

The world is no longer flat

ABSTRACT

Evidence supporting clinical decision-making in the specialty of ostomy care regarding prescriptive product use has been sparse. Many clinical decisions in ostomy care have been based on either clinician experience, or from teachings and beliefs that have evolved over many years but are not based in evidence. There is now a rich and varied tapestry of evidence supporting clinicians regarding the use of convexity earlier in the patient's journey, particularly of the more compressible types (soft) convexity products.

This article reviews the recent evidence concerning the use of more compressible barriers in ostomy care, a relatively newer addition to the clinician's armamentarium, for managing patients. It provides an analysis of the data that supports using these products, sooner rather than later, in achieving a more secure skin seal, and improving patient outcomes compared with using flat skin barriers.

Keywords convexity, evidence, soft convexity, compressibility, peristomal skin complications, ostomy care.

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INTRODUCTION

In the beginning, clinicians may have relied on their education, mentors, word of mouth and habit to help shape how they care for those living with an ostomy. Now, clinicians can rely on a plethora of evidence to guide and support their practice. Prevention and treatment of peristomal skin complications (PSCs), has always been a major focus of the stoma care nurse as PSCs can impact a person's quality of life, prolong hospital stays and have an economic burden for both the patient and the healthcare system. The newer evidence supporting the use of convex skin barriers with characteristics making these barriers compressible and flexible earlier in the patient's journey to help prevent and manage PSCs is now readily available. Section 2 of this supplement described the

development of these characteristics with descriptors and how they interplay to help achieve a reliable skin seal. In this article, we present clinical evidence highlighting the beneficial use of soft convexity and its impact on peristomal skin health, quality of life, and the economic and clinical burden of the management of PSCs. This evidence underscores the support for early adoption of soft convexity in the patient's journey.

THE CHALLENGE

Despite improved surgical techniques (such as robotic laparoscopic surgery), pre-operative stoma site marking, best practice guidelines from global professional ostomy nursing organisations (such as WOCN Society, ASCN etc.), industry product innovations (such as infused skin barriers), and new product improvements (such as softer, more compressible, convex skin barriers); one might assume the number of PSCs should be decreasing. However, in a multinational survey of 4235 people with ostomies in 13 countries, 73% of 4227 reported experiencing a peristomal skin complications (PSCs) in the past six months with only 31% of the respondents seeking help from a stoma care nurse or healthcare professional.¹ This is concerning, as individuals with ostomies are trying to cope and manage their peristomal skin problems as part of their day-to-day life.

ONSET OF PSCS AND RISK FACTORS

PSCs can be caused by peristomal irritant contact dermatitis, where there is prolonged exposure of the skin to ostomy effluent.² The onset of PSCs immediately after surgery is reported to occur between 21 and 64 days.^{3,4} This contact

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dermatitis is categorised as Peristomal Moisture Associated Dermatitis (PMASD). Rates of PSCs following ostomy surgery have also been reported in the ranges of 10–70%.⁵

The etiology of PSCs is multifactorial, involving aspects related to the stoma and surgical procedure, the topography around the stoma site, and individual patient characteristics. An understanding of these risk factors is essential for the prevention and effective management of these complications. Ileostomies are known to be linked to a higher incidence of PSCs, primarily due to the irritating nature of liquid fecal effluent on the skin.² Additionally, emergency stoma procedures, especially those conducted without pre-operative marking of the ostomy site, heighten the risk of PSCs due to potential issues with stoma placement and appliance fit, which can lead to effluent skin exposure.² Obesity not only potentially impacts the profile of the stoma, leading to flat or retracted stomas, but also affects the peristomal topography.

The risk of developing PSCs is significantly amplified by the presence of creases and fat folds around the stoma, which can undermine the ostomy system's seal, causing leakage and skin irritation.¹⁶ Factors such as gender, body mass index (BMI), age, and underlying health conditions also influence the likelihood of experiencing PSCs.² Females and individuals with obesity face a greater risk, while the risk interestingly diminishes with age, indicating a higher vulnerability among younger patients.²

Certain comorbidities can predispose a person with an ostomy to experience a PSC. Peristomal pyoderma gangrenosum is associated with immune or autoimmune disorders and diabetes is a risk factor for early post-operative peristomal dermatitis.⁴ Patients undergoing chemotherapy or radiotherapy further elevate the risk by compromising skin integrity and healing.² Bacterial or fungal infections and sensitivities to ostomy products are additional contributors to PSC development.⁴ The duration of stoma ownership can impact the risk for peristomal skin complications PSCs, which suggests that patients with a longer history of living with a stoma are less likely to experience severe PSCs.¹⁶ The likely reason behind this is the improvement in stoma management skills over time. This improvement underscores the importance of using a proactive approach with ostomy barrier selection to help prevent PSCs early on after stoma creation. Such an approach aims to reduce the risk of PSCs effectively. Tailoring prevention and treatment strategies to each patient's specific needs, considering their stoma type and profile, peristomal topography, and individual risk factors, is crucial. By being cognisant of these diverse contributing factors, healthcare providers can offer better support to stoma patients, potentially lowering the occurrence and severity of PSCs, thereby enhancing their overall quality of life.

