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ORIGINAL ARTICLE

A rare allergy to a polyether dental impression material

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Abstract Polyether impression materials have been used in dentistry for more than 40 years. Allergic reactions to these materials such as reported in the 1970s ceased after replacement of a catalyst. Very recently, however, patients have started to report symptoms that suggest a new allergic reaction from polyether impression materials. Here, we report on the results of allergy testing with polyether impression materials as well as with its components. Eight patients with clinical symptoms of a contact allergy (swelling, redness or blisters) after exposure to a polyether impression material were subjected to patch tests, two of them additionally to a prick test. A further patient with atypical symptoms of an allergy (nausea and vomiting after contact with a polyether impression material in the oral cavity) but with a history of other allergic reaction was also patch tested. The prick tests showed no immediate reactions in the two patients tested. In the patch tests, all eight patients with typical clinical symptoms showed positive reactions to the mixed polyether impression materials, to the base paste or to a base paste component. The patient with the atypical clinical symptoms did not show any positive patch test reactions. Polyether impression materials may evoke type IV allergic reactions. The causative agent was a component of the base paste. In consideration of the widespread use of this impression material (millions of applications per year) and in comparison to the number of adverse reactions from other dental materials, the number of such allergic reactions is very low. In very scarce cases, positive allergic reactions to polyether impression materials are possible.

Keywords Contact allergy · Patch testing · Impression material · Polyether

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Introduction

Clinical adverse reactions during dental restorative treatment may have several reasons, e.g. resin materials, alloys, anaesthetics or cements [1]. Few reports only are available on impression materials [2, 3]. However, clinical complications may be seen, and therefore the dentists should be aware of the possibility that patients may show allergic reactions to impression materials.

For more than 40 years, polyether impression materials have been used during the restoration of teeth with inlays, crowns or bridges and more recently for the implantology impression technique. In the 1970s, some allergic reactions were described after contact with the polyether impression material Impregum™ (ESPE, Seefeld, Germany) [4–7]. The patients reported swelling, itching and redness after oral contact with the impression material. Patch testing showed a component of the catalyst paste as the cause of these allergic reactions. As a consequence, the catalyst was replaced, and, to our knowledge, only one case of allergy to a catalyst paste component after contact with modified polyether impression materials has been published in the literature ever since [3].

Recently, however, according to information provided by the manufacturer [Klettke, private communication], dentists have again reported single cases of adverse reaction after patients had been exposed to a polyether impression material

with symptoms suggesting an allergic background. Therefore, multiple allergy tests with this impression material as well as with its components had been performed. Here, we report retrospectively on the results of these tests.

Patients, materials and methods

Between 2007 and 2009, nine patients in Germany were contacted by the Regensburg University Hospital because of suspected allergic reactions after alio loco dental treatment with a polyether impression material. Eight of these patients showed typical symptoms of an allergy (see Table 1). A 58-year old woman (patient 9) reported nausea and vomiting 3 h after oral contact with the polyether impression material Impregum™ Penta™. The patient declared to be allergic to formaldehyde, isocillin, celery, sesame and lilies of the valley. Therefore, she was included into this report. All patients or their dentists were asked about any previous exposition to polyether impression material.

Patients were allergy tested by means of prick tests on the forearm (patients 1 and 2) and patch tests on the upper back or upper arm (all patients) according to the ICDRG criteria. As a precaution, one patient with serious symptoms (patient 2) was tested under inpatient conditions, and a venous aditus was applied. Patch testing was performed either at the Department of Dermatology, University Clinics Regensburg or in the practice of a dermatologist because of the long travel distance to Regensburg. All patch test materials and detailed instructions were sent to the dermatologists prior to testing.

Prick test materials include the following:

- Standardized prick test protocols containing pollen, inhalation and food allergens (HAL Allergie GmbH, 40591 Düsseldorf; Allergo Pharma, 21462 Reinbeck; Bencard Allergie, 80992 München)
- The impression material (Impregum™ Penta™, see Table 2) was immediately applied after mixing and 3 and 10 min after mixing with Pentamix (3M ESPE, Seefeld, Germany) to test the influence of the setting reaction.
- Base paste and catalyst paste of Impregum™ Penta™ (catalyst paste diluted 1:10, except patient 1, undiluted) were also tested.

