

JDDG: Journal der Deutschen Dermatologischen Gesellschaft / Early View

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Modern diabetes devices for continuous blood sugar measuring: Limitations due to contact allergies

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First published: 09 November 2021

<https://doi-org.bibliosan.clas.cineca.it/10.1111/ddg.14621>

Summary

During the past years, diabetes diseases have increased significantly worldwide. However, new technologies such as continuous glucose measurement using a subcutaneous sensor are developing just as rapidly. A continuous improvement in insulin pump therapy is also contributing to an improved quality of life.

A common feature of these modern devices for diabetes therapy is that they remain fixed in place on the skin for several days. In recent years, skin reactions, in particular pronounced contact dermatitis due to the devices and their adhesives have been increasingly reported. In particular, isobornyl acrylate, which used to be included in a glucose measurement sensor set, was identified as a main allergen. Development of contact allergy can result both in a necessity to quit the measuring system and in allergic cross-reactions to other systems.

Modern technical tools in diabetes therapy

Diabetes mellitus is a disease that is increasing all over the world. According to the German Diabetes Aid, more than 8 million people in Germany currently suffer from diabetes type 1 or type 2 [1], with the number of unrecorded cases for the latter being significantly higher than assumed. More than 30,000 of the 350,000 patients affected by diabetes type 1 are children and adolescents. In this autoimmune disease, the insulin-producing beta cells of the pancreas are irreversibly destroyed by antibodies. Underlying causes are genetic changes and other factors (for example, infections with coxsackieviruses). Type 1 diabetics, but also many type 2 diabetics, have to take insulin for the rest of their lives and monitor their blood glucose several times a day. Especially in recent years, the therapy and quality of

life of diabetes patients have been markedly improved thanks to increasingly sophisticated techniques, such as continuous glucose monitoring in tissue.

A common feature of these new devices is that they are fixed on the skin for several days. This leads increasingly to unwanted irritative dermatitis and in the worst case to contact allergies to sensor components [2, 3]. In recent years, this has resulted in numerous publications on previously irrelevant or unknown contact allergens. We selected individual publications to provide an overview of the new diabetes tools and the associated challenges in the field of contact allergy.

Insulin pump therapy

In conventional insulin therapy, the patient injects an insulin bolus with rapidly acting human insulin with each meal; corrections are required in case of high blood sugar levels or for snacks between meals. In addition, long-term insulin is required every twelve to 24 hours for basic regulation. As an alternative, pump therapy has been available for years. Here, insulin is delivered via a tube connected to a subcutaneous catheter fixed in the skin for three days. The acceptance of these pumps is particularly high among children and athletes. Adjustment of the basic rate or the spontaneous delivery of an insulin bolus, if levels are too high or in case of larger appetite, can now be done conveniently via smartphone. The Omnipod® patch pump is a tubeless insulin pump adhered directly onto the skin, mainly in the periumbilical region. After adhesion, automatic needle insertion is activated by a key on the remote control (*Personal Diabetes Manager*). Since the tube and connected pump is perceived as annoying, especially during the night, the patch pump is becoming increasingly popular.

Continuous glucose monitoring

In recent years, blood sugar monitoring, in particular, has been greatly facilitated by the development of sensors. An increasing number of diabetes patients prefer the continuous reading of their glucose levels via an electronic system, for example by means of the smartphone, over the measurement of sugar on the fingertip. Modern glucose monitoring systems, with a measuring filament that is currently applied under the skin for up to 14 days, can, to a large extent, monitor blood sugar levels continuously. Trend arrows in the receiver's field of view indicate whether the blood sugar level is stable, increasing, or decreasing. Counter regulation via food intake or insulin delivery is possible at any time. Modern information technology is paving the way for new digitalization options. Whereas initially, the only software developed was for the analysis of glucose levels, now virtual data transfer and analysis can be performed via the cloud and customized supporting instructions for daily life can be reported back to the patient (patient-centered decision systems).

Currently, a distinction is still made between continuous glucose monitoring (CGM), for

example with Dexcom® (Figure 1) or Enlite®, and *Flash* glucose monitoring (FGM), for example with Freestyle Libre® (Figure 2). The first generation of Dexcom® was approved already in 2006, but only in recent years has there been a rapid increase in its use.



