

Allergic contact dermatitis caused by isobornyl acrylate in FreeStyle® Libre, a newly introduced glucose sensor

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doi:10.1111/cod.12866

Summary

Background. Glucose sensors, such as FreeStyle® Libre, are innovative medical devices developed for diabetes patients as a replacement for classic glucose meters, ensuring continuous glucose monitoring without the disadvantage of regular skin finger pricks.

Objectives. To report several cases of allergic contact dermatitis caused by FreeStyle® Libre, and to report on isobornyl acrylate as a culprit allergen.

Patients and Methods. Fifteen patients presented with allergic contact dermatitis caused by FreeStyle® Libre. All but 1 were patch tested with a baseline series, and with pieces and/or ultrasonic bath extracts of (the adhesive part of) the glucose sensor. Isobornyl acrylate was patch tested, in various concentrations and vehicles, in 13 patients. Gas chromatography–mass spectrometry (GC-MS) of the sensors was performed.

Results. All patients reacted to the adhesive part of the sensor, and 12 patients were shown to be sensitized to isobornyl acrylate. Simultaneous reactions to other allergens were rarely observed. GC-MS showed the presence of isobornyl acrylate in the sensors.

Conclusions. Cases of allergic contact dermatitis caused by FreeStyle® Libre are increasingly being observed, and isobornyl acrylate is a relevant culprit allergen. Cross-reactivity to other acrylates was infrequently observed, but other, hitherto unidentified, contact allergens may still be present in the device.

Key words: acrylates; adhesive; allergic contact dermatitis; CAS no. 5888-33-5; diabetes mellitus; FreeStyle® Libre; gas chromatography; glucose sensor; isobornyl acrylate; mass spectrometry; medical device; sesquiterpene lactone mix.

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Conflicts of interest: The authors declare no conflicts of interest pertinent to the present study.

Accepted for publication 3 June 2017

FreeStyle® Libre (Abbott Diabetes Care, Witney, Oxfordshire, UK) is a popular 'flash' continuous glucose monitoring system recently developed for diabetes patients (Fig. 1). It is largely replacing the self-monitoring of blood glycaemia by means of classic capillary blood glucose meters, the latter still necessitating repeated daily skin finger pricks. This innovative medical device, applied with an adhesive onto the skin for up to 14 days, offers a continuous and more dynamic way to measure interstitial glucose levels. However, following its introduction, several

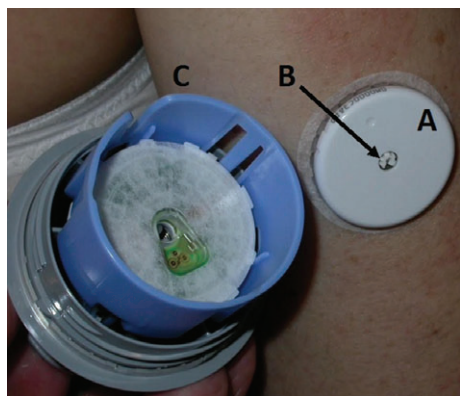


Fig. 1. The Freestyle® Libre glucose sensor device. This device consists of a sensor (A), affixed on the upper arm by an adhesive film, which analyses real-time interstitial glucose concentrations through a central catheter (B) inserted in the subcutaneous tissue. The sensor and catheter are applied, for up to 14 days, with an applicator (C). Information on the glycaemia is subsequently obtained by scanning the sensor with a reader.

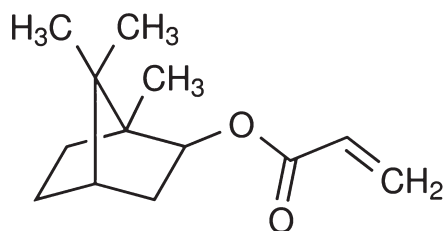


Fig. 2. Chemical structure of isobornyl acrylate.

patients, both adults and children, have presented with eczematous skin eruptions, provoked by the adhesive part of the sensor, and suggestive of allergic contact dermatitis. We here report 15 subjects suffering from severe allergic contact dermatitis caused by FreeStyle® Libre, and we highlight isobornyl acrylate (IBOA) (CAS no. 5888-33-5; Fig. 2) as a relevant and causative contact allergen in the majority of them.

