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# Cutaneous Reactions to Continuous Glucose Monitoring and Continuous Subcutaneous Insulin Infusion Devices in Type 1 Diabetes Mellitus

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**Abstract**

**Background:** Continuous glucose monitoring (CGM) and continuous subcutaneous insulin infusion (CSII) are the standard of care for type 1 diabetes in children. There is little reported on device-related skin complications and treatment options. This study documents cutaneous reactions to CGM and CSII devices in children and young adults with type 1 diabetes.

**Methods:** One hundred and twenty-one subjects (3-25 years) with type 1 diabetes and CGM and/or CSII use were recruited over a three-month period from the Naomi Berrie Diabetes Center at Columbia University Irving Medical Center. A five-question survey was completed for each subject detailing demographic data, diabetes management, and device-related skin complications.

**Results:** Sixty percent of subjects reported skin complications related to CGM and/or CSII use. Terms most frequently used to describe cutaneous reactions were "red," "itchy," "painful," and "rash." Subjects who used both CGM and CSII were more likely to report skin problems than those who used only CSII (odds ratio 2.9, [95% confidence interval: 1.2-6.7]; $P = .015$). There were no associations between skin complications and sex or race/ethnicity. Twenty-two percent of subjects with adverse skin event(s) discontinued use of a device due to their skin problem. Seven percent were evaluated by a dermatologist. Eighty-one percent used a range of products to treat their symptoms, with variable perceived clinical outcomes.

**Conclusions:** Skin complications related to CSII or CGM devices are commonly reported in pediatric patients with type 1 diabetes and may lead to interruption or discontinuation of device use. Future studies are needed to elucidate the causes of these reactions and determine the best methods for prevention.

**Keywords**

acrylates, continuous glucose monitoring, continuous subcutaneous insulin infusion, cutaneous reactions, insulin pumps

## Introduction

Continuous glucose monitoring (CGM) and continuous subcutaneous insulin infusion (CSII) have become the standard of care for management of type 1 diabetes in pediatric patients. These medical devices are applied to the skin of patients and allow for integrated monitoring and regulation of glucose metabolism. Use of CSII and CGM devices—either separately or as hybrid closed-loop systems—results in streamlined diabetes management. Both CSII and CGM have demonstrated improved glycemic outcomes, as well as improvements in quality of life, compared to multiple daily insulin injections and fingerstick blood glucose monitoring, respectively.[1-4] These devices have been widely adopted by patients in recent years as they have advanced in convenience and efficacy.

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Although serious adverse events such as hypoglycemic seizures or hospitalization related to the use of CGM and CSII devices are rare, skin reactions to these devices have been reported, ranging from mild to severe.[5,6] Cutaneous adverse events described include lipoatrophy, lipohypertrophy, scarring, local erythema, subcutaneous infection, exacerbation of pre-existing inflammatory skin conditions, and irritant or allergic contact dermatitis (ACD).[7-9] Recently, there have been increasing case reports of ACD related to components of both CGM and CSII devices and/or device adhesives, particularly acrylates.[10-12] Skin reactions can have a significant impact on quality of life, glycemic control, and treatment adherence.[7] Cutaneous adverse events have been reported as a reason for device discontinuation.[13-16]

The incidence and prevalence of device-related skin reactions among patients using CGM and CSII devices are not known. A small observational study reported a frequency of adverse dermatological effects of CSII use in pediatric patients as high as 43%.[9] A systematic review of cutaneous complications with interstitial glucose monitoring found a low incidence of one cutaneous event per eight weeks of device use based on 19 trials.[16] However, observational studies suggest a high prevalence among CGM users.[14,16,17] There are a number of reasons that trials may underestimate the rate of cutaneous adverse events. A history of skin reactions is often part of the exclusion criteria when investigating the safety profile of these devices. Sensitization to an allergen can take months to years to develop, and therefore a cutaneous hypersensitivity reaction may not be captured in trials with short-term follow-up.[13]

We propose that skin complications related to the use of glucose regulating and monitoring devices represent an underreported barrier to daily use of these devices in a subset of patients, leading to interrupted or discontinued use in some cases. Here we present the results of a questionnaire designed to capture skin reactions to CGM and CSII devices as well as their treatments, including perceived efficacy, in a cohort of pediatric patients at a comprehensive diabetes care center.

