

ORIGINAL ARTICLE

Contact dermatitis in children caused by diabetes devices

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Abstract

Background: Insulin pumps and glucose monitoring devices improve diabetes mellitus control and enhance patients' quality of life. However, a growing number of adverse cutaneous reactions related to the use of these devices have been reported.

Objective: To investigate the culprits of localized contact dermatitis in paediatric patients with diabetes caused by insulin pumps and glucose monitoring devices.

Methods: Retrospective analysis of 15 paediatric patients patch tested as part of a clinical investigation for skin reactions associated with insulin pumps and glucose monitoring devices.

Results: Seven patients had positive patch test reactions to isobornyl acrylate (IBOA) and five had positive reactions to benzoyl peroxide (BP). Positive patch test reactions to materials from the glucose sensor and/or insulin pump were seen in 10 of the 15 patients. Three had positive reactions to adhesive remover wipe from Smith and Nephew Remove and four had reactions to EMLA plaster.

Conclusion: A high share of patients showed positive reactions to IBOA and/or their medical devices (insulin pumps or glucose devices). A third of patients showed positive reactions to BP. The presence of additional unidentified allergens cannot be excluded, highlighting the importance of access to a full description of the chemical composition of the devices.

KEYWORDS

allergic contact dermatitis, benzoyl peroxide, children, diabetes mellitus, gas chromatography-mass spectrometry, glucose sensors, insulin infusion sets, irritant contact dermatitis, isobornyl acrylate, sesquiterpene lactone mix

1 | INTRODUCTION

Since 2005, when the first insulin pump was introduced into the American market,¹ several continuous subcutaneous insulin infusion (CSII) sets and glucose sensors (GS) have become available to patients with diabetes, improving disease control and enhancing their quality of life (QoL).² There are two main categories of GS, continuous glucose monitors (CGM) and flash glucose monitors (FGM).³⁻⁵ CGM provides continuous glucose measurements and triggers an alarm when defined limit values are exceeded,⁵ however, there is a delay in the measurements when compared to blood glucose and they require daily calibration against finger capillary

glucose measurement.^{3,4} Conversely, FGM only provides glucose measurement, when the user scans the sensor, and it does not require calibration.^{3,4}

Nevertheless, a growing number of adverse cutaneous reactions related to their usage has been reported, with apparently a higher incidence in children according to some studies.⁶⁻⁸ A Danish survey of 144 paediatric patients demonstrated that up to 90% of patients using CSII sets have experienced a skin problem.⁶ Lombardo et al. have found a prevalence of 8.4% skin reactions suggestive of allergic contact dermatitis (ACD) among children and adolescents using diabetes devices.⁸ A recent Danish report demonstrated ACD in 76.3% of patients referred for patch testing related to the use of GS and CSII.⁹

Irritant contact dermatitis (ICD) and ACD are common findings among patients with diabetes who use GS and CSII,^{8,10–15} usually presenting as annular erythematous lesions at the sites where the device has been applied.^{7,10} Compared to ACD, ICD usually has an earlier presentation of symptoms. Nonetheless, the two types of reactions can be clinically indistinguishable,⁷ especially if the time between the onset of symptoms and the start of using the devices is unknown. Thus, patients undergo patch testing to identify the culprit of any ACD. However, this task is complicated by the fact that manufacturers do not need to disclose the chemical composition of their product.^{7,11}

2 | PATIENTS AND METHODS

Fifteen patients under the age of 18 years with diabetes mellitus (DM) type I were referred to the Department of Dermatology and Venereology, Aarhus University Hospital, Denmark, between 1 January 2018 and 30 June 2020, for investigation of cutaneous reactions related to the use of GS and CSII. Some patients had used more than one GS and/or CSII, having had reactions both to the previous and current devices (Table 1).