THE IMPACT ON QUALITY OF LIFE (QOL)

Damage to the peristomal skin can affect the overall wellbeing and QOL of people with stomas.⁶ It can also influence adaptation to living with a stoma, increase the technicalities

of stoma care, and impact their psychological adjustment to body changes.⁷ Nichols and Inglese explored the quality of life burden of peristomal skin complications in the population of people with ostomies.⁸ QoL was assessed with the Short Form Health Survey–36 Questions, Version 2 (SF–36v2) which is a validated tool designed to measure overall health status and quality of life across eight domains representing physical function and mental health. The authors investigated the relationship between PSC severity (mild, moderate, and severe) and the Physical Component Summary (PCS) of the SF-36v2 which provided a summary measure of an individual's overall physical health status (such as physical functioning, role limitations due to physical health problems, bodily pain, and general health perceptions). Over 2200 individuals with ostomies were surveyed: 1230 males with an average age of 65 years and 1030 females with an average age of 62 years. The majority of patients had an ileostomy (44%), followed by colostomy (40%), urostomy (13%), and multiple or unknown stomas (3%). Median stoma durations ranged from 28–62 months. The authors found that individuals with severe PSCs have significantly lower QoL than those with healthy intact skin (score of 66 vs 81, respectively, where zero represents absolute poorest QoL and 100 absolute best). The authors also found that individuals with greater physical limitations (i.e. lower PCS scores) were more likely to have lower (poorer) QoL. Their findings highlight that successful PSC treatment not only offers clinical benefits, but also QoL benefits..

THE ECONOMIC BURDEN

Several studies point to the increasing cost of managing PSCs. The economic burden of experiencing PSCs was studied at two large US hospital systems.^{4,17} Both studies found that people with ostomies who developed PSCs had longer hospital stays (4–8 days longer) and were more likely to be readmitted within 120 days post-surgery (14–20% greater rate of readmission). Furthermore, patients with PSCs incurred greater cumulative health care costs over the 120 day post-surgery period compared with those who did not develop PSCs (\$8000–\$80,000). Martins et al., in the United Kingdom reported a range from GBP £106.29 to GBP £618.69 to treat mild to severe PSCs.⁹ Similarly, Meisner et al., in France, estimated the episodic treatment costs of severe cases of PSCs to be 2–5 times greater compared to mild cases (ranging from EUR €18.63 to EUR €195.82).¹⁰

THE IMPACT ON THE CLINICIANS' TIME

Managing PSCs can also contribute to an increasing workload for stoma care nurses. In a global survey of 456 nurses working within stoma care from seven different countries, it was found that 53% of nursing time with ostomy patients was spent managing PSCs (see Figure 1). This finding was consistent across acute care and community nurses.¹¹ The remainder of stoma care nurses' time was occupied with typical responsibilities including patient and staff education, pre-operative counseling, stoma marking, selection of appropriate products and discharge planning.

THE EVIDENCE

The benefits of using more compressible (soft) convex barriers as part of ostomy care were investigated across four global product evaluations.¹² All patients included in these evaluations were asked to use this type of convex skin barrier instead of the flat ostomy barriers they typically wore. For each patient, clinicians collected baseline demographic information prior to use including ostomy type, stoma duration, and typical ostomy product use.

In this study, approximately 300 patients residing in over ten countries participated across four product evaluations. Nearly half of the patients were living with an ileostomy (52%), followed by individuals with a colostomy (28%), and urostomy (20%). Stoma duration ranged from 1 day to 30 years with an average of 15 months. Prior to using the more compressible convex skin barriers, patients used a wide range of flat ostomy systems from various manufacturers (including Hollister, Coloplast, Dansac, and ConvaTec). Table 1 provides a demographic summary of these variables.

Clinicians were not provided any instruction as to which patients could use these barriers, including duration with ostomy prior to use, nor were they given instruction as to product wear-time, as well as which (if any) ostomy accessories to prescribe. Patient management was left entirely to clinician discretion and their standard of care. Furthermore, there were no restrictions on the state of peristomal skin (i.e., all peristomal skin conditions were eligible to participate). Lastly, all ostomy product manufacturers could participate. Accordingly, these product evaluations represent a very diverse and real-world population in which the impact of the more compressible skin barriers on ostomy care was assessed.

