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Clinical Evaluation of a Skin Protectant for the Management of Incontinence-Associated Dermatitis

An Open-Label, Nonrandomized, Prospective Study

Mary R. Brennan ◆ Catherine T. Milne ◆ Marie Agrell-Kann ◆ Bruce P. Ekholm

ABSTRACT

PURPOSE: The purpose of this study was to evaluate the efficacy of an investigational skin protectant product at managing severe skin breakdown associated with incontinence.

DESIGN: Open-label, nonrandomized, prospective study.

SUBJECTS AND SETTING: The sample comprised 16 patients; inclusion criteria were: patients older than 18 years, cared for in the intensive care unit of a level I trauma center hospital or in long-term care facilities in the northeast region of the United States, and had incontinence-associated dermatitis (IAD). Twelve of the patients had epidermal skin loss and 4 had severe redness.

METHODS: The investigational product is a formulation based on acrylate chemistry. The skin protectant application schedule was twice weekly for up to 3 weeks for a maximum of 6 applications during the study period. The skin was evaluated via a skin assessment instrument specifically designed for use in this study; this instrument has not undergone validation studies. The main outcome measure was changes in the instrument score over time. In addition, complete reepithelialization was recorded when observed, and pain scores (associated with IAD) were noted in participants who were able to report pain.

RESULTS: The IAD score improved in 13 of 16 patients, remained unchanged in 1 patient, and deteriorated in 2 patients. The median percent improvement in the skin assessment instrument was 96% ($P = .013$). Four of the patients with epidermal skin loss had complete reepithelialization of the skin surface with 4 to 6 applications of the skin protectant, and 5 had substantial improvement. The 4 patients with severe red skin returned to healthy normal skin with 2 to 4 skin protectant applications. Substantial pain reduction was reported by all 9 patients who reported pain at enrollment. No adverse events associated with the skin protectant application were reported during data collection.

CONCLUSION: Results of this study suggest that an acrylate-based product, evaluated here for the first time in patients, may be effective as a protective barrier in the presence of continued incontinence. Additional research is needed to confirm these findings.

KEY WORDS: Incontinence-associated dermatitis, Liquid polymer acrylate, Skin protectant.

INTRODUCTION

The skin is the protective layer of the body; it provides an important anatomical barrier against pathogens, irritants, water loss, and environmental threats. Various conditions can damage the skin and breach the integrity of the barrier resulting in inflamma-

tion, disruption of epidermal integrity, pain, and increased risk of infection. One example of such a condition is incontinence, which can lead to skin damage due to excessive moisture, high pH, and, in the case of fecal incontinence, the presence of fecal enzymes. Skin damage that results from incontinence is referred to as incontinence-associated dermatitis (IAD).¹⁻⁶

Prevention of skin damage is considered a standard of care,⁷ but IAD is not routinely monitored in all care settings;⁸⁻¹¹ rates vary from 3.5% in the nursing home setting⁸ to 36% in the critical care environment¹⁰ and up to 42% in the hospital setting.^{12,13} Incontinence-associated dermatitis is considered a significant risk factor for the development of pressure injuries⁷ and has been identified as a predictive factor significantly associated with the development of superficial pressure injuries.¹⁴ A systematic review and meta-analysis of the literature aiming to identify the association between IAD and pressure injuries found evidence for a likely association based on 58 studies included in the analysis.¹⁵ In addition, a recent article measuring the prevalence of incontinence in International Pressure Ulcer Prevalence surveys found not only that incontinence was associated with an increased risk for all pressure injuries including full-thickness injuries.¹⁶

