Original Article

Moldable Skin Barriers as a Clinical Option for Patients Following Ileostomy

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Key Words
Moldable skin barrier;
Ileostomy

Purpose. Peristomal skin problems are the most common physical complications following ileostomy and are often caused by leakage or a poorly fitting skin barrier. This study aimed to assess the incidence of peristomal lesions and patient satisfaction with moldable skin barriers compared with conventional cut-to-fit skin barriers.
Method. This was a prospective observational study designed to examine peristomal skin complications following ileostomy in patients within the first 2 months of surgery. Peristomal skin was assessed using the Studio Alterazoni Cutanee Stomale (SACS^{TM}) scale by enterostomal therapy nurses, and patients were asked to rate the product's effectiveness regarding skin protection, sealing effect, and ease of application. All patients were assessed at baseline, and 1 and 2 months post-surgery. Patient demographics, peristomal skin condition, and skin barrier performance were analyzed.
Results. Between June 2018 and June 2019, a total of 120 patients underwent ostomy surgery at Chi-Mei Hospital, of which 60 ileostomy patients were recruited in this study. There were no significant statistical differences in demographic features or peristomal skin complications between groups. However, up to 21.67% (13/60) ileostomy patients experienced peristomal skin complications and 70% (9/13) of peristomal skin complications occurred in the first month following surgery. The moldable skin barrier achieved significant satisfaction among patients, as wel as in effectiveness of skin protection, sealing effect and easy of application.
Conclusion. Our findings confirm that the prevalence of skin irritation among ileostomy patients is high and suggest that the moldable skin barrier is comfortable and easy to use.
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Surgical creation of a stoma for discharge of bodily waste products continues to have an important role in the treatment of colorectal cancer, bladder cancer, constipation, pelvic floor dysfunction, and inflammatory bowel disease.[1-9] A stoma is an artificial opening through which the bowel protrudes and is attached to the skin surface allowing stool or urine to be diverted to the outside of the body.[4-6,9] The effluent must be separated from the skin and contained within a pouching system that adheres to the skin.[5] Keeping this system operating well and healthy are critical in the maintenance of a well-functioning stoma.[4,8,9]

Peristomal skin complications have been reported to affect 18%-73% of stomy patients.[1,4,6,8-12] Ileostomies, specifically loop ileostomies, are responsible for the greatest proportion of peristomal skin complica-

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tions.[1,2,4-6,11] Other causes of peristomal skin complications vary, although the majority are related to leakage of the pouching system,[1,8] which allows effluent to come into contact with the skin. Pouch leakage can also be a source of anxiety for patients, particularly in those following a colostomy or ileostomy where fear of odor can be an issue. A skin barrier, which attaches the ostomy pouch to the abdomen, is designed to protect the skin from stomal output; however an ill-fitting barrier can allow effluent to come into contact with the skin, causing peristomal skin breakdown. Poorly sited or constructed stomas, obesity, adjacent wound complications, underlying disease, as well as improperly fitting ostomy appliances or poor skin care regimens, may increase the risk of developing peristomal skin problems.[1,2,6-8,11] Traditional ostomy barriers (eg, cut-to-fit and precut) have been used to help maintain the ostomy appliance/skin seal and prevent leakage, however they can require the patient to master complex skills. The barriers may not fit precisely, leaving exposed skin subject to the risk of breakdown, and the rough edges on cut-to-fit barriers may cause mechanical trauma to the stoma.[13] ConvaTec Moldable Technology™ Skin Barriers (ConvaTec Inc, Skillman, NJ) were developed to provide easy application and a customized fit around the stoma for a more secure seal. The barrier is fitted to an individual stoma by rolling the moldable barrier to match the approximate stoma size, applying the barrier to the body, and rolling back the moldable barrier so it securely hugs the base of the stoma. The moldable barrier allows a personalized fit, with improved adhesion onto irregular skin surfaces and around irregularly shaped stomas.

