A Prospective Multicenter Evaluation of a Moldable Stoma Skin Barrier

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Abstract

Ostomy skin barriers can be difficult to size and shape; gaps between the skin and the appliance can compromise peristomal skin protection. A multicenter evaluation was initiated to assess the satisfaction of persons with ostomies (n = 172, mean age 56.6 years) and enterostomal therapy nurses (ETs, n = 49; number of evaluations = 195) with a new moldable skin barrier. The majority (116) of participants had ostomy surgery >90 days before the evaluation. Study participants received up to five product samples. Evaluation forms included stoma background information and questions regarding the product's ease of application and molding, ease of creating a customized fit, adherence of the hydrocolloid collar, ability to shape and reshape, effectiveness of skin protection, level of satisfaction with the product, and concerns/problems. At baseline, skin irritation was noted in 41% of ET evaluations and by 46% of participants with a stoma and cited as a reason to discontinue product usage in 11 ET reports (6.4%) and by seven users (3.6%). Regardless of the type of ostomy surgery, the percentage of "very good"/"excellent" ratings from participants for all evaluation criteria was 84.2% for colostomies, 85.4% for ileostomies, and 92.5% for urostomies. Similarly, for the ET evaluations, the percentage of "very good"/"excellent" ratings for all evaluation criteria was 89.0% for colostomies, 92.7% for ileostomies, and 92.7% for urostomies and 87% of ETs noted that teaching product usage was easy. Although interpretation of the results is limited by the study design, these findings confirm previous reports that the prevalence of skin irritation among ostomy patients is high and suggest that the barrier evaluated is comfortable and easy to use. Controlled clinical studies to compare the safety and effectiveness of ostomy appliances as well as their effect on patient quality of life are needed.

Key Words: evaluation, peristomal skin, ostomy, skin barrier, safety

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Mastering selection and application of a pouching system is an important concern for an individual living with an ostomy. Effective patient education enables the individual to gain independence and confidence with routine care as well as pouching system application. Ideally, this education process begins in the pre-operative phase, progresses through hospital discharge, and continues to outpatient follow-up with an Enterostomal Therapy (ET) nurse or non-specialized nurse. Appropriate ostomy pouching system selection is of utmost importance across the continuum of care.

A well-recognized goal in ostomy care is to ensure a secure seal to protect the stoma and maintain peristomal skin protection. Choosing a system to achieve these goals will depend on how the stoma is shaped and whether it protrudes or is flush (flat) with the skin. The ideal stoma protrudes slightly to obtain a secure seal around its base and to facilitate stoma effluent drainage into the pouch.[1]

Incorrect selection or preparation of an ostomy appliance can lead to complications, such as peristomal skin disorders. According to Colwell and Beitz,[2] "The peristomal skin should

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be intact with no evidence of redness, loss of epidermis, or sensations such as itchiness, warmth, or pain. The ability to maintain healthy peristomal skin is related to the body's ability to react to the skin barrier and adhesive materials, the health of the persons with the diversions, and their associated care practices (fitting the skin barrier, wear time, and techniques for cleansing and application)."

A recent cross-sectional study by Herlufson et al[3] of 202 individuals with permanent stomas found that overall, 45% had peristomal skin disorders — of these, 57% had an ileostomy, 48% had a urostomy, and 35% had a colostomy. For 76% of the participants with skin disorders, the problems lasted for more than 3 months.

Dry, intact skin and a properly fitted skin barrier are required to achieve a sustainable, consistent wear time. Without one or the other, skin integrity may be compromised, leading to a cycle of leakage and skin erosion.[4] Poorly sited or constructed stomas, obesity, adjacent wound complications, and underlying disease, as well as improperly fitting ostomy appliances or poor skin care regimens, may increase the risk of developing peristomal skin problems.[4,5] Traditional skin barriers (such pre-cut or cut-to-fit) require the patient to learn and practice a complex set of skills (eg, how to measure the stoma and how to cut the barrier properly) and handle additional equipment and accessories. The learning curve can be particularly difficult for persons who have stomas that are not round or that change shape. Experience has shown that cutting out the opening for the stoma on some skin barriers can leave rough edges that may traumatize the stoma. Given these challenges, the need exists for a skin barrier that is easy to use and that adapts and conforms to the shape of the stoma.

