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Skin rash and contact allergy in continuous glucose monitor and insulin pump users

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Josefin Ulriksdotter



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DOCTORAL DISSERTATION

Doctoral dissertation for the degree of Doctor of Philosophy (PhD) at the Faculty of Medicine at Lund University to be publicly defended on 6th of March at 01:00 p.m. in Lilla Aulan, Jan Waldenströms gata 5, Skåne University Hospital, Malmö, Sweden

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Abstract:

Contact allergies to continuous glucose monitors and devices for continuous subcutaneous insulin infusion (diabetes medical devices, MDs) are commonly reported but the magnitude of the problem is not known. Patch test investigations are hampered by inadequate declaration of the device content.

In this project, the prevalence of skin rash from diabetes MDs and contact allergies to MD and baseline series allergens was investigated. Device-related skin rash was assessed by a questionnaire. Patch testing was performed with baseline and MD patch test series. Chemical analyses of diabetes MDs were performed with gas chromatography-mass spectrometry.

Among adults with type 1 diabetes using diabetes MDs (n=641) in southern Sweden, just over 40% had experienced device-related skin rash. Some of those affected had to change their MDs more often than recommended or discontinue use. Less than 5% of those with device-related skin rash had previously been patch tested. In the patch test study (n=204), 16.2% were positive to allergens found in diabetes MDs (mainly isobornyl acrylate, *N,N*-dimethylacrylamide, 2-hydroxyethyl acrylate, dicyclohexylmethane-4,4-diisocyanate and 1,6-hexanediol diacrylate). The prevalence was significantly higher in those with a history of device-related skin rash (28.1%) than without (1.1%, adjusted p-value <0.001). Chemical analyses were used to diagnose cases of contact allergy to a new allergen (dipropylene glycol diacrylate) in a CSII, and additional allergens were identified in other diabetes MDs. Contact allergy to the Swedish baseline series was as common in the 204 individuals with diabetes as in consecutive dermatitis patients. Contact allergy to some fragrance allergens and sesquiterpene lactone mix was significantly more common in the individuals with diabetes.

Skin rash from diabetes MDs and contact allergy to allergens in diabetes MDs are common. The problem is underdiagnosed and underreported. Those affected must be referred for patch testing and be reported to medical products agencies and manufacturers. Improved primary toxicological assessments of the products, monitoring of real-world data of skin rash and MD contact allergies, and labelling of diabetes MDs is urgently needed. Today, chemical analyses are necessary for identifying culprit allergens in the products and to enable relevance assessments of the contact allergies found.

Key words: contact dermatitis, allergic contact dermatitis, irritant contact dermatitis, continuous glucose monitor, devices for continuous subcutaneous insulin infusion.

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Josefin Ulriksdotter



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The more I learn, the more I realize how much I don't know –

Albert Einstein

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Abbreviations

1,6-HDDA	1,6-hexanediol diacrylate
2-HEA	2-hydroxyethyl acrylate
ACD	allergic contact dermatitis
AD	atopic dermatitis
CGM	continuous glucose monitor (also including ‘flash glucose monitor’)
CSII	devices for continuous subcutaneous insulin infusion
Diabetes MDs	diabetes medical devices (CGM and CSII)
DMAA	<i>N,N</i> -dimethylacrylamide
DMDI	dicyclohexylmethane-4, 4'-diisocyanate
DOED	The Department of Occupational and Environmental Dermatology, Skåne University Hospital, Malmö, Sweden
DPGDA	dipropylene glycol diacrylate
FM	fragrance mix
GC-MS	gas chromatography-mass spectrometry
IBOA	isobornyl acrylate
ICD	irritant contact dermatitis
MD	medical device
MP	<i>Myroxylon pereirae</i> resin
SLM	sesquiterpene lactone mix
T1D	type 1 diabetes
T2D	type 2 diabetes
UCD	unspecified contact dermatitis

Thesis at a glance

Study and objective	Method	Main findings/conclusion
I. To exemplify the importance of chemical analyses in personalised investigations of suspected allergic contact dermatitis from diabetes medical devices (MDs).	Case series and chemical analyses.	All cases were positive to dipropylene glycol diacrylate (DPGDA). DPGDA was found in their Omnipod pumps and interpreted as the main culprit allergen. Another Omnipod pump from the Swedish pump distributor had a different content. Possible batch variation in device content complicates patch testing and relevance assessment.
II. To report the prevalence of positive reactions: i) to baseline series allergens and isobornyl acrylate (IBOA) in adults with suspected ACD from diabetes MDs (diabetes patients) and general dermatitis patients. ii) to the MD series.	Retrospective study.	Patch test results for adults patch tested at DOED 2017-2020 were extracted from DOED's patch test register.
III. To investigate the prevalence of skin rash from continuous glucose monitors (CGM) and devices for continuous subcutaneous insulin infusion (CSI) in adults with type 1 diabetes (T1D).	Cross-sectional questionnaire study.	Of the 667 participants, 42.1% of CGM users and 44.9% of CSI users had experienced device-related skin rash. Less than 5% of those with a history of device-related skin rash had been patch tested.
IV. To investigate the prevalence of positive reactions to baseline series allergens in adults with T1D using MDs and to compare with consecutive dermatitis patients.	Cross-sectional patch test study.	In total, 204 adult diabetes MD users were patch tested. Significantly higher prevalences of positive reactions to SLM, myroxylon pereirae (MP) and IBOA were seen in the individuals with diabetes than in the control dermatitis patients.
V. To investigate the prevalence of contact allergy to MD-allergens in adults with T1D using diabetes MDs.	Cross-sectional patch test study.	Of the 204 participants 114 had experienced device-related rash. 16.2% were positive to allergens found in diabetes MDs and highest prevalences of positive reactions were seen for IBOA (10.3%), N,N-dimethylacrylamide (4.9%), 2-hydroxyethyl acrylate (3.4%), di(cyclohexyl)methane-4,4-diisocyanate (2.9%) and 1,6-hexamedio diacrylate (2.0%).

Overview of studies included

I. Ulriksdotter J, Svedman C, Bruze M, Mowitz M. Allergic contact dermatitis caused by dipropylene glycol diacrylate in the Omnipod® insulin pump. *Br J Dermatol.* 2022 Feb;186(2):334-340. doi: 10.1111/bjd.20751. Epub 2021 Nov 2. PMID: 34510410.

II. Ulriksdotter J, Sukakul T, Bruze M, Mowitz M, Ofenloch R, Svedman C. Contact Allergy to Allergens in the Swedish Baseline Series Overrepresented in Diabetes Patients with Skin Reactions to Medical Devices - A Retrospective Study from Southern Sweden. *Acta Derm Venereol.* 2024 Mar 29;104:adv19676. doi: 10.2340/actadv.v104.19676. PMID: 38551376; PMCID: PMC11000652.

III. Ulriksdotter J, Sukakul T, Bruze M, Hamnerius N, Mowitz M, Svedman C. A Cross-Sectional Study Demonstrating a High Prevalence of Skin Rash to Diabetes Medical Devices: An Underestimated Problem. *J Diabetes Sci Technol.* 2025 May 7:19322968251336261. doi: 10.1177/19322968251336261. Epub ahead of print. PMID: 40331898; PMCID: PMC12058707.

IV. Sukakul T*& Ulriksdotter J*, Mowitz M, Bruze M, Hamnerius N, Svedman C. Patch testing in individuals with diabetes using medical devices. Part 1 – contact allergy to baseline series allergens (submitted). (*shared first authorship)

V. Ulriksdotter J, Mowitz M, Sukakul T, Bruze M, Hamnerius N, Svedman C. Patch testing in individuals with diabetes using medical devices. Part 2- contact allergy to medical device allergens and new patch test recommendations (submitted).

Other relevant studies not included in the thesis

Ulriksdotter J, Mowitz M, Svedman C, Bruze M. Patch testing and diagnosis when suspecting allergic contact dermatitis from medical devices. *Contact Dermatitis*. 2020 Oct;83(4):333-335. doi: 10.1111/cod.13650.

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von Kobyletzki LB, Ulriksdotter J, Sukakul T, Aerts O, Agner T, Buhl T, Bruze M, Foti C, Gimenez-Arnau A, Gonçalo M, Hamnerius N, Johansen JD, Rustemeyer T, Stingeni L, Wilkinson M, Svedman C. Prevalence of dermatitis including allergic contact dermatitis from medical devices used by children and adults with Type 1 diabetes mellitus: A systematic review and questionnaire study. *J Eur Acad Dermatol Venereol*. 2024 Jul;38(7):1329-1346. doi: 10.1111/jdv.19908.

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Populärvetenskaplig sammanfattning

För individer med diabetes har användning av kontinuerliga blodsockermätare och insulinpump (diabetesmedicintekniska produkter (DMTP)) förenklat diabetesbehandlingen och förbättrat blodsockerkontrollen. Produkterna är mycket uppskattade av användarna och leder till förbättrad hälsorelaterad livskvalitet. Men produkterna sitter kontinuerligt fastklisterade mot huden och tyvärr utvecklar vissa användare kliande hudutslag vid applikationsstället och kontaktallergi mot ämnena i produkterna.

Vi har i detta projekt kartlagt hur vanligt det är med hudutslag och kontaktallergi mot DMTP och vilka ämnena i produkterna som ger upphov till kontaktallergi. Dessutom har vi undersökt hur vanligt det är att de som använder produkterna är allergiska mot våra vanligaste allergen som används för screening av kontaktallergi. Användning av DMTP och associerade hudutslag har rapporterats via frågeformulär. Kontaktallergi har diagnosticerats via lapptestning. Kemiska analyser (med gaskromatografi-masspektrometri) har använts för att identifiera allergen i DMTP.

Bland 667 vuxna med typ 1 diabetes i Södra sjukvårdsregionen hade drygt 40% av de som använt DMTP haft utslag under produkterna. Mindre än 5% av de med utslag under produkterna hade genomgått utredning med lapptest innan vår lappteststudie genomfördes. Vissa av de som utvecklade hudutslag under produkterna behövde byta till en ny DMTP oftare än vad som rekommenderas eller till och med sluta använda sin DMTP på grund av hudutslag. Bland de 204 som lapptestades var drygt 15% allergiska mot allergen i DMTP. Förekomsten av kontaktallergi mot allergen i produkterna var signifikant högre bland de som haft utslag under produkterna än de som inte haft utslag under produkterna (28.1% vs. 1.1%). De ämnena i DMTP som flest var allergiska mot var isobornylakrylat, N,N-dimetylakrylamid, 2-hydroxyethylakrylat, dicyclohexylmethane-4,4-diisocyanate och 1,6-hexanedioliakrylat. Med hjälp av kemiska analyser kunde vi diagnostisera fall av kontaktallergi mot ett nytt allergen (dipropylenglykoldiakrylat) i en insulinpump samt identifiera nya allergen även i andra DMTP. Dessa ämnena används framför allt som byggstenar i limmer i produkterna.

Individerna med diabetes som använder DMTP hade en högre förekomst (prevalens) av kontaktallergi mot parfymämnena (fragransmix II och perubalsam), samt mot växtämnen som finns i korgblommiga växter (sesquiterpenelaktoner) jämfört med andra patienter som utretts på Yrkes- och miljödermatologiska avdelningen i Malmö för misstänkt kontaktallergi.

Hudutslag och kontaktallergi mot DMTP är vanligt och kan medföra negativa konsekvenser för de som drabbas. Det är viktigt att de som utvecklar hudutslag under produkterna remitteras för kontaktallergiutredning och får en förklaring till sina besvär. Om känt allergiframkallande ämnena tas bort från produkterna, så kan fler använda dem utan besvär framöver.

Introduction

Medical devices (MDs) are important for treatment and monitoring of many different diseases. The use of continuous glucose monitors (CGM) and devices for continuous subcutaneous insulin infusion (CSII) (diabetes MDs) among individuals with type 1 diabetes (T1D) is increasing. These devices represent a new modern paradigm of patient-friendly and tailored diabetes treatment and monitoring. Many users experience improved glucose control which is important to reduce the risk of long-term disease complications. The devices are usually continuously attached to the skin with an adhesive and adverse skin reactions may negatively affect treatment compliance (1, 2).

In 2016, a patient was investigated at The Department of Occupational and Environmental Dermatology, Malmö, Sweden (DOED) due to suspected allergic contact dermatitis (ACD) to a CGM. Initially, there was uncertainty whether the adverse skin reaction was an ACD or irritant contact dermatitis (ICD) (3). However, as patch testing with ultrasonic bath extracts of the CGM resulted in a positive reaction in the patient and negative reactions in 20 controls (4), the patient's reactions were interpreted as an ACD. Similar cases with adverse skin reactions to the same CGM were observed at other patch test clinics in Europe and finally, after collaboration between dermatologists from different countries, isobornyl acrylate (IBOA) was identified in the CGM and interpreted as the main culprit allergen (5). After this, an increasing number of cases of adverse skin reactions to several different diabetes MDs were referred to our department (6, 7), raising the question whether an outbreak of ACD to diabetes MDs was on the rise. Further characterisation of this new group of diabetes MD users from a dermatological perspective was called for. Meeting children and adults with oozing adverse skin reactions motivated me to address this clinical problem, thereby possibly improving the situation for diabetes MD users in the future.

The skin as a barrier

The skin functions as an overall protective layer towards different factors in the surrounding environment, such as mechanical trauma/friction, UV-light, microorganisms, skin irritants and allergens. Moisturising factors, an acid surface pH, immune cells and stratum corneum with corneocytes (dead keratinocytes) and extracellular lipids all contribute to the skin barrier (8-10).

Multiple factors influence the absorption of a substance through the skin (10): occlusion, skin barrier disruption, intrinsic properties of a substance or mixes of substances (lipophilicity, hydrophilicity, molecular weight), the dose of a substance applied on the skin, and frequency and duration of skin contact. Penetration of substances can be either transcellular, intercellular or through skin appendages such as hair follicles (10).

General aspects of contact dermatitis and contact allergy

Contact dermatitis

Contact dermatitis is a localised skin inflammation caused by external factors. The clinical manifestations of contact dermatitis include oedema, erythema, papules, vesicles, hyperkeratosis, scales, and fissures (11, 12). Contact dermatitis can be divided into two major subgroups: ICD and ACD (13). Patch testing can help to distinguish between ACD and ICD. However, ACD and ICD can occur simultaneously (14).