All patients were patch tested with the European baseline series (TRUE TEST; SmartPractice), except patients under 12 years of age, for whom a smaller paediatric baseline series¹⁶ (Chemotechnique Diagnostics) was used. The baseline series was supplemented by a 'device screening series' (Table 2), including acrylates [including isobornyl acrylate (IBOA) 0.3% (in four patients), 0.1% and 0.01% obtained from the Malmö Department of Occupational and Environmental Dermatology, Sweden, or the Department of Dermatology, Aarhus University Hospital, through Sigma-Aldrich], other glue components, topical corticosteroids, analgesics, disinfectants, and other selected allergens (e.g., topical antibiotics), if not already present in the baseline series, following exposure analysis. The information provided by the manufacturer, such as chemical composition, and different parts of the devices concerning GS and CSII ingredients was insufficient. We obtained information regarding ingredients in topical treatments, wipes and emollients, and the patients were patch tested with identified relevant allergens as well. The patch tests were applied for 48 h to the upper back using 8-mm Finn Chambers (SmartPractice) on Scanpor tape Norgesplaster (AlfaCare Danmark APS). Readings were made on Days (D) 3 and 7, according to the guidelines from the European Society of Contact Dermatitis.¹⁷ As some allergens such as acrylates often give late-appearing reactions, D7 readings were mandatory.¹⁸

As we did not retrieve any additional useful information after contact with the manufacturer to guide our clinical work-up, a FreeStyle Libre sensor 1 and an Omnipod pump belonging to patient number six were extracted and analysed by gas chromatography-mass spectrometry (GC-MS) for the presence of IBOA at the Department of Occupational and Environmental Dermatology, Skåne University Hospital, Malmö, Sweden.¹⁹

Clinical procedures were conducted in accordance with the current Helsinki Declaration.

3 | RESULTS

A total of 15 patients, 8 boys and 7 girls, with a mean age of 9.3 years (5–17 years) were investigated. All of them presented similar cutaneous reactions with circular erythematous and scaling dermatitis in areas where their GS or insulin pump had been applied (Figure 1). Most of the patients described accompanying itching and oozing in addition to post-inflammatory hyperpigmentation. Bleeding, secondary infection, scarring, and pain were also observed. All patients received treatment with topical corticosteroids and moisturizers. In cases of secondary infection, a combination of topical corticosteroids and antibiotics was prescribed.

Seven patients had used the FreeStyle Libre sensor from Abbott, five the Enlite sensor from Medtronic, and the remaining three had used the G6 sensor from Dexcom. Four of the patients had previously used other GS; three had used Freestyle Libre and one Enlite (Table 1). Omnipod CSII (Insulet Corporation) was used by five patients, three patients did not use a CSII, two used Insuflon (IntraPump Infusion Systems), two used the Minimed 604G CSII (Medtronic), two used the Medtronic MiniMed Quick-set, and one used the Tandem t:slim X2 (Rubinmedical) (Table 1). Of the 15 patients, 2 had changed CSII devices; one from Insuflon to Omnipod and another from Animas Vibe by the Animas Corporation to Tandem t:slim X2 (Table 1). Only 2 of the 15 patients had a personal history of atopic dermatitis. Of the 15 patients, 5 had positive patch test reactions to IBOA 0.1%. One also had a positive to IBOA 0.01% and further two had doubtful positive reactions.

Three of seven patients using the FreeStyle Libre had a positive reaction to IBOA 0.1%. Two of three patients with reactions to Enlite GS had positive reactions to IBOA 0.1% and one had a doubtful reaction. Two using Dexcom G6 had a doubtful reaction to IBOA (Table 1).

Patients with negative or doubtful reactions to IBOA 0.1% were offered supplementary patch tests with IBOA 0.3%, and four agreed to participate (Patients 1, 5, 14, and 15). Patient 5 had + reaction on D3 and ++ reaction on D7, patient 14 had ?+ reaction on D3 and + reaction to IBOA 0.3% on D7, whereas patient 15 had a follicular reaction on both D3 and D7. Patient 1 remained negative at 0.3% IBOA.

Some of the patients had additional positive reactions to allergens in the European baseline series. Notably, three had positive reactions to the sesquiterpene lactone (SL) mix, all with simultaneous positive reactions to IBOA. Five patients had reactions to benzoyl peroxide (BP) 1% from the device series (Table 1). Of the 15 patients, 10 showed positive reactions to material from their sensor and/or insulin pump tested as is. Interestingly, three had positive reactions to Adhesive Remover Wipe from Smith and Nephew and four had reactions to EMLA Plaster (Aspen Nordic, AstraZeneca) (Table 1).