Patients and Methods

Patients

The demographic data, period of onset of the dermatitis, test series and allergens tested, and patch test results for all 15 patients are shown in Table 1. All patients suffered from diabetes mellitus type I, and had used FreeStyle® Libre on the upper arm. Figure 3 shows the skin lesions in patient 1.

Patient 14 had specifically noted the occurrence of the rash just beneath the adhesive part of the device, whereas the central needle opening remained unaffected. Some patients (e.g. patients 5, 14, and 15) had tried multiple protective barrier dressings, such as Opsite® (Smith & Nephew, London, UK) and Tegaderm® (3M™, Minneapolis, MN, USA), between the affected skin and the device, without improvement, or even with aggravation of the dermatitis. Patient 14 had additionally tried using corticosteroid nebulizers and barrier sprays under the adhesive, but again without any relief. A few patients had experienced similar skin reactions to other medical devices used for diabetes; for example, patient 4 had previously also reacted to an insulin pump (Minimed®, Medtronic, Los Angeles, CA, USA), whereas patient 6 had developed vesicular dermatitis a few days following the use of FreeStyle® Navigator (Abbott) on her abdomen.

Patch tests

Patients 1–3 were evaluated at the Department of Dermatology of University Hospital Antwerp, patients 4–9 were evaluated at the Department of Dermatology of the Cliniques Universitaires Saint-Luc in Brussels, patients 10–13 were evaluated at the Department of Occupational and Environmental Dermatology, Skåne University Hospital, Malmö, and at its branch clinic in Karlshamn, and patients 14 and 15 were evaluated at the Department of Dermatology in Leuven.

Patch tests were performed with a baseline series (except in patient 15), and sometimes with additional series, such as plastics and glues, (meth)acrylates, epoxy resins, and/or isocyanates. All commercial allergens were supplied by Chemotechnique (Vellinge, Sweden) in Antwerp, Brussels, Leuven, and Malmö, and/or by Trolab® (Hermal, Reinbek, Germany) in Brussels and Leuven.

In Antwerp, Brussels, and Leuven, all patients except for patient 15 were initially patch tested with (pieces of) the adhesive part of the glucose sensor FreeStyle® Libre. In Malmö, 2 patients were patch tested with acetone extracts made from the adhesive part of the sensor, and 1 patient was tested with an acetone extract made from the whole sensor (1). When these extracts were prepared, the adhesive patches and the sensor were extracted in ~20 ml of acetone in an ultrasonic bath for 5 min. The extracts were then concentrated to a volume of 1 ml with a rotary evaporator. Moreover, on the basis of literature research regarding potential contact allergens in diabetes medical devices (2), the Antwerp department, after obtaining IBOA raw material from Kowa Europe (Düsseldorf, Germany), prepared additional in-house patch test

Table 1. Demographic data, period of onset of the dermatitis, test series and allergens tested, and patch test results for 15 patients with diabetes mellitus showing contact dermatitis caused by FreeStyle® Libre

