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Allergic contact dermatitis caused by glucose sensors in type 1 diabetes patients

Heli S. I. Hyry¹ | Jussi P. Liippo² | Hannele M. Virtanen¹

¹Dermatology and Allergology, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

²Department of Dermatology and Allergy Unit, University of Turku, Turku University Hospital, Turku, Finland

Correspondence

Dr Heli S. I. Hyry, Skin and Allergy Hospital, Helsinki University Hospital, P.B. 160, Helsinki FI-00029, Finland.
Email: heli.hyry@hus.fi

Abstract

Background: Allergic contact dermatitis caused by glucose sensors has become an increasing problem. Contact allergies to isobornyl acrylate, colophonium, ethyl cyanoacrylate and *N,N*-dimethylacrylamide have been reported. However, there is a paucity of information regarding the prevalence of sensor-related dermatitis and detailed patient histories.

Objectives: To evaluate diabetes patients who have developed allergic contact dermatitis caused by glucose sensors.

Patients and methods: Seventy patients with suspected contact allergy to glucose sensors referred to university hospital dermatology clinics in southern Finland were patch tested with the baseline series, an isobornyl acrylate dilution series, and a number of other acrylates. Atopic constitution, contact allergies, the severity of the dermatitis and the ability to continue with the same or another type of sensor were recorded.

Results: Positive patch test reactions to isobornyl acrylate were seen in 51 of 63 (81%) Freestyle Libre users. Colophonium or its derivatives gave positive reactions in five of seven Medtronic Enlite users. The median duration of sensor use before dermatitis was 6 months. The estimated prevalences of contact allergy to sensor adhesives were 0.7% for Freestyle Libre and 0.8% for Enlite.

Conclusions: We suggest that patients who have difficulties in finding a tolerable glucose sensor or an insulin pump should be patch tested.

KEYWORDS

acrylates, adhesives, allergic contact dermatitis, CAS no. 5888-33-5, glucose sensors, isobornyl acrylate, medical device, type 1 diabetes

1 | INTRODUCTION

Patients with type 1 diabetes are increasingly using transdermal glucose sensors. These devices are required to tolerate physical exercise and sweating for up to 2 weeks, which imposes specific requirements on the adhesive materials. The patients often experience skin irritation on the areas covered by the sensors and their adhesives. Some patients develop more severe dermatitis, with redness, swelling, and vesiculation, suggesting contact allergy (Figure 1A-C). In this study, we examined type 1 diabetes patients with suspected contact allergy

to glucose sensors in southern Finland. There are three brands of glucose sensor device available in Finland: Freestyle Libre by Abbott, Enlite by Medtronic, and Dexcom G5 and G6 by Dexcom. The adhesive in Freestyle Libre has been shown to contain isobornyl acrylate (IBOA) (CAS no. 5888-33-5)¹ and *N,N*-dimethylacrylamide (DMAA) (CAS no. 2680-03-7),² which cause contact allergy in their users. Dexcom G4 Platinum, in turn, has been shown to contain ethyl cyanoacrylate (CAS no. 7085-85-0), which is a common constituent of instant glues.³ Enlite has been reported to contain colophonium (rosin).⁴ Later, Dexcom developed new sensors, G5 and G6, without

ethyl cyanoacrylate.⁵ According to the Dexcom website, the new sensors contain a pressure-sensitive acrylic adhesive coated on top of a polyester spun lace fabric. Dexcom sensors have also been shown to be free of IBOA.⁶

IBOA is a monomer that is typically used in, for example, coatings, inks, ultraviolet adhesives, cosmetics, and paints. It has not been considered to be a strong sensitizer, and it is not known to cross-react with other acrylates.⁷ It has been suggested that it should be patch tested at a concentration of 0.1%.¹ DMAA is used as a monomer or as polymers in, for example, adhesives, coatings, synthetic fibres, and drug-releasing hydrogels.⁸ It is often used in combination with IBOA.² Colophonium is one of the most common contact allergens, with a prevalence of 2%.⁹ It is widely used in adhesives, tapes, cosmetics, soaps, paper products, printing inks, polishes, stringed instruments, paints, lacquers, and soldering products.¹⁰ It may even be found in skin protectors used, for example, by diabetic patients, such as Duoderm Extra Thin hydrocolloid dressings.¹¹

2 | PATIENTS AND METHODS

The case histories of the patients with suspected allergic contact dermatitis caused by glucose sensors referred to the departments of dermatology in Helsinki and Turku University Hospitals between October

2017 and January 2019 were reviewed retrospectively. A total of 73 patients were identified, of whom 70 were patch tested.