Figure 1

[Open in figure viewer](#) | [↓ PowerPoint](#)

Dexcom® G6 on the upper arm.





Figure 2

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Freestyle Libre® on the upper arm.

The current model Dexcom® G6 is worn for ten days on the abdomen or the upper arm. The sensor and patch are then removed and the sensor is applied to another location. Glucose levels are permanently (that is, every 5 minutes) and automatically sent to the receiver and displayed as a curve (which is it is also called continuous monitoring). The measured values are transmitted via Bluetooth to a receiver, usually the smartphone. Imminent hypoglycemia is indicated by an alarm sound, which is particularly helpful at night or during sports activities.

With the Freestyle Libre® from Abbott, blood sugar monitoring underwent a real transformation. This monitoring system was introduced in Germany in 2015. The sensing element is inserted into the skin via a “stamp” and currently can remain at this location for 14 days. The glucose levels are only transmitted if the associated scanner or a mobile phone are held in close proximity to the sensor. This technology will also be further optimized in the near future. The process itself is called “*Flashing*”. With approximately 300,000 users in Germany and approximately 3.5 million worldwide, this remains the most frequently used sensor (personal communication from the work group Diabetes & Technology of the German Diabetes Society).

The introduction of the Eversense® from Roche Diabetes Care in 2018 saw the first sensor to be implanted under the skin on one side of the upper arm. Currently, it has a lifetime of six months. Directly above the sensor, a transmitter is fixed on the skin with a double-sided adhesive patch that requires daily replacement according to the manufacturer’s recommendations. To date, primarily local infections and skin irritations have been reported [4].

Closed loop

With the system known as “artificial pancreas”, a decade-old dream in diabetology is slowly

becoming reality. In a closed loop between sugar monitoring device and insulin pump, the pump automatically reduces or increases insulin delivery based on the determined glucose levels. The system is not yet working fully autonomously: the patient must enter the estimated quantity of carbohydrates postprandially and confirm the insulin administration suggested by the pump. Moreover, two conventional blood sugar measurements are required every day in order to “calibrate” the sensor. This system has now officially been approved in Germany. The sensor and the patch pump or the catheter patch of an insulin pump are also adhered to the skin.

Contact allergy as a result of the new diabetes technologies – a search for clues

Until 2017, there were only a few reports of skin reactions to medical devices for diabetes, such as pumps and sensors. With the spread of the new technologies, especially a few months after introduction of the Freestyle Libre[®], an increasing number of skin problems in association with this sensor were described.

In 1995, two patients with allergic contact dermatitis to the infusion set of the insulin pump were reported for the first time. At that time, isobornyl acrylate (IBOA) was identified as a component of the UV-hardened adhesive used to fix the catheter needle to its plastic holder with direct skin contact. In 2016, the case of a child was published that had developed allergic contact dermatitis to its Dexcom[®] G4 CGM. Ethyl cyanoacrylate, a component of the adhesive attaching the sensor to the skin patch, was identified as trigger [5]. At that time, the manufacturer responded rapidly and developed a thermal procedure for attaching the sensor to the skin patch without the intermediate adhesive layer [6].

Apart from skin patch adhesives, additional triggers of an allergic reaction may be adhesions on the undersides of sensors and patch pumps, on measuring filaments of the sensor and on catheter needles.

It was only after the introduction of the Freestyle-Libre[®] sensor that reports of skin reactions to diabetes devices, some of them severe, began to accumulate. In 2015, in one of the first studies on the use of this sensor over a period of 14 days, skin symptoms were reported with an incidence of < 9 % [7]. 0.5 % of the 72 study participants developed marked pruritus and 4 % suffered from “moderate” erythema [7]. In March 2016, the membership magazine *Insuliner* launched a survey among users, who had already had the sensor for months. More than two thirds of Freestyle Libre[®] users described skin reactions under the sensor that were not further differentiated [8]. At that time, it was not yet possible to differentiate between irritative and contact-allergic dermatitis.