Irritant contact dermatitis

ICD is induced by physical factors such as friction or by skin-irritating substances that directly or indirectly disrupt the skin barrier and initiate an innate immune response (14). Cytokines are released from cells in the epidermis and dermis which leads to a recruitment of proinflammatory cells resulting in ICD (12). The development of ICD may require a single exposure to a strong irritant or repeated exposures to weaker irritants (12, 14-16). The immune response in ICD is unspecific and occurs without previous sensitisation. The sensitivity to irritant exposure differs between individuals and atopic dermatitis (AD) is a known risk factor for ICD (12, 14, 15).

Contact allergy and allergic contact dermatitis

Contact allergy is a delayed type/type IV hypersensitivity reaction (12) to a specific antigen. Substances causing contact allergy (haptens) must be small enough, usually < 500 Da (17) (although haptens with higher molecular weights have been reported), (18) to penetrate stratum corneum. In the following, the terms hapten and allergen are used synonymously.

Most haptens are electrophilic and can directly bind to skin proteins and act as antigens. Other haptens require a previous activation, either outside (prehaptens) or inside (prohaptens) the body (19).

Development of ACD is a two-step process:

1. the sensitisation phase, when an individual becomes allergic to a specific allergen.
2. the elicitation phase, when re-exposure to an allergen that an individual is already allergic to causes ACD.

Sensitisation phase

Sensitisation takes at least 4 days up to a few weeks (20). Haptens penetrate through the skin, bind to skin proteins and trigger an immune response (17). Dendritic cells such as Langerhans cells ingest and present the antigen (the hapten-protein complex) (21, 22). Pro-inflammatory cytokines and 'danger signals', such as damage associated molecular patterns that bind to receptors on dendritic cells promote their activation, maturation and migration to the regional lymph nodes (23). In the regional lymph nodes, the dendritic cells present the antigen to naive T-cells that are then activated, and a proliferation of hapten-specific memory and effector T-cells is initiated (12, 21, 22).

Elicitation phase and the development of allergic contact dermatitis

The elicitation phase is usually faster than the sensitisation phase (21, 22). The hapten penetrates stratum corneum and bind to skin proteins. The hapten-protein complex (antigen) is taken up and presented by antigen-presenting cells such as Langerhans cells or even keratinocytes, which trigger a release of cytokines (21). T-cells, macrophages, eosinophils and mast cells are recruited to the skin. The antigen is presented for hapten-specific T-cells, and effector T-cells induce apoptosis of keratinocytes carrying the specific antigen (21). Clinically, an ACD is seen.

The amount of allergen molecules per skin area that are required to cause sensitisation is generally higher than that required to cause elicitation (24). Both the amount of allergen exposure per skin area and the individual reactivity are factors that influence whether an ACD is elicited or not. Cross-reactivity is when an ACD is elicited when an individual is exposed to a substance that is chemically/structurally similar to an allergen that the same individual has previously been sensitised to (25). Almost all allergens can also cause skin irritation, and ICD is a risk factor for both sensitisation and elicitation of ACD (12, 23). It has also been suggested that the immunological response to an allergen may be stronger when sensitised to the allergen in a mixture (of allergens) (23).

Diagnosis of contact allergy/patch testing

Patch testing and patch test readings

Contact allergy is diagnosed by patch testing, a provocation test where the skin is exposed to the allergen in a standardised manner. The allergens/test substances are applied in test chambers and occluded on the skin (usually on the upper back) for

48 hours (Figure 1). In analogy with what was previously described for ACD, the amount of the allergen molecules applied per skin area is important for whether a positive patch test reaction (ACD) is elicited or not. Therefore, defined doses of allergens (39-40 mg/cm² of solid preparations and 29-30 µL/cm² of liquid preparations) are used for different chamber systems depending on the chamber area (25).

Patch test reading days may differ in different departments. At least two patch test readings are recommended, usually on Day 3 or 4 and on Day 7, to prevent missing late-appearing positive reactions (25). The same morphology (erythema, infiltration, papules and vesicles/bullae) are seen in positive patch test reactions as in ACD (26). Positive allergic patch test reactions are graded as +, ++, +++ depending on the morphology of the patch test reactions according to standardised patch test reading criteria from the European Society of Contact Dermatitis (ESCD) and International Contact Dermatitis Research Group (ICDRG) (25-27).

Relevance assessment of the contact allergies is important but may be challenging. Contact allergies can be of past, current or unknown relevance. The individual allergen exposure (localisation, dose and frequency), localisation of the dermatitis, and the temporal relationship between exposure and clinical manifestations are important factors to consider (25).

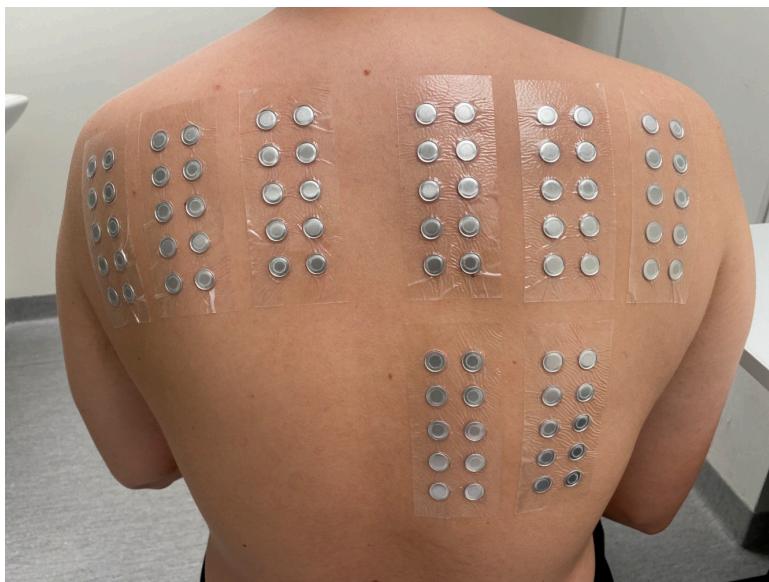


Figure 1. Patch tests chambers are occluded on the back for 48 hours.

What should be patch tested?

Screening for contact allergy

Baseline patch test series are used for screening of contact allergy (28), and contain the most common and important allergens that cause contact allergy. The Swedish baseline series is annually updated, and in 2025, included 29 different patch test preparations (28). By screening with the same allergens and patch test preparations in many countries, contact allergy prevalences can be compared between different geographical areas and over time.

Targeted patch testing

When investigating cases of suspected contact allergy, additional patch test series can be tested based on the exposure, such as plant series, cosmetic series or (meth)acrylate series.

Personalised investigations

Patch test investigations can be further personalised and tailored based on detailed evaluations of exposure in an individual patient. Patients' own products can be patch tested 'as is', diluted, or as ultrasonic bath extracts (29-31).

Why is diagnosing contact allergies important?

Contact allergy and ACD is common. In a previous study (32), 27.0% of the general European population were estimated to be positive to at least one baseline series allergen. ACD may have implications for those affected, resulting in reduced health-related quality of life (33) and increased costs (34, 35).

Contact allergies are lifelong. Since new exposures to contact allergens will continuously appear in society, it is important that cases with suspected contact allergy are patch tested and that trends for contact allergy prevalences are closely monitored (36). Potential needs for increased primary prevention of contact allergy to certain substances can thereby be detected early, and larger outbreaks of contact allergy may be avoided (36).

Diabetes and diabetes medical devices

Diabetes

Diabetes is characterised by hyperglycaemia due to an insufficient insulin production. In 2024, 589 million adults were estimated to have diabetes worldwide (37), and the prevalence of diabetes in Sweden was estimated to be 6.2% in 2024 (38). T1D and type 2 diabetes (T2D) are the main types of diabetes. Less common forms include gestational diabetes (37), secondary forms of diabetes and Latent Autoimmune Diabetes in Adults with characteristics of both T1D and T2D (39).

Individuals with T1D have an autoimmune mediated destruction of the β -cells in the pancreas. Individuals with T2D have a β -cell dysfunction and insulin resistance

(40). T1D often presents during childhood or adolescence (38) while T2D mainly affects adults.

Acute disease complications

Diabetes ketoacidosis is potentially life-threatening. It is characterised by a combination of high blood ketones, acidosis, and (generally) hyperglycaemia (41-43). It is caused by insulin deficiency. On the opposite extreme, individuals with diabetes may also experience hypoglycaemia (44). Maintaining a good glucose control is important to reduce the risk of both acute and long-term disease-related complications.

Long-term disease complications

Cardiovascular disease, peripheral neuropathy, retinopathy, and nephropathy are known long-term diabetes complications (45).

Treatment and monitoring

Individuals with T1D need close monitoring of blood glucose and daily insulin injections (37). In T2D, other blood glucose lowering medications (than insulin) are more commonly used (37). Lifestyle interventions, evaluation and treatment of cardiovascular risk factors (antihypertensive medications and lipid-lowering medications) and screening of potential disease-related complications are other important aspects of diabetes treatment and follow up (46).

Diabetes medical devices for glucose monitoring and insulin delivery

Definition of a medical device

MDs are products that are used in humans for medical purposes (47), and that are not classified as pharmaceuticals.

Regulation of medical devices

MDs are regulated by two EU legislations: 2017/745 (48) for MDs and 2017/746 (49) for *in vitro* MDs. There are additional regulations in individual countries (50).

Medical devices for glucose monitoring

Traditionally, individuals with T1D have used self-monitoring of blood glucose (SMBG) to achieve a glycaemic overview (51). A capillary blood sample is obtained by finger pricking using a lancet. The blood sample is analysed by a glucose meter that gives a value of the blood glucose (52). However, a regime of SMBG 4-10 times a day is difficult to adhere to (53). Given the importance of glucose control in diabetes, a simplified and more precise way of monitoring glucose levels was called for. Against this background, the introduction and continuous development of CGM have revolutionised glucose monitoring and diabetes care over recent decades (54). By continuously measuring and displaying glucose levels without the need for repeated manual finger pricking, a whole new way of overviewing glucose levels and tailoring insulin treatment is available.

A CGM has three main parts: i) a sensor that monitors the interstitial glucose levels ii) a transmitter receiving and transmitting the value, and iii) a receiver that shows the reading (Figure 2) (52). The CGM is continuously worn on the skin and the user changes to a new device every 7-15 days. Implantable CGMs are placed subcutaneously measuring the interstitial glucose levels. The glucose value is forwarded to a transmitter worn on the skin (52).

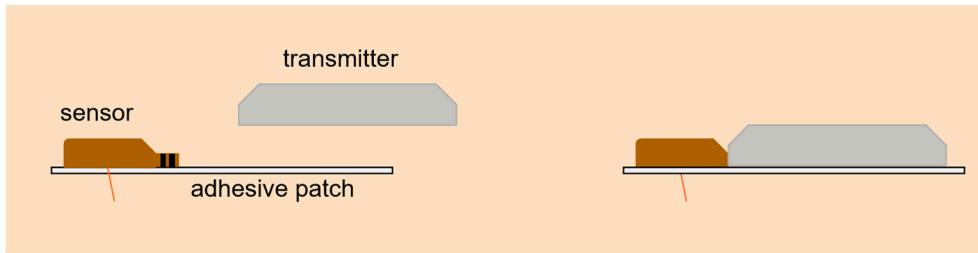


Figure 2. Schematic picture of a continuous glucose monitor (CGM).

The transmitter and sensor can be incorporated in one CGM-component or as in the figure in two different components attached to each other. The glucose value can be displayed in, for example, a mobile phone.

Medical devices for insulin delivery

Insulin can be administered manually through multiple daily injections with an insulin pen, or through a CSII (insulin pump) continuously delivering rapid-acting insulin (55). As for the CGM, technological development has vastly improved the CSII devices over the years. In the early days of CSII use, insulin pumps were large, heavy and worn as a backpack by the users. Today, the pumps are small devices easily covered under clothing. By directly communicating with the GGM, the most modern CSII can automatically adjust insulin doses depending on glucose levels, thereby tailoring treatment according to the needs of the user (56). The main types of CSII are insulin pumps with an infusion set and patch pumps (55). Patch pumps are tubeless and are worn on the skin, attached by an adhesive (55).

Use of diabetes medical devices

Diabetes MDs are mainly used by individuals with T1D. In 2024 in Sweden, 92.3% of adults with T1D used CGM and 35.8% used CSII (38). The use of diabetes MDs varies in different countries (57, 58).

Advantages with diabetes medical devices

Previous studies have shown that use of CGM among adults with T1D is associated with improved glucose control, improved health-related quality of life, and a lower risk of hypoglycaemia and diabetes ketoacidosis compared to SMBG (59-66). Studies have also demonstrated an improved glucose control (67-71), less severe hypoglycaemia episodes (69, 71), and an improved health-related quality of life (65).

when using CSII compared to multiple daily injections of insulin. Improved glucose control reduces the risk of long-term disease complications (72, 73).

Adverse skin reactions to diabetes medical devices

Different adverse skin reactions to diabetes MDs have been reported, such as leukoderma (74), scars and wounds, bruising, and contact dermatitis (1, 75-77). The most common skin reaction reported is contact dermatitis (75). As mentioned before, ACD and ICD cannot be correctly diagnosed and distinguished from one another without patch testing. However, if an individual can use a diabetes MD for a longer period (weeks to months or even years) and then develops a dermatitis within days upon repeated exposures, this pattern indicates sensitisation followed by elicitation of ACD (78). It may be difficult to diagnose ACD to diabetes MDs. Chemical analyses for identification of allergens in the products are not always available, the material available for chemical analyses is limited (79), and the analyses are time-consuming, so it is practically impossible to identify all potential allergens in a product. Not all MD allergens are commercially available for patch testing (80, 81) and the access to patch tests with non-commercially available allergens may vary among patch test clinics (76).

All cases with suspected ACD to diabetes MDs where no relevant contact allergies are found, cannot with certainty be diagnosed with ICD. When diagnosing cases of suspected contact allergy to diabetes MDs, the diagnoses ICD, ACD, ACD? and unspecified contact dermatitis (UCD) can be used (78). The two latter diagnoses are useful when there is uncertainty as to whether the patient has ACD or ICD (78). These differential diagnoses have been further characterised in a letter to the editor (78).

