ORIGINAL ARTICLE



Contact allergy to the Dexcom G6 glucose monitoring system—Role of 2,2'-methylenebis(6-tert-butyl-4-methylphenol) monoacrylate in the new adhesive

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Abstract

Background: Skin reactions to the glucose monitoring systems Dexcom G5 and G6 have been rare. In 2019, the components of the adhesive were exchanged for better skin fixation. Since then, more and more patients experienced severe skin reactions. A few months ago, 2,2'-methylenebis(6-tert-butyl-4-methylphenol) monoacrylate (MBPA) was identified as a new component in the adhesive of the G6 model. Furthermore, it was suspected that isobornyl acrylate (IBOA) was also a component of the exchanged adhesive.

Objectives: Our objective was to investigate if MBPA plays a major role in the increasing skin problems of patients without a history of IBOA-sensitization. Furthermore, our aim was to examine whether IBOA is contained in the newer model adhesive and may also contribute to allergic contact dermatitis (ACD).

Patients and Methods: Five patients with a newly occurred ACD caused by the glucose monitoring system Dexcom G6 were investigated. Patch testing including MBPA in three different concentrations, as well as IBOA, were performed. Gas chromatography-mass spectrometry of the newer system Dexcom G6 was carried out.

Results: All patients were shown to be sensitized to MBPA, while MBPA 0,5% showed the strongest reaction. On the other hand, IBOA was tested negative.

Conclusion: In our study group, MBPA was observed to be the triggering allergen of the recently changed adhesive.

KEYWORDS

2,2'-methylenebis(6-tert-butyl-4-methylphenol) monoacrylate, acrylate, allergic contact dermatitis, continuous glucose monitoring systems, Dexcom, Freestyle Libre, isobornyl acrylate, patch test

Abbreviations: ACD, allergic contact dermatitis; CGM, continuous glucose monitoring system; FGM, flash glucose monitoring systems; GC/MS, gas chromatography-mass spectrometry; IBOA, isobornyl acrylate; MBPA, 2,2'-methylenebis(6-tert-butyl-4-methylphenol) monoacrylate; MBP, 2,2'-methylenebis(6-tert-butyl-4-methylphenol).

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Recently, new technologies in glucose monitoring have made exciting developments. Conventional blood glucose measurement often leads to painful hardening of the fingertips. Furthermore, their handling especially at night and during travels is complicated and they reflect only a snapshot of the blood glucose level at that moment in time. Therefore, continuous glucose monitoring systems (GMS) and flash glucose monitoring systems (FGM) have revolutionized the life of many diabetic patients. When launching in Germany at the end of 2015, long waiting lists developed quickly.

With the spread of these new technologies, but especially after the introduction of the FGM product Freestyle Libre in 2015, a number of patients with increasing skin reactions including irritative and contact allergic skin lesions were described.^{1,2} Allergic contact dermatitis (ACD) is less frequent, but of great importance, because if ACD occurs under the sensor set, the product usually has to be removed immediately due to the increasing inflammatory skin changes. Typical symptoms include redness and blistering, usually with yellowish exudate.



The long exposure time and individual factors such as age, skin barrier disorders, moisture of the skin and sweating are predisposing factors for the development of ACD. Additionally, the amount and allergenic potency of one or more previously unknown but also known allergens contained in the sensor sets are relevant.

In 2017, a report by Belgian and Swedish dermatologists and chemists showed that several of their patients with skin reactions after usage of Freestyle Libre were sensitized to a specific acrylate (namely isobornyl acrylate; IBOA).³ Subsequently many studies followed about contact allergies due to IBOA, especially in the Freestyle Libre.^{4,5} IBOA was for instance used in the glue of the bottom side of the housing of the Freestyle Libre. IBOA could also be discovered in the Enlite sensor system and in the patchpump Omnipod.⁶⁻⁹ Many patients switched to IBOAfree sensor system Dexcom G5 and Dexcom G6.¹⁰ Finally, in 2020, IBOA was eliminated from the newer model of the Freestyle Libre 2.¹¹