Patch testing was performed according to the guidelines of the International Contact Dermatitis Research Group. The duration of occlusion was 2 days, and the test results were evaluated when the patches (Finn Chambers on Scanpor tape; SmartPractice, Phoenix, Arizona) were removed, and on day (D) 4 or D5. IBOA (Sigma-Aldrich Finland, Espoo, Finland) was tested 0.1% pet. alone or as a dilution series as 0.1%, 0.032%, 0.01%, 0.0032% and 0.001% pet. Colophonium and ethyl cyanoacrylate were tested as parts of other relevant series, such as baseline series, dental series, or acrylate series, or as solitary substances. In five patients, Enlite adhesive materials were tested "as is." The exact numbers of patients tested with each substance are shown in Table 1.

In Helsinki, an in-house acrylate series, containing methyl methacrylate 2%, triethylene glycol dimethacrylate 2%, diethylene glycol dimethacrylate 2%, bisphenol A-glycidyl methacrylate (bis-GMA) 2%, 2-hydroxyethyl methacrylate 2%, bisphenol A 1%, ethyl cyanoacrylate 10%, triethylene glycol diacrylate 0.1%, epoxy diacrylate 0.5%, 2-hydroxyethyl acrylate 0.1%, ethyl acrylate 0.1%, ethyl methacrylate 2%, hydroxypropyl methacrylate 2%, and diethylene glycol diacrylate 0.1%, all in pet., was tested in 35 patients. In addition, DMAA (Sigma-Aldrich Finland) 0.1% pet., sesquiterpene lactone mix 0.1%, abietic