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The presence of fecal incontinence has been associated with a 22% higher risk of developing pressure injuries in patients with spinal cord injury.¹⁷ Pressure, shear, friction, and moisture interact as extrinsic factors in the development of pressure injuries.¹⁸ The term “microclimate” has recently emerged to describe the local skin environment including temperature and moisture.^{19–21} Those conditions can change from site to site and can be especially unfavorable in skinfolds such as the gluteal fold, also known as the intergluteal or natal cleft. Clinicians generally agree that fecal incontinence puts the skin at a higher risk for IAD than exposure to urine alone.^{1–3,7} This difference in relative risk may be attributable to higher levels of bacteria and fecal enzymes; diarrhea is usually considered the most significant irritant leading to IAD. Overgrowth of the pathogen *Clostridium difficile* commonly precipitates an infection that results in frequent or continuous liquid stools, exposing the skin to damaging irritants and wetness.^{22,23} Incontinence-associated dermatitis carries its own morbidity that includes pain, increased risk of infection of the site, and failure to heal where the skin is denuded (partial-thickness wound), especially in the presence of continued incontinence.^{1,7}

Nursing care for patients at risk for developing IAD focuses on preventing exposure to feces and urine and protecting the skin. Numerous products and protocols are available for skin care.^{24–31} Cleansing removes irritants and debris from the skin and is considered an essential initial step. Cleansing is typically performed using a pH-balanced, no-rinse liquid cleanser formulation delivered as a spray, foam, or premoistened wipe. Protection of the skin is essential to repel moisture and irritants; it is generally accomplished by the application of a moisture barrier cream, ointment, or liquid barrier film. Moisturizers are believed to have benefit for the intact skin and are typically formulated into cleansing solutions or barriers; such combined products can optimize time efficiency and encourage adherence to a skin care regimen.³ In situations of severe skin damage where there is partial or complete epidermal loss and the tissue is moist, care consists of cleansing and applying a moisture barrier product. Zinc oxide ointments or specialized zinc oxide–based formulations referred to as pastes are commonly used. Pastes combine an ointment or cream with an absorbent powder (or gum), allowing the formulation to adhere to wet surfaces. The majority of these products have a thick consistency that helps the barrier remain in place during ongoing exposure to liquid stool. While clinical use is common, pastes have limitations: the absorbent can make them gritty; this texture makes them uncomfortable or painful on application, during wear, and especially during cleansing and removal.⁷ In addition, liquid stool can become embedded in the surface of the product, necessitating frequent removal and cleansing, which can increase the likelihood of mechanical trauma to already severely damaged skin. Pastes also transfer to incontinence pads and bed linen, most likely diminishing the barrier protection for the skin and compromising the effectiveness of the absorbent product, as demonstrated for ointments and petrolatum-based products.³² While fecal management systems are now used with an increasing frequency to contain and divert liquid feces from the skin,^{33,34} exposure still can occur due to device leakage. Consequently, an effective skin protection protocol remains a critical element of patient care.

Despite best clinical care efforts, management of IAD using current methods and products remains inadequate and does not prevent recurrence. The purpose of this study was to test whether a novel investigational skin protectant, shown to adhere to the

moist and wet skin in animal models,³⁵ can adhere to the severely damaged (denuded) and moist or wet skin in patients, protect patients' skin from irritating body fluids, and create an environment where healing can occur. This investigational formulation is based on acrylic polymers combined with 2-octyl cyanoacrylate. It is applied as a liquid and forms a film structure curing within 30 seconds after application. The aim of this research was to test the efficacy of the investigational product on patients with IAD. The outcomes measured were the clinician-assessed IAD score (primary endpoint), the patient self-reported pain score at baseline and at the end of the study, and the reepithelialization status at the end of the study (secondary endpoints). Additional observations recorded were the number of incontinence episodes for each patient during the study and the development of pressure injuries or of other adverse events.

METHODS

This open-label, nonrandomized, single-group, prospective study is the first report using this acrylate-based skin protectant product in patients with category 1 or category 2 IAD⁷ in the presence or absence of continued fecal and/or urinary incontinence. There was no comparison group. The research setting was a critical care unit of a level I trauma center hospital in the northeast region of the United States. Participants were also recruited from several long-term care facilities in the northeast region of the United States. Inclusion criteria were: IAD defined as breached epidermis or denuded skin, or very red epidermis; and patients older than 18 years. Patients with preexisting pressure injuries of the sacrococcygeal and buttock area, allergies to acrylates or cyanoacrylate, or any preexisting skin disease in the affected area were excluded.