Patient	Centre	Age		Onset of the dermatitis		Baseline series D2/D4*	Additional patch tests D2/D4*	(Pieces of)			
		(years)	Sex	following the use of FreeStyle® Libre				adhesive of FreeStyle®	D2/D4*	IBOA 0.1% D2/D4*	IBOA 0.05% D2/D4*
1	UZA	9	M		U	Negative	MA series: HPA +/+ P&G series: NT ISO series: NT ER series: NT	+/+	+++	+++	+/+
2	UZA	14	M		U	Negative	NT	+/+	+++	+++	+/+
3	UZA	7	M		U	Negative	NT	+/+	—/—	—/—	—/—
4	UCL	12	F		2 months	MP —/+ SQTL +++ TP +/+ FM I +/+ PG +/+ BIT +/?+ Nickel +++	MA series: negative P&G series: negative ISO series: NT ER series: epoxy resin(cycloaliphatic) +/+	+++	+++	+++	+++
5	UCL	40	F		1 month	Negative	MA series: negative P&G series: negative ISO series: negative ER series: negative	++	+++	+++	—/—
6	UCL	44	F		1 month	Negative	MA series: negative P&G series: negative ISO series: negative ER series: negative	?+/+	+++	+++	+++
7	UCL	52	F		U	SQTL +++ Nickel +++	MA series: negative P&G series: negative ISO series: negative ER series: negative	+++	+++	+++	+++
8	UCL	8	M		U	Negative	MA series: negative P&G series: abitol ++ (D3), hydroquinone ++ (D3) ISO series: HMDI ++ (D3) ER series: negative	+ (D3)	NT	NT	NT
9	UCL	41	F		U	FM I +/+ SQTL +++	MA series: negative P&G series: negative ISO series: negative ER series: negative	—/—	+++	+++	—/—
10	MAL	41	M		Several months	SQTL +/?+	NT	+/— [†]	NT	NT	NT
11	MAL	43	F		U	SQTL +++/+++ TDM ?+/+	MA series: negative P&G series: NT ISO series: NT ER series: NT	+/? [†]	+++	NT	+++
12	MAL	38	F		7 months	SQTL ?+/+ MP ?+/+ MI ?+/+	NT	++/+ [†]	+++	+++ [‡] (0.032%)	+/?+ [‡]
13	MAL	29	F		18 months	Negative	MA series: negative P&G series: negative ISO series: NT ER series: NT	+/—	++/+ [‡]	?+/ [‡] (0.032%)	?+/ [‡]
14	LEU	58	F		6 months	SQTL +/+ MP +/+ Nickel +/+ Palladium +/+ FM I +/+	MA series: negative	+/+	+++	+/+	?/+
15	LEU	8	M		2 weeks	NT	MA series: ethyl acrylate +/+	NT	NT	+/+	+/+

BIT, benzisothiazolinone; ER series, epoxy resin series; F, female; FM, fragrance mix; HMDI, hexamethylene diisocyanate; HPA, hydroxypropyl acrylate; IBOA, isobornyl acrylate; ISO series, isocyanate series; LEU, Dermatology, University Hospitals KU Leuven; M, male; MA series, (meth)acrylate series; MAL, Dermatology, University Hospital Malmö; MI, methylisothiazolinone; MP, *Myroxylon pereirae*; NT, not tested; P&G series, plastic & glues series; PG, propylene glycol; SQTL, sesquiterpene lactone mix; TDM, textile dye mix; TP, tixocortol pivalate; U, unknown; UCL, Dermatology, Cliniques Universitaires Saint-Luc; UZA, Dermatology, University Hospital Antwerp. —, negative; ?+, doubtful; + to +++, positive patch test reaction.

*In Malmö, the readings were performed on day (D) 3 or D4, and on D7.

[†]Adhesive patch tested as an acetone extract.

[‡]Dilutions made in acetone.



Fig. 3. Allergic contact dermatitis caused by FreeStyle® Libre in patient 1.

preparations of IBOA in three different concentrations, that is, 0.1%, 0.05% and 0.01% pet. These were patch tested in patient 1, and subsequently in all patients from the Antwerp, Brussels and Leuven departments, except for patient 8. The Malmö patients were patch tested with IBOA purchased from Sigma-Aldrich (Steinheim, Germany). Preparations with IBOA in pet. and acetone were made at the Malmö department. Patient 11 was tested with pet. preparations containing 0.1% and 0.01% wt/wt IBOA. Patients 12 and 13 were tested with a dilution series of IBOA in acetone, in the following concentrations: 0.10%, 0.032%, 0.010%, 0.0032%, 0.0010%, 0.00032%, 0.00010%, 0.000032%, 0.000010%, and 0.0000032% (wt/vol). Patch testing with IBOA has not yet been performed in patient 10, as he moved to another city.

