Original article

A litmus test for innovation: a real-world evaluation of a pH-buffering ostomy barrier

ABSTRACT

Background Preserving the skin's acid mantle can help reduce the formation of peristomal skin complications (PSCs). Ostomy products should strive to address this ongoing challenge.

Objective We assessed clinical outcomes and ostomy supply use associated with the use of a barrier designed with pH-buffering technology.

Methods This real-world observational user evaluation recruited 440 clinicians from 11 countries to complete an evaluation for 975 ostomates before and after use of a pH-buffering barrier. Evaluations included a validated discolouration, erosion and tissue overgrowth (DET) peristomal skin assessment tool, a peristomal skin pain scale, and scales for satisfaction and likelihood of recommending the product. Ostomy resource utilisation was also recorded.

Results Mean (SD) DET (n=797) and peristomal skin pain scores (n=392) decreased significantly by 1.9 (3.0, p<0.001) and 1.8 (2.6, p<0.001) points, respectively, after using the pH-buffering barrier. The proportion of patients not requiring ostomy accessories increased by 40.2%; half of patients (n=52) on topical peristomal skin medications reduced their usage. Wear times increased for 38.0% of patients (n=900). Most respondents were satisfied or highly satisfied with the barrier (88.2%, n=952) and likely or highly likely to recommend it (86.4%, n=960).

Conclusions Peristomal skin health and pain levels significantly improved, barrier wear time increased, and topical peristomal skin medication and accessory use decreased after utilising the pH-buffering barrier. These findings on healthcare resource utilisation suggest the pH-buffering barrier provides benefits beyond addressing the clinical burden of an ostomy.

Keywords acid mantle, pH-buffering, peristomal skin complications, peristomal skin pain, ostomy barrier

For referencing Summa S et al. A litmus test for innovation: a real-world evaluation of a pH-buffering ostomy barrier. WCET® Journal 2021;41(3):14-21

DOI https://doi.org/10.33235/wcet.41.3.14-21

Submitted 30 March 2021, Accepted 11 June 2021

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INTRODUCTION

Maintaining skin health and avoiding skin complications remain challenges for individuals living with an abdominal stoma[1,2]. Healthy skin has an acidic stratum corneum; this acid mantle is essential to sustain natural microflora and to reduce the risk of bacterial and yeast infections[3]. Intrinsic factors, such as age, genetic predisposition, sebum and skin moisture, and external factors, such as skin irritants and dressings, affect the pH level of the acid mantle[4]. Another variable affecting the acid mantle is stomal leakage, a common concern among ostomates and wound, ostomy and continence (WOC) nurses[5–7]. If not contained appropriately, enzymes found in stoma effluent can seep onto the skin to create an alkaline environment, disrupt the acid mantle, and increase the risk of peristomal skin complications (PSCs)[8–10]. For example, urease from urine increases skin pH levels and can lead to incontinence-associated dermatitis[8], and seepage of faecal enzymes with enhanced activity at the alkaline pH level is associated with skin irritation[9].

Other origins of PSCs include skin stripping from repeated barrier changes and irritation from applications and dressings[1,11]. Irritant contact dermatitis, a common PSC in ostomates, can develop from leakage or adhesive-related damage[1]. Mechanical damage from repeated dressing application and removal can also contribute to medical adhesive-related skin injuries[11].

Recently reported PSC incidence following an ostomy continues to be as high as 73%[12–14]. In addition, individuals with a stoma have reported pain, discomfort, decreased self-confidence, and a negative change in body image[15]. These factors can weigh greatly on a patient's social functioning, wellbeing, and health-related quality of life (HRQoL)[15,16].

In addition to the humanistic and clinical burdens that PSCs pose, the economic burden cannot be ignored. Higher readmission rates have been associated with patients with PSCs than patients without PSCs, leading to higher healthcare costs[2]. Treating PSCs also requires specialised care and additional healthcare resources such as topical medicines[17,18].