A power analysis was not completed for this initial evaluation of the skin protectant. A sample size of 12 is usually sufficient for this type of initial investigation,³⁶ and we increased our sample to 16 participants to allow for potential dropouts. One purpose of this study was to gather data allowing formal estimates of efficacy responses (such as mean and standard deviation) to enable sample size estimation for a future randomized controlled trial. Study procedures were reviewed and approved by the institutional review board of the North Shore–Long Island Jewish Health System, Feinstein Institute, New Hyde Park, New York.

Intervention

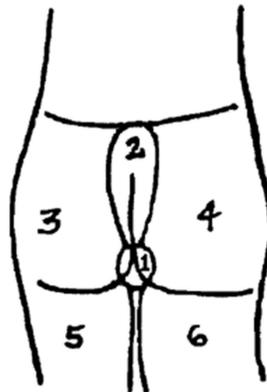
The investigational skin protectant was applied twice weekly by painting or dabbing on a thin coat on the affected skin exposed to urine or feces for a maximum of 3 weeks (21 days), after cleansing the skin with either a cleansing wipe (3M Cavilon Bathing and Cleansing Wipe product #9820 or 9821, Minneapolis, MN) or a skin cleanser (3M Cavilon No-Rinse Skin Cleanser #3380). The formulation is based on acrylate chemistry to produce a breathable film that will prevent urinary or fecal incontinence from reaching the skin surface. Acrylic polymers are combined with 2-octyl cyanoacrylate to create the film structure. This solvent-based formulation is designed to avoid interference of the skin surface even if it is already compromised by exposure to caustic bodily fluids such as urine, liquid feces, gastric fluid, or wound exudate. Standard biocompatibility testing (results not shown) completed prior to applying the product to humans included cytotoxicity, irritation, sensitization, genotoxicity, and systemic toxicity based on the criteria of expected use (>30 days in contact with

a breached skin barrier) and guidance covering the biological evaluation of medical devices outlined in EN ISO 10993-1:2009. The results support the conclusion that the product is safe for its intended use. Animal models were also used to test this product, with results suggesting that the new formulation presented here protects the intact and denuded skin from irritants and provides an environment favorable to healing, offering promise for the management of conditions involving loss of epidermis.³⁵ This is the first report of the clinical use of this product, intended to protect the skin from additional insult from incontinence and to provide an environment for the skin beneath the barrier to heal. It is the first skin protectant intended for IAD that adheres to the wet skin.

Instruments

Assessment of the skin was completed using the Skin Assessment Tool (SAT) developed for the purpose of this study; this instrument has not undergone testing for validity and reliability. The SAT evaluates the skin located in 6 zones: (1) the anus and 2 inches around the anal opening; (2) the crease between buttocks, above the anal opening, and 2 to 3 inches below the

natural waistline; (3) the left buttock; (4) the right buttock; (5) the left posterior and medial upper thigh; and (6) the right posterior and medial upper thigh (Figure 1). Each zone is evaluated for color, lesions, and skin loss. Each zone was assessed for its percent area including normal skin, intact pink skin, intact red skin, partial epidermal loss, and epidermal loss. A score was assigned based on the approximate proportion of skin damage noted: a score of 1 indicates 1% to 25% of the area affected, a score of 2 indicates 26% to 50%, a score of 3 indicates 51% to 75%, and a score of 4 indicates 76% to 100% skin damage. Weights were used to multiply the percent area score (0 for normal skin, 1 for pink skin, 6 for red skin, 30 for partial epidermal loss, and 150 for complete epidermal loss). If lesions were present (vesicles, papules, pustules), a value of 9 was added to the cumulative score. A cumulative IAD score was then calculated to take into account all 6 zones and the degree of damage present in each. For example, a patient with IAD only in zone 1 with 10% red, 50% partial epidermal loss, 40% complete epidermal loss, and no lesions present would receive a score of: 10% red = 1 (for area involved) × 6 (weight) + 50% partial epidermal loss = 2 (for area involved) × 30 (weight) + 40%



Instructions for Skin Assessment:

Assess each of the 6 body locations for Epidermal Loss (depth and area), Presence of lesions, and Skin Color of Intact Skin.