The GC-MS analyses demonstrated the presence of IBOA in both the FreeStyle Libre sensor and the Omnipod pump from Patient 6. Although these analyses were focused on IBOA, there was no obvious presence of BP in the analysed extracts.

TABLE 1 Demographics and patch test results of the European Baseline Series (EBS), supplementary allergens, glucose sensor (GS), continuous subcutaneous insulin infusion (CSII) sets, patients' own products and device screening series

Patient no.	Age	Gender	AD	Current/previous GS	Current/previous CSII	Patch test results D7							Supplementary allergens	Own products
						GS plastic	GS plaster	GS Glue	CSII plastic	CSII plaster	IBOA 0.3%	IBOA 0.1%	IBOA 0.01%	
1	14	G	-	FreeStyle Libre/-	Omnipod/-	-	-	-	+	-	-	-	-	-
2	9	G	-	FreeStyle Libre/Enlite	-/-	+	++	-	NA	NA	NT	+	+	+ Smith and Nephew wipes ^a
3	17	G	-	FreeStyle Libre/-	Omnipod/-	-	-	-	-	-	NT	-	-	NT
4	11	G	-	FreeStyle Libre/-	Insufion/-	-	-	-	-	-	NT	+	NT	+ EMLA cream ^b
5	8	B	+	FreeStyle Libre/-	-/-	+	-	-	NA	NA	++	+	+	+ TC ^b + Smith and Nephew wipes ^a
6	8	B	-	FreeStyle Libre/-	Omnipod/-	+	-	-	-	-	NT	++	+	+ TENSoplast ^c ++ EMLA plaster ^b IR Smith and Nephew wipes ^a
7	9	G	-	FreeStyle Libre/-	Insufion/-	+++	+++	+++	+	+	NT	-	-	++ EMLA plaster ^b ++ Tp ^b
8	13	B	-	Enlite/-	-/-	-	-	-	NA	NA	NT	-	-	+ EMLA plaster ^b
9	5	B	-	Enlite/-	MiniMed Quick-set/-	+	-	-	-	-	NT	+	-	+ Duoderm ^d
10	11	B	-	Enlite/FreeStyle Libre	Omnipod/Insufion	-	+	+	-	-	NT	+	-	+
11	4	B	-	Enlite/FreeStyle Libre	MiniMed Quick-set/-	+	-	-	-	-	NT	+	-	-
12	10	G	-	Enlite/-	MiniMed 604G/-	-	+	-	-	-	NT	-	-	+? Duoderm ^d
13	6	B	+	Dexcom G6/FreeStyle Libre	MiniMed 604G/-	-	+	-	+	-	NT	+	+	+ Smith and Nephew wipes ^a
14	7	B	-	Dexcom G6/-	Tandem t:slim X2/Animas Vibe	-	-	-	+	+	+	+	+	+ EMLA plaster ^b
15	8	G	-	Dexcom G6/-	Omnipod/-	+	-	-	+	+	F	-	-	+? Cutisoft wipes ^e +? Smith and Nephew wipes ^a

Abbreviations: AD, atopic dermatitis; B, boy; BA, benzyl alcohol; BP, benzoyl peroxide; BR, *p*-tert-butylphenolformaldehyde resin; CB, cocamidopropyl betaine; CC, Cavilon barrier cream; CL, colophonium; ECA, ethyl cyanacrylate; F, follicular reaction; G, girl; NA, not applicable; NT, not tested; ox-LL, linolol hydroxyperoxides; PR, prilocaine hydrochloride; SL-mix, sesquiterpene lactone; TC, Tapin cream; TO, *Taraxacum officinale*; TP, Tapin plaster; TREGDA, triethylene glycol diacrylate; WT, wood tar mix.

^aAdhesive remover wipes.

^bAnalgesics.

^cAdhesive bandage.

^dHydrocolloid.

^eDisinfectant wipes.