If no relevant contact allergies are identified in an individual that has been able to use a device for a longer time, and then develops dermatitis at every exposure, ACD must still be suspected, and the diagnosis ACD? can be used (78). If the same individual had developed dermatitis on first exposure to the device, the individual might have an ICD or an ACD (to allergen(s) that the individual was already sensitised to from beforehand but that was not identified upon the patch testing). In such cases, if there is uncertainty of whether the individual has ACD or ICD, the diagnosis UCD can be used (78).

Irritant contact dermatitis to diabetes medical devices

In general, a diagnosis of ICD to diabetes MDs requires exposure to skin irritating factors and that no relevant contact allergies are found. Irritants in the diabetes MDs, friction when wearing and removing the device, sweating and occlusion may contribute to the development of ICD to the devices (78). However, ICD is a diagnosis of exclusion and as ACD to diabetes MDs may be difficult to exclude it might be difficult to know whether the patient has an undiagnosed ACD or an ICD.



Figure 3. Allergic contact dermatitis to a device for continuous subcutaneous insulin infusion.
The patient gave consent to the publication of the photo.

Allergic contact dermatitis to diabetes medical devices

A diagnosis of ACD to diabetes MD (Figure 3) requires that an individual with contact dermatitis has contact allergy to allergen(s) that the individual is (sufficiently) exposed to in the device (78). The number of allergen molecules per skin area and the individual reactivity are important for whether an ACD to a MD is elicited or not.

Currently, there is no patch test series that is typically used when investigating suspected contact allergy to diabetes MDs. Different patch test series have been proposed/used in studies and in clinical practice (80-82). Planning of patch testing and relevance assessments are complicated by the fact that materials used in MDs are not sufficiently disclosed. It has also been difficult to obtain information on device content from manufacturers (83). Chemical analyses mainly by gas chromatography-mass spectrometry (GC-MS), have been necessary to identify culprit allergens in the devices. Findings of substances in a MD by chemical analyses must be related to patch test results for the same substances. All substances that are identified may not be culprit allergens causing ACD among users. Chemical analyses can be used prior to patch testing to identify possible allergens to patch test

or after patch testing to assess whether the device contains an allergen causing positive patch test results in a MD user. The amount of a substance/substances found in a device and the individual clinical presentation and reactivity to the same substance(s) in a MD user are important to consider in relevance assessments of contact allergies found.

Chemical analyses with gas chromatography-mass spectrometry

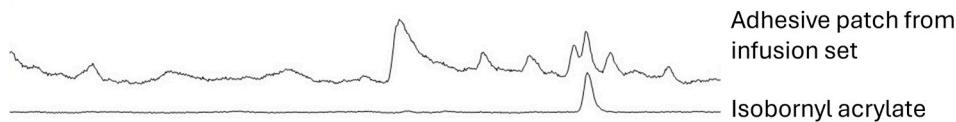
Gas chromatography-mass spectrometry (Figures 4-5) is a method used for separation and detection of substances. In the gas chromatograph the extract is heated and the sample components separated in a column. In the mass spectrometer the molecules are ionised, fragmentised, separated according to the mass to charge ratio and detected (84). The fragmentation pattern (mass spectrum) of a compound is unique and can be used for identification of unknown substances. Suggestions on the content of the sample are given by a mass spectrum reference library. A reference sample is used for verification.



Figure 4. The gas chromatograph-mass spectrometer used at our department.

Co-supervisor, chemist Martin Mowitz, injects an acetone extract of an adhesive patch of an infusion set, for chemical analyses in the gas chromatograph-mass spectrometer at the Department of Occupational and Environmental Dermatology, Skåne University Hospital, Malmö, Sweden.

Total ion chromatogram



Extracted ion chromatogram

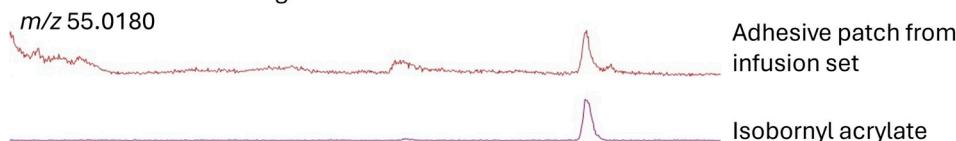


Figure 5a. Results from the gas chromatography-mass spectrometry (GC-MS) analysis. Ion chromatograms.

Total ion chromatogram and extracted ion chromatogram of m/z 55.0180 from the acetone extract of the infusion set, and a reference sample of isobornyl acrylate. If a high degree of matching in retention time and mass spectra is seen in the extract of the sample and in the reference compound, the results strongly indicate that the peak in the sample is the reference compound.

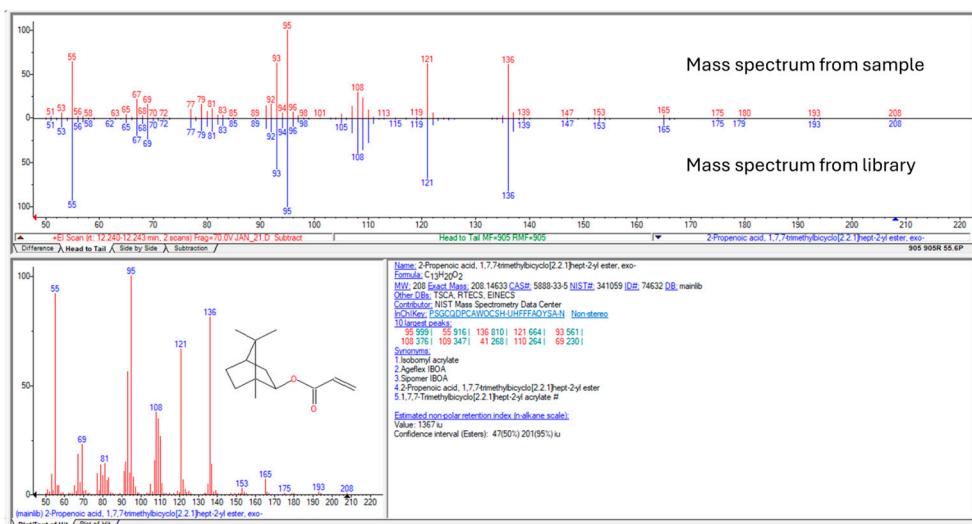


Figure 5b. Results from the GC-MS analysis. Mass spectrum.

Mass spectrum from sample (the acetone extract of the infusion set) matches with isobornyl acrylate in reference library.

Allergens in diabetes medical devices

Several case reports on contact allergy to diabetes MDs (Figure 6a), which have been summarised in reviews (76, 77, 80, 85-91), have been published in recent years. The main culprit allergens in diabetes MDs have been acrylates such as IBOA and 2,2'-methylenebis(6-*tert*-butyl-4-methylphenol) monoacrylate (MBPA) (5, 79, 92-102), *N,N*-dimethylacrylamide (DMAA) (7, 92, 95, 101-103) and colophonium (including modified variants) and colophonium-related substances (79, 97, 98, 102, 104, 105). In recent years, cases of contact allergy to antioxidants (other than MBPA) (81, 106) and isocyanates (98, 99, 102, 107) have also been reported. The allergens are thought to originate from adhesives used in the adhesive patch but also in other parts of the diabetes MDs (5). Light curing adhesives containing acrylate monomers may be used to assemble different parts of the diabetes MDs. When the adhesives are cured, the monomers polymerise, but residual monomers may still be present in the finished product and cause contact allergy among users. Colophonium is used as a tackifier in adhesives (108). Antioxidants are generally used to protect products from degradation.

Allergens reported to be present in diabetes MDs in the last ten years (2016-October 2025) according to chemical analyses or information from manufacturers, and that have been reported to cause contact allergy among users are listed in Figure 6a in chronological order (based on when they were first reported in the scientific literature). In Figure 6b, contact allergy prevalences to selected allergens in DOED's MD patch test series for adults tested 2017-2024 are also shown. The MD patch test series is tested in individuals with suspected contact allergy to diabetes MDs but also in individuals with suspected contact allergy to other MDs. In Table 1, basic information including the chemical structures of the culprit allergens in diabetes MDs, and information on possible sources of exposure outside diabetes MDs are listed. Allergens with an asterisk*, were identified in diabetes MDs as part of this PhD project.

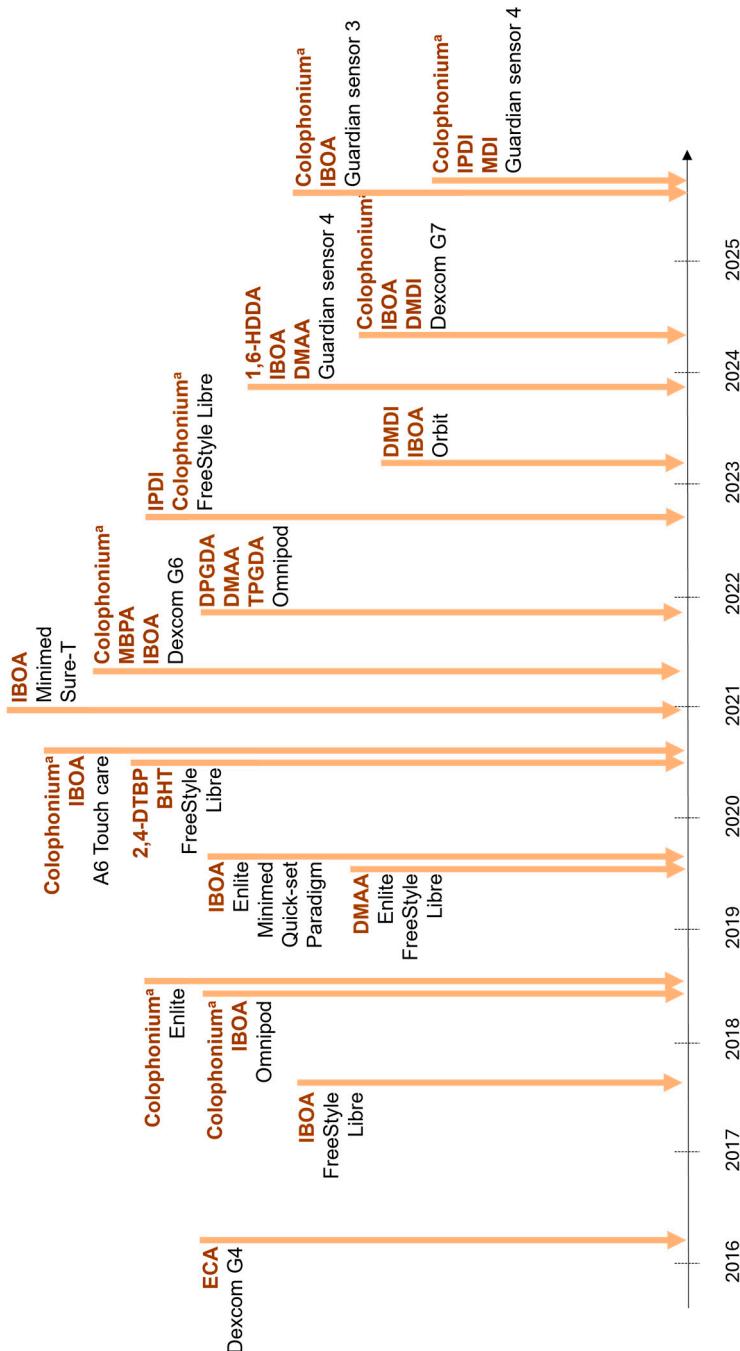


Figure 6a. Timeline with allergens reported to be present in diabetes medical devices 2016-2025^b.

For abbreviations see Table 1

For abbreviations, see Table 1.

^a Colloidal/moistened colloplatinum anion or colloplatinum-derivatives
^b Have caused contact allergy among users. Present in diabetes medical devices according to chemical analyses or information from manufacturers.
Arranged in the order in which the studies were published. Studies published up until 30 October 2025 were included (5, 7, 79, 81, 91-93, 95-102, 104, 105, 107, 109). Device manufacturers are listed in Study V.

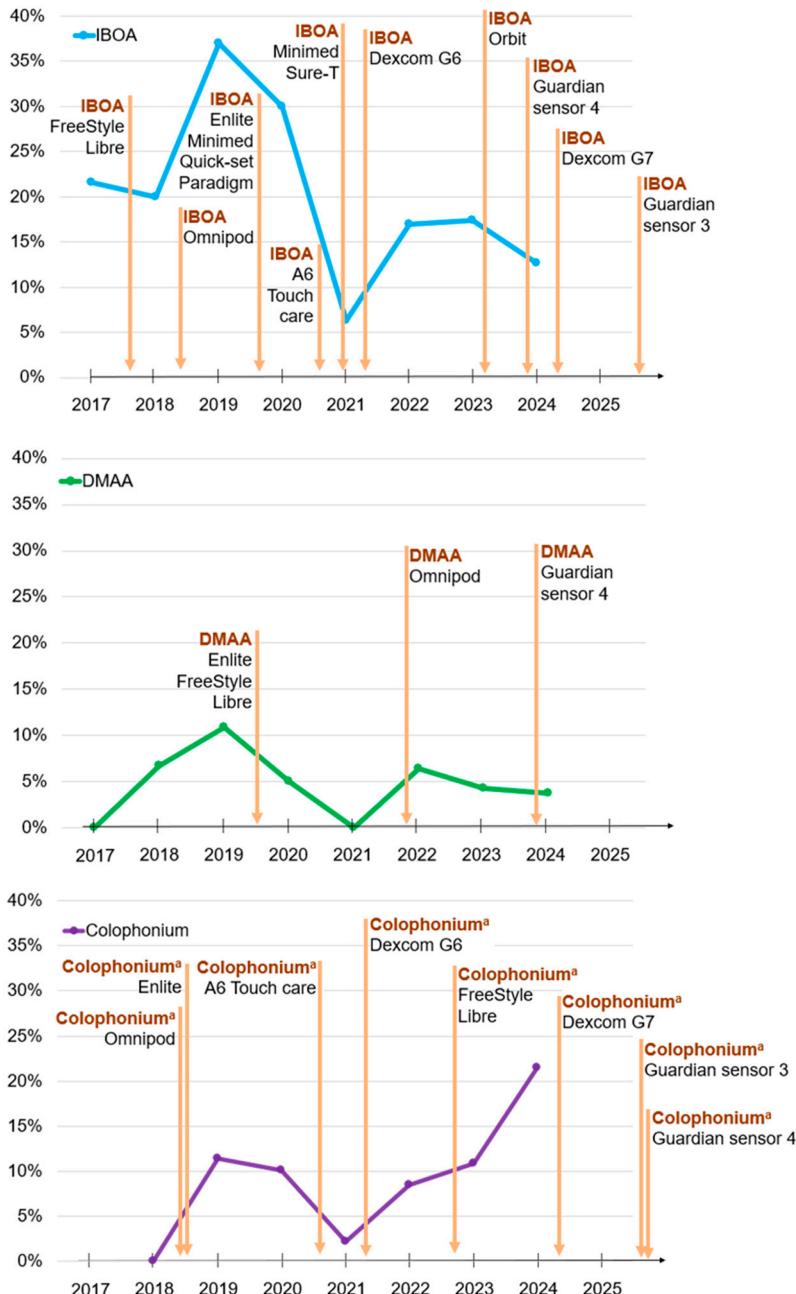


Figure 6b. Contact allergy prevalences for selected allergens in DOED's medical device patch test series 2017-2024 (to be continued).