In the beginning of 2020, more and more patients complained about sudden experienced skin problems with the Dexcom G6 sensor. Before, no severe skin reaction such as allergic dermatitis was reported regarding the GMS Dexcom G5 and Dexcom G6 (Figure 1). The described eczematous reaction did not only occur under the plastic sleigh of the sensor but also involved the whole area under the skin adhesive. The pattern of redness clearly demonstrated that the adhesive was responsible for the skin reaction (Figure 2). Furthermore, patients claimed that the skin lesions increased over time using the sensor which indicates an ACD. In consultation with the company, they confirmed that a component, namely an acrylate, had been exchanged to achieve better fixation to the skin, but did not reveal more information. However, they insisted that the new adhesive of the G6 was still IBOA-free.

Finally, Svedman et al.¹² identified a new allergen, 2,2'methylenebis(6-tert-butyl-4-methylphenol) monoacrylate (MBPA), in the adhesive of the newer Dexcom G6. All three patients had a mild positive reaction on patch test to MBPA. Furthermore, all patients reacted to IBOA in the skin test. Therefore they postulate that IBOA may be the



FIGURE 2 Allergic contact dermatitis by Dexcom G6

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TABLE 1	Demographic data (patient, age, sex), start of using Dexcom, onset of ACD, patch test series(standard, glue series) and specific
allergens tes	ted (MBPA 0.1%, 0.3%, 0,5%; IBOA 0,1%) for five patients with diabetes mellitus type 1 showing ACD to Dexcom G6

					MBPA 0.1%		MBPA 0.3%			MBPA 0.5%		IBOA 0.1%				
Patient	Age	Sex	Start Dexcom	ACD onset	D2	D3	D7	D2	D3	D7	D2	D3	D7	D2	D3	D7
1	51	f	4/2016	4/2020	Ø	Ø	Ø	Ø	?+	Ø	Ø	+	Ø	Ø	Ø	Ø
2	59	m	10/2016	3/2020	Ø	Ø	Ø	Ø	+	?+	Ø	++	+	Ø	Ø	Ø
3	34	m	2/2016	2/2020	Ø	Ø	Ø	Ø	?+	Ø	Ø	+	Ø	Ø	Ø	Ø
4	30	f	1/2019	2/2020	Ø	Ø	Ø	Ø	?+	Ø	Ø	+	?+	Ø	Ø	Ø
5	62	m	9/2019	3/2020	Ø	Ø	Ø	Ø	+	Ø	Ø	++	+	Ø	Ø	Ø

Abbreviations: ACD, allergic contact dermatitis; f, female; IBOA, isobornyl acrylate; m, male; MBPA, 2,2'-methylenebis(6-tert-butyl-4-methylphenol) monoacrylate; neg, negative.

triggering allergen. Concordantly, Svedman et al.¹³ found the allergen IBOA in the glucose sensor system Dexcom G6. In addition, all three patients had a history of Freestyle Libre allergy. The authors, therefore, suspected both IBOA and MBPA as culprit allergens.

After the exchange of the adhesive in Dexcom G6, skin reactions appeared in an increasing number of patients. Many patients rely on the sensor as it interacts with the pump (for example, the Insulet insulin pumps) and want to keep it. It is therefore very important to identify possible new contact allergens. The more knowledge we have about potential allergens, the better we can help concerned patients. Thus, we investigated if our patients with contact allergy to the new G6 adhesive were sensibilized to MBPA. Furthermore, in contrary to the company's claim, we wanted to examine whether IBOA also played a role in these newly appeared skin reactions.