Of primary interest in the evaluation was the condition of peristomal skin prior to and following the use of convex skin barriers. Peristomal skin condition was assessed via two methods: Firstly, using an ostomy skin assessment tool that measured: discolouration, erosion and tissue overgrowth (DET).⁹ The DET assessment score is a validated clinician reported measurement. The score ranges from zero (no PSC)

to 15 (severe PSC). The DET score can further be classified into PSC categories as follows: No PSC (score of 0), Mild PSC (score between 1 and 3), Moderate PSC (score between 4 and 6), and Severe PSC (score of 7 or greater).⁹ Secondly, clinicians were asked to rate the condition of the peristomal skin after using the more compressible skin barriers on a 5-point Likert scale from “much worse” to “greatly improved”. Due to the differing objectives of the four product evaluations, DET assessment was available for only two of the four evaluations; however, the Likert scale assessment was captured across all four.

Secondary outcomes of interest included changes in ostomy product utilisation, clinician satisfaction with various attributes of the more compressible barriers, and clinician likelihood to recommend continued use of these skin barriers to their patients. Wear-time prior to and following use of convex barriers was captured for two product evaluations. To estimate ostomy pouch utilisation, pre-evaluation and post-evaluation wear-times were converted to daily pouch utilisation. Daily usage was calculated by converting product wear-time into daily use (for example, wear-time of one day was recorded as use of one barrier per day, wear-time of two days was recorded as half a barrier per day, etc.). Patients who changed their pouches more than once daily were assumed to use two pouches per day. Patients who changed their pouches every seven days or longer were assumed to have a wear time of 10 days (i.e., to use of one tenth 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).

As the focus of this article is to discuss the benefits of using more compressible convex skin barriers as part of ostomy care, results from all four product evaluations have been aggregated where possible. For the instances where outcomes were not available across all product evaluations (namely, DET score and ostomy product utilisation), this has been noted. Product evaluation data has been summarised using standard descriptive statistics (i.e., average, minimum, and maximum for numeric outcomes; counts and percentages for categorical outcomes). Statistical testing of changes in DET scores was performed via a paired t-test.

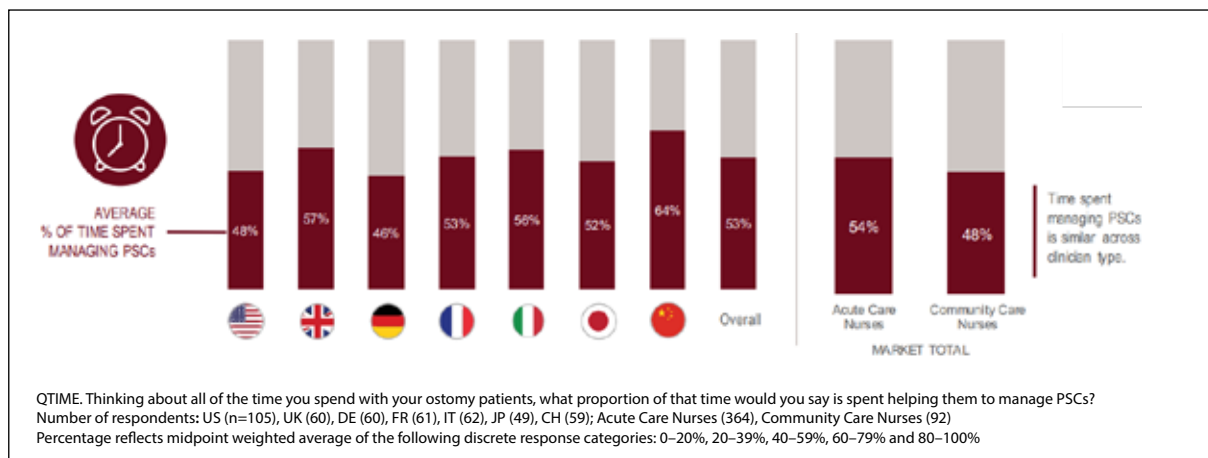


Figure 1. Nearly 50% of clinicians' time with their patients is spent on managing PSCs¹¹

Table 1: Demographic summary of patients

Ostomy Type	N (%)
Ileostomy	160 (52)
Colostomy	88 (28)
Urostomy	63 (20)
Stoma duration (months; average; range)	14.6; 1 day–30 years
Typical Ostomy Product Manufacturer	N (%)
Hollister	183 (59)
Dansac	55 (18)
Coloplast	39 (13)
ConvaTec	15 (5)
B. Braun	6 (2)
Other	12 (4)