Investment in ostomy barrier innovation, supported by robust evidence, is therefore necessary for clinicians to make informed decisions regarding their patients' ostomy care to maximise patient HRQoL through better clinical and economic outcomes. While there have been improvements in ostomy barriers to better fit the individual's needs, PSC rates continue to be very high. An ideal barrier would reduce PSCs, simplify stoma management, and provide an economic benefit by maintaining peristomal skin health and reducing the need for accessories and medication. This user evaluation analysed patients' peristomal skin health and healthcare resource utilisation before and after using a pH-buffering barrier. To the authors' knowledge, this pH-buffering barrier is the only barrier available on the market that has sustained pH-buffering capacity to preserve the peristomal skin's acid mantle. Various survey measures were utilised to determine the outcomes of using the pH-buffering barrier, including the effect on peristomal skin health, patient wellbeing, and clinician satisfaction levels.

METHODS

In this multinational, real-world, observational user evaluation, written feedback was gathered from clinician experiences of prescribing the pH-buffering barrier to individuals with a stoma. Between March 2018 and February 2020, responses were collected from 440 clinicians, representing 975 patients, using a paper-based two-part evaluation form. The clinicians were from hospitals and clinical centres based in 11 countries in Europe and the Asia-Pacific region. The evaluation forms were translated into each local language.

Patients were selected for inclusion based on the clinician's professional recommendation and on the patient's willingness to try the product. No incentives were provided for participating clinicians or patients. Clinicians were encouraged to complete part 1 (pre-evaluation) of the questionnaire for each patient before and part 2 (post-evaluation) after incorporating the pH-buffering barrier into the patient's ostomy care plan. After collection, responses were translated into English upon digitisation ex post facto.

The evaluation distribution, response collection and data analyses were not subjected to ethics review by an independent review board. Release forms were used to acquire clinician and patient permission to publish, reproduce and distribute any data or findings related to the evaluation. To ensure patient privacy, no identifying information (e.g., patient name, hospital identification number) or images were collected. Clinician and patient participation was entirely voluntary, and the patient could have discontinued the evaluation at any time without penalty.

Clinicians measured peristomal skin damage using the validated DET scale (Ostomy Skin Tool) evaluating discolouration, erosion and tissue overgrowth[19]. The combined DET score ranges from 0 for normal intact peristomal skin to 15 for severely damaged peristomal skin. Peristomal skin pain was rated on a numerical rating scale (NRS-11) of 0 ("no pain") to 10 ("worst pain imaginable")[20].

To estimate ostomy pouch utilisation, pre-evaluation and post-evaluation wear times were converted to daily pouch utilisation. Daily usage was calculated by dividing one pH-buffering barrier by the number of days that the pouch was worn (e.g., wear time of 2 days denoted use of half a barrier per day). Patients who changed their pouches more than once daily were assumed to use two pouches per day. Patients who changed their pouches every 7 days or longer were assumed to have a wear time of 10 days (i.e., use of 1/10 of a barrier per day). As a final step for ease of interpretation, daily usage was converted to monthly usage (assuming 30 days per month).

Analysis of forms for the 975 patients was performed with SAS v9.4 (SAS Institute, Cary, NC, USA) and Microsoft Excel (Redmond, WA, USA). Statistics were calculated based on the total non-missing response count. Statistical tests were performed when the sample size was at least 30 patients.

RESULTS

Patient demographics and baseline clinical characteristics

The mean patient age was 63 years (range 16–96 years, n=963). When responses were broken down by country, most (n=406) were received from the United Kingdom. The mean time between completing the pre-evaluations and post-evaluations was 18 days (range 1–354 days). Half of all evaluations were completed within 12 days, and 90% were completed within 42 days. At baseline, 231 (23.7%) of 973 patients were already using the pH-buffering barrier.

Stomal characteristics collected at baseline are described in Table 1. A total of 95% of patients underwent either a colostomy or ileostomy (n=974). The mean length of time with a stoma (n=898) was 22.1 months, with a median of 1.9 months. Three-quarters of respondents were living with