## Methods

Subjects with type 1 diabetes and present or past use of CGM and/or CSII device(s) were recruited from the Naomi Berrie Diabetes Center at Columbia University Irving Medical Center when they presented for scheduled clinical appointments over a three-month period in Spring 2017. Consent/assent was obtained from subjects and/or their caregiver. The study design, survey, and consent/assent forms were approved by the Institutional Review Board of Columbia University Irving Medical Center.

Each subject and/or caregiver completed one qualitative five-question standardized survey. Subjects were asked to report demographic information, including age, sex, race, and ethnicity. They were then asked to indicate each device they had ever used, including CSII infusion set types and CGM type, and to report whether they had experienced any skin problems related to their devices. Additional questions involved further characterization of reactions, if present, and their treatment, along with perceived efficacy. Subjects and families had the option to free-text any details regarding clarification of reactions and results of treatment.

**Table 1.** Demographics of Surveyed Patients.

| Sex | Patients (%) |
|---|---|
| Female | 47% (57/121) |
| Male | 53% (64/121) |
| Ethnicity/race | |
| Non-Hispanic white | 65% (79/121) |
| Non-Hispanic black | 5% (6/121) |
| Hispanic | 21% (25/121) |
| Other | 9% (11/121) |

Qualitative analysis of free-text responses characterizing skin reactions was performed in an iterative manner. Free-text responses were reviewed for each subject, and descriptive words and phrases were categorized by clinical relevance that was agreed upon by the study authors, including both clinical endocrinologists and dermatologists. For example, if subjects listed antibiotic use or drainage, the reaction would be classified as an "infection." Statistical analysis was performed using Stata 14 (2015). For categorical variables, we compared proportions with skin complications, using the Pearson chi-squared test or Fisher's exact test. To examine the association between the outcome of reporting a skin problem and using CGM and CSII vs CSII alone, adjusting for other predictors, we fit multiple logistic regression models.

## Results

One hundred and twenty-one subjects aged 3-25 years (mean age = $13.9 \pm 4.8$ years) responded to the survey (Table 1). Sixty percent (72/121) of subjects reported skin problems related to the use of a device. There were no significant associations found between skin complications and sex or race/ethnicity.

Among the clinically relevant terms used by subjects to describe skin problems, the most common were "red," "itchy," and "painful" (Table 2). Of note, 32% of subjects who reported skin complications ($n = 72$) specifically reported an adverse event related to a CGM device, whereas 18% attributed a reaction to an adhesive used to attach a device or sensor to the skin.

Thirty-six subjects reported using CSII devices only, 83 reported using both CSII and CGM devices, and 2 reported using CGM devices only. Among subjects using both CGM and CSII devices, 69% reported skin problems, compared

**Table 2.** Common Reported Terms of Cutaneous Reactions by Surveyed Patients.

| Reaction | Percent of patients reporting reaction ($n = 72$) |
|---|---|
| Red | 35% (25/72) |
| Itchy | 31% (22/72) |
| Painful | 22% (16/72) |
| Rash | 22% (16/72) |
| Skin change | 13% (9/72) |
| Infection | 11% (8/72) |
| Psoriasis exacerbation | 3% (2/72) |
| Eczema exacerbation | 1% (1/72) |

to 39% of subjects using CSII devices alone ($P = .002$). Adjusting for age, those who used both devices had 2.9 times the odds of reporting a skin problem ($P = .015$, 95% confidence interval [1.2, 6.7]), compared to those using only one device.

Eighty-one percent of subjects with skin problems used a range of both prescribed and over the counter medications and dressings to treat their symptoms. The most commonly used products reported were adhesive barrier wipes, transparent film dressings, and topical steroids. Additional products include adhesive bandages, topical antibiotics, adhesive removers, adhesive glue, and hydrocolloid adhesive pads. Common brands and specific types of products were also listed out for ease of identification by the subject. Within the survey, the subjects had the option of identifying if a product resulted in improvement, worsening, or no change of a skin reaction (Table 3). For those that used topical steroids, hydrocolloid adhesive pads, or topical antibiotics, there was an overall consensus of improvement with use (77%, 69%, and 82%, respectively). Within the product categories, there were further varied responses. For example, for subjects that used multiple brands of adhesive barrier wipes, they may have noted improvement with one brand and either no change or worsening with a second.