2 | MATERIALS AND METHODS

2.1 | Patients and data

The demographic data, period of onset of dermatitis, test series and allergens tested, and patch test results for all five patients are shown in Table 1. All patients suffered from diabetes mellitus type I and used Dexcom G6 on the upper arm. All of them developed an ACD towards Dexcom G6 containing the new formulation of adhesive and did not report problems with their previous Dexcom (Figure 2). All patients had no history of Freestyle Libre allergy, especially towards IBOA or other relevant allergens. They previously used the Freestyle Libre 1 without suffering skin symptoms and changed to Dexcom G6 because of better alarm function and compatibility with the insulin pumps.

2.2 | Patch test

Patch tests were performed using allergens from the standard series and from the plastics and glues series (SmartPractice), following recommendations of the German Contact Allergy Group (Deutsche Kontaktallergie-Gruppe; http://dkg.ivdk.org/). We tested for the recently detected substance MBPA (TCI) in pet at a concentration of 0.1%, 0.3% and 0,5% according to the investigations of Svedman et al.¹² Furthermore, we performed a patch test with the related substance 2,2'-methylenebis(6-tert-butyl-4-methylphenol) (MBP) (Merck), that is, without the acrylate-function, in the concentrations 0.1%, 0.5% and 1% pet., as we found a suspicious peak in the eluates of the new Dexcom G6 adhesive by GC/MS concordant to Svedman et al.¹² The first indication of MBP was provided by the MS database (NIST/ EPA library) and subsequently confirmed by comparing corresponding reference compound (see Section 2.3.2). Furthermore, we tested IBOA 0.1% pet. according to previous studies.^{3,7} Following occlusion for 2 days, all patch test reactions were read after 48 and 72 h, according to guidelines of the German Contact Allergy Group (Deutsche Kontaktallergie-Gruppe; http://dkg.ivdk.org/). In all cases, a later reading was carried out on Day 7, because of possible delayed reactions associated to acrylates.

Due to the clear clinical presentation, we did not test the patients with the adhesive patch from the sensor. The sleigh only covers a small part of the adhesive patch and the skin reactions corresponded to the whole area of the adhesive patch, so there is no comparison to the housings of the Freestyle Libre.

2.3 | Laboratory methods

2.3.1 | Sample preparation

The adhesive patches of three Dexcom G6 sensor sleighs (Dexcom) (n = 3) (series from 2020; LOT numbers, see Table 2) were removed. Each Dexcom sensor sleigh was transferred into individual weighing bottles with NS stopper (45 ml, 60×30 mm, neoLab). Six millilitres of methanol (MeOH; GC Ultra Grade, RATISOLV \ge 99.9%, Roth) was added in order to immerse the bottom side (dermal contact side) in a solvent level of about 2 mm. Internal standard caffeine (CF) solution (0.01 mg/ml) (HPLC \ge 99.0%, Sigma-Aldrich) was added. After 3-day incubation in the dark at room temperature, the samples were analysed by gas chromatography/mass spectrometry (GC/MS).

Corresponding removed adhesive patches (n = 3) in one piece were incubated in brown glass vials (8 ml, Macherey-Nagel) with 4 ml methanol at room temperature and analysed after 3 days by

TABLE 2Device, LOT numbers andanalytical results (Elution: sleigh in 6 mlMeOH; adhesive patch in 4 ml MeOH)



Medical device	LOT number		MBPA (µg)	MBP (µg)	
Series from 2020					
Dexcom G6	5270703	Sleigh	143.52	8.28	
		Adhesive patch	1164.44	214.80	
Dexcom G6	5272521	Sleigh	114.12	6.06	
		Adhesive patch	1410.84	324.40	
Dexcom G6	5273600	Sleigh	129.06	6.84	
		Adhesive patch	1341.36	325.00	
Series 2018/2019					
Dexcom G6	5249363	Housing	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>	
		Adhesive patch	<loq< td=""><td colspan="2"><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>	
Dexcom G6	5249363	Housing	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>	
		Adhesive patch	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>	
Dexcom G6	5249363	Housing	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>	
		Adhesive patch	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>	

Note: MBPA LOQ = 0.40 μ g/ml; MBA LOQ = 0.46 μ g/ml.