Enter percent of each area covered for each condition.	Area 1 Perianal skin	Area 2 Crease of buttocks	Area 3 Left buttock	Area 4 Right buttock	Area 5 Left posterior / medial thigh	Area 6 Right posterior / medial thigh
	%	%	%	%	%	%
Normal						
Intact pink skin						
Intact red skin						
Partial epidermal loss						
Complete epidermal loss						
Other*						
Total:	100%	100%	100%	100%	100%	100%
Are lesions present? (macules, papules, pustules, vesicles, etc.)	Y N	Y N	Y N	Y N	Y N	Y N

*For "Other", describe condition/color:

Figure 1. Delineation of zones assessed and the Skin Assessment Tool.



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Figure 2. FACES self-assessment pain scale.

total epidermal loss = 2 (for area involved) × 150 (weight) + no lesions = 0. Thus, the IAD score for that patient would be 366 (6 + 60 + 300 + 0). The maximum IAD score would be total epidermal loss in 76% to 100% of all 6 areas plus lesions in all areas, which would equal (6 × 4 × 150) + (6 × 9) = 3654, and the lowest would be 0 (no damage). We did not specifically set a cutoff score for severe IAD but looked for improvement in the score over time in the enrolled patients in this first study using the investigational new product.

Pain associated with IAD and its care was assessed in patients who were able to report it using the Wong-Baker FACES scale (Figure 2).³⁷ This instrument is used by showing an image of Figure 2 to patients who are responsive and able to express their pain and asking them to select the face/number that best represents their pain level at the time of the assessment. This scale was originally developed and validated for use in children.^{38,39} and has also been used in adults.⁴⁰ Another version of the FACES scale,⁴¹ later revised and validated to the current format⁴² and considered analogous to the Wong-Baker FACES scale,⁴³ was validated for use in older adults.^{44,45}

Pain scores were collected prior to cleansing, after cleansing, and after each product application. The pain score collected at the first product application may have been related to the removal of the product used before the new skin protectant was ever applied. Paste products, for example, are notorious for being difficult and uncomfortable to remove.⁷ We report here the change in pain score between day 1 (just prior to the first application of the investigational product) and the end of the study to reflect the overall trend.

Study Procedures

In order to complete baseline evaluation, the participant's buttocks and posterior aspect of the thighs were cleansed prior to assessments and photographs. The buttocks and thighs were then assessed for the amount and extent of denudement, redness, and normal skin condition using the SAT instrument described earlier. Photographs were taken of the buttocks and thighs.

An investigational skin protectant was applied twice weekly by painting or dabbing on a thin coat on the affected skin exposed to urine or feces for a maximum of 3 weeks (21 days), after cleansing the skin with either a cleansing wipe (3M Cavilon Bathing and Cleansing Wipe product #9820 or 9821; 3M,) or a skin cleanser (3M Cavilon No-Rinse Skin Cleanser #3380). Patients were followed twice a week for a maximum of 21 days, or less if completely healed or discharged from the facility. Incontinence-associated dermatitis was assessed using a semiquantitative scoring system twice per week, along with photographic documentation. Sites were instructed to follow the protocol for patient prepara-

tion/cleansing and to remove any obstacles from the target area such as soiled sheets. A secure digital memory card was inserted into the Canon Rebel T3i Camera w/Canon EF-S 18- to 55-mm Lens (purchased from Adorama, New York, New York). A label with the patient information was held in a nontreatment area near the buttock. The photographs were taken approximately 12 to 24 inches from the target affected area.

The principal investigator (M.R.B.) completed SAT scoring form for all patients and observation times at her site and the coinvestigator at her sites (to minimize variability, no other study personnel scored IAD). Interrater reliability was not assessed, but each patient was always assessed by the same person throughout the study. The frequency and nature (urinary, fecal, or both) of incontinence were monitored daily. Cleansing was performed after each incontinence episode; however, the investigational skin protectant was not reapplied each time but on a twice-a-week dosing schedule. The investigational skin protectant was supplied in a 1-time use sterile applicator wand with a sponge (Figure 3).