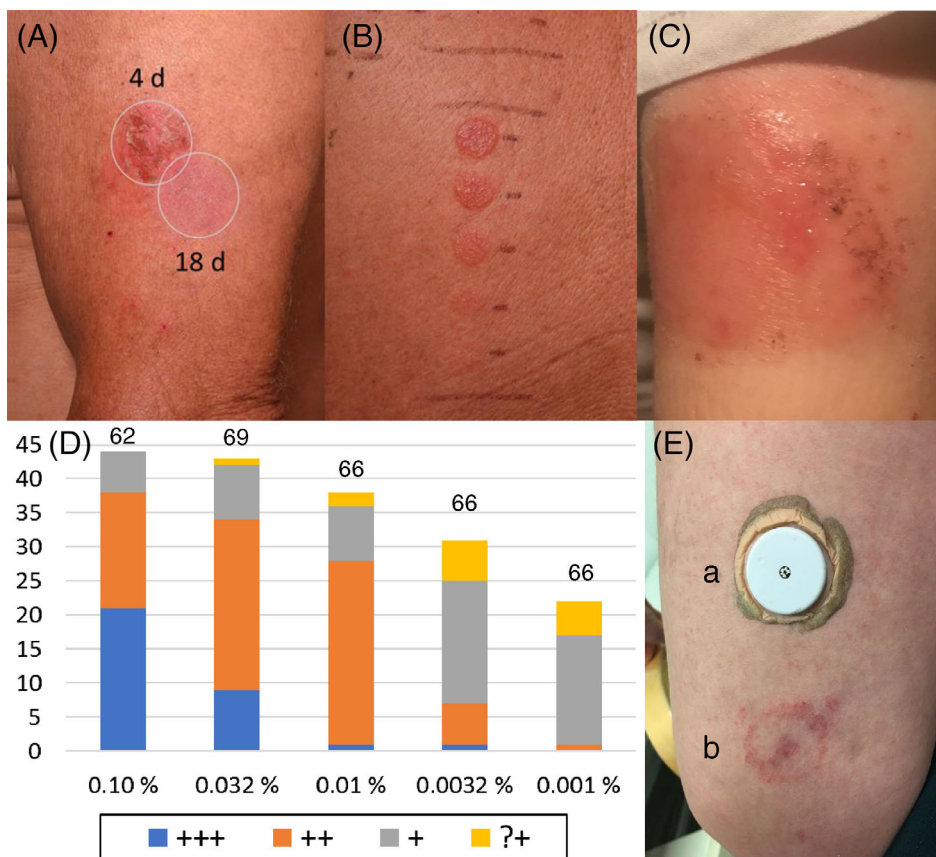


FIGURE 1 (A), Allergic contact dermatitis on the upper arm of a 73-year-old male Freestyle Libre user 4 days and 18 days after removal of the round sensor. (B), Positive isobornyl acrylate (IBOA) patch test reactions of the same patient. The top patch, with the highest concentration, that is, 0.1% shows a strong allergic +++ reaction. The other reactions are as follows: 0.032%, ++; 0.01%, ++; 0.0032%, +; and 0.001%, negative. (C), Severe allergic contact dermatitis on the upper arm of a 9-year-old boy at the time of the removal of an Enlite sensor. (D), Patch test readings for the dilution series of IBOA in Freestyle Libre sensor users. The vertical axis shows the number of patients, and the horizontal axis shows the test concentrations. The number of patients tested with each IBOA concentration is shown at the top of each column. (E), Freestyle Libre sensor with Eakin Surround skin protector cut to a suitable size on the upper arm of a young woman (a), and allergic contact dermatitis caused by IBOA 2 weeks after removal of the sensor (b). The skin protector did not completely prevent the dermatitis. The protector has a hole in its centre and a slit in the lower left area

TABLE 1 The diabetes patients divided into Freestyle Libre and Enlite glucose sensor user groups; their ability to continue with the same sensor despite contact dermatitis, their patch test results for suspected adhesive-related allergens and their background data are shown by group

	Glucose sensor type (n)	
	Freestyle Libre	Enlite
Glucose sensor users	66	7
Not able to continue using the sensor	44	1
Continuing with the original sensor type	16	5
Changed sensor type	6	1
Patch tested for isobornyl acrylate	63	7
Positive	51	0
Patch tested for colophonium	57	7
Positive ^a	1	5
Patch tested for ethyl cyanoacrylate	59	6
Positive	0	0
Patch tested for other acrylates	56	6
Positive	4	0
Patch tested for Enlite overtape	0	5
Positive		4
Patch tested for Enlite sensor tape	0	3
Positive		1
Females	45	3
Males	21	4
Children	25	7
Adults	41	0
Atopic eczema	12	3
Atopic constitution without eczema	16	1
Severe contact dermatitis	50	2
Mild contact dermatitis	16	5

^aOne in the Enlite group reacted positively to abitol.

acid 10% and dihydroabietyl alcohol (Abitol) 10% were tested in four patients. Atopic constitution, the duration of sensor use before the onset of dermatitis, the severity of the dermatitis, the type of the sensor used and the ability to continue to use the same or another type of sensor were recorded.

3 | RESULTS

3.1 | Participant characteristics

A total of 70 individuals were patch tested (40 in Helsinki and 30 in Turku). All subjects were Caucasian; there were 45 females, of whom 16 were aged <18 years, and 25 males, of whom 14 were aged <18 years. Their overall median age was 25 years (range 2-73 years); the median age of females was 26 years (range 2-68 years), and the median age of males was 16 years (range 4-73 years).

Freestyle Libre had been used by 63 patients, and Enlite had been used by seven patients. There were no Dexcom users among our patients. The median exposure time was 6 months (range 0-18 months) before the appearance of sensor-associated dermatitis. The sensor dermatitis was considered to be severe in 49 (70%) patients (two of them Enlite users) and mild in 21 (30%) patients (five of them Enlite users). The reaction was regarded as severe when the patients developed a red, swollen, intensively itching, oozing, bleeding or blistering dermatitis at the sensor contact site. A picture of partially healed severe allergic reactions with the patch test reactions to IBOA is shown in Figure 1A,B. An example of oozing severe contact allergy to colophonium is shown in Figure 1C. The dermatitis was considered to be mild when the bleeding and blistering were absent. All patients in this study had dermatitis that was severe enough to force the patient to use a skin protector under the sensor or to stop using the sensor in question.