^a Colophonium/modified colophonium and/or colophonium-derivatives

Abbreviations: DOED, The Department of Occupational and Environmental Dermatology, Malmö, Sweden. For abbreviations, see Table 1.

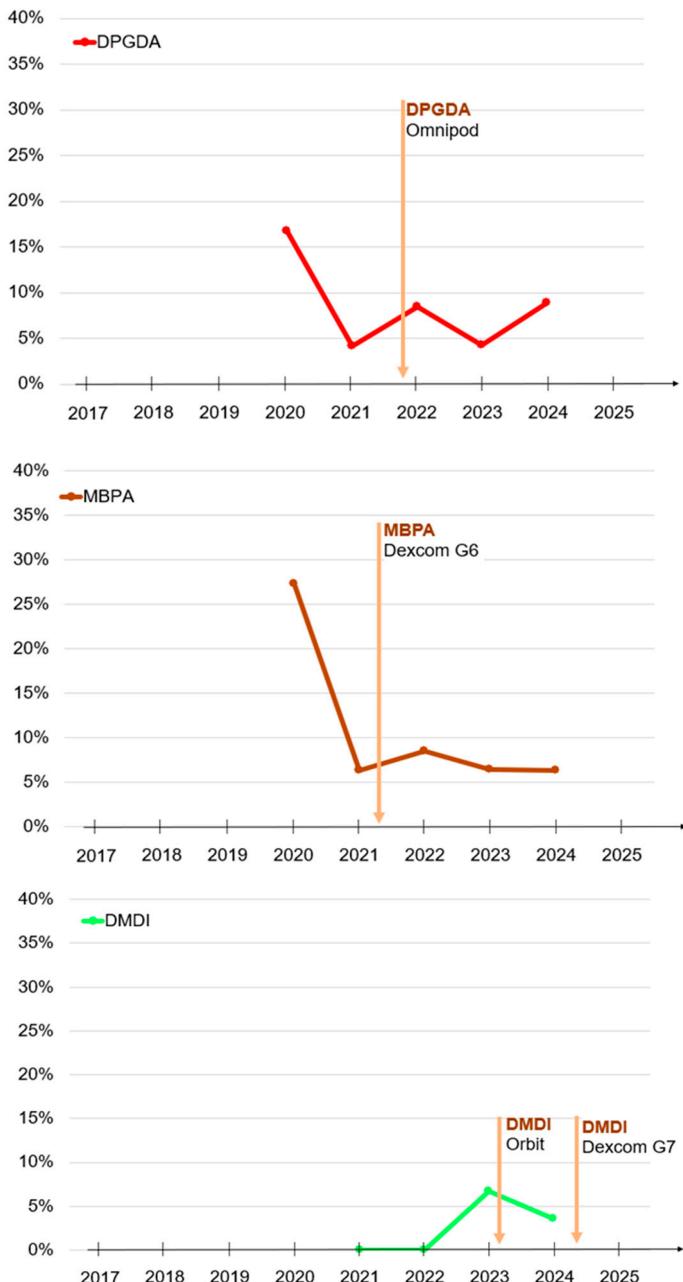


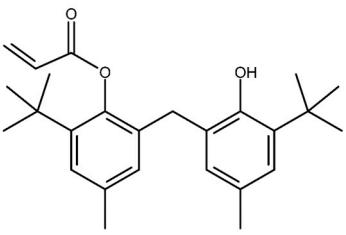
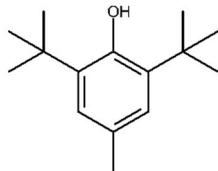
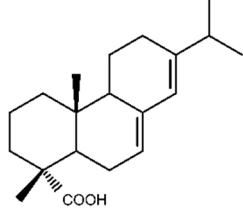
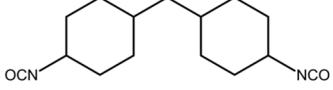
Figure 6b. Contact allergy prevalences for selected allergens in DOED's medical device patch test series 2017-2024 (continued).

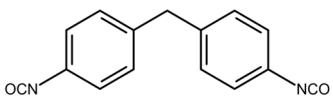
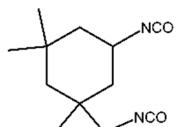
Abbreviations: DOED, The Department of Occupational and Environmental Dermatology, Malmö, Sweden. For abbreviations, see Table 1.

Table 1. Allergens indicated to be present in diabetes medical devices (MDs) in the last 10 years.
 Possible sources of allergen exposure are listed. For allergens that have already been reported to be present in diabetes MDs according to published results, the diabetes MDs in which they have been identified are listed in Figure 6.

Acrylates	
1,6-hexanediol diacrylate (1,6-HDDA) CAS number: 13048-33-4, MW: 226.3. Classified as allergen ^a : yes (skin sensitising 1). MDs: hospital wristband and ostomy materials (110, 111). Exposure outside MDs: materials in printing industry and at a paint factory. Ski boots (112-115).	
2-hydroxyethyl acrylate (2-HEA)* CAS-number: 818-61-1, MW: 116.1. Classified as allergen ^a : yes (skin sensitising 1). Diabetes MDs: FreeStyle Libre (Study V). Exposure outside MDs: UV-cured nail polish, acrylic accessories, face pack, embedding media for electron microscopy and during contact lens manufacturing (116-119).	
Dipropylene glycol diacrylate (DPGDA)* CAS number: 57472-68-1, MW: 242.3. Classified as allergen ^a : no. Exposure outside MDs: UV-cured lacquer and paint (120-122).	
Isobornyl acrylate (IBOA) CAS number: 5888-33-5, MW: 208.3. Classified as allergen ^a : yes (skin sensitising 1A). MDs: hospital wristband, blood pressure cuff, infusion set (123-125). Exposure outside MDs: nail glue and other gel nail products, glue for cell phone protector, in glass fibre production (126-129).	

<p>Tetrahydrofurfuryl acrylate (THFA)* CAS-number: 2399-48-6, MW: 156.2. Classified as allergen^a: no. Diabetes MDs: Orbit infusion set (Study V). Other MDs: adhesive for surgical needles (130). Exposure outside MDs: clip-on earrings (131).</p>	
<p>Tripropylene glycol diacrylate (TPGDA)* CAS-number: 42978-66-5, MW: 300.4. Classified as allergen^a: skin sensitising 1. Exposure outside MDs: coatings of black jack cards, UV-cured inks and nail gel (132-135).</p>	
<p>Cyanoacrylates</p>	
<p>Ethyl cyanoacrylate (ECA) CAS number: 7085-85-0, MW: 125.1. Classified as allergen^a: no. Exposure outside MDs: glue for nails and false eye lashes, handicraft glue and cobbler glue (136-143).</p>	
<p>Acrylamides</p>	
<p>N,N-Dimethylacrylamide (DMAA) CAS number: 2680-03-7, MW: 99.1. Classified as allergen^a: no. MDs: adhesive for surgical needles (130).</p>	
<p>Antioxidants</p>	
<p>2,4-di-<i>tert</i>-butylphenol (2,4-DTBP) CAS number: 96-76-4, MW: 206.3. Classified as allergen^a: no. MDs: wound dressings and sanitary pads (106).</p>	

<p>2,2'-methylenebis(6-<i>tert</i>-butyl-4-methylphenol) monoacrylate (MBPA)</p> <p>CAS-number: 61167-58-6, MW: 394.5.</p> <p>Classified as allergen^a: no.</p>	
<p>Butylated hydroxytoluene (BHT)</p> <p>CAS number: 128-37-0, MW: 220.4.</p> <p>Classified as allergen^a: no.</p> <p>MDs: bandages and wound dressings (106, 144).</p>	
<p>Colophonium and related substances</p> <p>Colophonium is obtained from coniferous trees and may contain more than 100 different substances. Colophonium consists of resin acids (abietic acid is one of the main components in colophonium) and oxidation products (108, 145). Colophonium can be chemically modified (98). Devices/products reported to contain colophonium (including modified variants), colophonium-derivatives and/or colophonium-related substances are listed below.</p>	
<p>Classified as allergen^a: colophonium is classified as skin sensitising 1.</p> <p>MDs: adhesive plasters/tapes, ostomy materials and sanitary pad (102, 146-151).</p> <p>Exposure outside MDs: adhesive in chairs and stickers, wood dust, epilating products, cosmetics, and fluoride varnish (152-157).</p>	<p>Abietic acid</p> 
<p>Isocyanates</p> <p>Dicyclohexylmethane-4,4'-diisocyanate (MDI)*</p> <p>CAS number: 5124-30-1, MW: 262.4.</p> <p>Classified as allergen^a: skin sensitising 1.</p> <p>Diabetes MDs: FreeStyle Libre (Study V).</p> <p>Other MDs: glue used at medical equipment factory (158).</p> <p>Exposure outside MDs: glue for ceramic tiles (159), Chem-Dec 808 isocyanate (160).</p>	

<p>Diphenylmethane-4,4'-diisocyanate (MDI)</p> <p>CAS-number: 101-68-8, MW: 250.3.</p> <p>Classified as allergen^a: skin sensitising 1.</p> <p>MDs: wound dressings and tapes (102, 107).</p> <p>Exposure outside MDs: glue, foam, floor coatings and at factories producing polyurethane products (161-163).</p>	
<p>Isophorone diisocyanate (IPDI)</p> <p>CAS number: 4098-71-9, MW: 222.3.</p> <p>Classified as allergen^a: skin sensitising 1.</p> <p>MDs: wound dressing (107).</p> <p>Exposure outside MDs: paint hardeners and polyurethane resin (163, 164).</p>	

^aAllergens that were identified in diabetes medical devices as part of this PhD project.

^aHarmonised classification as skin sensitiser according to the CLP-regulation of the European Union according to information available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1272-20250901> (Last accessed 251211).

MD, medical device; MW, molecular weight.

Overrepresentation of contact allergy to sesquiterpene lactones and fragrances

Contact allergy to sesquiterpene lactone mix (SLM) has been found to be overrepresented among diabetes MD users. In two previous studies, 33 of 52 (63.5%) (165) and 4 of 13 (30.8%) (81) of the IBOA positive FreeStyle Libre users were positive to SLM and/or SLM-constituents.

The SLM constituents have not been found in diabetes MDs, and the cause of the simultaneous positive reactions have been difficult to elucidate (165). Cross-reactivity between IBOA and SLM has been suggested as an explanation for the simultaneous positive reactions to the substances (166).

Contact allergy to fragrances has also been reported to be overrepresented in IBOA-positive individuals with adverse skin reactions to FreeStyle Libre (100).

Knowledge gap – why did we perform these studies?

When this project was initiated, we had mainly seen patients with ACD to a new CGM. The ACD in these cases was often severe, sometimes oozing. In 2017, IBOA was reported as a main culprit allergen in the sensor (5). Many users had strong positive patch test reactions to IBOA and simultaneous positive patch test reactions to SLM (165) tested in the baseline series. Later, additional cases with ACD to IBOA in a patch pump (109), another CGM and an infusion set (101) were reported. Additional culprit allergens (DMAA and colophonium) were also identified (7, 101, 104). Cases reported in the scientific literature had all been referred to dermatologists for patch testing, and the extent of the problem with ACD to diabetes MDs among overall users was unknown.

In cases referred for contact allergy investigations where the medical history indicated ACD, sometimes no relevant allergies were found. It had been difficult to obtain information on device content from manufacturers, and we suspected that all culprit allergens in diabetes MDs were not yet identified. There was no standardised investigation of the patient group, and it was difficult for dermatologists worldwide to know how individuals with adverse skin reactions to diabetes MDs should be investigated and advised.

CSII has been used in Sweden for many decades whereas CGM were first introduced around 2014 (167). As early as 2016, almost 80% of children with T1D in Sweden were using a CGM (168). Given the increasing use of these devices and the increasing number of reports of contact allergy to the devices we identified a need for further characterisation of the problem in a group of overall diabetes MD users. What is the prevalence of skin rash and contact allergy from diabetes MDs? What are the implications for those affected? Which culprit allergens are seen in the devices? How should the patients be patch tested? Was contact allergy in general (to baseline series) overrepresented in individuals with diabetes using diabetes MDs?

Research questions/overall aim

The aim of this PhD project was to describe the prevalence of skin rash from diabetes MDs, contact allergy to allergens in the devices and to screening allergens in baseline series in adult users with diabetes. Another aim was to illustrate how chemical analyses can be used in investigations of contact allergy to the devices.

- Among adults with T1D in the Southern Swedish Healthcare Region (Halmstad and Växjö) using CGM and/or CSII: What is the prevalence of skin rash from CGM and CSII? What is the prevalence of contact allergy to allergens found in CGM and CSII?
- What culprit allergens are found in CGM and CSII?
- Is the prevalence of contact allergy to baseline series allergens overrepresented in adults with diabetes using CGM and/or CSII compared to general dermatitis patients investigated due to suspected ACD?

Methods

The author participated in the detailed planning of Studies I-V, chemical analyses, planning of patch testing, patch test readings in all patch test studies, construction and distribution of the questionnaire, data curation, data analyses and writing of the ethical application for Studies III-V and wrote all manuscripts.