Due to the 14-day wearing period, users suffer more often from intermittent irritative dermatitis. Although this is unpleasant, it can largely be managed by various care procedures. The much rarer contact allergy has far greater consequences: usually, it

requires the premature removal of the sensor set after several days. The contact area presents with erythema and small blisters, usually with yellowish exudate (Figure 3).

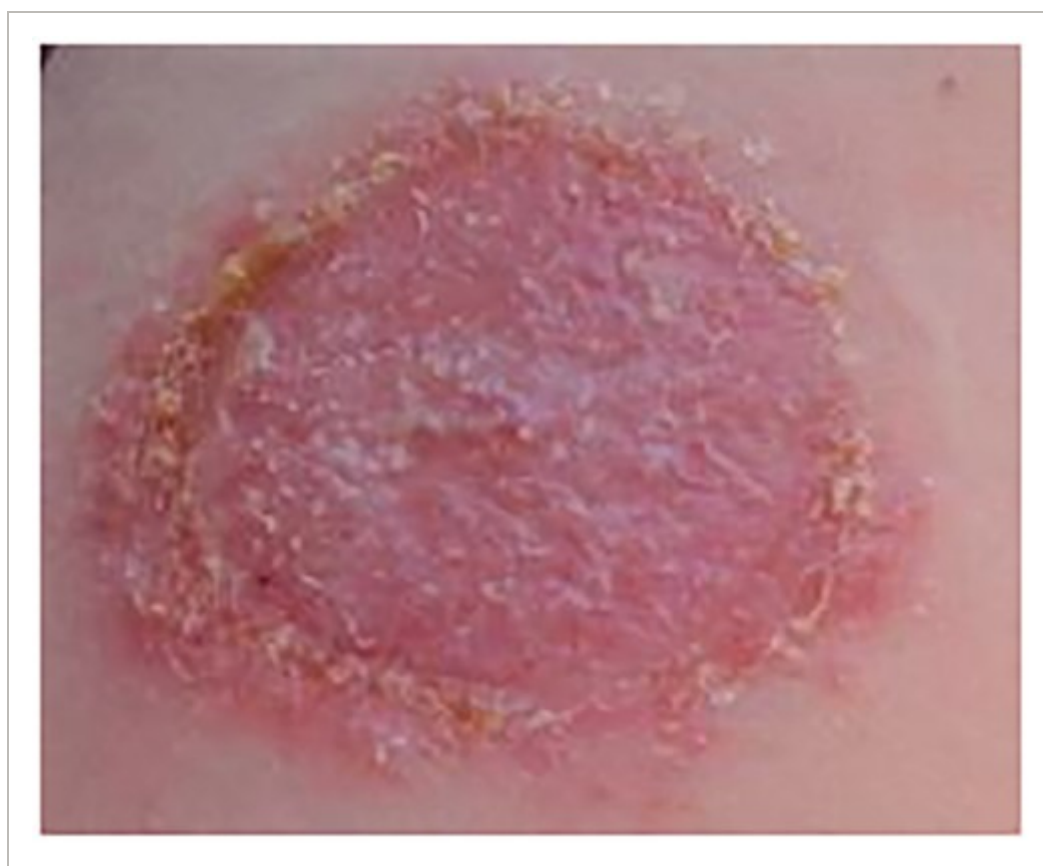


Figure 3

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Contact allergy to Freestyle Libre®.

The adhesive of the Freestyle Libre® patch (the skin patch to which the sensor is attached) consists of an acrylate polymer. Adhesive polymers are usually produced from three different acrylates. While polymers from acrylates are generally considered as hypoallergenic, no polymer is free of acrylate monomers that have strong allergenic potency. Physical effects, such as friction and heat, may also result in release of monomers [9]. In particular, sensitization is also promoted by repeated exposure over several years and the at times prolonged contact time of the allergens on the skin. In this manner, even otherwise rather insignificant or only weakly sensitizing contact allergens may grow in relevance.