Patch test materials are as follows:

- European standard series (Hermal, Hamburg, Germany)
- Dental standard series (Hermal, Hamburg, Germany and Hal Allergie, Düsseldorf, Germany)
- Impression materials (see Table 2) mixed as well as base pastes and catalyst pastes (see prick test)
- Nineteen components of the base and catalyst paste have been provided by the manufacturer of the polyether impression material. The components tested were the active component (sulfonium salt), polyether macromonomer (polyether), stabilizer (organic basic substance), setting modifier (derivative of an aromatic heterocycle), flavours, fillers, softeners, diluents, rheological additives, dyes and pigments.
- The components were diluted 1:10. The setting modifier was tested 1:100 in patients 2 to 9.
- Polyether adhesive (3M ESPE, Seefeld, Germany), used to provide a firm adhesion between impression trays and impression material, was tested in patients 1 and 2 (see Table 1).

Results

All patients or their dentists reported on a previous contact with polyether impression material. The two patients (patients no. 1 and 2), who were prick tested, showed no reaction in the

Table 1 Anamnestic information on patients with adverse reactions observed in contact with a polyether impression material typical for an allergic nature

Patient number	Age (years), sex	Symptoms	Time of appearance
1	66, female	Swelling, redness of tongue and lips	Starting 30 min after contact, abating after 2 days
2	23, female	Swelling, blisters, itching, shortness of breath, dysphagia	Beginning after 3–5 h, increasing after 10–12 h
3	43, female	Swelling, redness of the palate, dysphagia	Day after exposure
4	57, female	Swelling of lips, pain in the palate, dysphagia	3 h after exposure
5	56, female	Swelling of the face and lips	30 min after exposure
6	56, female	Blister and redness of the gingiva and oral mucosa, burning	2–3 days after exposure
7	42, female	Formication, later intraoral swelling and blisters, redness of the face	Formication immediately after exposure, other symptoms during the night
8	64, female	Swelling of face and lips, redness in the mouth	No information available

Table 2 Polyether impression materials specifications (manufacturer: 3M ESPE, Seefeld, Germany)

Material code	Name	Main component[a]	Mixing ratio Base to catalyst
I	Impregum™ Penta™	Base 55–65% polyether Catalyst 35–50% citric ester 20–30% silane-treated silica 15–30% sulfonium salt	5:1
II	Impregum™ Penta™ Soft	Base 50–60% polyether Catalyst 35–50% citric ester 20–30% silane-treated silica 15–30% sulfonium salt	5:1
III	Impregum™ F	Base 50–60% polyether Catalyst 30–40% sulfonium salt 30–40% citric ester 15–25% silane-treated silica	7:1
IV	Permadyne™ Garant™ 2:1	Base 80–90% polyether Catalyst 25–35% citric ester 20–30% sulfonium salt	2:1
V	Impregum™ Garant™ L DuoSoft	Base 75–85% polyether Catalyst 25–35% polymeric acetate 20–30% diatomaceous earth	2:1
VI	Polyether adhesive	25–50% ethyl cetate 25–35% heptane	Not relevant

[a]Information from material safety data sheets. All materials have been provided by the manufacturer

test readings after 20 min. However, patient 1 showed delayed reactions (+) in the prick test 2 days later; the base paste of Impregum™ Penta™, and Impregum™ Penta™ immediately applied after mixing induced skin reactions. The same was true for Impregum™ Penta™ applied 3 min after mixing.