The current prospective, observational study was conducted to determine the incidence of peristomal lesions, evaluate the progression of peristomal skin conditions at 1-month and 2-months following the application of the skin barrier, and assess the satisfaction level with these products in patients with new ileostomies and in patients with new ileostomies who experienced skin complications with traditional barriers.

Materials and Methods

Between June 2018 and June 2019, we performed a prospective observational study designed to examine peristomal skin complications following ileostomy in patients within the first 2 months of surgery at Chi-Mei Hospital. Inclusion criteria stipulated that patients should be 18 years of age or older with an ileostomy, colostomy, or urostomy, and they should use a traditional cut-to-fit barrier or a moldable skin barrier as part of the first (within 7 days of surgery) long-term management system. The study was conducted among 2 cohorts: Group A included 60 new patients with intact skin who used traditional cut-to-fit ostomy barriers as the first long-term system after ostomy surgery. Group B included 60 new patients using the ConvaTec SUR-FIT Natura® Moldable Technology Skin Barrier as the first long-term system after ostomy surgery (Fig. 1). In Group A, when stoma patients present peristomal skin lesions, the cut-to-fit skin barrier was changed to the ConvaTec Moldable Technologt™ Skin Barrier and patients were observed for at least one month (Fig. 2).

Demographic and clinical information was collected and each patient's stoma was assessed. Peristomal skin conditions were classified using the Studio Alterazoni Cutanee Stomale (Study on Peristomal Skin lesions, SACS™) Instrument.[14] The SACS™ scale is an objective classification system developed for and accepted by consensus of health care professionals in Italy. It subsequently has been validated in both Italy and the US (content validity of 0.94 out of 1.0).[15] This system classifies skin lesions in 2 dimensions: lesion type and topographical location. Lesion type was rated in order of increasing severity as hyperemic (presence of excess blood in the vessels), erosive (gradual destruction of surface tissue), ulcerative (open wound), ulcerative fibrinonecrotic (avascular), or proliferative (collagen synthesis, cell proliferation/extracellular matrix formation).[16] Lesion topography was described by peristomal quadrant: upper right, lower right, lower left, upper left, or all peristomal quadrants. Peristomal skin conditions were assessed at baseline and at each follow-up visit using the validated SACS™ Instrument. The progression of the peristomal skin condition was evaluated by comparing SACS™ assessment at each follow-up visit to the baseline SACS™ assessment, including other reasons for a barrier change such as stool characteristics and accessory