Patch tests were applied on the upper back with IQ Ultra™ test chambers® from Chemotechnique in Brussels and Leuven, with Allergeaze® patch test chambers (SmartPractice, Calgary, Canada) in Antwerp, and with 8-mm Finn Chambers® (Smart Practice, Phoenix, AZ, USA) in Malmö, and IQ Ultra™ test chambers at its branch clinic in Karlshamn, and when patch testing was performed with acetone solutions of IBOA. For fixation, Fixomull® stretch (BSN Medical, Hamburg, Germany) was used in Antwerp and Brussels, Scanpor® tape (Norgesplaster, Vennesla, Norway) in Malmö, and Mefix® (Mölnlycke, Göteborg, Sweden) in Leuven. In

Antwerp, Brussels, and Leuven, following occlusion for 2 days, all patch test reactions were read, according to ESCD guidelines (3), on day (D) 2 and on D3 or D4, and sometimes also later. In Malmö, following occlusion for 2 days, the tests were read on D3 or D4 and on D7. In Malmö, 20 dermatitis patients were patch tested with the ultrasonic bath extract of the device as controls.

Chemical investigations

Acetone extracts made from different parts of FreeStyle® Libre sensors were analysed by means of gas chromatography–mass spectrometry (GC-MS) at the Malmö department. Initially, extracts made from the adhesive patches from three different sensors (including those tested in patients 11 and 12), and also the extract of the whole sensor tested in patient 10, were analysed after being filtered and concentrated to a volume of 0.2 ml. Another sensor was disassembled, and separate acetone extracts were made from the adhesive patch, the transparent plastic on the top of the sensor (immediately under the adhesive patch), the circuit board, and the white plastic from the back of the sensor. Furthermore, the white plastic from the back of a different sensor was divided in two fractions, and separate extracts were made from these fractions. One fraction contained areas where the white plastic material was joined to the transparent plastic material from the top, whereas the other contained material taken from areas not fixed to the top material. The different materials were cut into small pieces and placed in test tubes. Two millilitres of acetone was added to the test tube containing the circuit board, and 1 ml of acetone was added to the rest of the test tubes. The test tubes were then placed in a shaker for 1 h. After the solid materials had been removed, the extracts were filtered and analysed.

The gas chromatography system consisted of an Agilent 6890N gas chromatograph (Agilent Technologies, Santa Clara, CA, USA) equipped with an HP-MSI capillary column (Agilent Technologies) with a length of 30 m, an internal diameter of 0.25 mm, and a film thickness of 0.25 µm. The carrier gas was helium of Alphagaz 2 quality (Air Liquide, Malmö, Sweden) with a flow rate of 1.0 ml/min. The injection was splitless, and the inlet was heated to 250°C. The injection volume was 1 µl. The temperature program was as follows: isothermal at 70°C for 3 min, raised by 8°C/min to a final temperature of 300°C, and isothermal at this temperature for 10 min. Electron-ionization mass spectra were recorded with a Jeol GCmate II mass spectrometer (Jeol Datum, Tokyo, Japan) in scan mode recording ions with m/z from 50 to 600 u, with a scan duration of 0.3 seconds and an interscan

delay of 0.2 seconds. The temperature of the ion source was 250°C, and the GC-MS interface temperature was 250°C. The electron energy was 70 eV. IBOA dilutions in acetone were used as reference standards.

Results

Patient characteristics and patch test results are shown in Table 1. All patients reacted positively to (pieces of) the adhesive part of FreeStyle® Libre, or to extracts made from the whole sensor, or from the adhesive part of the sensor. All patients patch tested with IBOA ($n = 13$) reacted positively to it, except for patient 3. Sometimes, positive reactions down to 0.01% pet. were observed (Fig. 4). In Malmö, no reactivity to IBOA <0.01% was observed with the dilution series of the allergen in acetone.

Positive patch test reactions could sometimes also be observed to allergens from additionally patch tested series. For example, patient 4 had a positive reaction (+) to cycloaliphatic epoxy resin, and patient 8 had positive reactions to abitol (++) and to hydroquinone (++) , as well as to hexamethylene diisocyanate (+). Remarkably, positive patch test reactions were often, in 7 of 15 patients, also observed to sesquiterpene lactone mix present in the baseline series. However, the relevance of all of these additional positive reactions could not be established. Whenever an acrylate series was patch tested, there were no positive reactions observed to acrylates other than IBOA, except in patients 1 and 15, who also reacted to hydroxypropyl acrylate (HPA) (+) and to ethyl acrylate (EA) (+), respectively. None of the controls reacted positively to the ultrasonic bath extract of FreeStyle® Libre (0/20 versus 1/1; $p = 0.048$, Fisher's exact test, two-sided). Moreover, patch testing in 14 Belgian control patients with IBOA 0.1% pet. did not result in any positive reactions, whereas 10 of 11 diabetes patients with exposure to the glucose sensor reacted positively (0/14 versus 10/11; $p < 0.001$; Fisher's exact test, two-sided).