SUR-FIT Natura® Moldable Skin Barrier (ConvaTec Inc., Skillman, NJ) is recommended for use on stomas that protrude ½ inches (12 mm) or more. The adhesive is rolled open to create a customized fit regardless of stoma size and shape and no cutting is necessary. The adhesive gently hugs stoma contours and eliminates gaps between the skin barrier and the stoma. This moldable skin barrier can be used with any SUR-FIT Natura® brand pouch (with the exception of the pouch with the 100-mm flange ring).

To assess overall satisfaction with this moldable skin barrier, a prospective study was conducted to evaluate participants' (people with an ostomy who used the product) and ET nurses' overall satisfaction with their experiences with the product.

Methods

Using a convenience sampling method, 60 ETs from acute care facilities across Canada were invited to participate in the evaluation. The evaluation sponsor provided participating ETs with a demonstration on product usage, written information illustrating the proper application technique, evaluation forms, and product samples (up to five per participant). ETs were asked to identify patient participants to enroll in the evaluation program. The product is designed for protruding stomas; however, it was up to the nurse's discretion to select eligible patients based on their expertise and clinical judgment. Every study participant, as well as the ETs, was asked to fill out an evaluation form. Evaluation forms could be completed while the patient was in hospital or in another healthcare setting depending on the clinical situation. The participant or the ET decided how long to trial the product and when to complete the evaluation forms; no minimum/maximum time frame was established. The length of time a participant wore the barrier was at the clinical discretion of the ET nurse; wear time was not recorded. Evaluation forms included guarantees of confidentiality and disclosure that the evaluation results could be used for the development of publications and marketing material.

Evaluation forms. Baseline assessment variables were similar for the participant and the ET evaluation forms. Questions included: type of ostomy surgery (ileostomy, colostomy, urostomy), time since ostomy surgery (0 to 7 days, 7 to 30 days, 30 to 90 days, >90 days), stoma shape (round, oval, irregular), stoma length (flush or protruding), condition of skin around the stoma (intact without redness, some redness and breakdown, extensive redness and breakdown), abdominal contours (firm/flat, flabby/soft, round/hard), skin barrier system applied (moldable extended-wear barrier 45 mm, 57 mm, 70 mm or moldable standard-wear barrier 45 mm, 57 mm, 70 mm), and prior products used. The only difference between the ET and participant evaluation forms with respect to the baseline questions was that the question on the participant form "time since ostomy surgery" was replaced by study participant type (new, follow-up, or referral) on the ET form.

Participants and ETs were asked to rate the product on a Likert scale from 1 to 4, where 1 represented "poor", 2 "satisfactory", 3 "very good", and 4 "excellent" on the following criteria: ease of application, ease of molding, ease of creating a customized fit, adherence of the hydrocolloid collar, ability to shape and reshape, effectiveness of skin protection, and level of satisfaction with the product. Additionally, respondents were asked to 1) choose or provide a word that best described the barrier (choice of: simple, adaptable, skin friendly, other),

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Key Points

- Although used worldwide by every person with a stoma, information about the effects of ostomy appliances on skin condition and quality of life is limited.
- The results of this prospective, multicenter survey confirm that skin irritation is very common and that the type of skin barrier used may affect skin irritation rates.
- Study design limitations preclude generalizations but the general agreement between appliance user and ET nurse evaluations about the overall performance of this skin barrier is encouraging.

2) state whether they would recommend the product (yes/no), 3) state whether discontinuation or any problems were experienced (yes/no, explain), and 4) share additional comments or suggestions.

Patient participants also were asked to rate the product on pain during application and removal, convenience of use, and level of comfort using a numerical scale from 1 to 4, where 1 represented "poor", 2 "satisfactory", 3 "very good", and 4 "excellent". Patients also were asked to indicate their level of confidence with the product by answering yes/no to the question "Have you been able to walk around with confidence?" The ET nurses were asked to rate how easy it was to teach product usage and if the barrier was simple to use and easy to teach (yes/no).