TABLE 2 Device screening series

Glue components ^a	Colophonium Abietic acid Abitol Woodtar mix Benzoyl peroxide
Acrylates	Ethyl cyanoacrylate ^b HEMA ^b IBOA ^c
Topical steroids	Betamethasone 17-valerate ^a Triamcinolone acetonide ^a Alclometasone-17,21-dipropionate ^b Clobetasol-17-propionate ^a Dexamethasone 21-phosphate disodium salt ^a Hydrocortisone ^a Prednisolone ^a Desoximetasone ^a Mometasone furoate ^a
Topical analgesics ^a	Benzocaine Lidocaine hydrochloride Procaine hydrochloride Tetracaine hydrochloride Cinchocaine hydrochloride Prilocaine hydrochloride Polidocanol Amylocaine hydrochloride
Topical disinfectants	Chlorhexidine digluconate ^a Chlorhexidine diacetat ^b Fusidic acid sodium salt ^a
Other allergens ^a	Nickel Sesquiterpene lactone mix Benzyl alcohol Hydroquinone

Abbreviations: HEMA, hydroxyethylmethacrylate; IBOA, isobornyl acrylate.

^aSmartPractice.

^bChemotechnique Diagnostics.

^cSigma-Aldrich.



FIGURE 1 Severely excoriated allergic contact dermatitis in an area, where the Omnipod insulin pump previously was placed and in close proximity around device (Patient number 6)

4 | DISCUSSION

We here present our approach to patch testing, including our device test series, in the management of children with cutaneous adverse reactions from diabetes devices.

Several clinical dermatological manifestations can be presented in patients using diabetes devices. CSII can lead to lipodystrophy,²⁰ however, none of our patients presented that symptom. ICD can be elicited by chemical irritants, physical irritation due to the repetitive removal of adhesive materials, moisture accumulation under the medical device,¹⁰ and a reaction to the plaster itself, which causes direct cutaneous injury.⁸ ACD may be due to allergens in the devices.²¹ ICD usually has a more abrupt presentation of symptoms, but since all our 15 patients had similar clinical presentations, it was not possible to establish the difference between ACD and ICD solely based on clinical presentation.

Several studies have described the different allergens present in various sensors and pumps: IBOA and *N,N*-dimethylacrylamide have been found in FreeStyle Libre; IBOA, *N,N*-dimethylacrylamide and colophonium in the Medtronic Enlite Sensor; 2-ethyl cyanoacrylate and 2,2'-methylenebis (6-*tert*-butyl-4-methylphenol) monoacrylate in the Dexcom Platinum G4 sensor and the Dexcom G6 sensor, respectively. IBOA was also found in the Dexcom G6 sensor. Furthermore, IBOA, dipropylene glycol diacrylate and colophonium have been found in the Omnipod CSII. In the Paradigm MiniMed Quick-Set insulin infusion set, IBOA has also been identified.^{2,9,10,13,22–27} Furthermore, ICD elicited by repeated device application may promote the development of ACD by diminishing the integrity of the skin barrier, thereby increasing the presentation of allergens to the skin's immune system. Other factors such as allergenic potency, the concentration of the allergen in the device, and period of use can also affect the development of ACD.^{25,28}

Nonetheless, one cannot exclude that additional allergens are present, but have yet to be identified.^{10,29} When patients do not present positive reactions on patch testing and suspicion of ACD is high, a use test may be performed, keeping in mind that both IBOA and DMAA are present at a lower concentration in the medical devices, which hampers use test.^{19,29–31} Such a use test will help demonstrate, whether the exposure to the medical device is clinically relevant or not. However, a positive use test will not always distinguish between an ICD and a weak ACD. It is important to combine patient history, pre-existing contact allergies, previously use of GS and CSII devices, the lag time before developing symptoms after introducing the devices and skin morphology with the test results. Many patients use the GS or CSII devices in the same areas after a rotation scheme and tissue-resident T cells are likely to be involved in the local allergic skin reaction. A use test in a previously exposed, healed skin area, might reveal weak ACD when compared with a standard patch test procedure or use test in non-exposed skin areas.