IBOA was found in all of the extracts analysed by GC-MS. The extracts made from the adhesive patches contained IBOA in concentrations corresponding to 2–50 $\mu\text{g}/\text{patch}$, which in turn correspond to a surface dose of 0.2–5 $\mu\text{g}/\text{cm}^2$. The IBOA concentrations in the different parts of the disassembled sensor were approximately 0.006% (wt/wt) in the adhesive patch, 0.004% in the top plastic, 0.003% in the circuit board, and 0.3% in the white plastic from the back of the sensor. The parts of the white plastic that were joined to the transparent plastic contained ~0.4% (wt/wt) IBOA, whereas the parts not fixed to the transparent plastic contained only 0.005% (wt/wt) IBOA.

Furthermore, IBOA was also found in the FreeStyle Navigator II sensor, used by patient 6, who had also

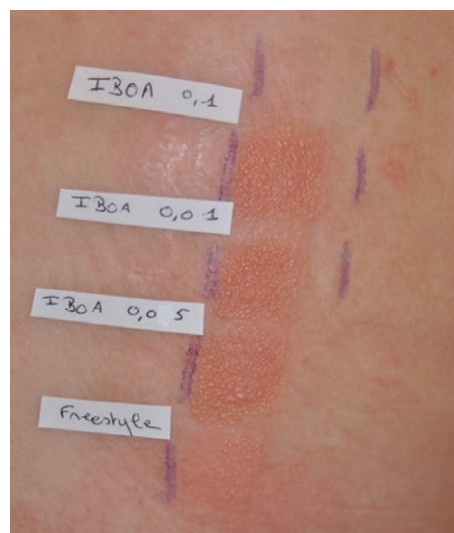


Fig. 4. Positive patch test reactions in patient 4 to isobornyl acrylate (IBOA) 0.1% (++) , 0.05% (++) , and 0.01% (++) , and to the adhesive part of FreeStyle® Libre (++) , all on day 3.

shown skin reactions to this specific device. Figure S1 shows chromatograms and mass spectra of the IBOA peak obtained from analysis of (a) 0.01% (wt/vol) IBOA in acetone and (b) an acetone extract of the adhesive patch from FreeStyle® Libre.

Discussion

Although Jadviscokova et al. (4) reported that ~18% of patients using continuous glucose monitoring devices may suffer from hypersensitivity reactions, such cases have only rarely been reported. Schwensen et al. (5) described sensitization to ethyl cyanoacrylate from a Dexcom G4® Platinum glucose sensor (Dexcom, San Diego, CA, USA), and we are the first to report cases of allergic contact dermatitis related to the use of FreeStyle® Libre.

IBOA, or acrylic acid isobornyl ester, is an acrylate monomer used in plasticizers, coatings, and ultraviolet (UV)-cured inks (6). Recently, it has also been suggested that IBOA might be a hidden allergen in commercial cosmetic samples of alkyl glucosides (6). The first two cases of allergic contact dermatitis caused by IBOA were reported by Busschots et al. (2) in 1995, and concerned 2 diabetic patients suffering from allergic contact dermatitis caused by insulin pumps. IBOA was one of the components contained in the UV-cured glue used to fix the needle into the plastic stand.

A third, occupational, case of IBOA contact allergy was described in 2013 by Christoffers et al. (7), and concerned a labourer with hand dermatitis working in a

glass fibre-producing factory. Kanerva et al. (8) reported another occupational case of a worker glueing glass, for example mirrors, suffering from hand dermatitis and respiratory symptoms while working with an adhesive containing 61% IBOA. However, patch tests performed with three dilutions of IBOA (0.1%, 0.032%, and 0.01% pet.) gave negative results.

