathlessness 16.2 3.4 <0.01 Cold hands and feet 25.6 18.2 <0.01	Facial sensory	14.2	2.7	< 0.01
Body itch         8.9         4.1         <0.01           Circulatory symptoms         Irregular heartbeats         7.9         1.8         <0.01	symptoms			
Circulatory symptomsIrregular heartbeats7.91.8<0.01	Body itch	8.9	4.1	< 0.01
Irregular heartbeats $7.9$ $1.8$ $<0.01$ Palpitation $9.7$ $1.6$ $<0.01$ Chest pain $7.0$ $1.3$ $<0.01$ Breathlessness $16.2$ $3.4$ $<0.01$ Cold hands and feet $25.6$ $18.2$ $<0.01$	Circulatory symptoms			
Palpitation         9.7         1.6         <0.01           Chest pain         7.0         1.3         <0.01	Irregular heartbeats	7.9	1.8	< 0.01
Chest pain         7.0         1.3         <0.01           Breathlessness         16.2         3.4         <0.01	Palpitation	9.7	1.6	< 0.01
Breathlessness         16.2         3.4         <0.01           Cold hands and feet         25.6         18.2         <0.01	Chest pain	7.0	1.3	< 0.01
Cold hands and feet 25.6 18.2 <0.01	Breathlessness	16.2	3.4	< 0.01
	Cold hands and feet	25.6	18.2	< 0.01

<sup>a</sup>The study group.

<sup>b</sup>The Swedish reference population (25).

	Having unchanged or almost unchanged complaints			Having compla	Having any kind of remaining complaints			
	OR	95% CI	<i>P</i> -value	OR	95% CI	<i>P</i> -value		
Gender								
Women $(n = 222)$	1.0			1.0				
Men $(n = 79)$	1.86	1.10-3.13	0.02	1.08	0.53-2.20	0.84		
Subgroups by symptoms								
Local symptoms only $(n = 83)$	1.0			1.0				
Local + general symptoms ( $n = 164$ )	1.80	1.05-3.07	0.03	1.30	0.63-2.70	0.48		
General symptoms only $(n = 54)$	1.12	0.56-2.25	0.74	0.78	0.32-1.88	0.58		
Replacement of restorations								
Total ( $n = 107$ )	1.0			1.0				
Partial $(n = 96)$	2.45	1.39-4.30	0.002	2.13	0.87-5.18	0.10		
No replacement ( $n = 65$ )	2.36	1.26-4.43	0.008	1.60	0.62-4.08	0.33		

Table 4. The risk of 'having unchanged or almost unchanged complaints' and the risk of 'having any kind of remaining complaints' at follow-up (P = 0.05)

The odds ratio (OR) is a way of comparing whether the probability of a certain event is the same for two groups. An OR of 1 implies that the event is equally likely in both groups. An OR >1 implies that the event is more likely in the first group.

## Discussion

## Study population

The examination at baseline was performed with structured interviews and clinical protocols according to a registration form specially designed for this purpose. This has made retrospective data collection easier and with a high degree of accuracy. Even though the examination at baseline was based on a structured protocol, data in the records might be incomplete in some cases because of the fact that the patients were recorded for routine treatment, not for research purposes, which can affect the validity of retrospective research.

The criteria for separating patients in subgroups in this study were based on clinical experience and some patients may have been misclassified. As the classification was performed by two well-experienced dentists (AT, LM) who were unaware of the follow-up results, the misclassification should be nondifferential. The differences between the subgroups might thus probably be underestimated as such misclassification dilutes the differences. Furthermore, symptoms change over time and therefore some patients may have moved between the subgroups based on symptoms.

The dropout analysis showed that several symptoms were more frequently reported among the nonresponders compared with the responders, which indicates a risk of underestimation of remaining complaints at follow-up for the entire study population. It can be speculated, judging from the dropout interviews, that many patients have refused to respond because they did not get the help they had anticipated at the first visit, or that they were offended by the part of the questionnaire dealing with psychological aspects. The letters returned by 45 of the dropout patients, enclosed with a more or less incomplete questionnaire where they claimed that the investigation at baseline did not fulfill their expectations can, to a certain extent, verify this.

The patient group referred to the Department of Oral Diagnosis was composed of highly selected individuals who believed that they had been adversely affected by their dental restorative materials. The patients were very heterogeneous and the cause for referral varied, even though dental amalgam was the most prominent material reported, which is supported by findings of earlier studies (10, 12, 13, 22). Most patients had several oral and general symptoms, while about 10% (n = 33) appeared to have oral lesions only,

mainly diagnosed by the referring dentist because they were symptom-free. These patients were removed from the analysis because of the fact that the analysis was based on subgroups stratified by symptoms.

The start of the problems was mostly related to dental treatment and the symptom profile reported in the present study, which included both general and oral complaints, was in agreement with the study populations in previous studies (10, 12, 13, 22).

#### Characteristics at the baseline

The oral lichenoid reaction was verified in 15.3% of the patients at baseline. This is higher than the estimated 1–2% reported earlier in a general population (26–28). However, the prevalence differences can be explained by the fact that the study population consists of patients referred to the School of Dentistry and is therefore not a random sample of the general population. These patients with lichenoid reactions are subjected to further studies, and the results from a clinical follow-up investigation will be reported in a future paper.