Table 1. Patient demographics and baseline clinical characteristics

Variables	Parameter
Age, years (n=963)	
• Mean (range)	63 (16 – 96)
Length of time with a stoma, months (n=898)	
• Mean (SD); range	22.1 (63.1); 1–677.5
• Median; IQR	1.9; 0.8–12
	n (%)
Ostomy type (n=974)	
• Colostomy	421 (43.2)
• Ileostomy	510 (52.4)
• Urostomy	33 (3.4)
• Other	10 (1.0)
Peristomal skin risk condition* (n=931)	
• None	567 (60.9)
• Receiving chemotherapy	136 (14.6)
• Diabetes	89 (9.6)
• Receiving steroid treatment	45 (4.8)
• Kidney failure	35 (3.8)
• Receiving radiation therapy	27 (2.9)
• Liver failure	7 (0.8)
• Other	113 (12.1)
Peristomal skin complication* (n=951)	
• None	486 (51.1)
• Acute irritant dermatitis	233 (24.5)
• Maceration	117 (12.3)
• Chronic irritant dermatitis	66 (6.9)
• Product sensitivity	47 (4.9)
• Granuloma	35 (3.7)
• Mucocutaneous separation	32 (3.4)
• Fungal rash	11 (1.2)
• Folliculitis	11 (1.2)
• Trauma	11 (1.2)
• Pyoderma gangrenosum	6 (0.6)
• Other	66 (6.9)
Country (n=974)	
• UK	406 (41.7)
• Germany	179 (18.4)
• Japan	147 (15.1)
• Australia	88 (9.0)
• Netherlands	42 (4.3)
• Belgium	35 (3.6
• Italy	34 (3.5)
• New Zealand	21 (2.2)
• Denmark	8 (0.8)
• Finland	7 (0.7)
• Switzerland	7 (0.7)

** Respondents were allowed to select more than one option*

their stoma for less than 12 months. Fewer than half of the pooled population indicated a comorbidity or a PSC. More than half, or 567 (60.9%) of 931 patients, had no comorbidities that would put their peristomal skin at risk, and 486 (51.1%) of 951 patients reported no PSCs at baseline. For those who reported a PSC at baseline, the most common was acute irritant dermatitis (24.5%, n=233) followed by maceration (12.3%, n=117) and chronic irritant dermatitis (6.9%, n=66).

DET and peristomal skin pain score results

A total of 797 patients met inclusion criteria and had valid data for DET scores. Skin improvement, as indicated by a decrease in DET scores, showed a significant improvement after using the pH-buffering barrier (Figure 1A). The mean pre-evaluation DET score (SD) was 3.21 (3.39) points, and the mean post-evaluation DET score (SD) was 1.36 (2.40) points. For the entire user evaluation population, the mean change in DET (SD) was significant, dropping by 1.85 (3.01) points ($p<0.001$) (Table 2).

The mean DET score for patients who had been using the barrier prior to commencing the evaluation decreased from 0.79 to 0.52 points; this change was not statistically significant. In contrast, patients who were introduced to the barrier at pre-evaluation had an average reduction in DET score of 2.35 points (from 3.98 to 1.63, $p<0.001$).

After observing the peristomal skin health of the overall population, we stratified the data by PSC types. Using the 635 PSCs documented from 465 patients, changes in DET scores were subcategorised by skin condition (Figure 2). DET scores decreased across all skin conditions. For those conditions tested for statistical significance (i.e., those with $n\geq30$), the greatest significant decrease in DET scores was observed in the subpopulation with maceration (3.9) followed by acute irritant dermatitis (3.5), product sensitivity (2.8) and chronic irritant dermatitis (2.3), while the smallest decrease (0.6 points) was found in patients without a PSC at baseline ($p<0.001$).

Similar to DET scores, peristomal skin pain scores showed a statistically significant reduction across the sampled cohort. Pain scores decreased for 208 (53.1%) of 392 patients, while 165 noted no change and 19 had increased pain scores (Figure 1B). Across 392 patients reporting scores, mean (SD) pain scores reduced by 1.8 (2.6) points ($p<0.001$) (Table 2). When stratified by PSC type, peristomal pain scores decreased for all skin conditions (Figure 2). For those conditions tested for statistical significance ($n\geq30$, $p<0.001$), scores significantly decreased for every category tested – acute irritant dermatitis (3.4), chronic irritant dermatitis (2.2) and maceration (3.3). Furthermore, a statistically significant reduction in pain score was reported for patients who did not have a PSC at baseline (0.7, $p<0.001$).

Noting this trend, we found a statistically significant correlation between DET and pain scores both pre-evaluation and post-evaluation. The correlation coefficient (rho) between DET and pain scores was 0.77 (pre-evaluation) and 0.53 (post-evaluation) ($p<0.001$ for both). A correlation was also observed between the change in DET and pain scores (0.73) (Figure 1C).

Taken together, these findings suggest a close alignment of the two aspects regardless of the pH-buffering barrier use. Although these correlations may be intuitive to clinicians, this is the first user evaluation to definitively report this trend.