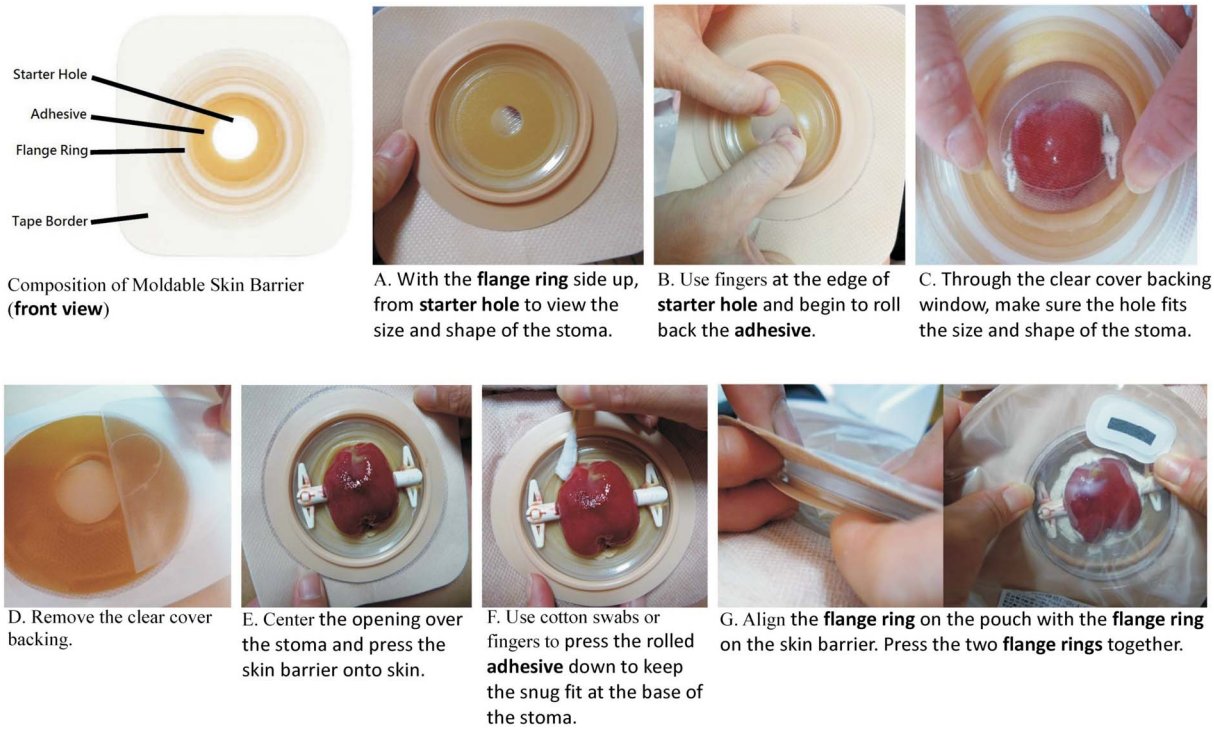

Fig. 1. ConvaTec SUR-FIT Natura® Moldable Technology Skin Barrier.