3.2 | Patch test results

A total of 51 (81%) Freestyle Libre users showed positive patch test reactions to IBOA (Table 1). The results of the IBOA series are shown in Figure 1D. Of the 12 Freestyle Libre users with negative IBOA results, three had active atopic dermatitis, two had atopic diathesis without active eczema, and seven were considered to have probable non-specific skin irritation. One of them showed a positive reaction to colophonium.

Of the seven Enlite users, four reacted positively to both colophonium and the sensor's adhesive overtape. One reacted positively to abitol, which is a derivative of colophonium. However, colophonium gave a negative result in this patient. One of the two patients who did not react to colophonium or abitol had atopic dermatitis. No reactions to ethyl cyanoacrylate were seen. The dermatitis was considered mild in 10 patients with no allergies to any of the tested adhesive-related materials and severe in three patients. No significant sex differences in the patch test results were seen. Patients with atopic dermatitis did not have more contact allergies to glucose sensors than non-atopic patients.

In addition to positive reactions to IBOA, four females with previous use of acrylic artificial nails had positive reactions to acrylates that are commonly present in these products: methyl methacrylate (one patient), triethylene glycol dimethacrylate (one patient), bis-GMA (one patient), 2-hydroxyethyl methacrylate (three patients), 2-hydroxyethyl acrylate (three patients), ethyl acrylate (two patients), hydroxypropyl methacrylate (two patients), ethylene glycol dimethacrylate (one patient), and diethylene glycol diacrylate (one patient). Only one of them reported skin symptoms related to the nails.

On being tested with the baseline series, 23 patients had contact allergy to substances that are probably not related to the glucose sensor materials, such as preservatives (11 patients), fragrances (seven patients), metals (seven patients), Compositae mix (two patients), *p*-phenylenediamine (one patient), and neomycin (one patient). Sesquiterpene lactone mix is included in the baseline series in some

countries. As this is not the case in Finland, we tested it in only four patients: two Freestyle Libre users and two Enlite users. Both Freestyle Libre users reacted positively to sesquiterpene lactone mix. In addition, DMAA was tested in these four patients, and gave a positive reaction only in an Enlite user.

3.3 | Management of allergic contact dermatitis

To control the dermatitis, the patients tried to use topical corticosteroids and different skin protector pads on the sensor area. Only 14 of 63 tested Freestyle Libre users were able to continue with the same sensor. Twelve of them were allergic to IBOA. In addition, two patients who were not tested were able to continue using the sensors. Nobody was able to continue using the sensor without any barrier material between the skin and the sensor. The sensor changes by sensor type are shown in Table 1. Despite the skin protection, the dermatitis continued in 13 patients. The skin protectors used included Cavilon spray, Compeed sheets, Eakin Surround protectors, and Silesse skin barrier spray, with or without topical corticosteroids. Three of 10 Eakin Surround users were able to continue using Freestyle Libre, with no dermatitis. An example of the reduction in activity of allergic contact dermatitis provided by Eakin Surround is shown in Figure 1E.

Five of seven Enlite users were able to continue using the same sensor despite the continuing dermatitis. Of these five patients, four reacted positively to colophonium or abitol. They used Cavilon spray, Silesse spray or topical corticosteroids to reduce itching. All of them replaced the Enlite overtape with other tapes (Hydrofilm, Opsite flexifix gentle, or Mefix). The adhesive under the sensor itself cannot be replaced. However, the area of the sensor is considerably smaller than the area of the overtape, so it is probably easier to tolerate. Of the four patients who reacted positively to colophonium, two were tested with the overtape and both showed positive reactions. In contrast, the patient who had a negative result with colophonium also had a negative result with the overtape. However, she reacted positively to the sensor tape. A 9-year-old Enlite user who had to change to Dexcom is shown in Figure 1C. He had positive reactions to colophonium, Enlite overtape and Duoderm ExtraThin hydrocolloid dressing. He had negative results with the sensor tape, Mepore film, and a kinesiotope.