Healthcare resource utilisation

From our resource utilisation findings, the barrier has the potential to lower ostomy care costs by providing a longer wear time as well as lower associated ostomy accessories and topical peristomal medication use. Wear time was extended for 342 (38.0%) of 900 patients while using the pH-buffering barrier. There was a 55% decrease in the number of patients who changed their pouch more than once per day. Furthermore, there was a 34% increase in the number of patients who achieved wear times of 2 days or longer. These improvements in wear time resulted in fewer pouches per month, from 31.2 (20.0) pouches pre-evaluation to 23.7 (16.3) pouches post-evaluation.

Our evaluation also collected information on the ostomy-related accessories used by each patient. The most common accessory used pre-evaluation was adhesive remover, followed by seals, ostomy belts and paste. Percentages of patient usage of pastes, seals, adhesive remover, skin preps, powder, ostomy belts, support belts, flange extenders and tape all decreased in the post-evaluations (Table 3). The percentage of patients not requiring any accessories increased from 24.6% to 34.5% ($p<0.001$), a relative change of +40.2%. A total of 52 patients used topical peristomal skin medications during the length of the evaluation; 26 (50%) patients noted a decrease in medication use in the post-evaluation, and seven reported increased use.

Clinician satisfaction and experience with the pH-buffering barrier

We next sought to record clinicians' satisfaction with the pH-buffering barrier across several dimensions, with the large majority reporting "satisfied" or "very satisfied"