Acrylates are potent sensitizers and several of them, including IBOA and DMAA, are acknowledged to be present within both the diabetic devices and in the adhesives. These allergens migrate through the devices to the skin, inducing ACD regardless of barrier methods in

some patients.^{2,19,25,28,32–34} As no standardized IBOA patch test concentration is yet settled, we performed a patch test with IBOA 0.01% and 0.1% IBOA, to explore a possible dose-related patch test reaction. Though, a recent Swedish study suggested that patients should be tested with IBOA and DMAA at a concentration of 0.3% to avoid false-negative reactions.^{12,29} As only five of our patients had positive reactions to IBOA 0.1%, we invited patients with a negative reaction to IBOA to supplementary patch test with 0.3% IBOA. Among the four patients who were re-tested, two had positive reactions to IBOA 0.3%, confirming the findings of the Swedish group.

Of particular interest, one-third of the patients had a positive reaction to BP of 1%. This substance is known as a strong irritant and a weak allergen. However, ACD has been described with a reported incidence of up to 6.5% within the population that has been exposed to it.³⁵ BP is used for several purposes such as topical medication for acne treatment, treatment of leg ulcers, dental surgery, hair bleaching, and teeth whitening agents, among others.^{35–38} All five patients were under the age of 12 (6–11) years of age. It is therefore hardly probable that they had been sensitized through the usage of anti-acne treatments. The medical records of the patch test-positive patients showed no prescribed medicine containing BP. The GC–MS analyses of the FreeStyle Libre sensor 1 and the Omnipod pump demonstrated the presence of IBOA, but no obvious presence of BP in the analysed extracts. However, it is known that BP may be present in stretch or adhesive tapes^{38,39} and we may therefore consider these a possible allergen source. Furthermore, one can hypothesize the potential use of BP as a catalyst in the acrylate polymerization process and the potential presence of residues in the diabetes devices.

Three of our patients who use FreeStyle Libre and had positive reactions to IBOA had a concomitant positive reaction to SL (Patient numbers 2, 4 and 6). Two of these had the same reaction strength to both allergens, while Patient number 6 had a stronger reaction to IBOA at 0.1%. However, none of the patients had relevant exposure to SL. Similar results have previously been reported in the literature^{28,33,40} and this reaction pattern remains a puzzle. Some hypothesize cross-reactivity with IBOA acting as a primary sensitizer.²⁸

Patient number 12 had a + reaction to colophonium and a doubtful reaction to Duoderm. This allergen has been identified in Duoderm Extra Thin⁴¹ and a recent Canadian study documented its presence in wipes used to clean and prime the skin before applying the glucose monitor.⁴² Moreover, it might be contained in the adhesives of both the Omnipod CSII, the Enlite GS,⁴³ and Dexcom G6.³³ Colophonium can be used in an unmodified or modified form, the first being included in our device screening series (Table 2). It has previously been demonstrated that to detect ACD to hydrocolloids, patients need to be patch tested with the modified form, since reactions to unmodified colophonium can remain negative, in case modified colophonium is the culprit.⁴⁴ Sensitization to colophonium can consequently be problematic for the patients, given its widespread presence.

Many patients use different strategies, such as barrier creams or dressings,^{2,6,15,20,23,30,41,45–47} to continue using GS and CSII, despite

their cutaneous reactions. However, these products are also able to induce both ACD and ICD. Four of our patients had a positive patch test reaction to EMLA plaster and one to EMLA cream, which is a local anaesthetic composed of lidocaine and prilocaine. Patients often use these products to diminish pain and discomfort associated with the application of diabetes devices. Although cutaneous adverse reactions are uncommon, reports exist of ACD to lidocaine and prilocaine, in relation to EMLA⁴⁸ as well as ICD.^{49,50} One of our patients had a + reaction to prilocaine (no. 7), another had a +? reaction to prilocaine (no. 6), whereas the remaining three patients had negative reactions to lidocaine and prilocaine.