Outcome Measures and Study Endpoints

The primary outcome measure for this study was change in the IAD score from baseline to the end of the patient's participation in the study at 3 weeks (or sooner if the patient was discharged from the unit). Secondary outcome measures were pain (as reported by patients using the FACES scale) at day 1 and at the end of the study and complete reepithelialization at the end of the study (as assessed visually by the clinicians using the SAT instrument, where complete reepithelialization corresponds to "normal skin," "intact pink skin," or "intact red skin").

DATA ANALYSIS

Statistical analyses were performed with SAS version 9.3 (Statistical Analytics Software, Cary, North Carolina). All measures were



Figure 3. Applicator for the investigational new advanced barrier film.

summarized using common metrics (mean, median, standard deviation, minimum, maximum). Due to nonnormality of the data, significance of the change from baseline in the SAT score was assessed using a Wilcoxon signed-rank test. In addition, the change in FACES pain scores from baseline to last visit was compared for those who could report pain using a Wilcoxon signed-rank test. For both responses tested, a *P* value of less than .05 was considered significant. All testing were done using data from all 16 patients in accordance with the principles of intent to treat.

RESULTS

Sixteen patients were enrolled at the study sites between September 2014 and February 2015. The mean age of the patients was 70.9 years (median: 75 years; range: 19-92 years). Seven patients were male (44%) and 9 were female (56%), and various races were represented. Two patients had a urinary catheter (13%), and 10 of 16 patients (62.5%) were considered at a moderate or high risk of developing a pressure injury based on their scores on the Braden Scale for Pressure Sore risk^{14,46}. Participants had a variety of diagnoses at enrollment including cardiovascular, central nervous system, digestive, hematologic, musculoskeletal, pulmonary, and renal diseases (Table 1).

All participants met study criteria for the presence of IAD at enrollment (category 1 or 2)⁷; 12 had epidermal skin loss and 4 had severe redness with no skin breakdown. The mean SAT score at baseline was 544 ± 163 (mean \pm SD), with a median of 220. The mean duration of IAD prior to enrollment was 11.3 days (median: 6 days; range: 2-49 days). Prior to this study, all participants had been treated with barrier films, barrier creams, and ointments; 2 had received pastes; and 2 had been treated with cleansing wash cloths. All were switched to the structured skin care protocol for the duration of this study.

Participants had urinary incontinence, fecal incontinence, or double (urinary and fecal) incontinence at enrollment. The number of incontinent episodes during the study period was recorded to document continued incontinence throughout the study and to have specific information on how often cleansing was needed (cleansing was performed daily and with each fecal incontinence episode). The median number of incontinence episodes per patient per day was 3, ranging from 1 to 11 episodes. The median number of episodes per patient throughout the duration of the study was 34.5, ranging from 9 to 119 episodes.

At study start, half of the subjects (8) had double urinary and fecal incontinence, 3 (19%) had fecal incontinence with liquid stools, 2 (13%) had fecal incontinence with formed stools, and 2 (13%) had urinary incontinence. Patients were considered at risk for pressure injury development if they had a cumulative Braden Scale score of less than 18.⁴⁷ The majority of patients enrolled had a Braden Scale score of less than 18 (median: 14; range: 10-18). Since the risk of pressure injury development increases in the presence of incontinence as discussed earlier, the data on how many patients avoided a pressure injury in this study may be indirectly considered a possible indication of the efficacy of the investigational product at managing the effects of incontinence.

SAT Scores

The median percent change in IAD scores at the end of treatment (96%) was significantly different from zero (Wilcoxon signed-rank $W = 104$; $P = .013$). The SAT score improved in 13 of 16 patients (81.25%), remained unchanged in 1 patient (6.25%), and deteriorated in 2 patients (12.5%).