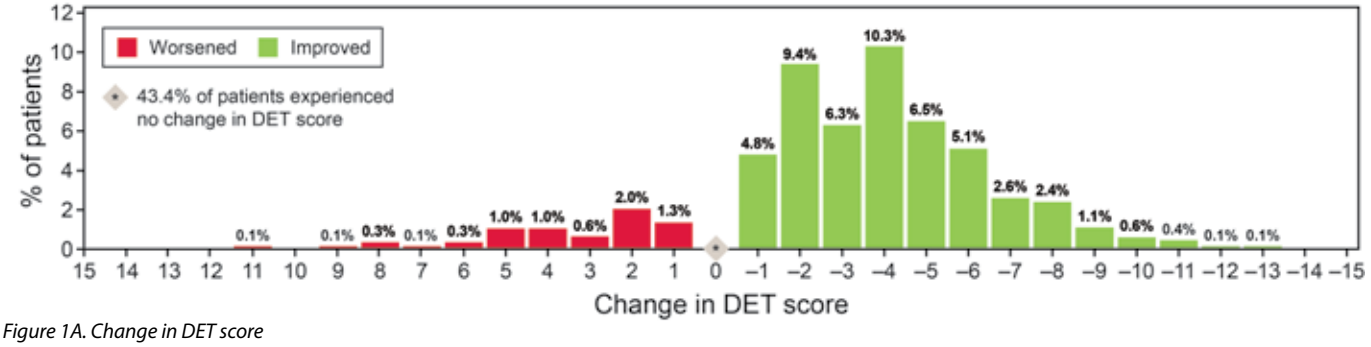

Figure 1A. Change in DET score

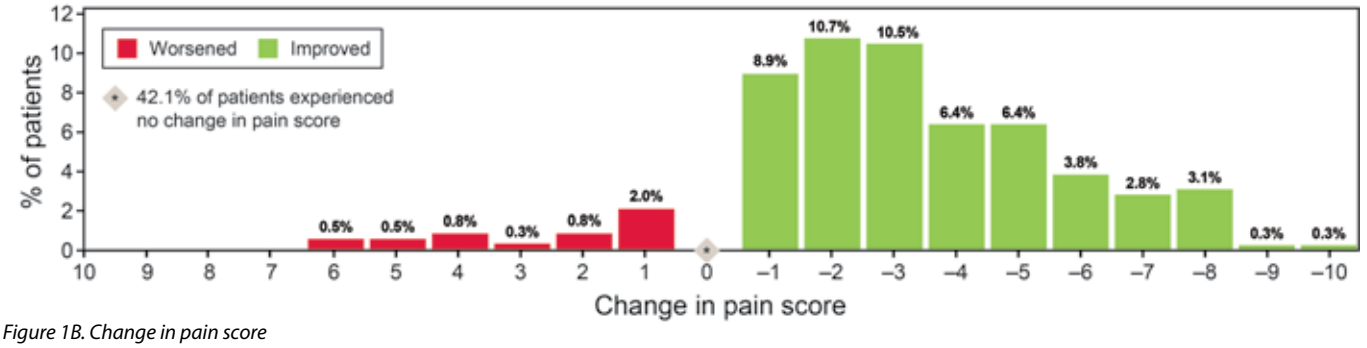

Figure 1B. Change in pain score

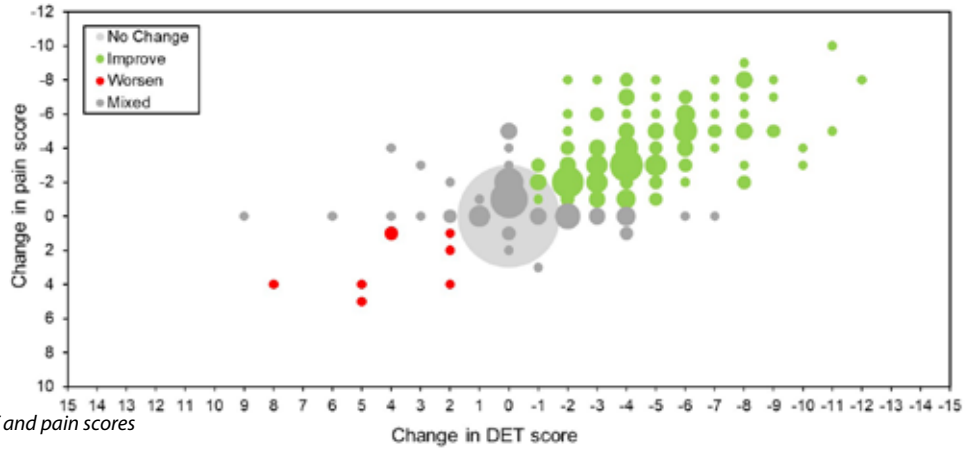

Figure 1C. Change in DET and pain scores

with all attributes examined (Figure 3). The four attributes acknowledged in the pH-buffering barrier's design – ease of use, adherence to peristomal skin, ease of removal, and the ability to absorb moisture – all received positive satisfaction from at least 86% of clinicians. The resulting high levels of satisfaction suggest that clinicians perceive such barriers and technology to be of high value to their practice and patients.

Satisfaction responses positively correlated with the likelihood of clinicians recommending the pH-buffering barrier (Figure 3). A total of 829 (86%) of 960 clinicians were "very likely" or "likely" to recommend the product as part of the ostomy care plan for the patient being evaluated. When asked the same question for all patients, 567 (83%) of 681 were "very likely" or "likely" to recommend the product. Unsurprisingly, the results from satisfaction responses and the likelihood to recommend the pH-buffering barrier align with positive skin outcomes.

DISCUSSION

The pH-buffering barrier was developed to maintain the skin's acid mantle under all fluid-exposure conditions. In vitro assessments demonstrated that the pH-buffering barrier remains in the healthy pH range for skin after exposure to alkaline saline, with a pH similar to effluent that may leak under the barrier[21]. These qualities may be desired by stoma care nurses who wish to provide their patients with the best possible experience from the outset of stomal surgery, when high stomal output and aggressive stools are especially common[22]. Our findings suggest that skin health improves with use of the pH-buffering barrier, as indicated by the statistically significant decreases in DET and peristomal skin pain scores. Approximately 24% of participants were using the pH-buffering barrier before pre-evaluation. As expected, results indicate no statistically significant changes in DET score prior to and after the evaluation. In contrast, participants who switched to the pH-buffering barrier at pre-evaluation experienced a statistically significant decrease in DET score after using the pH-buffering barrier. These two findings suggest minimal assessment bias, as we would expect that a patient already on the pH-buffering barrier (before pre-evaluation) would not have any substantive changes in DET score.