Cavilon barrier film, which is often used to prevent skin irritation, may also cause contact dermatitis.⁵¹ Nevertheless, its application can be reconsidered, as a recent study has demonstrated no benefit from it.⁵² A German article from 2019 demonstrated that Hansaplast blister plaster prevents ACD symptoms.⁴⁶

Only 2 of our 15 patients had a personal history of atopic dermatitis, which coincides with the results of a recent Italian study in which atopic predisposition was not associated with the development of ACD among patients with DM type I.⁸

Skin problems may cause the patients to discontinue using their device.^{14,15,20,25,33} Four of our patients had changed GS devices due to intense cutaneous manifestations. One of these had simultaneously changed CSII (Patient 10). One of the patients had switched CSII alone. Finding a suitable alternative may be difficult, principally because the same allergens may be present in other devices and due to the risk of cross-reactivity.⁴⁶

The primary limitation to the study is its retrospective nature with potentially missed sensitizations, the limited number of paediatric patients and like many other departments of dermatology, we do not have technical resources to perform batch-related chemical analyses of the devices.

Diabetes devices improve and simplify glucose control³³ reducing the impact of the disease in patients, especially in children. Cutaneous adverse reactions will therefore reduce patients' QoL and their adherence and compliance to treatment, and children tend to build a negative connotation to their treatment. These reactions will also have a negative impact on the family's daily life, particularly when the child needs to start using finger-stick glucose monitoring, which also reduces glucose control compared with continuous glucose monitoring. Switching from a CSII to insulin injections is also a factor that may negatively affect disease control and QoL. Furthermore, sensitization to cross-reacting substances may cause additional problems in patients' lives.³³ Finally, managing ACD symptoms with plasters or creams is associated with an economic burden to the patients and may influence the proper functioning of the GS. Moreover, these products may also elicit contact dermatitis.

Thus, it is important for medical professionals to have access to detailed product descriptions including their chemical composition in order to make appropriate patch testing, give advice to patients, and provide alternatives in case of allergies. Mandatory labelling of ingredients in medical devices is required before the products enter the market, preferably accelerated by legislation.

5 | CONCLUSION

Forty-six percent of patients showed positive reactions to IBOA, but occasionally only to IBOA 0.3% patch test concentration. Moreover, an even higher share of patients showed positive (morphologically contact-allergic) patch test reactions to their own medical devices, insulin pumps and/or glucose devices, indicating that hitherto unidentified allergens are still of importance. Of particular interest, we observed that a third of our patients showed a positive reaction to BP, without any known exposure, and thus currently without any relevance. Furthermore, 80% of patients showed additional positive reactions to a wide range of other products, used together with their diabetes devices, including (adhesive/remover) wipes, (analgesic) plasters and creams, barrier creams and (hydrocolloid) dressings, many of these products being medical devices themselves. Overall, our experience once more highlights the importance of having access to a full description of the chemical composition of diabetes devices, and related medical devices, to efficiently manage patients (including children), who experience adverse skin reactions from such devices.

AUTHOR CONTRIBUTIONS

Catarina Alves da Silva: Conceptualization (equal); data curation (lead); formal analysis (equal); investigation (equal); methodology (equal); project administration (lead); resources (equal); software (supporting); validation (equal); visualization (equal); writing – original draft (lead); writing – review and editing (lead). **Anne Bregnhøj:** Conceptualization (equal); data curation (supporting); formal analysis (equal); investigation (equal); methodology (equal); project administration (supporting); resources (equal); software (supporting); supervision (supporting); validation (equal); visualization (equal); writing – original draft (supporting); writing – review and editing (supporting). **Martin Mowitz:** Conceptualization (supporting); formal analysis (supporting); investigation (supporting); methodology (supporting); resources (supporting); writing – original draft (supporting); writing – review and editing (supporting). **Magnus Bruze:** Formal analysis (supporting); writing – original draft (supporting); writing – review and editing (supporting). **Klaus Ejner Andersen:** Formal analysis (supporting); writing – original draft (supporting); writing – review and editing (supporting). **Mette Sommerlund:** Conceptualization (equal); data curation (equal); formal analysis (equal); investigation (equal); methodology (equal); project administration (supporting); resources (equal); software (supporting); supervision (lead); validation (equal); visualization (equal); writing – original draft (supporting); writing – review and editing (supporting).

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions. The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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