Data analysis. ETs and participants mailed completed evaluation forms directly to a third party. All information was entered in a spreadsheet and analyzed using Microsoft Excel spreadsheet software (Microsoft® Corporation, Redmond, WA). Participant data were analyzed and stratified based on the type of ostomy surgery (colostomy, ileostomy, and urostomy). Percentages were calculated for each rating/response. Descriptive statistics (mean and SD) were used for "effective skin protection" and the baseline skin condition rating was assessed in relation to the skin protection rating for the skin barrier to determine whether any relationship could be established between the data, both for ET and participant responses.

Results

Of the 60 ETs invited, 49 (81.7%) from 39 Canadian acute care institutions agreed to participate and completed 195 questionnaires (mean 5.2 ± 4.08 per institution). One hundred, seventy-two (172) persons with a stoma participated in the evaluation and completed evaluations for a total of 367 completed evaluation forms. ETs were located in Quebec (nine), Ontario (18), Saskatchewan (three), Alberta (four), British Columbia (six), Newfoundland (two), Nova Scotia (three), and New Brunswick (four). Because the ETs and participants filled out and submitted their evaluations separately, it is not known whether all the participant evaluations corresponded with ET evaluations submitted or vice versa.

Baseline participant evaluations. The mean age of the participants was 56.6 years (range 17 to 88 years); eight (4.7%) had urostomy surgery, 62 (36%) had a colostomy, and 102 (59.3%) had an ileostomy (see Table 1). At baseline, a little more than half of the patients (89, 51%) reported intact skin without redness, 70 (40.7%) noted some redness or breakdown, and 10 (5.8%) reported extensive redness and breakdown. Examining

baseline skin condition related to type of ostomy surgery, 43 colostomy patients (69%) had intact skin without redness, 52 (51%) ileostomy patients had some redness or breakdown, and six (75%) urostomy patients had intact skin without redness (see Table 2).

Participant evaluation of skin barrier performance. Participant ratings of skin barrier performance were similar overall for the different types of ostomy surgeries with a trend toward higher ratings by participants with urostomies (see Table 3). The mean percentage of "excellent" or "very good" ratings across the 10 criteria was 84.2% for colostomies, 85.4% for ileostomies, and 92.5% for urostomies.

More specifically, for participants with colostomies the percentages of "excellent" or "very good" ratings ranged from 75.8% for overall satisfaction to 90.3% for ease of molding. For participants with ileostomies, the percentages of "excellent" or "very good" ratings ranged from 71.6% for overall satisfaction to 96.1% for ease of molding. For participants with urostomies, the percentages of "excellent" or "very good" ratings ranged from 87.5% for effective skin protection, painless to apply/remove, ability to shape and reshape, adherence, overall convenience, and overall satisfaction to 100% for all the remaining criteria (see Table 3).

When grouped by participant baseline skin condition, the average skin protection effectiveness rating for persons with intact skin (on a scale of 1 to 4) was 3.45 ± 0.74 for colostomy, 3.25 ± 0.85 for ileostomy, and 3.00 ± 0.63 for urostomy; whereas, for persons with some redness or breakdown at baseline, the mean ratings were

Table 1. Baseline evaluation data

		Participants (N=172)	ETs (N=49) Number of evaluations=195
Gender	Male	86	97
	Female	85	97
	Not indicated	1	1
Surgery type *(some subjects had multiple answers)*	Ileostomy	102	121
	Colostomy	62	60
	Urostomy	9	12
	Not indicated	0	2
Participant type	New	NA	58
	Follow-up	NA	114
	Referral	NA	21
	Not indicated	NA	2
Days since surgery	0-7	10	NA
	7-30	18	NA
	30-90	26	NA
	>90	116	NA
	Not indicated	2	NA
Previous product use *(some participants had multiple answers)*	Hollister	73	79
	ConvaTec	68	58
	Coloplast	17	10
	Other	2	24
	Not indicated/New participant	34	24
Stoma shape	Oval	87	87
	Round	69	85
	Irregular	16	17
	Not indicated	0	6
Stoma length	Protruded	147	162
	Flush	23	29
	Not indicated	2	4
Peristomal skin condition	Intact without redness	89	106
	Some redness or breakdown	70	70
	Extensive redness or breakdown	10	11
	Not indicated	3	8
Abdomen	Firm, flat	69	88
	Round, hard	34	33
	Flabby, soft	64	69
	Pregnant	1	1
	Not indicated	4	4
Moldable barrier system used	45 mm	120	133
	57 mm	44	59
	Not indicated	8	3