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Abbreviations: MBPA, 2,2'-methylenebis(6-tert-butyl-4-methylphenol) monoacrylate; MBP, 2,2'-methylenebis(6-tert-butyl-4-methylphenol).

GC/MS. Internal standard caffeine (CF) solution (0,01 mg/ml) was added.

For comparison, the GC/MS raw data of Dexcom G6 series 2019 eluates (adhesive patches and sensor sleighs; LOT numbers, see Table 2) (n = 3), performed in our previous study^{9,10} were analysed regarding MBP and MBPA content.

2.3.2 | Analytic procedure

The analysis of the eluates was performed according to our former study.^{9,10}

Identification of MBP and MBPA was achieved by comparing the mass spectra and retention time to the reference standards MBP (GC \geq 96.0%, Merck) and MBPA (GC \geq 98.0%, TCI). For the reference standards IBOA, MBP and MBPA, calibrations were performed (limit of quantification (LOQ) IBOA (MeOH): 0.10 µg/ml,⁹⁻¹¹ MBP (MeOH): 0.46 µg/ml, LOQ MBPA (MeOH): 0.40 µg/ml). The quantity of identified IBOA or MBP or MBPA was calculated by correlating its characteristic mass peak area to the corresponding achieved calibration curve (internal standard caffeine).

3 | RESULTS

3.1 | Patient data and patch test

Patient characteristics and patch tests results are shown in Table 1.

All patients reacted to Dexcom G6 with ACD. None of the patients using the older model of Dexcom G6 sensors (before the end of 2019) reacted with ACD. Therefore, the patients initially tolerated the Dexcom G6 well and only developed skin symptoms after the adhesive patch was changed in early 2020. Patients patch tested with

MBPA 0.1% to 0.5% pet (n = 5) showed a positive reaction with the strongest reaction at 0.5% but no reaction at 0.1%. No patient reacted to IBOA 0.1%. Additionally, no reaction to MBP appeared.

3.2 | GC/MS results

Elution results of MBPA and MBP are shown in Table 2. As already shown in a previous study from 2018/2019 about the Dexcom G6 sensor set,^{9,10} the IBOA content in methanol eluates of the new adhesive of the G6 was below the limit of quantification (<LOQ) in the GC/MS analysis. Yet, in the same Dexcom G6 adhesive, MBPA and MBP could be identified (Figure 3).

4 | DISCUSSION

Until the beginning of 2020, skin reactions to the Dexcom sensor have been rare. There were almost no records on skin reactions on social media forums or in diabetic practices. In 2016, the case of a child was published developing ACD towards its Dexcom G4 set.¹⁴ In the patch test, a positive reaction to ethyl cyanoacrylate was found. An ethyl cyanoacrylate-containing glue was used to fix the sensor housing to the adhesive patch. The company reacted quickly by attaching the sensor to the dermal patch using a thermic heat staking technique and thus avoiding the triggering intermediate adhesive layer.¹⁵ After this changing process, there were only a few individual cases described in an earlier study¹³ on skin reactions to the Dexcom, especially not to next generation models G5 and G6. In the last years, severe skin reactions were provoked by glucose monitoring devices and insulin pumps, particularly caused by the Freestyle Libre. The culprit allergen IBOA interestingly was not contained in the original adhesive but was used to glue the plastic case together. Presumably,