Previous research has assessed pain as an adverse consequence of living with a stoma[23]. However, to the authors' knowledge,

Table 2. Change in mean DET and pain scores

Parameter	Pre-evaluation: mean (SD)		Post-evaluation: mean (SD)		Change*	
DET score (n=797)	**Overall**	**3.21 (3.4)**	**Overall**	**1.36 (2.4)**	**Overall**	**–1.85 (3.0)****
	Discolouration	1.77 (1.7)	Discolouration	0.79 (1.2)		
	Erosion	1.16 (1.5)	Erosion	0.43 (1.0)		
	Tissue overgrowth	0.28 (0.9)	Tissue overgrowth	0.14 (0.6)		
Pain score (n=392)		**2.9 (2.8)**		**1.1 (1.6)**		**–1.8 (2.6)****

* Post-evaluation score – pre-evaluation score
** p<0.001

Table 3. Ostomy accessory usage recorded at pre-evaluation and post-evaluation time points

Accessory*	Pre-evaluation (n=910) number of accessory users	Post-evaluation (n=829) number of accessory users	Relative change (%)**
None	224	286	+40.2
Adhesive remover	368	186	–44.5
Seals	323	205	–30.3
Ostomy belt	160	125	–14.2
Paste	149	128	–5.7
Skin prep/skin film wipe	134	86	–29.6
Powder	57	38	–26.8
Support belt	5	4	–12.2
Flange extenders	9	5	–39.0
Tape	6	5	–8.5
Other	41	62	+66.7

* Respondents were allowed to select more than one accessory
** $\frac{\text{(\% accessory users post-evaluation – \% accessory users pre-evaluation)}}{\text{(\% accessory users pre-evaluation)}}$

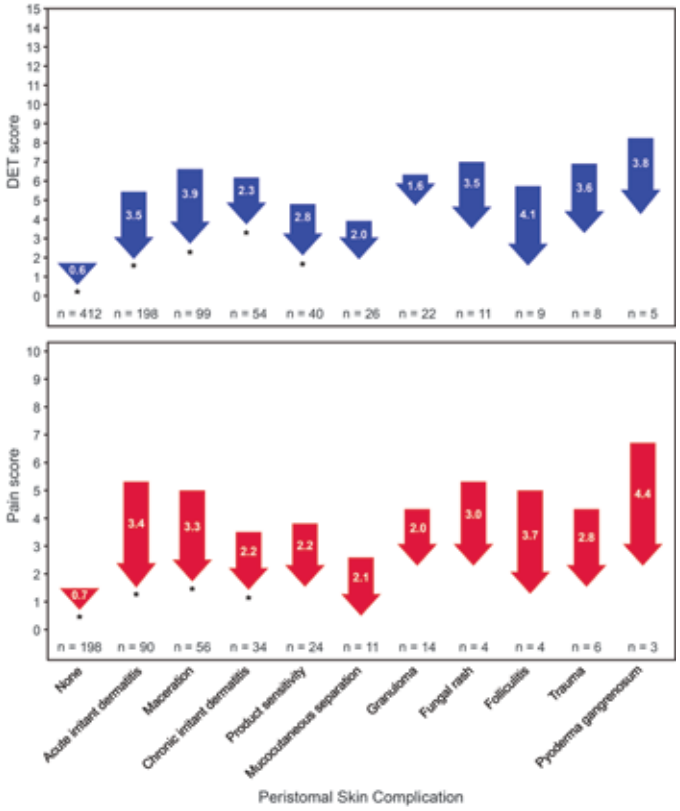

Figure 2. Change in DET and pain scores according to PSC

the present analysis is the first published evaluation of the association between peristomal skin pain and DET scores. Pain has been a resounding theme reported by clinicians, and the effects on HRQoL can be debilitating. Findings from a study by Kini et al. show that the average patient with chronic pain had a symptom utility score of 0.77[24]. In other words, patients were willing to trade 23% of their life expectancy to avoid pain. Our findings suggest that barrier use correlates with significantly decreased patient-reported peristomal skin pain. We believe that this is strong evidence for stoma care nurses to consider when identifying patient pain and offering informed solutions. Moreover, we found a positive correlation between change in skin damage (as measured quantitatively via DET scores) and pain, which suggests a relationship not previously explored.