Twenty-two percent of subjects who reported a skin problem discontinued the use of the device due to the adverse skin reactions listed in Table 2. Among all subjects who reported skin problems, 7% had been evaluated by a dermatologist.

## Discussion

This study suggests that cutaneous reactions are a common adverse event for pediatric patients using CSII and CGM devices. The majority of subjects reported skin problems that they attributed to a reaction to such devices. These adverse skin reactions were variable in how they were defined and in their perceived response to treatments. A small percentage of subjects stated that the use of a device caused a flare of pre-existing eczema or psoriasis. Tolerability of devices for many patients may be dependent on skin sensitivity and the ability to find effective solutions for dermatological problems that arise.[18]

Given the relative safety of CGM and CSII devices, skin reactions may represent a significant barrier to uninterrupted use for a subset of pediatric patients. Younger patients often have less body surface area for device attachment, meaning that if a skin reaction occurs, there are fewer alternative sites for application. In addition, high levels of physical activity in young patients may compromise the ability of adhesives to stick to patients' skin, requiring supplemental adhesives,[13] which increases exposure to potentially irritating or sensitizing products. We did not assess for lack of adhesion with diabetes devices. However, many patients reported the use of extra adhesives to ensure that their devices remained in place.

Adhesives used to bind components of devices or attach them to skin are potential causes of contact dermatitis, both irritant and allergic. Eighteen percent of subjects who reported adverse events describe a rash that they attributed to a CGM sensor sticker or other adhesive. Irritant contact dermatitis (ICD) is a direct toxic effect at the site of exposure and could be caused by sweat and friction under an adhesive pad or other material, whereas ACD is immune-mediated response and requires prior sensitization. Patients may experience symptoms such as redness, itching, burning, and blistering. One study evaluating ACD in insulin pump users noted that earlier use of another wearable diabetes device may have contributed to new skin reactions through prior sensitization.[19] As subjects using CGM and CSII together conferred a higher risk/odds ratio of reported skin problems compared to CSII alone in this study, it is possible that using multiple devices over time allows for increased opportunity to become sensitized to allergens.

Isobornyl acrylate (IBOA), found in plastic material used for the housing of some CGM devices and insulin pumps, has recently been identified as a major allergen causing ACD in patients using medical devices for diabetes therapy.[19-25] Other allergens implicated include ethyl cyanoacrylate,[26] *N,N*-dimethylacrylamide,[27] and colophonium.[11] Contact dermatitis, including both allergic and irritant, from repeated exposure to adhesives has been well described in the context of other medical devices or surgical materials, such as peristomal adhesive products[28,29] and surgical glue.[30-33] Further studies are needed to better characterize the prevalence of ACD related to medical devices for diabetes therapy. Patch testing can help confirm if a skin reaction is due to ACD or ICD as determined by the appearance, size, and duration of the resulting inflammation. Patients who present with ACD related to an insulin pump or CGM device may require patch testing with an expanded series of acrylates. IBOA is not included in the Food and Drug Administration standard patch testing series, and historically has not been included in common acrylate series used in screening by patch testing clinics.[34]