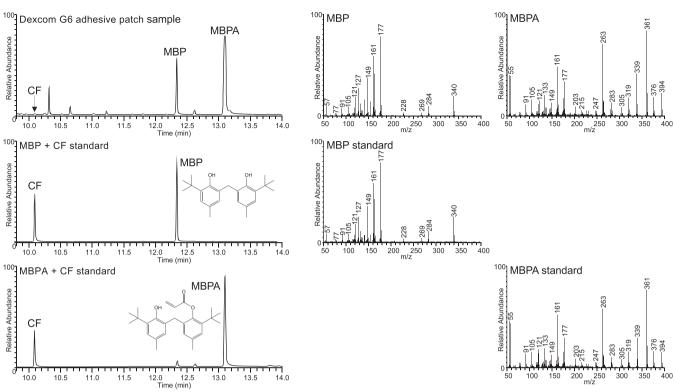


FIGURE 3 Left: total ion chromatogram (TIC) of Dexcom G6 adhesive patch sample; MBP (retention time [RT] 12.33 min) + CF (RT 10.09 min) standard; MBPA (RT 13.10 min) + CF standard. Other signals in Dexcom G6 adhesive patch sample represent background impurities. Right: corresponding mass spectra

IBOA was able to dissolve and diffuse through the adhesive where it came in contact with the skin.⁹ Skin reactions included red papules up to yellowish pustules and weeping. IBOA moved into focus for a longer period of time, as it was also contained in further diabetic devices such as the Enlite sensor and the patch pump Omnipod.^{6–9}

In contrary to the findings of Svedman et al.¹² according to our studies from 2018 and 2019, IBOA concentrations in the adhesive patches of the Dexcom G5 and G6 sensor including the plastic sleigh and transmitter^{9,10} were below limit of quantification. Therefore, patients with IBOA allergy were able to use IBOA-free devices (e.g., Dexcom). In the meantime, the situation has changed again. As mentioned above, IBOA was omitted in newer models of the Free-style Libre 2, presumably since the middle of 2020.¹¹ Some of our patients were therefore able to wear Freestyle Libre again. Since then, no patients with Freestyle Libre allergy were seen in our clinic. Unfortunately, since the beginning of 2020, more and more patients have been registered with skin problems to the modified adhesive patch of the Dexcom G6.

Svedman et al.¹² reported a new acrylate called MBPA, which they found in the new Dexcom G6 adhesive patch. In their study, all three tested patients had a positive, but mild, reaction to MBPA. Thus, we investigated this substance in five patients with newly occurred skin reactions after wearing Dexcom G6. All patients had typical symptoms and clinical presentation of ACD. Before the end of 2019, tested patients did not suffer skin reactions towards Dexcom G6. In the beginning of 2020, after the adhesive patch was modified by the manufacturer, the same patients developed ACD for the first time. Additionally, none of the tested patients had a history of allergic reaction on Freestyle Libre. In the present study, all patients showed a positive reaction to MBPA, confirming results of Svedman et al.¹² Furthermore, we were able to largely affirm their GC/MS findings of approximately 1-mg MBPA in the adhesive patch and 0.12 mg in the sleigh of the Dexcom G6.

The chromatogram of the MBPA reference standard (Figure 3) shows a small signal at retention time 12.33 min, which was identified as MBP. Apparently, MBPA is only discriminated as MBP to a very small extent in the GC injector due to its thermolability. MBP was also found in the Dexcom G6 adhesive patch sample (Figure 3). It can be assumed that this MBP signal is not only a discrimination product of MBPA. Hence, it is not clear whether the detected MBP is also a released component of the sensor housing or the adhesive patches of the Dexcom G6. Therefore, the source of the MBP is unclear.

Furthermore, there are still discussions about possible small IBOA contents in the Dexcom G6. However, our IBOA findings differ from Svedman et al.¹² In their study, all three investigated patients did not only have a positive MBPA test, but also a positive IBOA test.¹² This result led the authors to assume that IBOA may also play a relevant role in the new adhesive patch of the Dexcom G6. Yet, all their tested patients had a history of a Freestyle Libre allergy. Therefore, it seems more likely that the positive reaction to IBOA is due to their previous usage as well as allergy of Freestyle Libre. The five patients in our present study had no known Freestyle Libre allergy and showed no

sensibilization to IBOA in the patch test. In a further study Mowitz et al.¹⁶ also reported four cases sensitized to MBPA without a simultaneous allergy to IBOA.