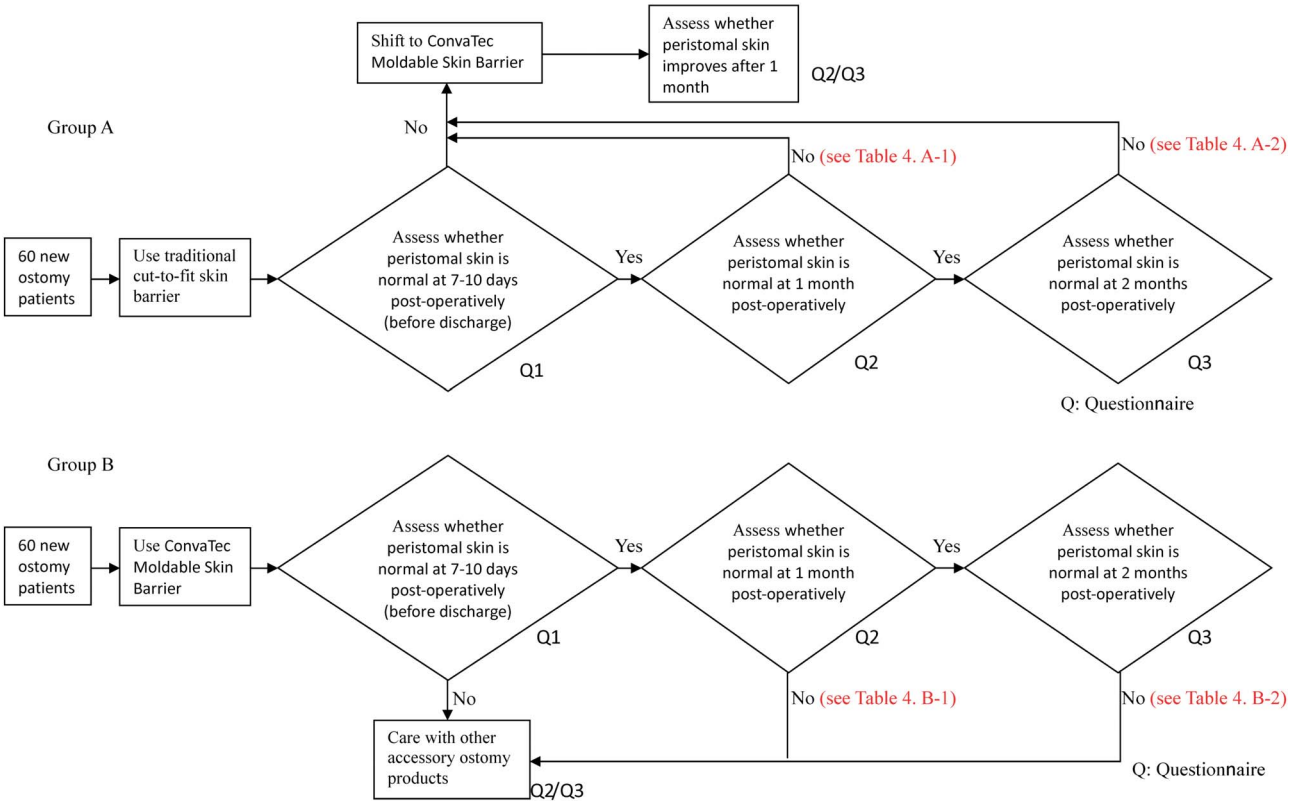

Fig. 2. Diagram of study flow.

usage (ie, use of powder, belts, paste, deodorant/odor control products, and adhesive remover wipes).

Patients evaluated the performance of the cut-to-fit or moldable skin barrier at each follow-up visit by completing a Satisfaction Questionnaire which rated effective skin protection, stable sealing effect, and ease of application of the skin barrier. The 3 response options were good/excellent, not bad, and poor.

Data were collected via case report forms at baseline (within 7 days of surgery), at 1 month (±7 days) following enrollment, and at 2 months (±7 days) following enrollment. Groups A and B followed the same schedule and study procedures. After informed consent was obtained, baseline demographic data were collected, which included date of stoma surgery, type of stoma, stoma shape, stoma appearance, stoma state (temporary or permanent), stool characteristics, and SACS^{TM} scale.

Statistical analysis

All data were recorded on the case report forms and data entry verified by double key entry. All primary and secondary parameters reported were summarized by Group (A and B). Continuous variables such as age, gender, and stoma characteristics were summarized by mean, standard deviation and number of valid cases. Categorical variables such as incidence of skin lesions and participant evaluations were described as the total number, relative percentage of participants per response category, and 95% confidence interval. Summaries were reported according to the predefined evaluation subgroups. SPSS version 20 for Windows (SPSS, Chicago, IL, USA) was used for data analysis. The chi-square test was used to test differences between the two groups where appropriate. Differences were considered significant at $p < 0.05$.

Results

Participant demographics and stoma characteristics

A total of 120 new ostomy patients were enrolled in this study. Sixty patients underwent ileostomy during this period (19 patients in Group A and 41 patients in Group B). Patient demographics are listed in Table 1. The majority of stomas in both groups were temporary, oval, and protruding. Patients in Group A (cut-to-fit) had predominant hyperemic peristomal lesions ($p = 0.0283$). No significant differences were identified between the two groups in the other observed parameters, including age, gender, nature of stoma, shape of stoma, appearance of stoma, stool consistency, state of peristomal skin (SACS^{TM}), and topographical location (SACS^{TM}).

All patients in both groups had no abnormal peristomal skin at baseline. The primary outcome in this study was development of new skin lesions or worsening of existing lesions. Three patients (15.79%) in Group A and 6 patients (14.63%) in Group B reported a peristomal skin lesion at the 1-month follow-up visit, whereas three patients (15.79%) in Group A and 5 patients (12.20%) in Group B reported peristomal skin lesions at the 2-month follow-up visit. Subgroup analysis of peristomal skin lesions revealed 2 new lesions, respectively, in Group A and Group B at the 2-month follow-up visit. During the study periods, there were 4 refractory peristomal skin lesions (one in Group A and three in Group B). A total of 13 patients reported peristomal skin lesions in this study (5 patients in Group A [26.32%] and 8 patients in Group B [19.51%]; $p = 0.7372$)

Patients assessed the effective skin protection, stable sealing effect, and ease of application of the skin barrier in a Satisfaction Questionnaire at the 2-month follow-up visit (Table 3). Patients reported significant satisfaction in effective skin protection ($p = 0.0031$), stable sealing effect ($p = 0.0049$), and ease of application ($p = 0.0006$) with the moldable skin barriers compared with traditional cut-to-fit skin barriers, respectively.