For a long time, the triggering contact allergen in Freestyle Libre® could not be identified with the common patch test series (standard, glues and plastics series, dental materials). In addition, patch tests with the original patches and adhesive layers, respectively, provided by the patch supplier of Freestyle Libre®, Adhesive Research, did not show any reaction in serial testing of our patients in early 2017 (not published). This pointed to a different source, for example in the sensor housing itself. Strikingly, some affected patients also developed

allergic dermatitis against the patch pump Omnipod® after manifestation of the contact allergy to Freestyle Libre®.

Isobornyl acrylate

Eventually, in mid-2017, a Belgian-Swedish work group succeeded in identifying the main allergen of Freestyle Libre® [10]. Using gas chromatography, chemists in the interdisciplinary work group were able to detect isobornyl acrylate (IBOA) in the sensor set. Twelve of 13 patients were also positive in the patch test with IBOA 0.1 %.

Subsequently, we tested IBOA 0.1 %, which was kindly provided by the authors, in a boy with Freestyle-Libre® allergy. Here, we also observed a positive reaction after 48 and 72 hours [11].

Similarly, the majority of our tested patients with Freestyle-Libre® allergy showed a positive reaction in patch tests for IBOA 0.1 %. Previously, these patients had shown no reaction to the plastics/glues block and testing of the original patches of Freestyle Libre® had also provided negative results [11, 12].

In the meantime, IBOA was also detected in the patch pump Omnipod® by gas chromatography, while the corresponding skin patch was free of IBOA [13, 14]. This clearly demonstrated that the allergen IBOA in the patch pump Omnipod® is – similar to Freestyle Libre® – derived from the adhesion on the bottom side of the plastic housing, but not from the skin patch.

Additionally, IBOA has also been detected, by gas chromatography, in Medtronic's Enlite® sensor, both in the sensor housing itself and in the skin patch [12, 15, 16].

The concentrations of IBOA measured by gas chromatography in the respective eluate (3 days, methanol) are 2.64 µg/ml for Freestyle Libre®, 1.11 µg/ml for the Enlite® sensor, and 10 µg/ml for the patch pump Omnipod® [12].

Until then, isobornyl acrylate was known from the automotive industry, where it is used for UV and weatherproofing of painted automotive components due to its good moisture resistance and adhesion properties. In safety data sheets, it is classified as an irritant for skin and eyes. In August 2013, Christoffers et al. conducted a study with various acrylates and concluded that inclusion of IBOA in patch tests is not required [17]. Now, however, the situation has changed, as an increasing number of diabetes patients are exposed to IBOA from adhesions in diabetes tools. Furthermore, a relevant amount of IBOA appears to already have been incorporated into the Freestyle Libre® in particular, at least until about May 2020. At present, it is not possible to say how many patients have already developed a contact allergy to IBOA as a result of their diabetic devices. Typically, the reaction only emerges after prolonged use, usually after several months [18].

In contrast, IBOA has not yet been detected in either the patch or the sensor of Dexcom[®] G5 and G6 [12, 19]. This was confirmed by the manufacturer. Patients with IBOA allergy could switch to the model G5, and later G6, without developing skin problems in the form of contact allergy. In a conflicting study, however, a small quantity of IBOA was detected in Dexcom[®] [20].

The implantable sensor Eversense[®] from Roche Diabetes Care and the corresponding skin patches and transmitter are free of IBOA and may therefore also be considered as an alternative in case of IBOA allergy [21].

No doubt in response to pressure from the internet community for diabetes and following numerous publications, IBOA has now been eliminated from the newer models of Freestyle Libre[®] 2. Indeed, in the newer models (as of expiry date May 2020) of Freestyle Libre[®] 2, no IBOA could be detected by gas chromatography [22]. Patients with pronounced IBOA contact allergy were able to return to Freestyle Libre[®] 2 if they wished, and have tolerated it ever since [22].

Nevertheless, IBOA remains an important allergen that requires patch testing. It is still used in relevant quantities in the Enlite[®] sensor and its patch, the patch pump Omnipod[®] and, possibly, in numerous patches or adhesions of plastic housings, catheter needles, or sensor filaments. Sensitized patients are likely to react even to minute quantities of IBOA.