NA = Not assessed

Table 2. Baseline skin condition

Evaluation Criteria	Participants (N = 172)			ETs (N = 193 evaluations)		
	Colostomy (n= 62)	Ileostomy (n=102)	Urostomy (n=8)	Colostomy (n=60)	Ileostomy (n=121)	Urostomy (n=12)
Intact without redness	43	40	6	43	58	4
Some redness or breakdown	18	52	0	12	52	5
Extensive redness and breakdown	0	8	2	3	6	2
Not reported	1	2	0	2	5	1

2.94 ± 0.87 and 3.08 ± 0.97 for colostomy and ileostomy, respectively. Mean ratings for persons with extensive redness and breakdown at baseline were 2.5 ± 1.07 for ileostomy and 3.5 ± 0.71 for urostomy (see Table 4).

Overall, for all ostomy surgery types combined, 82% of participants felt they could walk around with confidence and 83.7% of participants would recommend the product.

The most commonly reported problems (>5%) were concerns with adhesion or attachment (eg, problems with adhesion following bathing); issues with the flange, seal, or filter (eg, leakage); or with wear time or skin condition (eg, leakage leading to skin breakdown) (see Table 5).

ET baseline evaluation results. Baseline assessment data from the ET evaluation forms are summarized in Table 1. The mean age of the participants was 52.4 years (range 17 to 88 years). Twelve (6.2%) patients had urostomy surgery, 60 (30.8%) had colostomy surgery, 121 (62%) had ileostomy surgery, and two (1%) did not indicate surgery type.

With respect to baseline skin condition, 105 ET evaluations (53.8%) reported intact skin without redness, 69 (35.4%) reported some redness or breakdown, and 11 (5.6%) reported extensive redness and breakdown. Analysis of the baseline skin condition relative to the type of ostomy surgery included 193 evaluations (two did not specify surgery type); 43 colostomy patients (71.7%) and 58 ileostomy patients (47.9%) had intact skin without redness, although a large percentage (52, [43%]) of the latter had some redness or breakdown. Five urostomy patients (41.7%) had some redness or breakdown (see Table 2).

ET evaluation of skin barrier performance. ET ratings of skin barrier performance were similar overall for the different types of ostomy surgeries in the 193 evaluations included in the analysis (see Table 3). The mean percentage of "excellent" or "very good" ratings was 89% for colostomies, 92.7% for ileostomies, and 92.7% for urostomies. Overall, the ratings from the ETs tended to be higher than those of patient participants.

More specifically, for ET evaluations of participants with colostomies, the percentages of "excellent" or "very good" ratings ranged from 81.7% for effective skin protection to 95% for ease of application. For ET evaluations of participants with ileostomies, the percentages of "excellent" or "very good" ratings ranged from 84.3% for effective skin protection to 95.9% for ease of application and ease of teaching. For ET evaluations of participants with urostomies, the percentages of "excellent" or "very good" ratings ranged from 83.8% for effective skin protection up to 100% for ease of molding and ease of application (see Table 3).

Average ratings (scale of 1 to 4) of skin protection effectiveness for persons with intact skin at baseline ranged from 3.47 ± 0.69 for colostomy, 3.46 ± 0.73 for ileostomy, and 3.00 ± 0.00 for persons with a urostomy. For persons with some redness or breakdown or with extensive redness and breakdown reported at baseline, mean skin barrier effectiveness ratings were 3.55 ± 0.52 and 1.00 ± 0.00 for colostomy, 3.60 ± 0.54 and 3.4 ± 0.55 for ileostomy, and 3.75 ± 0.5 and 3.00 ± 0.00 for urostomy, respectively (see Table 4).

Overall, for all surgery types combined, 88.2% of ETs found the moldable skin barrier to be simple for participants to use, 86.7% felt it was easy to teach, and 90.8% would recommend the product to another healthcare professional.