Pouching failure and pain have negative psychological effects on patients. Evidence has shown that HRQoL scores are higher for patients with healthy peristomal skin than for those with irritated peristomal skin[16,25]. In addition, leakage and a lack of pouch security contribute to patient activity withdrawal and may elicit various social and physical coping mechanisms.[26] In our assessment, improvement in DET and peristomal pain scores occurred in all PSC categories, and the changes were statistically significant for acute irritant dermatitis, chronic irritant dermatitis and maceration. These findings suggest that the pH-buffering barrier mitigated the effects of leakage at the barrier to reduce the severity and incidence of PSCs and

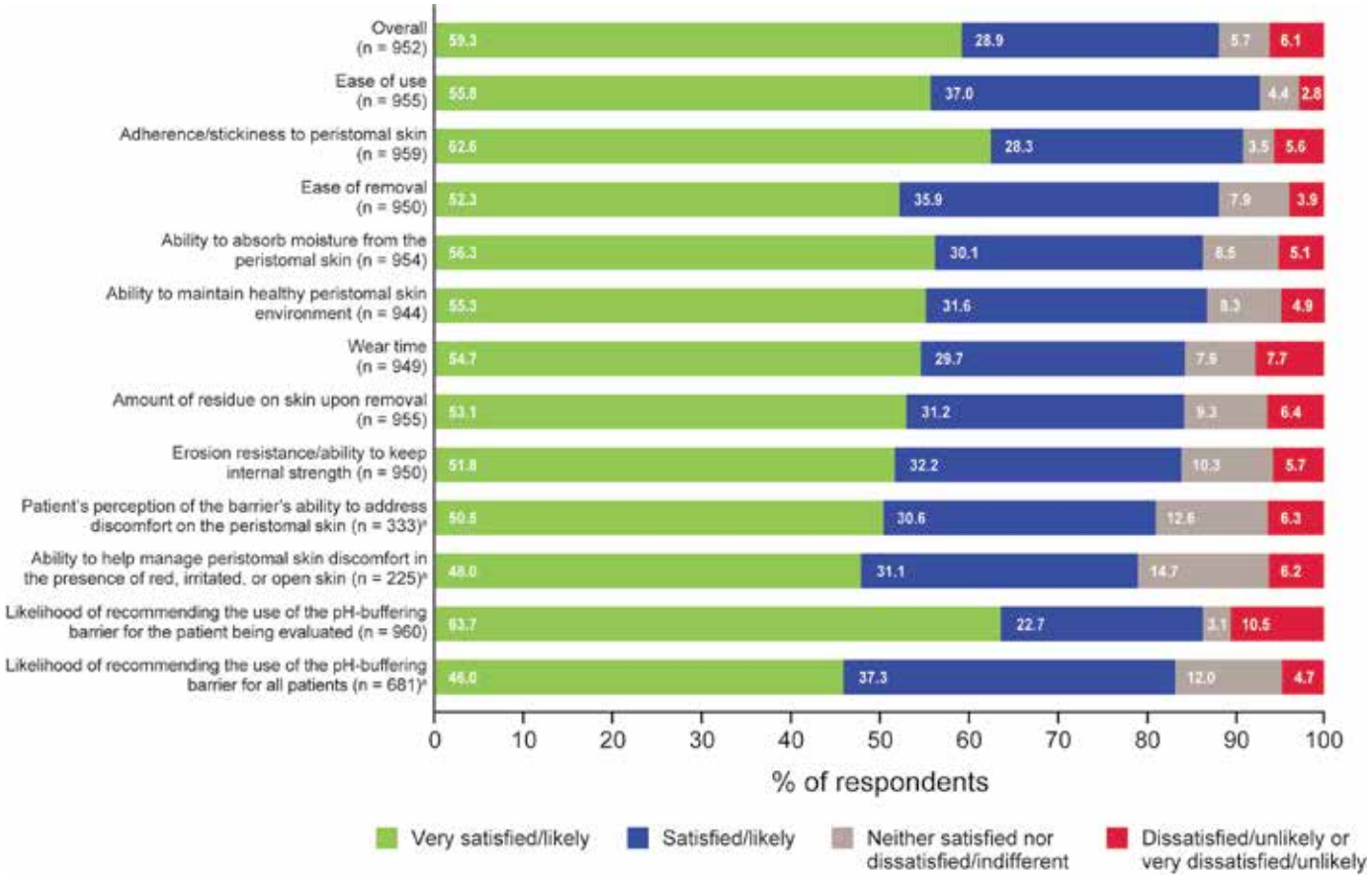

Figure 3. Respondents' satisfaction with the pH-buffering barrier across several dimensions

improve pain scores. Therefore, the pH-buffering barrier has the potential to improve HRQoL via reduction or prevention of PSCs.