N,N-dimethylacrylamide

In addition to IBOA, another contact allergen, N,N-dimethylacrylamide (DMAA), was identified in Freestyle Libre[®] in 2019 [23]. Isobornyl acrylate was detected in the sensor set at a six-fold higher concentration than DMAA. Patch testing revealed comparatively few patients reacting positive to DMAA and less pronounced test reactions. Mowitz et al. described a superglue, Loctite[®], with 25 % to 50 % IBOA and 20 % to 40 % DMAA. There has been some debate as to whether the upper and lower plastic housing of the Freestyle-Libre[®] sensor may have been held together by this or a similar glue [23]. Gas chromatography could clarify whether the new model of Freestyle-Libre[®] 2 is not only free of IBOA but also of DMAA.

Sesquiterpene lactone mix

In patch testing, five of twelve children with IBOA allergy tested positive for sesquiterpene lactone mix (SLM) [24]. In another study, five of 15 tested adults with IBOA allergy were also positive for SLM [25]. Sesquiterpene lactones (SLs) may, for example, be present in cosmetic products. An explanation for this finding may be that IBOA and three compounds of SLM (alantolactone, costunolide, and dehydrocostus) share the same chemically reactive functional group (Michael acceptor) [26]. Given that camphene is a common basic substance of SLs and IBOA, immunological cross-allergy may be possible [27]. In the general population, however, sensitization to SLM is also relatively high [2].

Colophony

While the contact allergen colophony was relevant in patches in the past, it has increasingly been substituted by supposedly better-tolerated acrylate adhesives. It is not included in Freestyle Libre® and Dexcom®. Colophony was, however, detected in Enlite® [24].

Colophony is included in both the Enlite® sensor and the patch itself, as well as in other products from the company Medtronic. Lombardo et al. showed in their study a high sensitization rate to colophony of 41.1 % in 18 children. Twelve of these used the Enlite® sensor in combination with the Medtronic® pump [28]. Although we are less often faced with this substance in Germany, given that here children and adolescents are supplied significantly more often with Dexcom® and Freestyle Libre® compared to Enlite® (personal communication of the work group Diabetes & Technology of the German Diabetes Society and offices for pediatric diabetes patients), companies should be urgently requested to eliminate colophony permanently from their products.

monoacrylate

Since the reports of allergic reactions to the intermediate adhesive layer of the then G4, no significant intolerance reactions to the Dexcom® sensor had been observed. This changed abruptly with the introduction of a new patch with the aim of improved adhesion at the end of 2019. An increasing number of patients were affected by eczematous skin reactions involving the entire area beneath the patch (Figure 4). Again, standard patch tests and tests with the plastics and adhesive panel did not provide any relevant insights. In cases with a known history of allergy to Freestyle-Libre® prior to the switch to Dexcom G5/G6, tests with IBOA 0.1 % were positive, as expected. However, patients without a known allergy to Freestyle-Libre® and IBOA appeared to be similarly affected by contact allergy to the newer model Dexcom® G6. Moreover, these patients did not show any reaction to IBOA in patch tests (data not published). Therefore, it was quickly suggested that the trigger could be another potent contact allergen.



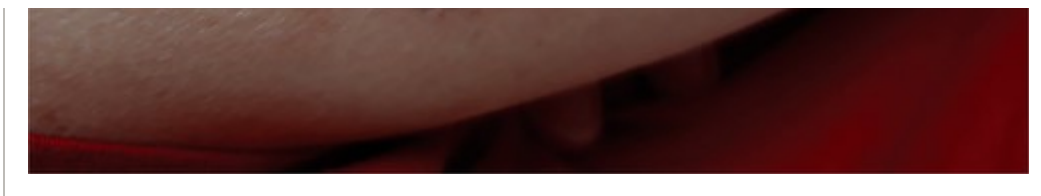


Figure 4

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Contact allergy to Dexcom® G6.