Discussion

A well-recognized goal in the care of patients with ostomy is to ensure a secure seal to protect the stoma and maintain peristomal skin protection. Loop ileostomies represent the greatest proportion of peristomal

Table 1. Patient demographics (intent-to-treat population)

	Group A (n = 19)	Group B (n = 41)	*p*-value
Age, years			
Mean (SD)	62.84 (12.84)	60.54 (12.94)	0.5225
Gender			0.2409
Male	9 (47.37)	26 (63.41)	
Female	10 (52.63)	15 (36.59)	
Nature of stoma, n (%)			0.1476
Permanent	1 (5.26)	9 (21.95)	
Temporary	18 (94.74)	32 (78.05)	
Shape of stoma, n (%)			0.6682
Round	3 (15.79)	4 (9.76)	
Oval	16 (84.21)	37 (90.24)	
Appearance of stoma, n (%)			0.7547
Flat	10 (52.63)	19 (46.34)	
Protruding	6 (31.58)	17 (41.46)	
Retracted	3 (15.79)	5 (12.20)	
Stool consistency, n (%)			> 0.9999
Semi-liquid	17 (89.47)	36 (87.80)	
Liquid	2 (10.53)	5 (12.20)	
State of peristomal skin (SACS^{TM})			0.6995
Normal	16 (84.21)	36 (87.80)	
Abnormal	3 (15.79)	5 (12.20)	
Type of lesion (SACS^{TM})			
Hyperemic	3 (15.79)	0 (0.00)	0.0283
Erosive	2 (10.53)	4 (9.76)	> 0.9999
Ulcerative	0 (0.00)	1 (2.44)	> 0.9999
Ulcerative fibrinonecrotic	0 (0.00)	0 (0.00)	-
Proliferative	0 (0.00)	0 (0.00)	-
Topographical location (SACS^{TM})			
Upper right peristomal quadrant	2 (10.53)	2 (4.88)	0.5846
Lower right peristomal quadrant	2 (10.53)	1 (2.44)	0.2332
Lower left peristomal quadrant	1 (5.26)	0 (0.00)	0.3167
Upper left peristomal quadrant	1 (5.26)	1 (2.44)	0.5367
All peristomal quadrants	2 (10.53)	4 (9.76)	> 0.9999

Table 2. Incidence of new peristomal skin lesions or worsening lesions at each visit by group (analyzable population: participants who completed every follow-up visit)

	Group A (n = 19)	Group B (n = 41)	*p*-value*
Peristomal skin lesion			
At discharge (baseline)	0	0	
1-month post baseline	3 (15.79%)	6 (14.63%)	0.6995
2-months post baseline	3 (15.79%)	5 (12.20%)	0.6995
Subgroup analysis of perostomal skin lesion			
New lesion at 1-month post baseline	3 (15.79%)	6 (14.63%)	0.6995
New lesion at 2-months post baseline	2 (10.53%)	2 (4.88%)	0.5846
Worsened and refractory skin lesion	1 (5.26%)	3 (7.32%)	> 0.9999
Overall peristomal skin lesion	5 (26.32%)	8 (19.51%)	0.7372

skin complications in patients. In one study, 79% of patients with a loop ileostomy suffered from a peristomal skin complication.[11] A recent cross-sectional study by Herlufson et al.[17] reported that of 202 individuals with permanent stomas, 45% had peristomal skin disorders; of these, 57% had an ileostomy, 48% had a urostomy, and 35% had a colostomy. The problems lasted for more than 3 months for 76% of the participants with skin disorders. The moldable skin barrier is rolled open to create a customized fit regardless