Of the tested Freestyle Libre users, four changed to Dexcom sensors. They all reacted positively to IBOA. The dermatitis of three patients cleared, and one had mild remaining dermatitis. One patient who reacted positively to IBOA changed to Enlite, but her dermatitis continued. She needed topical corticosteroids and Tegaderm film under the sensor to protect the skin. She did not react positively to colophonium. In addition, one patient who was not tested changed from Freestyle Libre to Enlite, but she could not tolerate Enlite at all. Finally, she could use Dexcom G5 successfully, without dermatitis. These patients are not included in the group of Enlite users.

4 | DISCUSSION

4.1 | Prevalence of contact allergy to sensors

According to the present results, dermatitis symptoms related to glucose sensor materials are most often caused by contact allergy to IBOA or colophonium, depending on the device in question. Previously, IBOA has rarely caused contact allergy as compared with, for example, methacrylates.⁷ However, with continuous occlusive exposure it is able to cause sensitization. In recent years the role of colophonium as contact allergen in medical dressings has decreased, although it is still found in some products that are common in Finland, such as Duoderm Extra Thin. In contrast, acrylates are becoming increasingly important in modern dressings and adhesives, and should be included in the patch test programme for patients with medical adhesive-related dermatitis.^{12–14} In this study, contact allergy to IBOA was far more common than allergy to colophonium, as only five patients were sensitized to it following Enlite use. However, Freestyle Libre is the most common sensor type offered to diabetes patients in southern Finland, with 6567 users in Helsinki and Turku university clinics in November 2018, followed by 385 Enlite and only 18 Dexcom users. Thus, in our study population, ~0.7% of Freestyle Libre users had developed allergic contact dermatitis as compared with 0.8% of Enlite users. The actual proportion may, however, be higher, because, apparently, not all sensor-allergic patients were referred for testing.

The nurses taking care of the adults using Freestyle Libre at Helsinki University Hospital estimate that ~5% of the patients complain about sensor-related dermatitis. In addition, they estimate that ~1% of the adults using Freestyle Libre need to stop using the sensor or need to use skin protectors under the sensor. This 1% were sent to be patch tested. The actual proportions remain to be studied in Finland. In contrast, 35% and 46% of glucose sensor users in Denmark have been reported to have skin problems related to their sensors.^{15,16} However, not all of the findings were eczematous lesions, and the patients were not tested for contact allergies. Thus, most probably, there are a significant number of patients suffering from glucose sensor-related irritant contact dermatitis as well.

4.2 | Patch testing

The majority of our patients reacted positively to at least the 0.032% concentration of IBOA, and only eight reacted positively to only the strongest concentration of 0.1%. The test reactions were typically already strong at the first reading on D2. To avoid these severely itching reactions, the 0.032% concentration can be used for patch testing. The 0.1% concentration could be added on D2 if the 0.032% test preparation remains negative.

Interestingly, one patient who was sensitized to colophonium had clearly Freestyle Libre-related contact dermatitis, but had negative results with IBOA. This patient had no previous history of colophonium-related dermatitis symptoms. Theoretically, he might thus have been sensitized to colophonium via Freestyle Libre use. It is possible that some of the IBOA-negative but symptomatic patients

may have become sensitized to other, so far unknown, contact allergens present in sensor adhesives. In support of this hypothesis, three Freestyle Libre users with no demonstrated contact allergies to possible adhesive ingredients had severe symptoms on their sensor sites. In the majority of these patch test-negative patients, the symptoms were nevertheless mild, and were most likely attributable to sensor-induced local irritation. The new allergen DMAA in Freestyle Libre sensors had not yet been reported when the majority of our patients were tested. Only one positive reaction in an Enlite user was seen. IBOA is used to combine the different components of Freestyle Libre, and it has been suggested that it migrates to the adhesive part from these upper components. Therefore, the adhesive part itself is not considered to be the actual source of IBOA.¹

Herman et al¹ have reported a high proportion (7/15) of patients who are allergic to sesquiterpene lactones among Freestyle Libre users. One of them was allergic to abitol as well. Sesquiterpene lactones are common allergens found in Compositae plants. Compositae plant extracts cross-react, in some cases, with colophonium.¹⁷ However, the Abbott Diabetes Care Scientific Affairs Department replied, in response to our request, that Freestyle Libre does not contain colophonium, abitol, or sesquiterpene lactones.