Recently, Svedman et al. could identify an acrylate, 2,2'-methylenebis(6-tert-butyl-4-methylphenol) monoacrylate, previously unknown in this product, by gas chromatography. It was not included in the older model of the G6 patch, but could be detected in the new patch of Dexcom® G6. All three patients presenting with a new contact allergy to Dexcom® G6 tested positive for this substance [29]. However, all three patients also suffered from an allergy to Freestyle-Libre® and IBOA. Therefore, the authors speculated that, in addition to 2,2'-methylenebis(6-tert-butyl-4-methylphenol) monoacrylate, IBOA might also be present in the newest model of Dexcom®. However, the manufacturer has repeatedly confirmed that Dexcom® G6 is free of IBOA. This is consistent with the tolerability of the new Dexcom® G6 in patients with known IBOA allergy (data not published). The extent to which the “new” acrylate is the key culprit for the increasing reactions to the new Dexcom® G6 patch or whether a small quantity of IBOA has been processed in the G6 model after all, remains to be clarified.

Patch testing with acrylates, especially isobornyl acrylate

Since summer 2019, IBOA 0.1 % in vaseline has been included in the block “synthetic resins/glues” of the German contact allergy group. Patch testing should be performed according to the guidelines of the German contact allergy group [30, 31]. Isobornyl acrylate can be purchased from the company Chemotechnique. It should be noted, however, that the test substances purchased from this company are not subject to recommendation or assessment by the Paul Ehrlich Institute. In general, the risk of sensitization should always be taken into account.

Procedure in case of contact allergy to glucose monitoring systems and insulin pumps

Notification

If contact allergy is suspected, immediate notification of the distributor/manufacturer of the device is essential. Usually, the patients themselves call the relevant hotline. This is the only way to identify the problem and give companies the opportunity to change the composition

if reactions become more frequent. In principle, the Federal Institute for Drugs and Medical Devices [32] and the Drug Commission of the German Medical Profession (expert committee of the German Medical Association) should be notified of all affected patients.

Therapeutic options

Skin care and protection measures are paramount for prevention and therapy of irritative skin damage. Skin protection sprays, such as Cavilon[®] spray, are frequently recommended.

In case of a true contact allergy, these interventions are insufficient, since the skin barrier is strengthened for a maximum of 72 hours. In addition, skin protection sprays, such as Cavilon[®], may themselves act as irritants, and they also contain an acrylate-containing film that can, in principle, also trigger contact allergies [33]. Patients with a peristaltic pump have the opportunity to switch to other tolerated catheters that are attached with an alternative patch. In addition, the patch can be carefully removed and the catheter needle applied, for example, with a skin-friendly silicone patch or other tolerated patches for the three days. Currently, this is also successfully being done by some patients with the new Dexcom[®] G6 patch.

Currently, options for continued use of the sensors over a protective plaster despite a contact allergy are limited. The patch should meet several requirements: it must be impermeable and should not contain any acrylate. Tried and tested are, in some patients, protective patches based on hydrocolloid and/or silicon, for example BSN Cutimed[®] Hydro B, blister prevention patches (for example, Hansaplast Blister Plaster[®] or Compeed[®]), or stoma patches (for example, Stomahesive[®]) [34]. Depending on the size of the diabetes device, the patches have to be applied in an overlapping manner. The sensing element of the sensor is guided through a hole punched by a belt hole puncher. Measurement errors must be excluded by continuous (blood-based) monitoring. In this manner, some affected patients may retain their sensor and insulin pump system with minor restrictions.

Outlook

As long as modern diabetes aids have to be adhered to the skin, irritative and contact-allergic reactions will continue to occur. Therefore, it is all the more important that manufacturers provide the maximum level of transparency possible with respect to the composition of patches and adhesives and communicate changes of the components. Unfortunately, this has not been sufficiently ensured to date; rather, it appeared to be dependent on the goodwill of the individual manufacturers. A forthcoming, urgently awaited international position paper now explicitly points out that the *Medical Devices Regulation* needs to be tightened to ensure the rights of patients and their physicians.

The notification of skin reactions and the cooperation of allergologists, diabetologists, affected patients and manufacturers remains important and contributes to the earliest possible identification of potential contact allergens.

Conflict of interest

Stefanie Kamann received honoraria for workshops and lectures from various companies, including Roche, Dexcom, Abbott, Novonordisc, and Lilly.

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