When, in Malmö, the first patient was seen with dermatitis corresponding to the contact area of FreeStyle® Libre, a patch test was performed with an ultrasonic bath extract of the whole sensor. A positive reaction consistent with an allergic morphology was noted. To substantially diminish the possibility of a false-positive reaction to the extract, 20 dermatitis controls were tested, and all had negative test results. The diagnosis was thus allergic contact dermatitis caused by the sensor. Which substance, then, was the culprit? An acrylate seemed to be the likely cause. Up to this point, only ethyl cyanoacrylate had been tested, with a negative result. GC-MS screening of the extract was performed to look for acrylates, as well as for other sensitizers, but this did not result in a positive match. However, following the clinical observation in Antwerp that IBOA was potentially a likely culprit allergen in patient 1, the chemical analysis was more precisely focused on this acrylate, which was subsequently detected in the extract of the device. To facilitate the investigation of the culprit sensitizer, the Swedish Abbott branch was contacted for information on compounds used in the production of the sensor, but this approach proved very unfruitful. Other Abbott affiliates in Europe and the United States also did not contribute to a solution.

Although all patients who were tested with the adhesive part of the sensor 'as is', or as an acetone extract, showed positive test reactions, the chemical analyses indicated that the adhesive patch itself may not have been the actual source of IBOA. Rather, it is suspected that IBOA was released from a glue used to join the top and bottom part of the sensor, and subsequently migrated into other parts of the sensor. Interestingly, ethyl cyanoacrylate, which was reported to be the sensitizer in another glucose sensor, was not contained in the adhesive of this particular device either, but also originated from another part of the sensor (5).

In the present study, patch tests with IBOA at a maximum concentration of 0.1% were performed. Higher test concentrations might potentially lead to contact irritant reactions, or even active sensitization, whereas the use of lower dilutions might result in sensitization being missed (9). Patch testing in 14 Belgian control patients with this preparation did not result in any positive reactions, whereas 10 of 11 diabetes patients with exposure to the glucose sensor reacted positively. In view of our

test results, and as also suggested by others (7), 0.1% does indeed seem to be a well-justified patch test concentration for IBOA. Although some of our patients reacted down to IBOA 0.01%, the use of only the latter concentration carries the risk of a false-negative patch test reaction (e.g. patients 5 and 9). It should be noted that, although patient 3 reacted to the FreeStyle® Libre adhesive, he did not react to IBOA, indicating that other contact allergens might still be involved.

Despite IBOA being an acrylate, many sensitized patients reported here had negative patch test results with other acrylates, except for patients 1 and 15, who also showed positive reactions to HPA and to EA, respectively, which might be regarded as cross-reactions. However, on the basis of the present study, dealing with only a limited number of patients in whom not all commercially available acrylates were systematically patch tested, no reliable statements can be made regarding the cross-reactivity profile of IBOA. On the basis of experience from other centres (7, 10) that previously patch tested IBOA routinely in their (meth)acrylate-sensitized patients, it does appear unlikely that IBOA cross-reacts easily with other acrylates. Aalto-Korte et al. even reported in 2008 that they had ceased testing IBOA in their acrylate series (10). This might open perspectives regarding potential acrylate alternatives to IBOA in the FreeStyle® Libre sensor, and perhaps in similar medical devices.

Although Compositae allergens have previously been suspected to be 'hidden' allergens in medical devices, for example self-adhesive electrocardiography electrodes (11), hitherto no clear relevance has been found for the occurrence of concomitant, and sometimes strong, patch test reactions to sesquiterpene lactone mix in 7 of our 15 patients.

Conclusion

Several cases of severe allergic contact dermatitis caused by FreeStyle® Libre, a recently introduced glucose sensor, can be attributed to IBOA, a rarely reported but potent acrylate allergen. A diagnostic patch test concentration of IBOA 0.1% pet. seems to be justified, and little to no cross-reactivity with other acrylates is to be expected. However, other and hitherto unknown contact allergens might play a role as well.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Total ion chromatogram of (a) 0.01% isobornyl acrylate (IBOA) in acetone and (b) an acetone extract of the adhesive patch from a Freestyle Libre sensor. Next to each chromatogram, the mass spectrum of the IBOA peak at 14.5 min is shown.

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