The most commonly reported reasons reported by ETs for discontinuing the product (>5%) were study participant preference for another product and/or need/desire to try another product (8.7%), difficulty with attachment or adhesive (eg, adhesion following bathing, 6.2%), and leakage (5.6%) (see Table 5).

Discussion

The moldable skin barrier evaluated in the current study is designed for stomas that protrude ½ inch (12 mm) or greater. The adhesive barrier is rolled open to create a customized fit regardless 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. Published studies investigating the safety or performance of ostomy pouching systems are limited. In part, this may be due to the fact that regulatory bodies do not require trials of ostomy products for their licensing under Class I medical devices in the US.[6]

One comparative crossover study[7] (N = 39) compared two two-piece ostomy systems: *Esteem* Synergy® with Adhesive Coupling Technology (ACT, ConvaTec Ltd., Skillman, New Jersey) and Assura® AC (Coloplast A/S Humlebæk, Denmark). Both systems were found to be safe based on the number of reported adverse events and discontinuations (four [10.3%] withdrawals per group, five [12.8%] adverse events reported overall). However,

Table 3. Evaluation of skin barrier performance

Evaluation Criteria	Rating	Percent of Responses					
		Colostomy		Ileostomy		Urostomy	
		Participants (n=62)	ETs (n=60)	Participants (n=102)	ETs (n=121)	Participants (n=8)	ETs (n=12)
Ease of creating customized fit	Excellent	43.55	61.67	49.02	66.12	37.5	66.66
	Very Good	43.55	28.33	46.08	28.1	62.5	33.33
	Satisfactory	11.29	3.33	2.94	4.13	0	0
	Poor	1.61	0	0	0	0	0
Ease of molding	Excellent	46.77	63.33	51.96	66.94	62.5	58.33
	Very Good	41.94	30	44.12	28.1	37.5	41.67
	Satisfactory	8.06	1.67	1.96	3.31	0	0
	Poor	1.61	0	0	0	0	0
Ease of application	Excellent	54.84	65	50	71.07	50	58.33
	Very Good	35.48	30	42.16	24.8	50	41.67
	Satisfactory	6.45	0	4.9	2.48	0	0
	Poor	3.23	0	0	0	0	0
Effective skin protection	Excellent	45.16	48.33	39.22	52.89	25	33.33
	Very Good	41.94	33.33	35.29	31.4	62.5	50
	Satisfactory	4.84	1.67	13.73	4.13	12.5	0
	Poor	4.84	3.33	7.84	0.83	0	0
Painless to apply/remove	Excellent	53.23	NA	42.16	NA	50	NA
	Very Good	32.26	NA	38.24	NA	37.5	NA
	Satisfactory	8.06	NA	13.73	NA	12.5	NA
	Poor	3.23	NA	3.92	NA	0	NA
Ability to shape and reshape	Excellent	41.94	51.64	44.12	52.07	25	58.33
	Very Good	38.71	38.33	45.1	42.98	62.5	33.33
	Satisfactory	14.52	5	4.9	1.65	12.5	0
	Poor	1.61	0	0.98	0	0	0
Adherence	Excellent	40.33	48.33	44.12	58.68	25	41.67
	Very Good	40.32	38.33	38.24	29.76	62.5	50
	Satisfactory	9.68	3.33	6.86	4.96	0	0
	Poor	8.06	1.67	6.86	2.48	12.5	0
Overall comfort	Excellent	50	NA	44.12	NA	37.5	NA
	Very Good	38.71	NA	37.25	NA	62.5	NA
	Satisfactory	1.61	NA	9.8	NA	0	NA
	Poor	6.45	NA	3.92	NA	0	NA
Overall convenience	Excellent	64.52	NA	58.82	NA	50	NA
	Very Good	12.9	NA	32.35	NA	37.5	NA
	Satisfactory	11.29	NA	5.88	NA	0	NA
	Poor	3.23	NA	0.98	NA	0	NA
Overall satisfaction	Excellent	41.94	45	35.29	61.99	37.5	66.67
	Very Good	33.87	38.33	36.27	30.58	50	16.67
	Satisfactory	14.52	1.67	13.73	0.83	12.5	0
	Poor	6.45	3.33	11.76	0	0	0
Easy to teach	Excellent	NA	66.67	NA	76.86	NA	75
	Very Good	NA	25	NA	19.01	NA	16.67
	Satisfactory	NA	1.67	NA	0.83	NA	8.33
	Poor	NA	0	NA	0	NA	0

NA = Not assessed

Table 4. Skin barrier protection effectiveness rating (1 = poor to 4 = excellent) by stoma type and baseline skin condition.