TABLE 1.
Demographic and Pertinent Clinical Characteristics of Participants

Characteristic	Number of Patients (%) (Total = 16)
Gender	
Male	7 (44)
Female	9 (56)
BMI >30 (obese)	
Yes	6 (38)
No	10 (63)
Race	
Asian	1 (6)
Black or African American	2 (13)
White	11 (69)
Other	2 (13)
Hispanic ethnicity	
Yes	1 (6)
No	15 (94)
Indwelling catheter ^a	
Yes	2 (13)
No	14 (88)
Pressure injury risk ^b	
Mild risk (Braden Scale score 15-18)	6 (38)
Moderate risk (Braden Scale score 13-14)	6 (38)
High risk (Braden Scale score 10-12)	4 (25)
Incontinence episodes per day, median (range)	3 (1-11)
Total incontinence episodes per patient during the study, median (range)	34.5 (9-119)
Incontinence type at study start	
Both urinary and fecal	8 (50)
Fecal liquid	3 (19)
Fecal formed	2 (13)
Urinary only	2 (13)
Admitting diagnosis	
Renal	4 (25)
Pulmonary	3 (19)
Cardiac/vascular	3 (19)
Musculoskeletal (fracture)	2 (13)
Digestive disorders	2 (13)
Hematologic disorders	1 (6)
Central nervous system disorder	1 (6)

Abbreviation: BMI, body mass index.

^aNone of the patients used a fecal management system.

^bPatients are considered at risk for pressure injury development if they have a Braden Scale score of less than 18.⁴⁷ The majority of patients enrolled had a Braden Scale score of less than 18 (median: 14; range: 10-18). The ranges for the mild-, moderate-, and high-risk categories are from Ayello and Braden.⁴⁷ The Braden Scale score ranges from 6 to 23; we had no patients at very low or no risk (19-23), nor at very high risk (6-9).

Four of the 12 patients with epidermal skin loss had complete reepithelialization with 4 to 6 applications of the barrier film. Five patients with epidermal loss had substantial improvement

TABLE 2.
Summary of Concomitant Medications

Concomitant Medications	Number of Patients (%) (Total = 16)
Laxatives/stool softeners	9 (56)
Antihypertensive agents	7 (44)
Antibiotics	6 (38)
Diabetic agents	6 (38)
Cardiac drugs	6 (38)
Proton pump inhibitors	5 (31)
Anticoagulants	3 (19)
Immunosuppressive agents	3 (19)

with 2 to 6 applications of the product but still had a small amount of epidermal loss at the end of the study. Three of these 5 patients were on warfarin therapy (an anticoagulant that could possibly have a negative impact on wound healing),⁴⁸ and they showed significant improvement in their IAD.

Table 2 summarizes the concomitant medications by listing the categories of medications taken by at least 3 subjects. One participant showed no improvement in the IAD score; this patient developed a pressure injury on day 15 and was discontinued from the study but included in the final analysis based on intention-to-treat principles used for analysis. Figure 4 displays the cumulative SAT score for each patient at the baseline evaluation and at the end of the study. Figures 5 and 6 illustrate specific patient cases and their progression over time.

Changes in FACES Pain Scale Scores

Eleven patients were able to assess their pain at enrollment. Of those, 9 reported pain at enrollment and 2 reported no pain throughout the study. Four patients were either nonresponsive or paraplegic with no sensation below the waist at enrollment, and there was 1 patient for whom pain information was missing (not collected) at enrollment and who later became unresponsive due to a myocardial infarct. Of the 11 subjects able to assess pain at enrollment, the median FACES Scale scores was 8 (range: 0-10), compared with a significantly (Wilcoxon signed-rank $W = 45$; $P = .009$) lower median of 0 (range: 0-3) at study end.