Also, the IBOA content was again below limit of quantification in our GC/MS analysis which argues against a major role for IBOA in the new adhesive patch of the Dexcom G6. Preliminary tests (data not shown) indicated that other solvents (e.g., ethanol, acetone) and shorter/longer extraction time had no significant impact on IBOA concentration. Even traces of IBOA could not be detected in the sensor housing or in the adhesive patches of the Dexcom G6 series from 2018/2019^{9,10} and 2020. In contrast to Svedman et al.,¹² we analysed the entire extracted samples, whereas they sectioned their samples. Therefore, the detected traces of IBOA could be released upon sample processing or due to the greater surface area after fragmentation. Indeed, the manufacturer and the supplier of the new adhesive patch both insisted in personal communications and medical conferences that IBOA still was not a component of the new model Dexcom G6 and its adhesive patch. Of note, in previous cases, it has been shown that companies do not know the exact composition of their products. This is supported by the finding that all of our patients had a positive reaction to MBPA but did not react to IBOA. However, a limitation may be the fact that IBOA concentrations 0.3% and 0.5% pet. were not patch tested to avoid irritation and/or active sensitization.³ Nevertheless, in some centres, patch testing with IBOA 0.3% pet. has meanwhile been recommended in order not to miss weak IBOA sensitization,¹⁷ therefore IBOA allergy cannot be completely excluded. But maybe the low concentrations of IBOA in the adhesive patches of Dexcom G6 reported by Svedman et at.¹² may not be clinically relevant to each patient. More studies are necessary to investigate the relevance of IBOA in Dexcome G6.

When evaluating the patch test, we found a stronger response to MBPA with increasing test concentration from 0.1% to 0.5%. A late reading after 1 week was also performed, but a crescendo reaction was only observed from Day 2 to Day 3.

MBPA is a mono acrylate of MBP and appears to be a relevant contact allergen, which plays a dominant role in the development of allergic contact eczema in relation to Dexcom G6. Acrylates are generally known to be potent contact allergens. The acrylate component in MBPA is probably necessary to trigger contact allergies. Furthermore, MBPA is predicted as likely to meet the criteria of category 1A or 1B carcinogenicity, mutagenicity or reproductive toxicity.¹⁸

MBP is an antioxidant derived from bisphenol basic structure and is commonly used to increase the oxidation stability in plastic and rubber industries.¹⁹ It stabilizes elastomers, paints, rubber and polymers as an anti-ageing agent. Contact allergies have not been reported so far. In the present study, MBP was detected in the 2020 generation of Dexcom G6 adhesive patches, but not in the adhesive patches of former generations. Since we could not detect any contact allergy to MBP in the patch test, it does not seem to play a dominant role in the reported contact eczema. However, it should be noted that medical devices remain on the skin of patients with diabetes for several days till 2 weeks, which means that the contact is much more intense than usual. The probability of developing contact allergy is therefore increased. Further observations are necessary.

In conclusion, MBPA as a component of the adhesive patch in Dexcom G6 should be avoided to prevent further contact allergies and ACD considering the importance of glucose monitoring devices. On top of that, possible small amounts of IBOA still need to be monitored in the Dexcom G6.

In summary, emerging contact eczema associated with diabetic devices should still be closely monitored to diagnose possible new triggering allergens.

AUTHOR CONTRIBUTIONS

Eva Oppel: Conceptualization (lead); data curation (lead); investigation (lead); methodology (lead); project administration (lead); supervision (lead); writing – original draft (lead); writing – review and editing (lead). **Christof Högg:** Formal analysis (lead); investigation (lead); methodology (lead); writing – review and editing (supporting). **Anna Oschmann:** Project administration (supporting); writing – review and editing (supporting). **Burkhard Summer:** Formal analysis (supporting); methodology (supporting). **Stefanie Kamann:** Conceptualization (lead); investigation (lead); project administration (lead); supervision (lead); viting – original draft (supporting); writing – review and editing (supporting).

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data are openly available in a public repository that issues datasets with DOIs.

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