Participants

Study I

A case series describing personalised diagnostics of ACD to the CSII Omnipod (Insulet, Billerica, USA) in three patients with T1D referred to DOED in 2020 due to device-related skin rash. Cases 1, 2 and 3 were a 40-year-old female, and two males aged 8 and 10, respectively. None of the patients had a history of AD. Their first skin rash appeared after at least 6 months use of the CSII. Upon re-exposure, the skin rash appeared after 1 day. When examined, all cases had eczematous patches where the pump had previously been placed.

In total, 23 adult consecutive dermatitis patients were included as controls.

Study II

A retrospective study in adults with diabetes (diabetes patients) with suspected ACD to diabetes MDs and adult consecutive dermatitis patients (dermatitis patients), that were patch tested at DOED between October 2017 and October 2020. Basic demographic data was extracted from DOED's patch test register.

Studies III-V

Individuals with diabetes

In 2021-2022, all adults (n=1943) followed at the diabetes clinics at the hospitals in Halmstad (n=902) and Växjö (n=1041) due to T1D received a written invitation to participate in the online questionnaire study (Study III) and the respondents were also invited to participate in the patch test studies (Studies IV-V) (Figure 7). The

individuals with diabetes were subcategorised into those with a history of device-related skin rash and those without.

Control dermatitis patients

Adult consecutive dermatitis patients patch tested at the DOED, during the same period, were included as controls in Study IV (Figure 7).

Ethical approval and considerations

Written consent for publication of their cases and clinical photo was obtained from the diabetes patients/parents in Study I. The controls gave consent to participation and data in Studies I and II was used according to the approval by the Swedish Ethical Review Authority dnr 2020-02190. Studies III-V were approved by the Swedish Ethical Review Authority (dnr 2020-03160).

Before the studies were initiated, ethical aspects were thoroughly considered and potential risks and benefits were assessed.

For individuals with skin rash and relevant contact allergies, information on which allergens should be avoided could possibly resolve the dermatitis. For individuals without skin rash, knowledge on their contact allergies could possibly help to prevent future dermatitis.

Patch test concentrations were carefully chosen and the risk of sensitisation during patch testing was weighted against the risk that the patch test concentration was too low to elicit a positive reaction in those sensitised. When possible, commercially available patch test preparations that have been tested worldwide were used. Patch test sensitisation is unusual but strong patch test reactions may occur. If a strong contact allergy resulted in a strong positive reaction that might be itchy, the test reaction could be treated with a strong topical corticosteroid. Therefore, the potential harm for the study participants was considered limited.

Real-world data on skin rash and contact allergy from diabetes MDs can possibly help to guide preventive measures such as removing known allergens from the products, which would be of great benefit for users for many years to come. Altogether, the potential benefits of the research were considered greater than the potential risks for the study participants.

Investigations

Patch testing

Chamber systems and patch test methodology

Patch test routines/methodology in the different studies are shown in Table 2.

Table 2. Overview of patch test systems and test routines in the studies.

	Study I	Study II	Studies IV and V
Chamber system used	Case 1: FCA ^a Cases 2 and 3: IQ Ultimate ^b	FC ^a (before 2018), FCA ^a (from 1 January 2018). IQ Ultimate ^b and IQ Ultra ^b on branched clinics	Individuals with diabetes: IQ Ultimate ^b Control dermatitis patients: FCA ^a
Amounts of test substances applied on chambers(25)	FCA: 20 mg ^c , 15 µL ^d IQ Ultimate: 25 mg ^c , 20 µL ^d	FC, FCA: 20 mg ^c , 15 µL ^d IQ Ultra, IQ Ultimate: 25 mg ^c , 20 µL ^d	FCA: 20 mg ^c , 15 µL ^d IQ Ultimate: 25 mg ^c , 20 µL ^d
Occlusion time	48 hours	48 hours	48 hours
Patch test reading day	Day 3 or 4 and Day 7	Day 3 or 4 and Day 7	Day 3 or 4 and Day 7

FCA, Finn Chambers Aqua; FC, Finn Chambers.

^a SmartPractice, Phoenix, Arizona.

^b Chemotechnique Diagnostics, Vellinge, Sweden.

^c Petrolatum preparations

^d Liquid preparations

Patch test readings

Reading and scoring of patch test reactions were performed according to the ESCD and ICDRG-criteria (25-27).

Overview of patch testing in the different studies

The commercially available patch test substances in Studies I, II, IV and V were provided by Chemotechnique Diagnostics, Vellinge, Sweden. The other test substances were prepared in house. Table 3 shows an overview of what was patch tested in the different studies.

Table 3. Patch test preparations/materials presented in the different studies.

	Study I ^a	Study II ^b	Study IV	Study V
Swedish baseline series	Case 1: all allergens Case 2: selected allergens from CBS Case 3: CBS	x	x	
DOED's MD patch test series	x	x (diabetes patients)		
A new MD patch test series				x
Additional test preparations	DPGDA 0.1% and 0.01% in petrolatum ^c	IBOA 0.1% ^d and 0.3% ^e in petrolatum	Selected allergens from DOED's extended baseline series ^f	
Patients' own materials	Omnipod: adhesive patch ('as is' and acetone extract ^g). The rest of the CSII (acetone extract ^g)			

CBS, children baseline series; CSII, device for continuous subcutaneous insulin infusion; DOED, Department of Occupational and Environmental Dermatology, Skåne University Hospital, Malmö, Sweden; DPGDA, dipropylene glycol diacrylate; IBOA, isobornyl acrylate; MD, medical device.

^aThe allergens tested in all cases are shown. Other allergens and own products tested in some of the cases are described in Study I.

^bPatch test results were extracted from the DOED patch test register.

^cTested in controls.

^dTested in consecutive dermatitis patients at DOED since 2018.

^eTested in consecutive dermatitis patients at DOED since 2020.

^fIBOA, hydroperoxides of limonene and linalool, 2-hydroxyethyl methacrylate and gold (I) sodium thiosulfate dihydrate

^gUltrasonic bath extract (29, 30).

Details on patch test series and allergen groups

The different versions of the Swedish baseline series tested in Studies I-II (Study II, table 2) and Studies IV-V (Study IV, Table 3) consisted of 30 and 29 test preparations, respectively. The version in Study II contained a lower patch test concentration of cobalt(II)chloride hexahydrate, mercapto mix and methylchloroisothiazolinone/methylisothiazolinone than the version used in Studies IV-V. Methylisothiazolinone was included in the version in Study II but not the version in Studies IV-V. Some of the allergens in the Swedish baseline series were divided into allergen groups for statistical analyses in Studies II and IV (Table 4).

Table 4. Examples of allergen groups in the Swedish baseline series.

Allergen groups	Patch test substances included
Fragrance allergens	Colophonium Fragrance mix I and II Lichen acid mix <i>Myroxylon pereirae</i> resin
Preservative allergens	Methylchloroisothiazolinone/methylisothiazolinone ^a Formaldehyde Paraben mix Diazolidinyl urea Methyldibromoglutaronitrile Quarternium 15
Metal allergens	Nickel(II)sulphate hexahydrate Cobalt(II)chloride hexahydrate Potassium dichromate
Rubber allergens	Mercapto mix Black rubber mix Thiuram mix

^a In Study II methylisothiazolinone was also tested as a separate test preparation.

The MD patch test series used at DOED (Studies I and II (Study II, Table 3) has been continuously updated upon identification of new allergens in diabetes MDs. A new MD patch test series was developed for Study V (Study V, Table 1). Included in the MD patch test series were allergens identified in diabetes MDs by chemical analyses at DOED, that had been reported as culprit allergens in MDs according to the literature, substances that were suspected to cross-react with MD allergens, and allergens to which contact allergy was suspected to be more common among individuals with diabetes using MDs than in other patient groups.

In Study V, the term ‘allergens found in diabetes MD’ was used for the allergens in the diabetes MD patch test series indicated to be present in diabetes MDs and that are known to have caused contact allergy among users. Colophonium 20% in petrolatum from the Swedish baseline series was also categorised as an allergen found in diabetes MDs. The other allergens in the MD patch test series in Study V were categorised as MD-related allergens.

Chemical analyses

At DOED, chemical analyses are continuously performed of diabetes MDs used by patients referred to our department due to suspected ACD to these products. Analyses are mainly performed by GC-MS. In general, separate ultrasonic bath extracts are made of the adhesive patch and the rest of the device using acetone as a solvent. The method for GC-MS analysis used at DOED has been described in detail elsewhere (97).

In Study I, chemical analyses with GC-MS were performed of separate acetone extracts of the adhesive patch and the rest of the patients' CSII. Chemical analyses were also performed of acetone extracts from one additional Omnipod pump from the Swedish Omnipod distributor.

Questionnaire

In the online questionnaire (Study III), atopic diseases (a history of childhood AD, asthma and allergic rhinoconjunctivitis), the use of diabetes MDs, and associated skin rash, and treatment attempts were assessed.

Statistical analyses

In the studies, a positive reaction to a group of allergens in a participant was defined as positive reaction(s) to one or more allergen(s) in the group.

Statistical analyses were performed using PASW statistics for Windows, SPSS. A p-value < 0.05 was considered statistically significant.

An independent t-test was used for comparisons of mean age between two groups.

When comparing the proportion of study participants in two groups with a specific outcome, a two sided Pearson's χ^2 test or Fisher's exact test was used for categorical variables such as the prevalence of contact allergy or skin rash, or categorical demographic data.

In Study III, the association between skin rash from diabetes MDs and age, gender, childhood AD, and number of diabetes MDs used were assessed using multivariable logistic regression analyses. The trend for skin rash when using different numbers of diabetes MDs was assessed by linear-by-linear regression.

In Studies IV-V, the prevalence of contact allergy between two groups was compared using multivariable logistic regression, adjusting for age and gender. McNemar's test was used to compare the prevalence of positive reactions to IBOA patch tested in different test concentrations in the same individual.

Overview of studies included

In Table 5 and Figure 7 an overview of the studies included is shown.

Table 5. Overview of studies included.

Study	Study design	Participants	Main outcomes
Study I	Case series	Cases with allergic contact dermatitis to Omnipod	- Patch test results - Relevance assessment - Chemical analyses of Omnipod
Study II	Retrospective study	Adults referred to DOED (diabetes patients and dermatitis patients)	- Patch test results for the Swedish baseline series, IBOA and DOED's MD patch test series
Study III	Cross-sectional questionnaire-based study	Adults with T1D	- History of diabetes MD use and device-related skin rash
Study IV	Cross-sectional patch test study	Adults with T1D using diabetes MDs Control dermatitis patients	- Patch test results for baseline series allergens
Study V	Same as Study IV	The same as in Study IV, but without controls	- Patch test results for the MD patch test series

DOED, The Department of Occupational and Environmental Dermatology, Skåne University Hospital, Malmö, Sweden; IBOA, isobornyl acrylate; MD, medical device; T1D, type 1 diabetes.

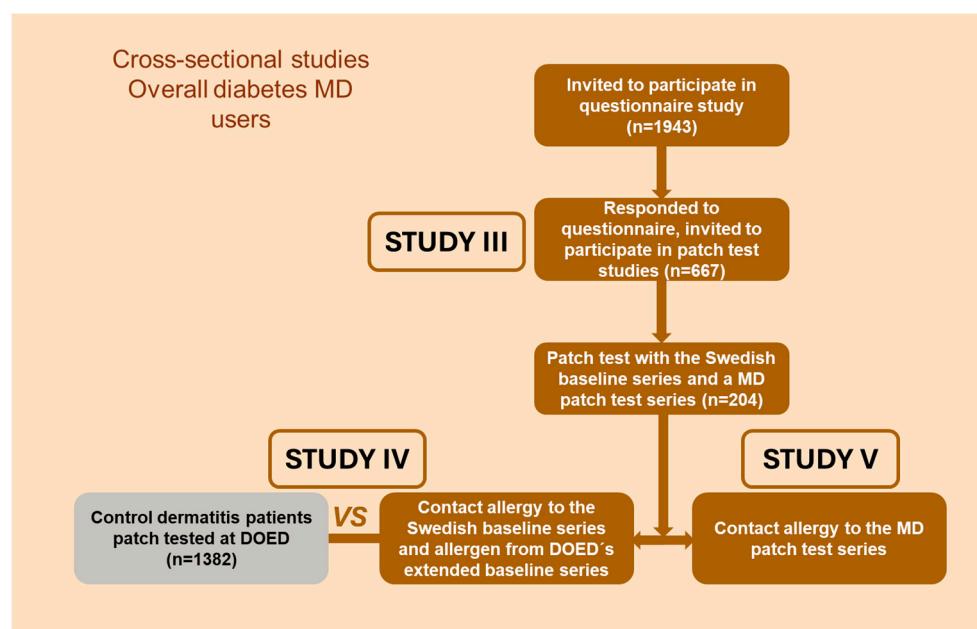


Figure 7. Overview of study participants in Studies III-V.

DOED, The Department of Occupational and Environmental Dermatology, Skåne University Hospital, Malmö, Sweden; MD, medical device; n, number.

Results

Study I

Chemical analyses

In the extracts of the patients' Omnipod pumps, a total of 1-10 μ g dipropylene glycol diacrylate (DPGDA) was identified in the adhesive patch and the rest of the CSII, respectively. IBOA, DMAA, di(ethylene glycol) ethyl ether acrylate and tripropylene glycol diacrylate (not quantified) were identified in the Omnipod from the Swedish distributor, but not DPGDA (<0.03 μ g/ml).

Patch test results

The three cases had positive reactions (+++, + and +) to DPGDA tested at concentration 0.1% in petrolatum. Cases 1 and 2 also had positive reactions (+-reactions) to the 0.01% concentration. Case 1 had additional positive reactions to several other acrylates (Table 6) and DMAA. Case 1 had positive reactions (+-reactions) to the Omnipod adhesive patch tested 'as is' and acetone extracts of the adhesive patch and the rest of the pump.

Table 6. (Meth)acrylates that yielded positive reactions in Case 1.