Evaluation Criteria	Participants (N = 172)			ETs (N = 193 evaluations)		
	Colostomy	Ileostomy	Urostomy	Colostomy	Ileostomy	Urostomy
Intact without redness (mean score)	3.45	3.25	3	3.47	3.46	3
Some redness or breakdown (mean score)	2.94	3.08	NA	3.55	3.6	3.75
Extensive redness and breakdown (mean score)	NA	2.5	3.5	1	3.4	3

NA = no participants in this group

Table 5. Discontinuations/problems reported

Reason for discontinuing/problem reported (multiple responses possible)	ET N (%)	Participant N (%)
Participant preference for another product or need/desire to try other products	17 (8.7)	N/A
Adhesion/attachment	12 (6.2)	25 (14.5)
Flange/seal/filter	0	24 (14)
Wear time	6 (3.1)	14 (8.1)
Leakage	11 (5.6)	0
Skin irritation	7 (3.6)	11 (6.4)
Water infiltration caused tape or collar to wrinkle	3 (1.5)	0
	2 (1.0)	0
Stoma surgically reversed/closed	NA	2 (1.2)
Pouch	7 (3.6)	10 (5.8)
Other		

the ACT system was found to provide longer wear time and have better ratings for the attributes of comfort, flexibility, ease of removal, and overall performance.

A recent randomized comparative crossover study[8] (N = 61) compared two one-piece systems, possibly the first published study comparing the performance of one-piece ostomy systems: the SenSura ostomy pouching system (Coloplast A/S Humlebæk, Denmark) and a system from Dansac A/S, Fredensborg, Denmark. The study found that the SensSura product was preferred by significantly more participants (P <0.0001) and was assessed as having better "security as a whole" compared to the competitor product (94% of participants rated it as "good" to "very good" versus 76% for the competitor). With respect to safety, three participants (5%) reported adverse events (with one of the comparator systems) and two (3.3%) discontinued use.

Given the limited published information available, the results of the current evaluation offer valuable information regarding participant and ET opinions and experiences that may be beneficial in helping healthcare professionals make product choices.

The results of the Canadian multicenter evaluation program showed that the moldable skin barrier was very well accepted by both appliance users and ETs and their responses were similar although, in general, the ET product ratings were somewhat higher (the mean percentage of "very good" or "excellent" ratings was 87.3% for stoma patients and 91.4% for the ETs). Specifically looking at the proportion of responses with a difference of ≥5% between the ETs and participants, ETs gave higher ratings than participants for product's ability to shape and reshape, general satisfaction, adherence for colostomies and ileostomies, and effective skin protection for ileostomies; whereas, more participants with a colostomy than ETs rated the effectiveness of skin protection as excellent or good.

Participants and ETs found the product easy to apply, mold, and create a customized fit; high levels of satisfaction regardless of the type of ostomy surgery were reported. A trend toward higher ratings for urostomies was observed but the numbers are too small to generalize.

Ease of use of the moldable skin barrier is an important finding, especially for persons with limited hand strength or dexterity and those with an irregularly-shaped or poorly visible stoma. Achieving a consistent fit can be a challenge that requires time, practice, teaching time, and the ability to customize pre-cut or cut-to-fit barriers.

In healthcare facilities, the use of the moldable skin barrier may reduce waste and inventory of pre-cut barriers. The vast majority (95%) of ETs indicated that barrier application and instruction were easy, suggesting potential benefits for healthcare professionals.