None of the nine patients showed any positive reactions in the patch test readings after 20 min. Furthermore, the patient with the atypical clinical symptoms did not react positively at any reading time. However, the eight patients with clinical symptoms typically related to an allergy showed 2 or 4 days after application crescendo positive allergic reactions (see Table 3). Interestingly, all eight patients also reacted positive (either + or ++) to the base paste of the impression materials. Seven out of eight patients reacted positively to one of the freshly mixed materials. Only two out of eight patients reacted positive to the catalyst paste. On one of these patients, being the first to be tested, the catalyst was tested undiluted and a toxic reaction could not be excluded. For this patient, the results for the active component (sulfonium salt) were negative. For all following tests, the catalyst paste was diluted 1:10. In one patient, the positive reaction towards the catalyst paste could be confirmed by the positive result for the active component (sulfonium salt). In two patients, the impression material has also been applied as set specimens. One patient (patient 2) reacted positive even with the 10-min set specimen, while the other patient (patient 1) only showed a + reaction for one product set for 3 min.

Results from patch testing of the ingredients are listed in Table 4. The polyether macromonomer was diluted 1:10 and evoked a positive reaction in all eight patients with the typical clinical symptoms. The stabilizer caused skin reactions (+, ++ and +++) in six out of eight patients. This stabilizer is dissolved in the polyether macromonomer in a

Table 3 Results of patch tests for impression material pastes and mixes (grades: +, ++ and +++); material codes I–V (see Table 2)

Patient number	Fresh mix	Base paste	Catalyst paste
1	I: +	I: +	I: +[a]
	III: +	III: +	III: +[a]
2	I: −	I: ++	I: −
	III: +	III: ++	III: −
3	II: +	I: ++	I: −
		II: ++	II: −
		III: ++	III: −
4	II: +++	I: ++	I: −
		II: ++	II: −
		III: ++	III: −
5	III: ++	I: ++	I: −
		II: ++	II: −
		III: ++	III: −
6	I: +++	I: ++	I: ++
	IV: +++	II: ++	II: ++
		III: ++	III: ++
		IV: ++	IV: ++
7	II: +	II: +	II: −
	V: +	V: +	V: −
8	I: −	I: +	I: −
9	I: −	I: −	I: −
	II: −	II: −	II: −

[a] Tested non-diluted. As a toxic reaction could not been excluded, the tests for the other patients were conducted in 1:10 dilutions for the catalyst paste

very low concentration. In a dilution of 1:10, formation of a big blister to the setting modifier which is also a component of the base paste was observed. The next day, reading confirmed these results. This was regarded as a toxic reaction. Flavours, fillers, softeners, diluents, rheological additives, dyes and pigments were tested negative in all patients in the patch test as well as the polyether adhesive in the two patients, where it had been applied.

Discussion

In the presented cases, the verification of an allergic nature of the observed adverse clinical reaction was done using mainly the patch testing and in two patients additionally the prick test. The patch test is considered to be indicative for a delayed type contact allergy which requires a previous exposition to the allergen [8–10]. For two patients, additionally a prick test was conducted because the reaction occurred within a very short period of time after the exposure, being indicative for an immediate type (type I) of allergy, for which the prick test would be adequate for verification [11]. Prick tests were done with the mixed material and the base and catalyst paste. Pollen, inhalation and food allergens were prick tested because patients with atopic reactions might show unspecific allergic patch test reactions. As in both patients, the results were negative; prick testing was abstained for further patients.

Patch testing has been performed according to accepted standards using the European standard series and the dental standard series, beside the actual target substances, the mixed impression material, the base and catalyst paste and 19 components of the impression material.

The selection of the different polyether materials (see Table 2) to be included into the allergy test for an individual patient was based on the anamnesis, i.e. the material towards the clinical adverse reaction had been observed. All tested impression materials are based on a polyether macromonomer, although the concentration of the single

Table 4 Results of patch tests for ingredients from polyether impression material (grades: +, ++ and +++)

Name of the component	Patient number								
	1	2	3	4	5	6	7	8	9
Polyether macromonomer	+++	+[b]	++	++	++	+++	+[a]	+[b]	−
Stabilizer	+	Not tested	+	+++	−	++	++	+	−
Setting modifier	Toxic reaction[c]	−	−	−	−	−	−	−	−
Active component	−	−	−	−	−	++	−	−	−

All ingredients have been provided by the manufacturer. Flavours, fillers, softeners, diluents, rheological additives, dyes and pigments tested were negative in all patients

[a] With stabilizer as used in material V (see Table 2)

[b] With stabilizer as used in materials I, III and IV (see Table 2)

[c] The setting modifier was used diluted 1:100 in the other patients

components may be different between the different brands listed (see Table 2). Furthermore, all polyether impression materials are produced by one manufacturer.