Dipropylene glycol diacrylate
1,6-hexanediol diacrylate
Isobornyl acrylate
2-Phenoxyethyl acrylate
Tetrahydrofurfuryl acrylate
Ethyl acrylate
1,4-Butanediol diacrylate
Butyl acrylate
Diethylene glycol diacrylate
Hydroxypropyl acrylate
Triethylene glycol diacrylate
Trimethylolpropane triacrylate
Tripropylene glycol diacrylate

Study II

In total, 2621 individuals (54 diabetes patients and 2567 dermatitis patients) were included. The prevalence of AD was higher in the control dermatitis patients than the diabetes patients (28.1% vs. 13.0%, $p=0.014$). There was no significant difference in mean age and the proportion of males in the two groups.

Swedish baseline series and isobornyl acrylate

Positive reactions to SLM were seen in 13% of the diabetes patients and 0.5% of the dermatitis patients ($p<0.001$). Positive reactions to fragrance mix (FM) II were seen in 7.4% of the diabetes patients and 2.3% of the dermatitis patients ($p=0.041$).

Positive reactions to IBOA were seen in 63.0% of the diabetes patients and 0.2% of the dermatitis patients ($p<0.001$). The prevalence of positive reactions to SLM was significantly higher in the IBOA-positive diabetes patients (20.6%) than the IBOA-negative diabetes patients (0%, $p=0.038$).

No other significant differences in contact allergy prevalences were seen between the groups (diabetes patients vs. dermatitis patients, and IBOA-positive diabetes patients vs. IBOA-negative diabetes patients).

Medical device patch test series

Of the diabetes patients, 70.4% were positive to at least one of the allergens in the MD patch test series.

Study III

Of the 1943 individuals with diabetes invited to participate, 667 completed the questionnaire (34.3%). Their mean age was 49.8 years ($SD=17.6$). The proportion of male and female respondents were 52.7% and 47.3%, respectively. The prevalence of childhood AD was 21.4%.

Use of diabetes medical devices

In Figure 8, the number of CGM and CSII users is illustrated. The diabetes MDs that had been used by ≥ 50 participants were FreeStyle Libre (n=589), FreeStyle Libre 2 (n=198), Guardian sensor 3 (n=92), Dexcom G6 (n=94), the MiniMed CSII (n=172) and Omnipod (n=54).

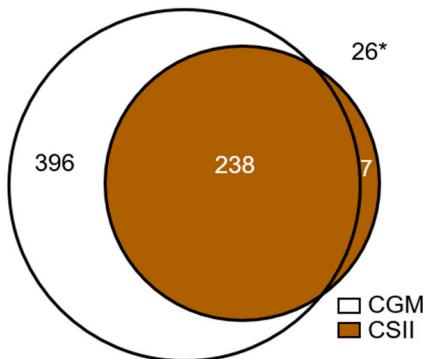


Figure 8. Number of CGM and CSII users in Study III.

Abbreviations: CGM, continuous glucose monitor; CSII, device for continuous subcutaneous insulin infusion.
*Have not used CGM or CSII

Skin rash from diabetes medical devices

Among CGM users, 42.1% had experienced skin rash from the devices. Among CSII users, 44.9% had experienced skin rash from the devices. Of those with a history of device-related skin rash, 4.5% had been patch tested prior to this study. For the diabetes MDs used by ≥ 50 respondents, depending on which diabetes MDs they used, 18.0-56.5% of the users had to change to a new MD more often than recommended and 4.0-18.0% had to stop using the devices, due to skin rash.

Factors associated with skin rash from diabetes medical devices

Factors that were significantly associated with skin rash from diabetes MDs in multivariable regression analyses are listed in Table 7.

Table 7. Factors significantly associated with skin rash from diabetes medical devices^{a, b}

	n=570	Adjusted OR for skin rash from diabetes MDs (95% CI)
Age	18-49 years	2.07 (1.40-3.07)
	≥ 50 years	1
History of childhood AD	Yes	2.04 (1.29-3.25)
	No	1
Number of diabetes MDs^a used	1	1
	2	1.88 (1.18-2.98)
	3	5.31 (3.07-9.19)
	4	9.15 (4.50-18.60)
	≥ 5	15.10 (4.94-46.18)

AD, atopic dermatitis; CI, confidence interval; MD, medical device; n, number; OR, odds ratio.

^a Factors included in the multivariable analysis: age, gender, childhood AD, and number of diabetes MDs used.

^b Adapted from Table 3, Study III.

Treatment of medical device-related skin rash

More than half of those with a history of skin rash from diabetes MDs had tried at least one treatment. The most common treatments were over the counter/weak corticosteroid creams (31.0%), prescribed/strong corticosteroid creams (9.9%), barrier sprays and solutions (25.0%) and barrier patches (8.8%).

Studies IV and V

Of the 667 participants in the questionnaire study (Study III), 204 participated in the patch test studies. Of the 204, 114 had experienced skin rash from diabetes MDs. In total, 1382 control dermatitis patients were included.

The individuals with diabetes had a significantly higher mean age than the control dermatitis patients (50.1 vs. 44.0 years, $p<0.001$). The proportion of males was significantly higher among the individuals with diabetes than the control dermatitis patients (46.6% vs. 31.3%, $p<0.001$). The prevalence of childhood AD was 23.9% in the individuals with diabetes and the lifetime prevalence of physician-diagnosed AD was 35.3% in the dermatitis patients.

Contact allergy to baseline series allergens

Individuals with diabetes and control dermatitis patients

Positive reactions to the Swedish baseline series were seen in 34.3% of the individuals with diabetes and 39.6% of the control dermatitis patients (adjusted p -value = 0.30). A significantly lower prevalence of positive reactions to preservatives was seen in the individuals with diabetes than in the control dermatitis patients (3.9% vs. 8.8%, adjusted p -value = 0.022). For the other allergen groups in the Swedish baseline series (fragrances, metals, rubber allergens), no significant differences were seen between the two groups.

In Table 8, the baseline series allergens with significantly different prevalences of positive reactions in the individuals with diabetes and control dermatitis patients are shown.

Subgroups of individuals with diabetes

The prevalence of positive reactions to the individual allergens and allergen groups in the Swedish baseline series were not significantly different in the individuals with diabetes with rash than in those without rash from diabetes MDs. However, all SLM positive had experienced device-related rash (and had simultaneous positive reactions to IBOA).

Table 8. Baseline series^a allergens with significantly different contact allergy prevalences in individuals with diabetes and control dermatitis patients^b.

Patch test preparation	Individuals with diabetes n= 204	Dermatitis patients	Adjusted p-value ^c
Myroxylon pereirae resin 25% pet.	17 (8.3%)	52/1373 (3.8%)	0.0033
Sesquiterpene lactone mix 0.1% pet.	5 (2.5%)	4/1377 (0.3%)	0.0011
Isobornyl acrylate 0.3% pet.	20 (9.8%)	3/1331 (0.2%)	<0.001
Potassium dichromate 0.5% pet.	1 (0.5%)	54/1373 (3.9%)	0.039

DOED, The Department of Occupational and Environmental Dermatology, Skåne University hospital, Malmö, Sweden; n, number; Pet., petrolatum.

^a The Swedish baseline series and selected allergens from DOED's extended baseline series.

^b Adapted from Study IV, Table 3.

^c Adjusted for age group and gender.

Contact allergy to allergens found in diabetes medical devices

Positive reactions to allergens found in diabetes MDs were seen in 33 of the 204 (16.2%) individuals with diabetes and the prevalence was significantly higher (28.1%) in those who had experienced device-related skin rash than in those who had not (1.1%, adjusted p-value <0.001). Of the 33 individuals, 32 had a history of skin rash from diabetes MDs. Contact allergy was seen to over 10 allergens found in diabetes MDs; the five allergens with highest prevalences of positive reactions are listed in Table 9.

Table 9. The five allergens found in diabetes MDs with highest contact allergy prevalences in the individuals with diabetes.

Patch test preparation	Rash to diabetes MDs		
	All (n=204)	Yes (n=114)	No (n=90)
Isobornyl acrylate 0.3% pet.	20 (9.8%)	19 (16.7%)	1 (1.1%)
Isobornyl acrylate 0.1% pet.	11 (5.4%)	10 (8.8%)	0
N,N-Dimethylacrylamide 0.3% pet.	10 (4.9%)	10 (8.8%)	0
2-Hydroxyethyl acrylate 0.1% pet.	7 (3.4%)	7 (6.1%)	0
Dicyclohexylmethane-4,4'-diisocyanate 1.0% pet.	6 (2.9%)	6 (5.3%)	0
1,6-hexanediol diacrylate	4 (2.0%)	4 (3.5%)	0

MD, medical device; n, number; pet., petrolatum.

Patch test recommendations

In Study V (Table 3), suggestions for a MD patch test series updated in 2025 are presented. The test series includes allergens found in diabetes MDs, additional fragrances that are not included in the Swedish baseline series, and SLM constituents. Patch testing of the adhesive patch of the MDs 'as is' and in ultrasonic bath extract and an acetone extract of the rest of the device is recommended.

Discussion

When this PhD project was initiated, skin rash from diabetes MDs had been reported as common among diabetes MD users in Denmark (75, 169). In line with their findings, a high prevalence of device-related skin rash (around 40%) was seen in our questionnaire study. We suspected that contact allergy to allergens found in diabetes MDs was common among overall users, which was later confirmed as around 15% of diabetes MD users from Halmstad and Växjö had contact allergies to allergens found in diabetes MDs. The device-related skin rash had implications for those affected including changing to a new device more often than recommended or discontinuing use of their MDs due to the skin rash. Once sensitised to allergens in diabetes MDs, ACD can be elicited upon renewed allergen exposure from many different sources (Table 1).

Since 2020, when the PhD project was initiated, several new culprit allergens have been identified in diabetes MDs (Figure 6a and Table 1). Many allergens have been identified by chemical analyses at DOED. Preventing or reducing adverse skin reactions and contact allergy to diabetes MDs is important as use of these devices in individuals with diabetes (especially T1D) is essential to reduce or postpone disease-related complications or even premature death. These skin reactions including ACD add to the already heavy burden of the diabetes disease (170). Although use of diabetes MDs is associated with an increased health-related quality of life (65), it has also been shown that skin rash to diabetes MDs increase the disease burden in adults with T1D (169). Among the individuals patch tested in Studies IV-V, a significantly lower health-related quality of life (measured by dermatology life quality index) was seen in those with current skin rash from diabetes MDs than in those without (Källberg K et al., in manuscript).

Contact allergy to medical device allergens

Contact allergy to medical device allergens related to skin rash

The high prevalence of contact allergy to allergens found in diabetes MDs among individuals with device-related skin rash compared to those without indicates that these contact allergies are related to skin rash from the devices and are clinically relevant.

However, since we did not patch test the participants in Study V before they started to use their diabetes MDs, we cannot know if they were sensitised before or after initiation of these devices. However, we analysed the time to first and subsequent device-related skin rashes among those of the 33 individuals with contact allergy to allergens found in diabetes MDs that reported skin rash to one diabetes MD (Study V, figure 2, n=12). For eight of the 12 individuals the time between first use and first skin rash was more than 6 months, for three individuals more than one month and in only one individual less than one week. On subsequent exposures, all 11 participants (data was missing for one respondent) developed skin rash within 14 days (four within 1-2 days, four within 3-4 days and three within 8-14 days). This pattern indicates sensitisation followed by elicitation of ACD while using the diabetes MDs.

Most prevalent contact allergies to medical device allergens

The contact allergy pattern seen in diabetes MD users in a specific geographical region will depend on which products are used in the area. The allergens found in diabetes MDs with the highest contact allergy prevalences in Study V (IBOA, DMAA, 2-hydroxyethyl acrylate (2-HEA), dicyclohexylmethane-4, 4'-diisocyanate (DMDI) and 1,6-hexanediol diacrylate (1,6-HDDA)) are presented below.

Isobornyl acrylate

IBOA is an acrylate monomer used in UV/light-curing adhesives (4, 5) and a well-known sensitiser in diabetes MDs. IBOA was initially reported as a culprit allergen in insulin infusion sets in 1995 (94), since when it has been reported as a culprit allergen in at least ten other diabetes MDs (Figure 6).

Cross-reactivity

Cross-reactivity between IBOA and SLM has been proposed as an explanation for the simultaneous positive reactions to SLM in those sensitised to IBOA (165, 166), as the patch test reaction to SLM was stronger when SLM was re-tested at the localisation of a previous positive IBOA-patch test reaction (166). However, to confirm whether cross-reactivity between the substances occurs, animal studies would be required, such as guinea pig maximisation tests.

Three of the four isobornyl methacrylate(IBOMA)-positive individuals with diabetes in Study V, had simultaneous positive reactions to IBOA. Simultaneous positive reactions to IBOA and IBOMA have been reported in a previous study, where three of four IBOA positive patients had simultaneous positive reactions to IBOMA. The authors (100) proposed cross-reactivity between the substances as an explanation for the simultaneous positive reactions, but concluded that neither concomitant exposure in diabetes MDs nor sensitisation to IBOMA from other sources of exposure could be ruled out. IBOMA has been reported as an ingredient

in long-lasting nail polish and a glue for a cell phone screen protector (100, 171) and, although unlikely, primary sensitisation to IBOMA with cross-reactivity to IBOA is also at least theoretically possible.

Patch testing with isobornyl acrylate

A patch test preparation of IBOA 0.1% in petrolatum is commercially available, but there is no commercially available patch test preparation of the 0.3% concentration. IBOA 0.3% has detected more IBOA-allergic individuals than IBOA 0.1% (Study V) (81), so the 0.3% concentration should be patch tested to avoid false negative reactions. In a study from 2012 (126), suspected irritant reactions to IBOA 0.3% were reported in three of 14 individuals with known acrylate allergies. However, among the 204 participants in Study V and the 1331 controls (Study IV, Table 3), no irritant reactions were seen, and no signs of active sensitisation to IBOA 0.3% in petrolatum were reported.

Prevalence of contact allergy in different settings

The prevalence of positive reactions to IBOA among cases with suspected ACD from diabetes MDs referred for patch testing has been reported to be around 60-90% (81, 103, 172, 173) (Study II).

In previous studies, the prevalence of IBOA allergy among overall diabetes MD users has been estimated from the number of referred cases diagnosed with contact allergy divided by the total number of users in the referral area. Among FreeStyle Libre users such estimates of IBOA allergy have ranged from 0.8-4.2% (103, 172, 173). In Study V, the prevalence of positive reactions to IBOA among all participants was higher (10.3%). Assuming that diabetes MD users with skin rash were more inclined to participate in Study V, the prevalence found might be an overestimation. However, the prevalence found in the previous studies (103, 172, 173) where IBOA at 0.3% concentration was not tested and where all cases were probably not referred for patch testing, is likely an underestimation.