With the pH-buffering barrier, patients experienced longer wear time and lower usage of ostomy accessories and topical skin medications. Such favourable outcomes may lead to more simplified ostomy care plans devoid of multiple prescriptions and time-consuming steps. The reduced need for costly ostomy-related resources also suggests potential economic benefits of the pH-buffering barrier. Additional analyses would be required to affirm the translation of our findings into potential cost savings.

In parallel with clinical outcomes, we observed high rates of satisfaction and likelihood of recommendation of the pH-buffering barrier among clinicians, as well as satisfaction with ease of barrier use and removal, adherence to peristomal skin and wear time. Although patient satisfaction was not surveyed, clinician-reported satisfaction was found in the patient's perception of the ability of the pH-buffering barrier to address discomfort.

Taken together, the evaluations provide real-world evidence of the impact of pH-buffering technology on peristomal skin health outcomes. We employed a within-subject design to minimise selection bias and ensure adequate statistical power to estimate effects of the pH-buffering barrier on outcomes. The evaluation did not dictate any changes to each clinician's standard of care, thus reflecting real-world practices. In addition, specific survey instruments were used which are validated and reliable assessment tools that permit comparison of results across different studies.

Limitations

Due to the observational nature of this research, only an association (not a causation) can be established from the findings. The time between completing the pre-evaluation and post-evaluation varied from patient to patient, which may have caused bias of an unknown direction in the responses. Regarding DET scores, the sensitivity analysis demonstrated that the amount of elapsed time did not affect the statistical significance in DET score change. For this user evaluation, no formal training on the use of DET or pain scales was provided to participating clinicians; hence, the assessments themselves may vary by clinician experience. It was also necessary to revise the evaluation form to ensure its compliance with European Union General Data Protection Regulation. Overall, three versions were distributed. Therefore, certain survey responses were not available for every patient.

Although we believe that our multinational clinician and patient population is a strength, we did not account for differences in standard of care in each country or typical patient or clinician practice patterns in ostomy care. The overall time an individual was living with their stoma was not factored into data analyses. Moreover, our research was not a comparative evaluation, so we were unable to separate the effect of the pH-buffering barrier from other factors.

CONCLUSIONS

Skin barriers should be secure, reliable, financially feasible, and keep peristomal skin healthy. Our assessments, based on information-rich evaluations, demonstrate real-world outcomes of a product addressing a fundamental aspect of maintaining the peristomal skin. This research is aimed to help patients and their healthcare providers make informed decisions in caring for their stoma and peristomal skin. It utilised both clinician- and patient-reported outcomes to generate comprehensive data with feedback on varied survey instruments. With the pH-buffering barrier, patients experienced positive outcomes as evidenced by reduced DET and peristomal pain scores while presenting a potential financial benefit through increased wear time and decreased ostomy accessory and topical peristomal skin medication use.

One unique finding we noted was that peristomal skin pain, while often unaccounted for, is a prominent issue for patients with a stoma. Use of the pH-buffering barrier correlated with decreased pain. Furthermore, skin health improved across multiple skin ailments in our user evaluation population. These results may be informative for stoma care nurses treating patients with specific PSCs or seeking to prevent PSCs. Choosing an ostomy barrier addressing skin pH may contribute to skin health and improve patient wellbeing.

ACKNOWLEDGEMENTS

The authors wish to thank Gary Inglese, RN, MBA, of Hollister Incorporated, Libertyville, IL, for his invaluable input regarding the manuscript. Medical writing services were provided by Sabiha Runa, PhD, of Oxford PharmaGenesis, Incorporated, Newtown, PA, and funded by Hollister Incorporated, Libertyville, IL.

DECLARATION OF INTEREST

This research was sponsored by Hollister Incorporated, Libertyville, IL, USA. David Fischer, Jimena Goldstine and George Skountrianos are employees of Hollister Incorporated. Louise Hannan was an employee of Dansac A/S, Fredensborg, Denmark at the time of the research. Scarlett Summa receives personal fees and non-financial support from Lectures, Erlangen, Germany and ICEF consulting, Bonn, Germany. Lastly, 44% (81 of 184) of the UK clinicians who participated in this evaluation were employed or sponsored by Dansac A/S; no incentives were provided to any participating clinicians.

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