Table 3. Evaluation of skin barrier performance

Evaluation criteria	Rating	Group A (n = 19)	Group B (n = 41)	*p*-value*
Effective skin protection	Good/excellent	2 (10.53)	23 (56.10)	0.0031
	Not bad	13 (68.42)	12 (29.27)	
	Poor	4 (21.05)	6 (14.63)	
Stable sealing effect around the stoma to prevent leakage	Good/excellent	3 (15.79)	25 (60.98)	0.0049
	Not bad	12 (63.16)	12 (29.27)	
	Poor	4 (21.50)	4 (9.76)	
Ease of application	Good/excellent	5 (26.32)	31 (75.61)	0.0006
	Not bad	12 (63.16)	9 (21.95)	
	Poor	2 (10.53)	1 (2.44)	

Table 4. Patient with skin complications

	Sex	Age	Diagnosis	OP procedure	Emergent	SACS	TI	TII	TIII	TIV	TV
A-1	F	56	Rectal adenocarcinoma	LAR + loop ileostomy	N	2	0	0	0	0	1
	F	76	Rectal cancer s/p neoadjuvant CCRT	Laparoscopic ISR + loop ileostomy	N	2	0	2	2	0	0
	F	42	Recurrent presacral mucinous tumor	LAR + protective loop ileostomy	N	2	0	0	0	0	1
A-2	F	72	Ascending & rectal cancer	Laparoscopic right hemicolectomy + loop ileostomy	N	2	0	0	0	2	0
	M	81	Retroperitoneal liposarcoma with invasion to descending colon	Loop ileostomy	N	2	1	0	1	1	0
B-1	F	59	Multiple perforation of descending colon	Resection of descending colon with side-to-side anastomosis + loop ileostomy	Y	2	0	0	0	0	2
	F	37	Recurrent colon cancer with carcinomatosis	Loop ileostomy + enterolysis	N	2	0	0	0	0	2
	F	67	Rectal cancer s/p neoadjuvant CCRT	Laparoscopic LAR + loop ileostomy	N	2	0	2	2	0	0
	F	87	Ascending colon cancer with obstruction	Loop ileostomy	Y	2	0	2	0	2	0
	F	51	Sigmoid colon cancer with obstruction	Loop ileostomy	Y	1*	0	0	0	0	0
	M	65	Rectal cancer with multiple liver metastases	Loop ileostomy	N	2	2	0	0	2	0
B-2	M	82	Rectosigmoid colon cancer with liver metastasis	LAR + loop ileostomy	N	2	0	0	0	0	2
	M	66	Rectosigmoid colon cancer with liver metastasis	Laparoscopic LAR + loop ileostomy	N	2	0	0	0	0	1

* Peristomal abscess.

of stoma size and shape, eliminating the need for cutting the barrier to size. The barrier "turtlenecks" (gently swells up around the stoma) to create a snug fit without traumatizing the stoma while protecting the surrounding skin from stoma effluent. Moldable skin barriers provide a customized fit and can assist in the prevention and treatment of peristomal skin complications. In a pilot study using moldable barriers,[18] 5.6% of patients with a new stoma developed peristomal lesions. In patients who changed from a traditional ostomy system to moldable barrier peristomal lesions were reduced from 100% to 16.3%.[19,20] In the current study, the peristomal skin complication rate following ileostomy was 21.67% (13/60) and 70% (9/13) of peristomal skin complications that occurred in the first month. Four peristomal skin complications developed