The results of the allergy testing (positive patch test reactions) verified the allergic nature of the observed adverse reaction for all eight patients with clinical symptoms typical for an allergic reaction. The one patient with atypical clinical reaction did not respond to patch testing. Testing had been performed because the patient had a history of sensitivity to several substances.

In the diagnosis of clinical adverse reactions, allergic reactions must be distinguished from toxic reactions. In consideration of the widespread use of the polyether impression materials (millions of applications per year according to the manufacturer) and the low number of cases with adverse reactions, the allergic nature seems to be obvious. Furthermore, exposure of all patients in this study to the polyether impression material prior to the clinical situation, when the adverse reaction had been observed, was reported.

Early or immediate reactions as reported by some patients (five patients reacted within 3 h, see Table 1) may be an indicator for type I allergies. However, the two patients, who had been prick tested, did not show any immediate test readings. Thus, type I reactions could not be verified. Patch tests, however, ascertained delayed hypersensitivities (type IV) to the mixed materials, the base paste or to a base paste component in all eight patients. The delayed prick test reaction may also be interpreted as a delayed type IV reaction. The reported early reactions after application of the impression materials into the mouth, which are typical for type I reactions, are difficult to explain. However, in the literature, some other positive patch test materials, such as formaldehyde [12], are reported to induce early symptoms similar to type I reactions.

The setting modifier diluted 1:10, a component of the base paste, caused a big blister formation in patient 1, which was interpreted as a toxic reaction. Therefore, the setting modifier was applied in dilute form 1:100 in the following eight patients, who then showed no reaction.

The link between the eight patients with typical clinical symptoms of a contact allergy seems to be the polyether macromonomer, which is a long-chain molecule with reactive cyclic end groups. The polyether macromonomer is a component of the base paste, which explains the reactions to the base pastes of all polyether materials. Another option as responsible agent would be the stabilizer. Six out of eight tested patients showed positive reactions. The positive patch test reaction to the catalyst paste in one patient, which was further verified by the positive result evoked by the active component, is difficult to explain. However, it occurred consistently in one patient only and thus can be regarded as a very seldom event.

For more than 40 years, polyether impression materials have been used in dentistry. In recent years, however, the use of these materials in dentistry has increased because of the implantology impression technique. Thus, the risk of sensitization may also have increased, which could be the reason why single cases with allergic reactions are reported again. For the first time, the series of cases presented describes a contact allergy to a polyether impression material, after the catalyst of the materials had been changed in 1980s. Both dermatologists and dentists should be aware of this allergy. Even though the material is in contact with the oral mucosa for a few minutes only, it may elicit an allergic reaction. Similar symptoms are described in the literature for the former polyether impression material Impregum™ containing the previous catalyst [4–7] and for the new polyether impression material Impregum™ Penta™ in a case report [3]. Patch tests showed in these cases the catalyst paste as the causative agent, whereas in the presented study, mainly the base paste and the polyether macromonomer were found to contain the allergen.

A literature search in PubMed from July 2011 concerning reports on allergic adverse reactions after contact with other impression materials used for the same purpose as polyether materials, especially polyvinylsiloxane preparations, gave no indication for such reactions. However, the database of the U.S. Food and Drug Administration [13] contains a number of reports on adverse reactions also to polyvinylsiloxane products, but detailed information is not available.

In conclusion, the polyether impression material used in dentistry may evoke type IV hypersensitivity reactions, probably caused by a base paste component. However, with regard to the widespread use of this impression material (millions of applications per year), these cases are scarce.

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Conflicts of interest There are no conflicts of interest for this study.

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