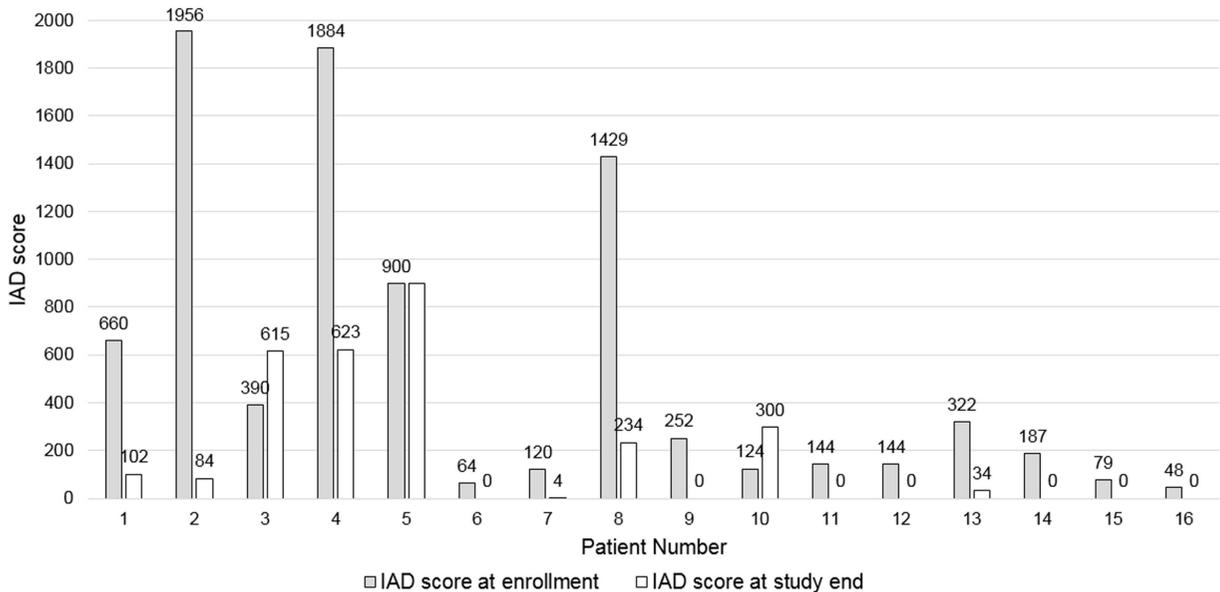


Figure 4. IAD scores for each patient at enrollment and at the end of the study. IAD indicates incontinence-associated dermatitis.



Figure 5. Patient 2. Patient at baseline (day 0), day 1, and day 5. The new barrier film was applied after the photograph was taken at day 0 and at day 4 (a total of 2 applications). The patient was discharged on day 5.



Figure 6. Patient 15. Patient at baseline (day 0), day 4, and day 7. The new barrier film was applied after the photograph was taken at day 0 and at day 3 and day 7 (a total of 3 applications; last photograph shows the result after 2 applications).

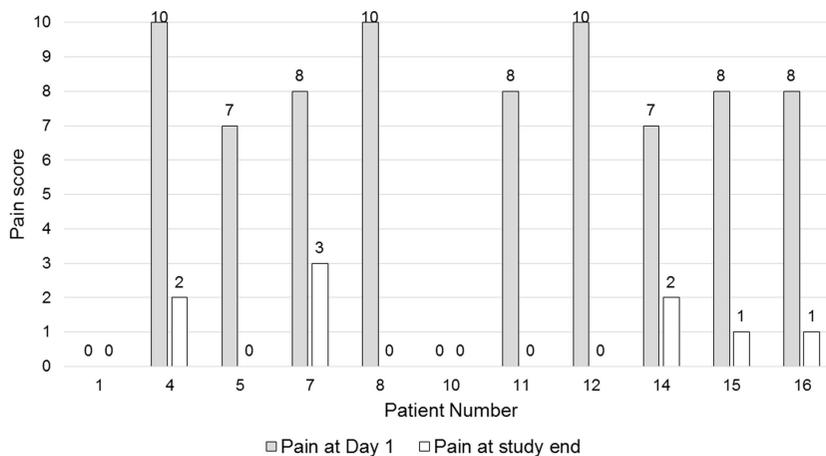


Figure 7. Pain scores at enrollment and end of study for the patients able to report pain.

All 9 patients who reported pain at the beginning of the study reported reduction, with initial scores ranging from 7 to 10 to scores of 0 to 3 at study end. Figure 7 summarizes the pain reported at the beginning and at the end of the study.

