

Stoma care products represent a common and previously underreported source of peristomal contact dermatitis

Brienne D. Cressey^{1,†}, Viswanath R. Belum^{2,†}, Pamela Scheinman^{3,4}, Dianne Silvestri⁵, Nancy McEntee⁶, Vashti Livingston⁶, Mario E. Lacouture² and Jonathan H. Zippin¹

¹Department of Dermatology, Weill Cornell Medical Center and New York-Presbyterian Hospital, New York, NY 10065, USA, ²Dermatology Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY 10022, USA, ³Department of Dermatology, Tufts Medical Center, Boston, MA 02111, USA, ⁴Department of Dermatology, Brigham and Women's Hospital, Boston, MA 02115, USA, ⁵Division of Dermatology, Department of Medicine, University of Massachusetts Medical School, Worcester, MA 01605, USA, and ⁶Sidney Kimmel Center for Prostate and Urologic Cancers, Memorial Sloan-Kettering Cancer Center, New York, NY 10065, USA

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Summary

Background. Peristomal dermatitis is a common complication for the >700 000 patients in the United States with an ostomy. The role of stoma skin care products in peristomal dermatitis is poorly understood.

Objective. To evaluate stoma skin care products as a cause of peristomal dermatitis.

Methods. A retrospective chart review of patients with peristomal dermatitis at four academic hospitals from January 2010 to March 2014 was performed. Patient demographics, clinical information and use test and patch test results were documented.

Results. Eighteen patients identified as having peristomal dermatitis were tested. Twelve of these had peristomal contact dermatitis. We identified numerous stoma skin care products as triggers of irritant and/or allergic contact dermatitis. The most common stoma skin care product used and/or involved in dermatitis was Cavilon™ No Sting Barrier Film.

Conclusions. Our data support a paradigm shift whereby healthcare workers treating patients with peristomal dermatitis, which is currently considered to be a reaction mainly to bodily fluids, must now consider those products used to protect the skin as potential triggers for this disease. Therefore, patients with peristomal dermatitis should be tested with their stoma skin care agents to determine the need for removal or change of these products. Additionally, full ingredient labelling by manufacturers would help identify new allergens and irritants.

Key words: allergic contact dermatitis; irritant contact dermatitis; ostomy; patch test; peristomal dermatitis; skin barrier; skin care products; stoma.

Correspondence: Assistant Professor Jonathan H. Zippin, Department of Dermatology, Joan and Sanford I Weill Medical College of Cornell University, 1305 York Avenue 9th Floor, New York, NY 10021, USA. Tel: +1 646 962 5511; Fax: +1 646 962 0033. E-mail: jhzippin@med.cornell.edu

[†]Shared first authorship.

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It is estimated that >700 000 patients in the United States are living with a stoma (colostomy, ileostomy, ileal conduit, or urostomy) (1). These patients receive regular stoma care in wound ostomy and continence clinics, and complicated cases are sometimes referred to the dermatologist for management. Peristomal skin disorders represent the most common postoperative complication in ostomates, and the incidence ranges from 15% to 65% (2, 3). It has been estimated that these events account for more than one-third of stoma care clinic visits, resulting in a substantial economic burden on the patient and the healthcare system (2). Peristomal skin is constantly exposed to a number of substances, including urine, faeces, medicaments, ostomy pouch systems, and stoma skin care products such as barrier films and adhesive paste/removers. The above can result in a variety of peristomal events, including physical skin abrasion and/or infections, dermatologic conditions (pyoderma gangrenosum, psoriasis, etc.), and contact dermatitis (4). Bodily fluids are known to constitute an important cause of peristomal dermatitis. To protect the peristomal skin, medical professionals recommend the application of stoma skin care products designed to prevent peristomal irritation. Because of the presence of known allergens/irritants in peristomal skin products (e.g. fragrances and colophonium), we reasoned that stoma skin care products may represent a previously unappreciated cause of peristomal dermatitis. Allergic contact dermatitis (ACD) has been infrequently reported (0.5–4.7%) (5–8), but, when it is present, it is often caused by stoma skin care products (9). The role of these products as irritants is also poorly understood. Most of the evidence in the literature is in the form of case reports and case series, and there are no large-scale studies reporting on these events (8, 10). Herein, we evaluate irritant and allergic aetiologies for peristomal dermatitis, and identify commonly used products as culprits.