in the second month, whereas 2 new lesions were reported in Group A and B (10.53 % vs. 4.88 %, p = 0.5846). Although not statistically significant, the moldable skin barrier reduced skin complications in the second month following ileostomy. In both experimental groups, there were refractory peristomal skin complications (one in Group A [5.26%] and three in Group B [7.32%] $p > 0.9999$). Upon further analysis, all of these refractory cases had flat or retracted stomas. This may be related to poor bowel condition in emergent surgeries, or immature surgeon's skill (residents in training course despite of under senior surgeon's instruction). Loop ileostomies often empty effluent close to the skin because the stoma itself frequently does not protrude sufficiently (ie, too flat).[2] While performing an ileostomy, or called the conventional Brooke ileostomy, we everted the mucosal surface of the bud and suture the mucosa to the skin. Therefore the stoma protruded and elevated from the skin, and let the moldable skin barrier create a snug fit, without skin exposure to body waste. However a low-lying stoma can lead to effluent pooling near where the stoma empties directly into the pouch away from the flange opening,[1,2,11] invalid the barrier "turtlenecks".

This is an important finding because leakage is a critical factor in the formation of peristomal lesions and a common source of anxiety for patients.[21] Stoma formation is a simple, but not trivial, undertaking. When performed poorly, it can leave patients with a legacy of complications such as leakage, prolapse, parastomal hernia, and retraction. Sometimes, these complications are difficult to manage even with newly advanced care tools and well-experienced enterostomal therapy nurses.

Patient comfort and ease of use regarding an appliance are also necessary for successful rehabilitation after ostomy surgery.[22] Patients with an ostomy traditionally wear skin barriers that are precut or need to be cut to fit the stoma opening, requiring teaching and practice. Patients with compromised dexterity may have difficulties completing these tasks. Moldable skin barriers require minimal preparation and enable easy and flexible application. The current study shows significant levels of patient satisfaction with moldable skin barriers compared with traditional cut-to-fit skin barriers. Greater than 55% of all patients rated the effective skin protection, stable sealing effect around the stoma to prevent leakage, and ease of application of the moldable barrier as excellent or good.

The number of patients enrolled in this study was small and this is the major limitation of this study. The effect of moldable skin barriers at maintaining and improving peristomal skin integrity is not fully elucidated and further studies with larger sample sizes are needed.

Conclusion

An ostomy system that is comfortable and easy to use will help ease the transition for new ostomy patients and reduce the risk of peristomal skin complications. The current results demonstrated moldable skin barriers are comfortable and easy to use for ileostomy patients.

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原　著

單一機構在迴腸造口患者使用可塑形保護皮的臨床經驗

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目的　造口旁皮膚問題是造口手術後最常見的身體併發症，通常是由滲漏或保護皮不適用所引起。本篇研究目的在評估使用可塑形保護皮的病患，其造口旁皮膚問題的發生率及使用上的滿意度。

方法　本篇為前瞻性觀察性研究，旨在描述接受造口手術後的前二個月，病人所遇到的造口旁皮膚併發症。造口旁皮膚病灶是由造口治療師使用 Studio Alterazoni Cutanee Stomale (SACS^{TM}) scale 來評估，且由病人為產品的皮膚保護功效、密合效果及使用容易度評分。所有病患皆在基線、術後一個月及二個月進行評估。患者的統計資料、造口旁皮膚情形，及保護皮性能的評估皆納入分析。

結果　於 2018 年 6 月至 2019 年 6 月期間，有 120 位病患在奇美醫院接受造口手術。本研究納入其中 60 位迴腸造口的患者。兩個組別在基本資料及造口旁皮膚併發症並沒有統計上的差異。然而，高達 21.67% (13/60) 的迴腸造口病患發生造口旁皮膚併發症，且其中 70% (9/13) 的併發症發生在術後的第一個月。而可塑形保護皮在皮膚保護功效、密合效果及使用容易度上有顯著的滿意度。

結論　我們的研究發現證實迴腸造口的病患其皮膚刺激的發生率很高，因而我們建議使用可塑形保護皮較為舒適且容易。

關鍵詞　可塑形保護皮、迴腸造口。