4.3 | The ability to use different sensors

In this study, we found no IBOA-allergic patients who would have been able to use Enlite without developing eczema. They were not allergic to colophonium, which is the known allergen in Enlite. It is possible that Enlite contains a compound related to IBOA, or that there is an unknown allergen in one or both sensors. To date, it is unknown whether Enlite contains, for example, DMAA. However, as only three of our IBOA-allergic patients tried to use Enlite, it is also possible that their skin was irritated by the adhesive of Enlite.

Previously, some of the diabetes patients using Dexcom became sensitized to ethyl cyanoacrylate.³ Ethyl cyanoacrylate is typically used in eyelash glues, superglues, and liquid wound closure materials used in surgery. New sensors and glucose-monitoring devices with different adhesive components are likely to be available in increasing numbers in the future. Therefore, at least young diabetic patients should be advised to avoid exposure to, for example, eyelash glues containing cyanoacrylates, and artificial acrylic nails known to contain easily sensitizing acrylates.

This study provides some information on what to recommend for protection of the skin. Eakin Surround was the only protector that totally prevented sensor dermatitis in some patients with severe contact allergy to IBOA. The skin protection materials may hamper the proper function of the glucose sensor, so changing to another sensor type would be the best solution. Actually, the Medicines and Healthcare Products Regulatory Agency has advised against the use of barrier materials in the United Kingdom.¹⁸ In addition, contact allergy is permanent, and avoidance of the culprit allergen is recommended. Continuous exposure to the allergen will worsen the eczema over time, and may lead to chronic eczema not resolving despite allergen avoidance. Unfortunately, it is almost impossible for a

patient with IBOA allergy to know what medical devices to avoid, as no ingredient information is available.

4.4 | Testing indications

In this study, only a small number of patients could continue using the sensor to which they were allergic. Thus, the use of patch tests helps to predict which sensor would suit them best. IBOA, ethyl cyanoacrylate, colophonium and DMAA are not known to cross-react with each other. The sensitized patients may thus try to change to another glucose sensor.

Type 1 diabetes patients also use other medical devices attached to the skin, for example, insulin pump needles. The adhesive of the Omnipod insulin pump is known to contain both IBOA and colophonium. Information on the adhesive compounds found in medical devices is presented in a recent review.¹⁹ Interestingly, some of our patients were able to use Omnipod without symptoms, despite their allergy to IBOA. We suggest that patients who have difficulties in finding a tolerable glucose sensor or insulin pump should be patch tested with at least IBOA, ethyl cyanoacrylate, colophonium, DMAA, and possible relevant allergens found later. In addition, testing with the baseline series helps to identify other causes of eczema.

In obvious cases, large-scale patch testing with acrylates should be avoided, to prevent active sensitization, as this may, in theory, reduce the possibility of patients using future diabetes devices with various adhesives. However, if initial screening tests with the above-mentioned known allergens give negative results, other acrylates can then be tested in more detail. In particular, screening with larger acrylate series can be performed when novel devices and adhesives become available and are causing allergic symptoms. The contact allergies resulting from the use of sensors should be reported to the manufacturers and local authorities, in order to obtain sensors with safer adhesives or more options for adhesives in the future. We have not received any personal responses from the authorities or manufacturers. However, Abbott has confirmed that it has revised the formulation of the adhesive of Freestyle Libre.¹⁸

Many type 1 diabetes patients are likely to wear skin-adherent devices throughout their lives. It is of great importance for the manufacturers to supply information about the possible allergens in their products and develop more tolerable adhesive materials.

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CONFLICTS OF INTEREST

This study did not receive any financial support. The authors have no conflicts of interest to report.

ORCID

Heli S. I. Hyry  <https://orcid.org/0000-0002-5388-7499>

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