Methods

We utilized an Institutional Review Board-approved retrospective chart review of patients with peristomal dermatitis who were managed by dermatologists at the Memorial Sloan Kettering Cancer Center, New York-Presbyterian Hospital & Weill Cornell Medical Center, Tufts Medical Center, and UMass Memorial Medical Center, during a 4-year period (January 2010 to March 2014). In most cases, the status of the peristomal skin lesions was noted clinically and also according to the validated Studio Alterazioni Cutanee Stomali (SACS™) instrument, which was originally developed by wound ostomy continence nurses and surgeons for objective assessment and classification (Fig. S1) (4, 11).

Product testing was performed either as a use test or a patch test. In most patients (1–15), the use test was employed, as the product being tested is normally either applied and then occluded under adhesive dressings or is the adhesive dressing itself. For the use test, we identified an area of uninvolved skin of ~10 cm² on which to apply the product. If the patient was tested by our staff, the back was chosen. Otherwise, if the patient was unable to come to the office three times in 1 week and was able to reapply the product to their own skin as instructed, we utilized the arm or abdomen, and instructed patients to treat this area as if it were their ostomy site. Stoma skin care products were applied 'as is' to accurately mimic the conditions under which the products would be used. Liquid or spray products were applied to dry skin in parallel with changing the ostomy dressing. The site was then covered with adhesive dressing that is known to not react with the patient's skin, in an attempt to mimic clinical occlusion. Exposure was continued for 2–7 days, and reactions were then assessed. For those who were able to come to the office for all three appointments, our staff photographed and recorded skin findings. For those who were unable to come to all three appointments, if the patient noted a reaction, pictures were taken by family or home care nurses. For all patients, sites were examined for epidermal changes including, but not limited to, erythema, oedema, vesiculation, or ulceration. In some instances, the brand name of the stoma care product could not be confirmed, so the general product category only is listed. All data were recorded in a Microsoft Excel database, and descriptive frequencies were used to summarize the data.

Patients 16–18 were patch tested with stoma care products as follows: ConvaTec™ Sur-fit Natura Stomahesive wafer, Coloplast™ Sensura Wafer, Hollister™ Wafer, Durahesive™ Wafer, Eakin™ material, Hollister™ Adapt Material, Coloplast™ Strip Paste, Coloplast™ Wafer, Hollister™ Adapt Barrier Ring and Tegaderm were applied as a 2-cm² piece of wafer under paper tape occlusion for 48 h (patients 16 and 17); Cavilon™ No-Sting Barrier Film was applied as the pledget form of the product directly to the skin and covered with tape (patient 17); or a small amount of ConvaTec™ Stomahesive Protective Powder, Cavilon™ No Sting Barrier Film, ConvaTec™ Stomahesive Paste, Adapt stoma powder®, Mupirocin Ointment, Desonide 0.05% Cream, Alkare™ Protective Wipe, StomaCare™ Wipe or Smith & Nephew™ No Sting Skin-Prep Wipe was placed on a Finn Chamber® 'as is', allowed to dry, and occluded for 48 h (patients 16 and 18). In most cases, areas were examined again 48 h after application of the product, and then again 48 h after removal, that is, on day (D) 4. Regardless of the method

Table 1. Stoma skin care products of relevance in our patients

No.	Stoma skin care product	Number of positive reactions	Ingredients (as listed in the MSDS/PDS/SDS)*
Adhesive/barrier removers			
1	PDI™ Adhesive Tape Remover Pad	2	Hydrotreated heavy naphtha (petroleum), isopropyl esters fatty acids (C14–18), isopropyl alcohol, light aliphatic solvent naphtha (petroleum), xylene
2	Reliamed® Adhesive Remover Wipes	2	C11–12 isoparaffin, petroleum naphtha, isopropyl alcohol, isopropyl palmitate, isopropyl myristate, isopropyl stearate, fragrance
3	Uni-Solve® Adhesive Remover	1	Isopropyl alcohol, C10–11 isoparaffin, dipropylene glycol methyl ether, aloe extract, fragrance
4	Hollister™ Adhesive/Barrier Remover Wipes	1	Stearic acid, ethanol, dimethylsiloxane cyclic tetramer, propylene glycol monomethyl ether, proprietary fragrance, ethyl acetate, decahydronaphthalene
5	ConvaTec AllKare® Wipes (barrier/adhesive remover not specified)	1	Barrier wipes: dimethyl phthalate, isopropanolol, ethyl acetate, non-hazardous ingredients Adhesive remover wipes: D-limonene, acid-treated distillate oil, balance of ingredients – non-hazardous
Skin barriers/fillers			
6	Cavilon™ No Sting Barrier Film	5	Hexamethyldisiloxane, foam applicator, isooctane, acrylate terpolymer, polyphenylmethylsiloxane copolymer
7	Adapt® Stoma Adhesive Paste	1	Proprietary composition
8	ConvaTec™ Stomahesive Paste	1	Ethyl alcohol, butyl alcohol, balance of ingredients – non-hazardous
9	ConvaTec™ Stomahesive (product not specified)	1	–
10	ConvaTec™ Durahesive (product not specified)	1	–
11	ConvaTec™ Sur-fit Natura Stomahesive Wafer	1	No MSDS for this product
Others			
12	Adhesive tape (brand not specified)	1	–