Low prevalences of IBOA allergy (0.2-0.6%), have been found in consecutive dermatitis patients (Studies II and IV)(174). However, some cases of ACD from IBOA in non-diabetes MDs and other consumer products (Table 1) have been reported and when first sensitised to IBOA from diabetes MDs, ACD can more easily develop when re-exposed to the substance in other settings.

N,N-dimethylacrylamide

DMAA is used as a monomer in UV/light-curing adhesives (7). It has been reported as a culprit allergen in the FreeStyle Libre sensor in 2019 (7) and in several other diabetes MDs (Figure 6 and Study V, Table 1) since then. In a previous study (81), DMAA was patch tested at both 0.1% and 0.3% concentration. In one of four DMAA positive individuals, positive reactions were seen only to the 0.3% concentration, which has since been used for patch testing at DOED. IBOA and DMAA have been reported to be present simultaneously in UV-curing adhesives (7,

175). In a previous study, six of seven patients with ACD to FreeStyle Libre had simultaneous positive reactions to DMAA and IBOA (7). In Study V, nine of ten of the DMAA-positive participants had simultaneous positive reactions to IBOA, most likely due to concomitant exposure.

2-hydroxyethyl acrylate

2-HEA is an acrylate monomer used in coatings, paints and adhesives (176, 177). In previous studies, concomitant positive reactions to IBOA and ethyl acrylate (EA) as well as 2-HEA have been reported among FreeStyle Libre users (4, 5, 91, 165). In Study V, 2-HEA was identified in the Freestyle Libre sensor by GC-MS analyses at DOED. Two of the 2-HEA positive participants in Study V had simultaneous positive reactions to EA and even though cross-reactivity between the substances can be suspected, sensitisation to both substances due to concomitant exposure in the diabetes MDs cannot be ruled out. Chemical analyses with GC-MS at DOED have not identified EA in the sensor, but the analytical method used in the GC-MS analyses was not optimal for detecting the smallest, most volatile acrylates, and the presence of low amounts of EA in diabetes MDs cannot be ruled out. ACD to 2-HEA due to both occupational and non-occupational exposure has previously been reported (Table 1).

Dicyclohexylmethane-4, 4'-diisocyanate

DMDI is an isocyanate used in polyurethane production. Isocyanates and polyurethane are used in a variety of products such as lacquers and adhesives (158). Only one case of DMDI contact allergy in a child with ACD from the Orbit infusion set (99) and Dexcom G7 (98) has previously been reported from our department, and DMDI was indicated to be present in these devices. In Study V, DMDI was indicated to be present in the FreeStyle Libre sensor by GC-MS analyses at DOED and six of the users with skin rash had positive reactions to the substance (Study V). However, it has been reported that isocyanate monomers were formed during heating of polyurethane coatings (178). During GC-MS analyses, the analysed sample is heated, and possibly isocyanates could be formed by polyurethane degradation, which makes it more difficult to know for certain whether isocyanate monomers were originally present in a product analysed. Therefore, further chemical analyses of diabetes MDs using another type of chemical analysis (such as liquid chromatography-mass spectrometry) may be necessary for isocyanate identification.

Previously, cross-reactivity to DMDI and 4,4'-diaminodiphenylmethane (MDA) has been reported in guinea pigs sensitised to diphenylmethane-4,4'-diisocyanate (MDI), whereas cross-reactivity to MDI and MDA was not reported in guinea pigs sensitised to DMDI (179). In Study V, no positive reactions were seen to MDI (and MDA was not tested). However, in recently published studies, an overrepresentation of contact allergy to MDI, toluene-2,4-diisocyanate (TDI) and isophorone

diisocyanate (IPDI), has been reported among individuals with skin rash from diabetes MDs (102, 107). Both MDI and IPDI have been identified in diabetes MDs and reported to cause contact allergies among users (102, 107). Therefore, MDI, MDA (as a marker of MDI contact allergy), DMDI and IPDI are all important allergen to patch test when investigating suspected ACD from diabetes MDs (Study V, Table 3) (80).

1,6-hexanediol diacrylate

1,6-HDDA is an acrylate monomer used in lacquers, UV-curing inks, and different MDs (Table 1). In a recently published article (102), it was highlighted that individuals with diabetes that are positive to 1,6-HDDA often have simultaneous positive reactions to multiple (meth)acrylates. In line with this, Case 1 in Study I had many simultaneous positive reactions to several acrylates (Table 6) including a +++-reaction to 1,6-HDDA that was not identified in the CSII. The four 1,6-HDDA-positive individuals in Study V had ++ or +-reactions to 1,6-HDDA. Positive reactions to other (meth)acrylates were seen in two of the cases. One of them was positive to tetrahydrofurfuryl acrylate (THFA), IBOA and IBOMA and the other to THFA, IBOA, di(ethylene glycol) ethyl ether acrylate, 2-HEA and EA. All cases except the last mentioned had experienced skin rash from Guardian sensor 3 and/or 4 in which 1,6-HDDA has been identified (92) (Study V, Table 1).

In a previous study (180), four guinea pigs sensitised to 1,6-HDDA had positive reactions when challenged with EA, pentyl acrylate, 1,5-pentanedioldiacrylate, 1,2-ethanedioldimethacrylate, 1,4-butanedioldimethacrylate and 1,6-hexanedioldimethacrylate. THFA was not tested in this study (180). As neither the content of diabetes MDs nor the cross-reactivity pattern between all (meth)acrylates are fully known, it is difficult to elucidate whether simultaneous exposure to several (meth)acrylates, cross-reactivity or a combination of these factors is the cause of the simultaneous positive reactions. The purity of patch test materials must also be considered (100). As cases of ACD to 1,6-HDDA from multiple sources of exposure (from MDs to industrial products and ski boots (Table 1)) have been reported, those sensitised to 1,6-HDDA may develop ACD when in contact with this substance in different settings.

Medical device content changes over time

As the content of diabetes MDs changes, new contact allergy patterns can be seen among users (93) (Figure 6). Consequently, the main culprit allergens in Study V (performed in 2021-2022) may not be the main culprit allergens if patch testing were to be performed in another group of diabetes MD users today.

There are several examples showing that the content of even the same diabetes MDs has changed over time. IBOA was the first culprit allergen reported in Omnipod

(Figure 6). In Study I, DPGDA had taken the role as the new main culprit allergen. However, the content of the other Omnipod pump provided by the distributor differed from both previous versions analysed (Study I). The content of the CGM Dexcom G6 has also been reported to have changed over time. Initially, cases of ACD to IBOA in the sensor were reported (79), then the adhesive was changed and MBPA identified as a new culprit allergen (93).

The contact allergy prevalences for MD allergens have changed over time in those tested at DOED (Figure 6b). In Study II, the prevalences of IBOA and DMAA allergy among referred patients with suspected contact allergy to diabetes MDs decreased from 2017-2020 to 2021-2022. In 2021-2022, high prevalences of contact allergy to DPGDA and MBPA were seen, and these allergens had recently been identified in diabetes MDs used by individuals with diabetes in DOED's referral area. In recent years, the prevalences of contact allergy to colophonium and related substances have increased among those tested with the MD patch test series at DOED (Figure 6b) and since 2023 methyl hydrogenated rosinate and glyceryl hydrogenated rosinate (modified colophonium) are routinely tested in individuals with suspected contact allergy to diabetes MDs.

Repeated chemical analyses are necessary to stay updated on the content of diabetes MDs. Hopefully more information on which substances are used in diabetes MDs will be provided by MD manufacturers in the future.

Contact allergy to fragrances

In Study II, contact allergy to FM II was overrepresented in individuals with skin rash from diabetes MDs but not significantly associated with IBOA allergy. In Study IV, contact allergy to *myroxylon pereirae* resin (MP) was overrepresented in individuals with diabetes (compared to consecutive dermatitis patients) but not associated with skin rash from diabetes MDs. GC-MS analyses have identified the MP constituents benzyl benzoate and benzyl cinnamate in a diabetes MD (181), but it is not known whether the individuals with diabetes are allergic to these substances.

At DOED, the prevalence of positive reactions to MP varied from 3.0 to 6.6% in 2020-2025 and was towards the lower end of the interval in 2021-2022 when the control dermatitis patients in Study IV were patch tested. The control dermatitis patients and the individuals with diabetes were not tested with the same batch of MP or the same test chamber system, which might have influenced the results.

Other possible explanations for the overrepresentation of fragrance allergy have been discussed in Studies II and IV, but the cause of the higher prevalence of fragrance allergy among individuals with diabetes using diabetes MDs is not known and needs clarification.

Patch testing when suspecting allergic contact dermatitis from diabetes medical devices

In Study V Table 3, a recommended diabetes MD patch test series updated in 2025 is presented. Similar series have previously been published (80, 81) (Study II), but we still do not know which patch test series is most optimal. The suitability of a series depends upon the geographical exposure profile and, as the device content changes over time, the series needs to be continuously updated.

When patch testing was performed in Studies IV-V, late-appearing reactions after Day 7 were reported by three of the 101 individuals patch tested in Växjö. These reactions are reported in detail in a separate manuscript (Svedman et al., submitted). At retesting, positive reactions were seen to fragrance substances, DMDI, DMAA and (meth)acrylates that were not positive within ordinary reading days at the initial testing. All three cases were positive to 2-hydroxyethyl methacrylate (2-HEMA), hydroxypropyl methacrylate (HPMA), and 2-HEA at retesting but not (within ordinary reading days) at the initial patch testing. The possibility of late-appearing reactions to these substances has previously been reported (182, 183). The test reactivity upon retesting was analysed for the three cases. None of the cases reacted to the substances that were positive within ordinary reading days for the first time at retesting when these substances were diluted 100 times. When the substances were diluted 10 times, late-appearing reactions after 10 days were seen as in the initial testing. This pattern indicates that the cases were most probably pre-sensitised to the substances to which they had late-appearing positive reactions at the initial testing, and that they were most likely not sensitised during the patch testing.

The three individuals had all experienced skin rash from diabetes MDs, and two of them also to other MDs (ECG-electrodes and a skin tape). Simultaneous positive reactions to these three (meth)acrylates (2-HEMA, HPMA, and 2-HEA) have previously been reported and, since cross-reactivity to (meth)acrylates is common it is difficult to know to which allergen(s) these individuals were primarily sensitised (184, 185). However, when investigating cases of suspected ACD from MDs it is important to be aware that late-appearing patch test reactions can occur and that the patients should be informed, to avoid missing late-appearing but still relevant positive reactions. As it is well known that positive patch test reactions to (meth)acrylates tend to appear late, a reading on Day 7 is mandatory (78).

Rash without allergies – what is/are the cause(s)?

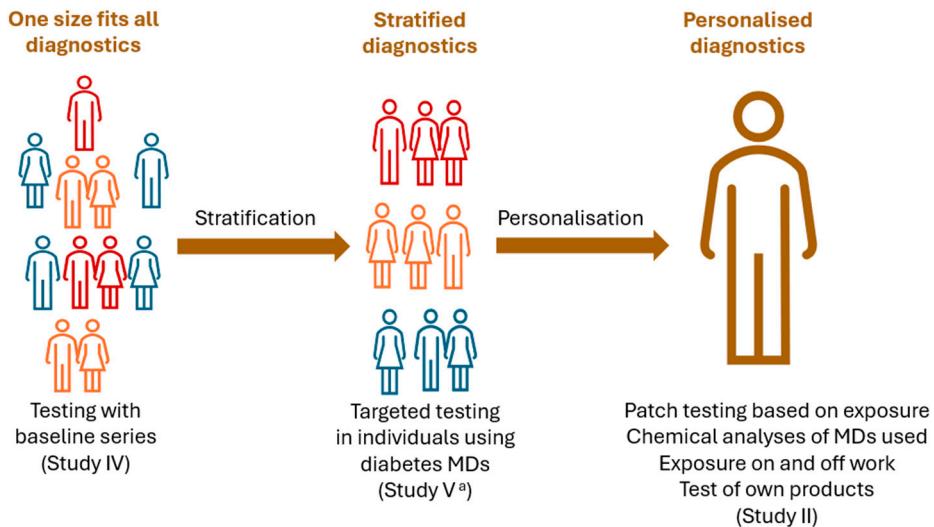
In Study V, patch testing was performed with both commercially and non-commercially available patch test substances and according to updated chemical analyses of diabetes MDs used among the study participants. Despite this, contact allergy to allergens found in diabetes MDs was only seen in around 30% of the diabetes MD users with a history of device-related skin rash.

It is reasonable to suspect that not all allergens in the diabetes MDs have yet been identified and were therefore not patch tested.

Some substances known to cause contact allergy to diabetes MDs have not previously been routinely patch tested or even classified as allergens (such as MBPA (93)). At DOED, patch test concentrations of some MD allergens have been adjusted over time. IBOA was initially tested at the concentration 0.1% in petrolatum (Study II), while today the 0.3% concentration is tested. MBPA was initially tested at concentrations 0.1% and 0.3% in petrolatum (Study II) but is today tested at the concentration 1.5% in petrolatum (Study V). It might be that not even the currently used test concentrations in the MD series are all optimal.

Due to incomplete patch testing, non-optimised patch test concentrations and the fact that the patients' own materials (e.g. their MDs) were not patch tested in Study V, some cases without diagnosed contact allergies to allergens found in diabetes MDs might still have had an ACD. In clinical practice we still see cases where ACD from diabetes MDs is strongly suspected but where no relevant contact allergies are found. The likelihood of detecting contact allergies to diabetes MDs increases when the contact allergy investigation is tailored according to the individual exposure (Figure 9). All participants in Study V were tested with an adapted MD series, but the patch test investigations were not personalised in the same way as in Study II. Without chemical analyses of the patients' MDs in Study II and tailored patch testing including DPGDA, ACD from the CSII would not have been diagnosed.