**Table 3.** Perceived Clinical Effects of Supplemental Product Use on Reported Cutaneous Reactions.

| Product category | Patients using products in category (*n*)[a] | Patients reporting clinical improvement (%) | Patients reporting no change (%) | Patients reporting clinical worsening (%) | Patients reporting discordant effects (%)[b] |
|---|---|---|---|---|---|
| Adhesive barrier wipe | 27 | 26% (7/27) | 48% (13/27) | 11% (3/27) | 15% (4/27) |
| Transparent film dressing | 27 | 33% (9/27) | 48% (13/27) | 11% (3/27) | 7% (2/27) |
| Topical steroid | 22 | 77% (17/22) | 18% (4/22) | 0% (0/22) | 5% (1/22) |
| Adhesive bandage | 13 | 15% (2/13) | 54% (7/13) | 23% (3/13) | 8% (1/13) |
| Hydrocolloid adhesive pad | 13 | 69% (9/13) | 15% (2/13) | 15% (2/13) | 0% (0/13) |
| Topical antibiotic | 11 | 82% (9/11) | 18% (2/11) | 0% (0/11) | 0% (0/11) |
| Adhesive remover | 10 | 50% (5/10) | 40% (4/10) | 10% (1/10) | 0% (0/10) |
| Adhesive glue | 2 | 50% (1/2) | 0% (0/2) | 50% (1/2) | 0% (0/2) |

[a]Among subjects with skin problems, 81% (58/72) reported using products to treat their symptoms. Many subjects reported using multiple products, and thus totals should not add up to 58 and percentages should not sum to 100%.
[b]"Patients reporting discordant effects" refers to patients who used multiple supplemental products in a category with different perceived clinical effects.

If a patient develops an adverse event such as ACD, therapeutic options include avoidance of the allergen by switching to an alternative device, or placement of a barrier to prevent direct contact with the skin.[35,36] To improve tolerability of these devices, various supplemental products have been used by patients to improve skin adhesion and prevent rashes and other cutaneous reactions. In the absence of clear best practice recommendations, many patients use social media forums to seek solutions to skin-related reactions to their devices. Here we outlined commonly attempted product types used by patients, to inform clinicians.

The majority of subjects who reported adverse skin reactions used one or more products to attempt to improve their symptoms, with variable perceived clinical effects (Table 3). Although successful use of hydrocolloid adhesive pads in the setting of ACD related to acrylates has been reported,[35,36] it is worth noting that using additional products has the potential to exacerbate an ACD or ICD.

Twenty-two percent of subjects who reported skin problems attributed device discontinuation to a cutaneous adverse event. This suggests that cutaneous reactions to CSII and/or CGM devices may prevent a subset of patients from continuing a beneficial treatment modality. Patients with cutaneous reactions may present first to the endocrinologist or pediatrician, as evidenced by the fact that only 7% of subjects with skin reactions reported being evaluated by a dermatologist. We recommend asking patients about potential skin reactions while they are using these devices and early referral to dermatology when indicated. With further characterization of these reactions and assessment of prevalence among pediatric patients with type 1 diabetes, we hope to develop a more uniform screening protocol. As the field of technology in diabetes management continues to advance, a standardized approach will be necessary to define, treat, and possibly prevent cutaneous reactions to ensure continued benefit from these devices. We also recommend at this time that patients with risk factors for ACD who are manifesting an adverse skin reaction without improvement to treatment be considered for patch testing to known components of the device and adhesives.

### *Limitations*

The small sample size in this observational study precludes drawing conclusions regarding the prevalence of cutaneous reactions to CSII and CGM devices in a larger pediatric population with type 1 diabetes. The high rate of adverse cutaneous reactions reported may be in part due to response bias, as patients may have been more inclined to complete the study if they had a history of reactions. Subjects were not directly asked which devices or device components were associated with specific skin reactions. Subjects were asked to report historic and current cutaneous reactions and were not directly examined, precluding standard criteria documenting adverse events. Furthermore, information was not collected regarding prior dermatologic history, including prior cutaneous reactions to adhesives or history of atopy.

## Conclusion

We report these findings to increase awareness of the potential impact of cutaneous adverse events related to CGM and CSII devices in type 1 diabetes patients. There may be a significant subset of pediatric and young adult patients who discontinue use of their device as a result of these reactions, even as the technology continues to become an important and advantageous treatment of type 1 diabetes. Future studies that survey a larger population, as well as patch testing of patients with suspected ACD, are recommended.

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## Previous Publication as Abstract

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## Author Contributions

KMW is responsible for design, oversight, execution, interpretation of data, and management of collaborations for this study. MCG, RG, and KMW are responsible for conception of this study. RSR, RG, and KMW performed data collection and analysis. RSR and KMW wrote the manuscript and prepared displays with input from RG, LEL, DVB, and MCG.

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