MSDS, material data safety sheet; PDS, product data sheet; SDS, safety data sheet.

*In some cases, ingredients and/or the %wt/%vol may not have been disclosed, for proprietary reasons.

used for stoma care product testing, control patients were not used.

In addition to stoma care product testing, patients were also patch tested with a baseline series, which included either the 80 screening allergens recommended by the North American Contact Dermatitis Group (NACDG) (12), the NACDG 65 allergen screening series (patient 16 only), or a modified NACDG standard series (AllergEAZE, Smart Practice® Canada, Calgary, Alberta, Canada; Dormer Laboratories, Etobicoke, Ontario, Canada), along with other supplemental series (Table S1). Allergens were applied to the back with Finn Chambers® (Epitest, Tuusula, Finland) on Scanpor® tape (Norgesplaster, Vennesla, Norway) or AllergEAZE patch test chambers. Reactions were graded on D2 or D3 and D4 or D5 according to ICDRG criteria. The results presented are those of the final reading day.

Results

Demographics

We identified 54 patients who were treated by a dermatologist for peristomal dermatitis. Clinical data, including reactivity patterns for patch test results with a defined allergen (n = 10) or testing results with a stoma care product (patch or use testing) (n = 18), were available for 18 patients in total (Table S1). The mean age of these 18 patients was 60.4 years (range: 35–87 years), and there were 11 males and 7 females. The majority (82%) of the patients had a current or prior history of cancer, including colorectal (n = 7), genitourinary (n = 6), and ovarian (n = 2). The ostomy types were as follows: colostomy (n = 9), ileostomy (n = 3), and ileal conduit diversion (n = 6). One patient with an ileostomy also had a wound vacuum-assisted closure. Patients referred to

dermatology had ostomies for at least 3 months. Coexisting dermatological conditions were found in 33% of the patients: psoriasis ($n = 2$), lichen sclerosus et atrophicus ($n = 1$), melanoma ($n = 2$), and basal cell carcinoma ($n = 1$).

Clinical characteristics

The peristomal skin in our patients showed a range of clinical reaction patterns. In all cases, the peristomal skin was erythematous, extending out from the stoma ($n = 18$). In some cases, erosion ($n = 1$) or even ulceration ($n = 1$) of the skin was noted, and in some instances vesiculation. In those patients with more chronic dermatitis, lichenification was found. The peristomal regions (quadrants; Fig. S1) affected at the time of presentation were as follows: all ($n = 11$), right upper ($n = 2$), and right/left lower ($n = 1$ each). Skin reactions were limited to the area around the stoma, and reached the border of the adhesive dressing, with rare extension beyond. Patients reported symptoms ranging from pruritus alone to both pain and pruritus. Most of the patients improved with oral antihistamines, topical steroids, and avoidance and/or change of the causative stoma skin care products; in rare instances, oral antibiotics for superinfection were needed.

Skin testing results

Overall, the frequency of peristomal contact dermatitis in our patients was 14 of 18, with 12 of 18 reacting to a stoma care product and 7 of 10 to a defined allergen. Of the 15 patients who were use tested with stoma products, 9 (60%) had positive reactions. In those who were patch tested, 25 positive patch test reactions were recorded, 5 of which were to a stoma care product; for further details, see Table S1. Regardless of the method used for testing, the patients reported pruritus in association with test reactions. Several patch test reactions to stoma products were irritant bullous reactions (Fig. 5, patient 18). In the use test-negative patients, an erythematous irritant reaction (IR) to adhesive tape and a doubtful reaction to PDI™ Adhesive Tape Remover Pads were recorded, but were not counted as positive reactions. The stoma skin care products of relevance in our patients were mainly skin barriers/fillers [e.g. Cavilon™ No Sting Barrier Film (3M, St Louis, MN, USA), $n = 5$] (Figs. 1–5), which are intended to fill in the unevenness in skin surfaces, help increase the ostomy system wear time, prevent leakage around the stoma, and protect peristomal skin. Adhesive removers (e.g. PDI™ Adhesive Tape Remover Pads; Reliamed, Unisolve; $n = 6$), which are used to remove the adhesive residue from various stoma-related products (ostomy bags, tapes, etc.), constituted the other major