Adherence and skin protection, rated as good or excellent by the majority of participants and ETs, are important to prevent skin problems. Given the high incidence of peristomal skin disorders reported in a recent study of persons with permanent ostomies,[3] skin protection is an important issue. In this study, ETs (41%) and participants (46.5%) reported some or extensive skin redness or breakdown at baseline. This is similar to the 45%

frequency of peristomal skin problems reported by Herlufsen et al,[3] suggesting that the study population was a representative sample of individuals living with an ostomy.

In this study, the mean effective skin protection ratings were low only in the three participants in the subset with a colostomy who had extensive redness and breakdown at baseline. More studies are needed to explore the relationship between these variables.

In this study, when participants were asked, "Can you walk around with confidence?" 82% responded, "Yes". The Montreux Quality of Life Study[9] found that a good relationship with an ostomy care nurse and confidence in changing the appliance significantly (P <0.01 for both factors, respectively) affect quality of life for persons living with an ostomy. A recent review[10] stated, "Prevention of skin problems and good management of the stoma and surrounding skin are critical components of ostomy care with regards to quality of life."

The primary concerns and reasons for discontinuing use of the product by persons with a stoma were adhesion or attachment concerns (n = 25, 14%) and problems with the flange, seal, or filter (n = 24, 14%). For the ET, the main reasons for discontinuing the product were participant preference, need or desire to try other products (8.7%), or difficulty with attachment or adhesive (6.2%). The reported problem rates may appear high but this evaluation was not monitored and reported problems may have been the result of incorrect usage. Specifically, 23 ostomy patients (13%) and 24 ETs reported product use with a flush stoma even though the product is designed for use with protruding stomas. It is possible that the ETs suggested using the product with a flush stoma because of problems with other appliances.

The main objective of the product evaluation was to assess participant and clinician satisfaction with the product. Further studies might include comparative clinical trials to compare the safety and efficacy of the moldable skin barrier and other skin barriers.

Limitations

The study limitations are inherent to survey design characteristics and the non-random sampling method used. All responses were self-reported and not evaluated by an independent observer and voluntary participation may not reflect the experiences of the entire population. In addition, there was no control group and participants and ETs were allowed to complete the evaluations forms whenever they wanted (up to 10 weeks); therefore, some may have filled it out after trying the product once while others may have assessed the product for a longer duration, potentially affecting the ratings. Furthermore, the use of evaluation forms limited the amount of detail available from the responses — eg, problems experienced. Also, there is the possibility that one ET could have "weighted" the responses by having multiple patients, as opposed to someone who just tried the product on one patient, as well as potential discussion among clinicians at a facility. Although rating differences between the ETs and participants with a stoma were minimal, no direct comparisons could be made because the questionnaires were submitted anonymously and without unique identifiers.

Conclusion

Overall, the Canadian multicenter evaluation program results show very high levels of satisfaction with the moldable skin barrier, regardless of the type of ostomy surgery. Participants with a stoma and ETs rated the product easy to use, easy to learn to use, and easy to teach. It provided effective skin protection regardless of the type of ostomy surgery and/or regardless of baseline skin condition and very few skin irritation concerns were reported. All these benefits have potentially significant implications for ETs and people living with an ostomy who require viable options in ostomy care. ■

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An ostomy (or stoma) is a surgical opening made in the skin as a way for waste products to leave the body. An ostomy can allow wastes to leave from the intestines (ileostomy or colostomy) or. from the bladder (urostomy). â€œ Ostomateâ€ is a term used for someone who has a stoma.Â â€œMoldable Technology can dramatically improve the quality of life for a person with an ostomy,â€ said Steve Bishop, Vice President of R&D at ConvaTec. PRESS RELEASE. â€œIt can also reduce readmission rates and provide significant cost savings for healthcare providers and payers.â€Â 6Durnal A. A Clinical Comparison of a Moldable Skin Barrier versus a Shape-to-Fit Skin Barrier in Healthy Volunteers. Presented at the WOCN conference, Seattle, WA, June 2013. 7Wick EC, Shore AD, Hirose K, et al. Ostomy skin barriers can be difficult to size and shape; gaps between the skin and the appliance can compromise peristomal skin protection. A multicenter...Â A prospective multicenter evaluation of a moldable stoma skin barrier. Jo Hoeflok, Delilah Guy, Sandy Allen, Diane St-Cyr.