Adverse Events

One patient had a myocardial infarction during the study period and 1 developed a pressure injury. We believe neither was related to the investigational product. The myocardial infarction is unlikely to be triggered by a skin care protocol; a possible cause for the pressure injury was development of depression due to imminent transfer from home to skilled nursing facility. This individual declined or resisted efforts to turn, position, or increase mobility, which may have contributed to pressure injury risk.

DISCUSSION

Sixteen patients with IAD were managed with an acrylate-based skin protectant designed for use in the denuded skin. Based on SAT scores, 13 of 16 patients improved, 1 patient was unchanged, and 2 deteriorated (one who had a myocardial infarct and subsequently died, and one who refused 2 doses). These results were obtained in spite of continued incontinence throughout the study, ranging from 9 to 119 episodes per patient. One participant developed a pressure injury during the 3 weeks of data collection, even though the majority had a Braden Scale score of less than 18. There were no reported adverse events believed to be associated with the investigational product. The formulation was able to create a protective barrier in the presence of oozing exudate and con-

tinued incontinence. All 9 patients who reported pain associated with IAD and its care at enrollment reported a decrease in their pain score over the duration of the study.

A growing body of literature has been published that discusses the incidence and prevalence of IAD in various settings,^{9,49-51} principles of care based on etiology,^{4,6,52} importance of nursing education and structured care regimens,^{8,53-55} and the efficacy of various skin protectants or other products.^{25,26,29,56-58} A best practice document was recently published summarizing the current state of knowledge.⁷ In general, the categories of products currently available provide good protection against urinary incontinence, but clinical experience suggests that dealing with fecal incontinence is especially challenging, especially when diarrhea is present and occurs at a high frequency. Feces can be more difficult to clean than urine, and it may require more friction to remove residue from the skin. The new product tested in this study offers a smooth film formulation (designed to be easy to clean over) that acts as a skin protectant for patients experiencing fecal incontinence.

Study findings suggest that the skin protectant evaluated in this study may be effective for the management of IAD. Thirteen of 16 participants experienced improvement in their SAT scores. In addition, one subject with *C difficile*-associated diarrhea did not experience skin breakdown despite 97 incontinence episodes during data collection.

In addition, a reduction in self-assessed pain score was noted in every participant who was able to report pain at the beginning of the study. Participants described the pain in the denuded areas as burning and unrelenting. Subjects who experienced loose stools described passage of liquid stool as

“torture,” and they further indicated they dreaded cleansing. Among nonverbal patients, we noted grimacing and pulling away when cleaning the patients prior to the first application. Patients who were able to verbalize said the product did not sting or result in any additional discomfort upon application.

LIMITATIONS

This study has several limitations. The sample size was small (16 patients), and no comparison group was included. Therefore, random allocation of participants to a treatment or control group was not possible.

Changes in IAD over time were measured via the SAT that has not been validated. Over the years, various instruments for the assessment of IAD have been developed and evaluated for level of agreement among users.⁵⁹⁻⁶¹ A Global IAD Expert Panel recognizes the need for a systematic assessment of IAD and recommends an approach based on the level and severity of skin injury.⁷ We chose to develop our own instrument for this study, accompanied with photographic documentation, because we believe there was a need for a scale with a broader range of scores to improve discrimination between the various degrees of severity. Even a currently validated tool such as the Incontinence-Associate Dermatitis and its Severity (IADS) Instrument⁵⁹ displays wide variability; for example, the ranges of minimum to maximum scores given by the 3 groups of testers for one of the test cases were 18 to 52, 16 to 52, and 4 to 52, respectively (this scale has a scoring range of 0-52). There may not be any statistical differences in scoring between the groups, but there is broad variability in the scores assigned to the same case by various caregivers within each group. Our assessment tool attempts to improve discrimination by taking into account the surface area affected within each zone observed, a feature not present in the IADS instrument.

CONCLUSION

The novel skin protectant evaluated in this study led to a significant reduction in IAD scores and IAD-associated pain scores during cleansing and subsequent product applications. Additional research, including a randomized controlled trial, is needed to more fully evaluate the efficacy of this barrier film in the management of severe IAD.

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