Fig. 1. Peristomal allergic contact dermatitis around the colostomy in a 49-year-old patient who had undergone surgery for a perianal adenocarcinoma. The patient showed reactivity to multiple stoma skin care products: Reliamed adhesive remover wipe (++), Cavilon™ No Sting Barrier Film (+), and the PDI™ Adhesive Tape Remover Pad (++). L1, TV as per the SACS™ instrument (patient 13) (L = location, T = type).



Fig. 2. Peristomal contact dermatitis caused by Cavilon™ No Sting Barrier Film in a 78-year-old bladder cancer survivor. Note the marked erythema and scaling around the stoma (ileal conduit urinary diversion). L1, TV as per the SACS™ instrument (patient 14) (L = location, T = type).

group of products (Table 1). In addition, products from various manufacturers elicited positive reactions, and their ingredients are shown in Table 1 (13–21).

Seven patients showed positive allergic patch test reactions to one or more potentially relevant agents: colophonium ($n = 2$, tackifier resin), abitol ($n = 1$, dihydroabietyl alcohol balsamic resin, derived from rosin



Fig. 3. Peristomal ulcer and dermatitis in a 41-year-old male with a history of Crohn's disease and a colostomy. The patient reacted positively to Convatec™ Stomahesive Paste and Cavilon™ No Sting Barrier Film (patient 16).



Fig. 5. A bullous, probably irritant, reaction to Cavilon™ No Sting Barrier Film at the day 3 reading in a 35-year-old female with a history of Crohn's disease and an ileostomy. The patient experienced dermatitis at her ostomy site that persisted despite changing to several bags and products (patient 18).



Fig. 4. Positive patch test reaction at the day 3 reading to Cavilon™ No Sting Barrier Film (++) in a 68-year-old woman with a history of ulcerative colitis and a colostomy (patient 17).

acids), ethyl acrylate ($n = 1$, adhesive), hydroxyethyl methacrylate ($n = 1$, adhesive), cinnamal ($n = 1$, fragrance), *Myroxylon pereirae* (balsam of Peru, $n = 1$, fragrance marker), benzalkonium chloride ($n = 1$, preservative), fragrance mix I ($n = 1$), glutaraldehyde ($n = 1$, disinfectant), propylene glycol ($n = 1$, humectant), triethanolamine ($n = 1$, pH adjuster), and isophorone diisocyanate (IPDI) ($n = 1$, polyurethane plastics). Positive allergic patch test reactions with unlikely clinical relevance were those to nickel ($n = 4$, metal), benzoyl peroxide ($n = 1$, bleaching agent, initiator of polymerization),

carmine ($n = 1$, colouring pigment), and potassium dichromate ($n = 1$, metal).

Discussion

Previous reports estimated a prevalence of both allergic and irritant peristomal contact dermatitis caused by an external agent of 0.5–4.7% (4–8). Our series was heavily biased by our referral population of patients with recalcitrant peristomal dermatitis and several reactions that were probably IRs; hence, relative frequencies cannot be compared. We identified several stoma skin care products (stoma skin barriers and adhesive removers) as triggers of allergic or irritant contact dermatitis, including severe bullous IRs to Cavilon™ No Sting Barrier Film, which has not been previously implicated.

The occluded peristomal milieu, along with repeated ostomy bag changes involving skin stripping, mechanical trauma, etc., probably renders the skin vulnerable to contact sensitization or irritation as a result of epidermal barrier disruption (22). In our patients, stoma skin care products were the most common causative agents; however, the specific chemical components of those agents that are responsible are currently unknown. It would be interesting to test as much as possible with the specific causative agents in appropriate concentrations and vehicles, respectively, to distinguish between allergy and irritancy. The published literature suggests that the most common allergens causing ACD in ostomates are epoxy resins (no longer used), Gantrez® copolymers (ChemPoint, Bellevue, WA, USA),

D-limonene, and (un)known allergens in various stoma skin care products (ostomy pouching systems, skin barriers, and adhesive removers) (8, 9, 23–28). Gantrez® is a polymethylvinyl ether maleic anhydride copolymer (two formulations: Gantrez®-425 and Gantrez®-335) that is used in various personal care products, and as an adhesive component in a range of stoma pastes. Our literature review showed that Gantrez®-425 is a component of Stomahesive® (ConvaTec, Greensboro, NC, USA), Adapt® (Hollister, Libertyville, IL, USA) and Dansac® (Dansac, Kernersville, NC, USA) pastes, whereas Gantrez®-335 is an ingredient in Karaya® paste (Hollister) (27).