The most common intra-oral symptoms in our study were burning mouth, dry mouth and taste disorder, reported by 21-55% of the patients. The prevalence of the reported temporomandibular dysfunction was 18.9%, which is considerable lower compared with that previously reported (10, 22). The discrepancy could be caused by the fact that the figures from the present study only consist of pain and stiffness of the temporomandibular joint whereas the above-referred studies report figures that included various additional symptoms such as pain from teeth, grinding and clenching of teeth and clicking from the temporomandibular joint. The patients also showed a broad spectrum of general symptoms at the baseline investigation. Symptoms like pain in muscles and joints, headache, and fatigue were the most prevalent.

The reported frequency of asthma, allergic rhinitis and atopic dermatitis are difficult to compare with similar patient groups, because there are no relevant reference data available for these symptoms. In comparisons with previous studies on groups of office workers with perceived hypersensitivity to electricity and skin symptoms related to use of visual display terminals (23, 24), our figures on asthma and allergic rhinitis did not differ, whereas our figures for atopic dermatitis are higher than those reported by Stenberg et al. (24).

#### Exchange of dental restorative materials

Of the 76.8% who replaced their restorations completely or partly, just above 50% reported adverse health effects in connection with removal of dental materials. General symptoms such as fatigue, nausea, headache and pain from muscles were the most common symptoms. Strömberg and Langworth (21) reported improved health in 66% of a group of patients after exchange of amalgam fillings. Of those, 14% claimed that they were free of symptoms. About 11% of the study population felt no improvement after 3 years. In comparison with the results of the present study, no major differences of the prevalence figures were found except for that part of the patients in whom the removal of dental restorations had no effect, which was 19% of the patients in the present study after an average of 5.3 years. In connection with the removal, 19% of the women and 36.5% of the men claimed that no effect was gained. Among men, this had decreased to 23.3% at the time for the follow-up while the prevalence figures for women were unchanged. As in the study referred to above (21), the time between the removal of dental restorations and the questionnaire had no influence on the perceived alleviation of symptoms.

#### Follow-up

In the present study, the pattern of symptoms reported at baseline was similar to that at followup, even though the frequency of the intra-oral symptoms reported had decreased over time. Among the general symptoms, the majority had increased instead of decreasing (Table 2). However, as the symptoms from baseline and the time of the follow-up have been registered and collected in different manners, it is difficult to draw firm conclusions. Another aspect that must also be taken into consideration is that the follow-up time for the patients in the present study varies; clinical criteria and routines might have changed slightly over time.

However, in comparison with our adult control population (25), the prevalence of symptoms was significantly higher for the patients in the present study (Table 5). This is in agreement with the results of Bratel et al. (12) and Langworth et al. (22), who found that symptoms were more common in patients who related their problems to dental restorative materials than in a control group.

Despite the improvements found between baseline and the follow-up, both women and men reported intra-oral symptoms, such as burning mouth and dry mouth, significantly more often (P < 0.01) than the reference population. It has been suggested that there is a relationship between oral symptoms, such as burning mouth, and psychological distress (29, 30) and moreover, these symptoms are more common among women (31). This indicates the importance of a psychosocial as well as an odontological/medical investigation and evaluation of this group of patients.

The women in the present study reported more symptoms compared with men, which is in agreement with earlier research (32). They also seemed to be more attentive to their health, as they had undergone more treatment by physicians at health clinics and specialist physicians than men. However, it was found that men with complex symptoms had a more unfavorable long-term prognosis concerning remaining complaints than women (P < 0.05).

Regarding the ability to recover completely, it was found that there were no significant differences between patients who had exchanged their dental restorative materials, either completely or partly, and those who had not replaced any of their dental materials. This is in contrast to the finding that the risk of having 'unchanged or almost unchanged complaints' is significantly higher for those who had not exchanged any or only a part of their restorations. This shows that the result differ depending on how the outcome (depending variable) is defined (Table 4). However, many patients reported that their health had improved over time after the replacement of their dental restorations. Less improvement was found among patients with complex symptoms. Regarding long-term prognosis, these results support the clinical impression that patients can be grouped by the type of symptoms present.

The patients had been subjected to many different treatments, even though dental treatment was the most common action taken for both genders. Many of our patients sought complementary care, which is an indication that traditional dental and medical care has, to some extent, failed in caring for these patients. The interest for complementary care can also be a result of dentists' shortcomings in the management of these patients' symptoms, which are not defined by generally recognized criteria. Attitudes and plans for action have also varied over time during the last two decades. Comparing our long-term follow-up results with those of others is difficult. There are only a few studies (2, 21) and the patients in these studies are not divided in the same manner as in the present study. Many patients have also been subject to different treatment actions and the effect of separate interventions can therefore not be evaluated.

In comparison with similar follow-up studies of patients with sensitivity to electricity and visual display units and sick building syndrome, this study shows that the prognosis for patients with 'symptoms allegedly caused by dental restorative materials' is more favorable (P < 0.05) than the prognosis for patients with electrical hypersensitivity and sick building syndrome (18, 23) and equal to that for those with sensitivity to visual display units (23).

## Conclusions

The present study shows that patients with complex symptoms have a more unfavorable long-term prognosis concerning persistent complaints than those with local symptoms only. Furthermore, the results indicate that patients may experience health improvements after removal of their dental restorative materials. The reason for this improvement, however, is unclear. Somewhat contradictory is that the majority of general symptoms have increased, while the patients perceive that their health has improved. Even if the patients after replacement of their dental restorative materials claim that the alleviation of their symptoms is an effect of decreased exposure to the materials suspected, there might be other explanations for the patients' improved health. The alleviation of symptoms might also be an effect of patients' expectations, spontaneous recovery, changes of attitudes and changes in psychosocial situations. Therefore, this group of patients will be subjected to further analyses, where other possible explanations to the patients' symptoms and health improvements than the odontological/medical will be discussed.

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