Negative patch test results despite a clinical suspicion of ACD from diabetes MDs is also a well-known clinical problem in other departments (186). Depending on the access to a MD patch test series adapted to cover the exposure among MD users in the referral area, access to chemical analyses and non-commercially available test preparations, the likelihood of detecting the relevant contact allergies may vary between clinics (187). Today, laboratory equipment to identify allergens in diabetes MDs (such as GC-MS) is only available at a few centres worldwide. Diabetes MDs are complex and contain many different substances (188). Chemical analyses of the products are time-consuming and therefore not possible to conduct for all patients referred. If more information on device content was available from manufacturers, many resources spent on chemical analyses of these devices could be saved.



MDs, medical devices.

^aIn the study further optimised by chemical analyses of procured diabetes MDs in the region.

Figure 9. Diagnosis of allergic contact dermatitis to diabetes medical devices.

Different levels of diagnostics of allergic contact dermatitis from diabetes medical devices from screening to personalised patch test investigations.

A history of childhood AD was associated with skin rash from diabetes MDs (Study III) but not with contact allergy to allergens found in diabetes MDs (Study V). As we know that AD is a risk factor for ICD, it is reasonable to assume that ICD from diabetes MDs might be overrepresented among individuals with a history of childhood AD (189). Some cases with skin rash from diabetes MDs without contact allergy to allergens found in diabetes MDs might have had ICD.

Skin rash (definition used in Studies III-V) is a broad definition, and the clinical manifestations were not physician diagnosed. A closer clinical examination would have been necessary to further evaluate the cases without MD contact allergies, as other clinical manifestations than contact dermatitis could have been present (75).

A wider perspective on the problem

Based on clinical experience from investigating cases of adverse skin reactions such as ACD from diabetes MDs including those seen in this PhD project, some obstacles/problems have been identified. Some of them, together with possible solutions, are presented below.

The problem is underdiagnosed

In Study III, less than 5% of the individuals with skin rash from diabetes MDs had been referred for patch testing. It was more common that they used strong corticosteroid creams (requiring a prescription in Sweden) or barrier patches, for which there is limited evidence of a treatment effect (190-192).

Cases that are referred for patch testing will also likely be underdiagnosed with ACD.

Potential solution: An increased awareness of adverse skin reactions including contact allergy to diabetes MDs and potential benefits with contact allergy investigations can increase the number of cases referred. An awareness campaign on adverse skin reactions and contact allergy to diabetes MDs is planned in Sweden in 2026, as an initiative from a focus group on skin rash from diabetes MDs with representatives from the MD industry, the Swedish Medical Product Agency, and health-care professionals (dermatologists and endocrinologist).

It is evident that the diagnostic accuracy would increase if more information on device content was provided by the manufacturers and if additional patch test substances (Study V, Table 3)(80) are made commercially available for patch testing (187).

The problem is underreported

According to the Swedish Medical Products Agency (personal communication) they have received 157 reports from health care professionals on adverse skin reactions from diabetes MDs between 2020 and September 2025. In total, 84 of the 157 reports (53.5%) have been sent from DOED. As around 18% of the Swedish population live in the Southern Swedish Healthcare Region which is the referral area to DOED (193), this indicates an uneven distribution of the number of reports sent across the country. A minority of the participants in Study III had been referred for patch testing and even if cases can be reported without a certain diagnosis it might be that those that are not referred are not reported either. Without reports on adverse skin reactions there is no available real-world data on the extent of the problem (36).

Potential solution: Greater awareness of the importance of referring and reporting cases is needed. It is important for clinicians to receive feedback on their reports and to know whether these have resulted in for example a change in content of a MD or improved labelling of allergen content. This would probably increase the incentive to report cases with adverse skin reactions to medical products agencies and manufacturers.

Limited possibilities for secondary prevention

The same allergens have been found in many different diabetes MDs (Figure 6) (91). Many of the 33 individuals with contact allergy to allergens found in diabetes MDs in Study V had experienced skin rash from more than one diabetes MD. If the content of the MDs is unknown, it is difficult to advise those sensitised on how to avoid re-exposure. For other products such as cosmetics (194), ingredient labelling is required. It is surprising that no similar demands exist for diabetes MDs that are prescribed by health care professionals and are widely used also among children and adolescents (83).

Potential solution: If the substances (or at least known allergens) used in MDs were declared, those already sensitised could be better advised on how to avoid re-exposure (83).

If users and prescribers of MDs were alerted when known allergens are removed from the products (195), they would know when the products are safe to use for those sensitised.

Primary prevention is insufficient

MDs are continuously used in close skin contact. When first introduced in diabetes MDs, neither MBPA (93), DPGDA, DMAA nor IBOA were classified as allergens but still caused contact allergies among users. MDs consist of many different components that may be supplied by different manufacturers. However, the manufacturer of the diabetes MD must consider the release of potential allergens from all materials in the final product before it is released on the market. After a product is released on the market, there will always be a delay before culprit allergens are identified, cases of ACD are diagnosed and the device content may be changed (36).

As several cases of contact allergy to allergens in MDs have been reported in the last ten years, many allergens in the products are well known (Study V, Table 1). Nevertheless, 'new' diabetes MDs released on the market still contain known allergens (98) (Figure 6a).

Potential solution: Known allergens should be avoided in diabetes MDs or their concentration lowered. However, in users already sensitised to allergens found in diabetes MDs (Study V, Table 1), lower amounts of the allergens may still elicit a dermatitis.

A better primary toxicological assessment of new/altered MDs is needed before they are released on the market or their content is changed (36). Some studies on the effectiveness of *in vitro* methods to assess the sensitising capacity of known allergens in diabetes MDs have recently been published. IBOA, colophonium and MBPA were predicted as skin sensitisers by Keratinoscens (196, 197). However,

MBPA is still not classified as a skin sensitisier according to the CLP regulation (93). *In vitro* methods may also be a promising tool to use in the assessment of the sensitising potential for mixtures of substances used in diabetes MDs/the devices.

After MDs are released on the market, manufacturers should also closely monitor trends for adverse skin reactions in a real-world setting (36).

Importance

This PhD project contributes to increasing the overall understanding of skin rash and contact allergy from substances in diabetes MDs. By highlighting important aspects all the way from production of diabetes MDs to investigation and reporting of adverse skin reactions and implications for those affected, it is relevant not only to individual users and their health care professionals but also to manufacturers, authorities within the European Union, and medical products agencies. During the PhD project, new hypotheses have been generated, for example regarding the possible association between AD and T1D and possible explanations for the late-appearing patch test reactions to (meth)acrylates. These hypotheses may help to guide future research.

Diabetes medical device users

The individuals with diabetes that participated in the patch test studies have been informed about their contact allergies and, as far as possible, on how to avoid future allergen exposure to prevent elicitation of ACD. They have received a diagnosis and an explanation of the cause of their adverse skin reactions. With increased awareness of skin rash and contact allergy from diabetes MDs, more individuals are likely to be investigated for contact allergy and receive evidence-based recommendations for their adverse skin reactions.

Prescribers of diabetes medical devices

For endocrinologists, paediatricians and diabetes nurses, knowledge on the prevalence of skin rash and contact allergy from diabetes MDs and associated clinical implications is useful when informing patients about possible adverse events prior to use of the MDs. If clinicians address possible adverse skin reactions to diabetes MDs on follow up as part of routine clinical practice, early detection and relevant contact allergy investigations are facilitated.

Dermatologists

Dermatologists investigating cases of suspected contact allergy to diabetes MDs will have increased knowledge about contact allergy to diabetes MDs and which allergens are important to patch test.

Medical device manufacturers

Adhesive manufacturers and MD manufacturers have been provided with new information on which allergens to avoid in their products. Greater understanding of the clinical benefits (for users, prescribers of diabetes MDs and patch testing dermatologists) of labelling diabetes MDs can encourage manufacturers to be more transparent about product contents.

Manufacturers of patch test preparations

For manufacturers of patch test preparations knowledge on relevant allergens will help guide which patch test preparations are important to make commercially available for patch testing.

Staff responsible for procurement of diabetes medical devices

Staff responsible for procurement of diabetes MDs can use the information on contact allergy prevalences to MD allergens to set up requirements for which substances must not be present in procured products.

Authorities within the European Union

Authorities within the European Union may work to restrict the permitted amounts of the known main culprit allergens in the MDs. It may also be possible to introduce stricter requirements on declaration of the content of the products.

Medical products agencies

Medical products agencies such as the Swedish Medical Products Agency can work to increase awareness of skin rash and contact allergy from diabetes MDs and increase the number of reports on adverse skin reactions and contact allergy.

Methodological considerations and possible limitations

Low response rate

The response rates in the questionnaire (Study III) and patch test studies (Studies IV-V) were low, which means that the results in the study population may not represent the target population. Efforts were made to limit the number of questions (including the number of mandatory questions) in the questionnaire (Study III) to increase the response rate. Unfortunately, a low response rate in questionnaire studies is not unusual (198-200).

If participants with skin rash from diabetes MDs were more inclined to respond to the questionnaire and be patch tested, the prevalence of skin rash and contact allergy from MD allergens would be overestimated. However, the prevalence of skin rash was in line with previous studies (75, 169) and the group of participants without a history of skin rash from diabetes MDs in the patch test study was relatively large, possibly indicating that this selection bias was rather limited.

Our studies present real-world data in a group of diabetes MD users, the vast majority of whom used the FreeStyle Libre sensor. The number of users was lower for other diabetes MDs, and further studies might be needed to investigate adverse skin reactions from other diabetes MDs. The contact allergy pattern to allergens found in diabetes MDs will change over time and depend on exposure, which limits the generalisability of the contact allergy pattern seen among the study participants in the studies included in this thesis.

No control group of device-naïve participants

A limitation in Studies IV-V is that no control group of individuals with T1D that had not used diabetes MDs could be included. The ideal study design to investigate the contact allergy prevalence among diabetes MD users would be to patch test individuals with diabetes both before and after use of diabetes MDs has been initiated. This would enable conclusions to be drawn on possible ways of sensitisation. However, for practical reasons this might be difficult or impossible since use of diabetes MDs is often started shortly after diagnosis of T1D. In such a setting contact allergy investigations might not be prioritised.

Questionnaire

A similar questionnaire to the one used in Study III had been tried as a pilot and then been further adapted (81) to include the models of diabetes MDs used at the diabetes departments from where the study participants were recruited.

When available, validated questions such as “Have you had childhood eczema?” were used. This question has been used in dermatological questionnaire studies to assess the prevalence of childhood AD (201-207) in an adult population. However, the question might overestimate the prevalence of childhood AD (208). The prevalence of childhood AD among the study participants (Studies III-V) was high, and further studies on AD among individuals with T1D are called for.

Skin rash was self-reported in the questionnaire. A more precise definition of the adverse skin reactions would have been possible if the current skin rashes were physician-diagnosed.

Patch testing

As previously highlighted, all allergens in diabetes MDs were probably not tested. However, the allergens tested were tested in a standardised way.

In Studies I and II, due to the retrospective study design, not all participants were tested with the same allergens. In contrast, in Studies IV and V, all individuals with diabetes were patch tested with the same test substances, the same batches of allergens, and the same test chambers.

In all studies, patch testing was standardised. However, it is well known that patch test results differ over time if patch testing is repeated in the same individual (209). The contribution of seasonal variations (210) and hormonal factors (phases in the menstrual cycle) (211) have previously been highlighted. An interindividual

variability in patch test readings (212) has also been described. Even though DOED is a clinic with great experience in patch testing in a standardised way both in studies and clinical practice, these potential pitfalls need to be taken into consideration.

Future studies

Additional studies on skin rash and contact allergy in individuals with diabetes and individuals with diabetes using diabetes MDs are needed. Patch test studies in other geographical areas and among larger groups of diabetes MD users are called for.

A prospective study where individuals with diabetes are patch tested before and after the use of diabetes MDs is initiated would contribute to our understanding of the contact allergy pattern in individuals with diabetes in general vs. individuals with diabetes using diabetes MDs.

Further studies on the impact of adverse skin reactions and contact allergy to diabetes MDs on both health-related quality of life and health economy are also needed.

Since the use of diabetes MDs is needed for individuals with diabetes, further studies on primary prevention of skin rash and contact allergy from diabetes MDs (possibly with *in vitro* methods) and the effect of secondary preventive measures such as the use of barrier patches are needed.

Summary and conclusion

Around 40% of CGM and CSII users with T1D in Halmstad and Växjö had experienced skin rash from the devices. The skin rash negatively affected treatment compliance. Despite that, a minority of those affected had been referred for patch testing. Contact allergy to allergens found in diabetes MDs was seen in slightly over 15% of the 204 individuals with T1D that were tested. The prevalence was significantly higher in those with skin rash from diabetes MDs than without. The main groups of allergens found in diabetes MDs are acrylates and acrylamides, isocyanates, antioxidants, colophonium and related substances. Contact allergies were seen to over ten different allergens that have been found in diabetes MDs. The allergens with highest contact allergy prevalences were IBOA, DMAA, 2-HEA, DMDI, and 1,6-HDDA.

We have exemplified how personalised investigations of contact allergy to diabetes MDs could identify a new allergen (DPGDA) in a CSII. Furthermore, chemical analyses and a tailored patch testing based on the individual exposure can be used i) to diagnose ACD to diabetes MDs and ii) to identify new culprit allergens in the products, and iii) to perform relevance assessments of the contact allergies found.

The overall prevalence of contact allergy to allergens in the Swedish baseline series was not significantly different in the individuals with diabetes using diabetes MDs and consecutive dermatitis patients. However, contact allergy to sesquiterpene lactones and some fragrances (MP and FM II) was significantly more common among the individuals with diabetes. Contact allergy to SLM was associated with IBOA allergy whereas FM II allergy was not. Contact allergy to MP was neither related to IBOA allergy nor rash from the diabetes MDs.

This PhD project has shown that skin rash and contact allergy from diabetes MDs are common, that the problem is underdiagnosed in clinical practice, and has implications for those affected. It has highlighted the main culprit allergens in the devices and the importance of chemical analyses.

Although many individuals already benefit from the use of diabetes MDs, a better primary and secondary prevention of MD-related contact allergies is needed. Joint efforts from manufacturers, health care professionals and medical product agencies are needed to make this possible. Such efforts would make a difference for millions of diabetes MD users worldwide for many years to come.

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ADVERSE SKIN REACTIONS to medical devices for glucose monitoring and insulin infusion are undesired treatment complications. Increased knowledge on the magnitude of these reactions and the main allergens involved are important first steps towards achieving successful prevention of these complications ahead.

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