IPDI belongs to the group of (di-)isocyanates, which are used as raw materials in the manufacture of polyurethane plastics (29). Despite its extensive use, there have been very few reports of contact allergy (30, 31), with mostly respiratory symptoms gaining attention (32). The cause for the long-standing (~9 months) peristomal dermatitis in our IPDI-positive patient, who was a retired metalworker with an ileal conduit, remains unclear, although IPDI may have been present in the plastic or glue of one of his stoma products. IPDI was not listed in the material safety data sheets (MSDSs).

Marketed as a 'hypoallergenic, non-cytotoxic liquid,' Cavilon™ No Sting Barrier Film is a liquid film-forming product that is claimed to form a waterproof barrier that acts as a protective interface against skin irritation from moisture, adhesives, epidermal stripping, friction and seal protective or prescription powder under an ostomy appliance. Contact dermatitis caused by Cavilon™ No Sting Barrier Film was relatively common (5 patients), being more common than that caused by any other stoma skin care product tested in this series. Of those 5 patients, 2 had severe bullous reactions to Cavilon™ No Sting Barrier Film. Given the morphology in these 2 patients, a severe IR appears likely. Two patients who reacted to Cavilon™ No Sting Barrier Film also reacted to colophonium, and 1 reacted to both ethyl acrylate and 2-hydroxyethyl methacrylate, all of which are present in many adhesives; however, 3M neither confirmed or denied their presence in Cavilon™ No Sting Barrier Film. It is concerning that a leave-on product intended for direct skin application and improvement of barrier function could cause such a response. This highlights the importance of patch/use testing of peristomal dermatitis patients with all of their ostomy products.

Further studies should be focused on detailing patch test results with individual components of stoma skin care products sourced from manufacturers. Prospective studies using high-performance liquid chromatography may also significantly improve the characterization

of such allergens. Our study has some limitations. First, the retrospective study design precluded further patch testing with individual components. In many cases, evaluation was limited to application of the products on uninvolved skin, as the majority of our cancer patients refused the additional perceived burden of patch testing, with its requirement for repeated office visits.

We recommend that healthcare providers (surgeons, and wound ostomy and continence nurses) use low thresholds for suspecting peristomal contact dermatitis caused by ostomy products, especially when the dermatitis does not improve with general stoma care measures (meticulous skin care, and proper re-fitting of the appliance) and/or follows a protracted clinical course. The clinical morphology characterized by erythema in the peristomal region involving any or all quadrants does not permit distinction between irritant and allergic reactions, and patch/use testing is therefore helpful. Manufacturers should be required to disclose all ingredients in the product's label and MSDSs in order (i) to enable targeted patch testing of constituents, (ii) to avoid recommendation of similar products, and (iii) to facilitate the selection of safe alternative products. Treatment for peristomal contact dermatitis includes avoidance of the offending product and the use of topical corticosteroid (triamcinolone and clobetasol) sprays with oral antihistamines (33). It is noteworthy that, in this patient population, the vehicle in which the topical corticosteroid is administered is critical, so that adhesion of the stoma appliances is not impeded.

With the increased use of ostomies as a permanent surgical solution for diseases of the bowel and bladder, or as a temporary measure for organ rest, healthcare professionals can expect peristomal contact dermatitis to become more common. In conclusion, our study highlights that a view of peristomal dermatitis as simply a reaction of the skin to bodily fluids is incomplete, and it is imperative that healthcare workers consider the stoma care products prescribed to protect the skin as the cause of disease. The causative products that we identified appear to mirror those reported in other studies, and our results extend those of other authors. The zealous marketing of a plethora of stoma skin care products, some of which are sources of undisclosed allergens, calls for more stringent regulatory approval standards and allergen labelling on products. Properly trained wound ostomy and continence nurses, patient education and timely referral to the dermatologist are critical to avoid peristomal complications, reduce clinic visits, and maintain good health-related quality of life in ostomates.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. The SACS™ instrument for the objective assessment and classification of peristomal skin lesions.

Table S1. Clinical characteristics of ostomates and the allergens (including stoma skin care products) responsible for ACD.

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