With respect to changes in PSC, use of the more compressible convex skin barriers as part of ostomy care resulted in significant improvements to the patients’ peristomal skin condition. In the two evaluations in which the DET tool was used, DET score significantly improved by 2.7 points (from 3.9 to 1.2, $p < 0.0001$). Furthermore, clinicians were asked to rate the change in peristomal skin condition after use of convex skin barriers. Across all four evaluations, clinicians reported the peristomal skin improved or greatly improved for 66% of their patients, remained the same in 30% of patients, and only worsened for 3% of patients (see Figure 2).

Significant benefits of using convex skin barriers with greater compressibility as part of ostomy care were also found in ostomy product utilisation. Patients were found to use significantly fewer skin barriers after switching from flat skin barriers. Monthly utilisation decreased from on average 34 flat skin barriers per month to 21 convex skin barriers per month ($n = 178$; $p < 0.001$). This reduction in utilisation was due to patients experiencing increased wear times with their more compressible convex skin barriers.

Clinician satisfaction with these skin barriers was also very positive with an overall satisfaction rate of 95%. Additionally,

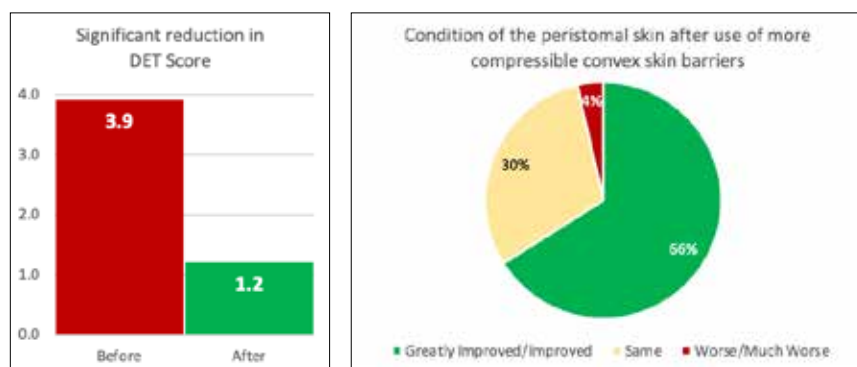


Figure 2. Significant improvement in peristomal skin condition after use of more compressible convex skin barriers

clinicians were satisfied with the convex barriers’ ability to maintain a healthy peristomal skin environment (92%), ability to get a best fit/prevent leakage (91%), and the barriers’ ease of use (98%) (see Figure 3). With respect to continued use, clinicians reported being likely or very likely to recommend continued use of the more compressible convex skin barriers for 89% of their patients.

In summary, these product evaluations suggest that using more compressible convex skin barriers as part of ostomy care provides significant benefit to patients in terms of improved peristomal skin health, reduced ostomy product utilisation, and positive clinician experience.

THE SOLUTION

In the ever-evolving landscape of healthcare, optimising patient comfort and well-being throughout the continuum of care is paramount. Since the introduction of more flexible and compressible convex product options – evidence continues to build supporting the use of convex products earlier in the patient’s journey and across various healthcare settings. From acute facilities to home health and beyond, the range of convex options offers advantages that positively impact patients and caregivers alike. As ostomy specialists, we should challenge ourselves to adopt new and innovative products and services along with the entire journey of the person with an ostomy: from the surgical table to living daily life with stoma.

Soft convexity refers to the use of compressible, flexible materials and designs in ostomy pouching systems and come in both one and two-piece options. Unlike their traditional rigid counterparts, this type of convex product adapts to the body’s contours, providing a snug yet comfortable fit. This adaptability plays a pivotal role in helping prevent leakage, achieving adequate flexible tension, and promoting skin integrity, particularly crucial for individuals with complex abdominal topography.

To help better define and standardise the different stages of the patient journey, Colwell and colleagues¹³ published a national consensus article and reached consensus on three post-operative time periods being: 1) the immediate postoperative period (0–8 days); 2) the postoperative period (9–30 days); and 3) the transition phase (31–180 days). In addition to defining these postoperative periods, Colwell and colleagues published a consensus statement that encourages and supports the use of convexity throughout any of these periods. The consensus statement reads “a convex pouching system can be safely used regardless of when the stoma was created.” It has been common practice in the past to avoid using convexity immediately after surgery due to the perceived risk of mucocutaneous separation. However, this concern has been without supportive evidence.¹⁴ With these new consensus statements, clinicians are encouraged to use

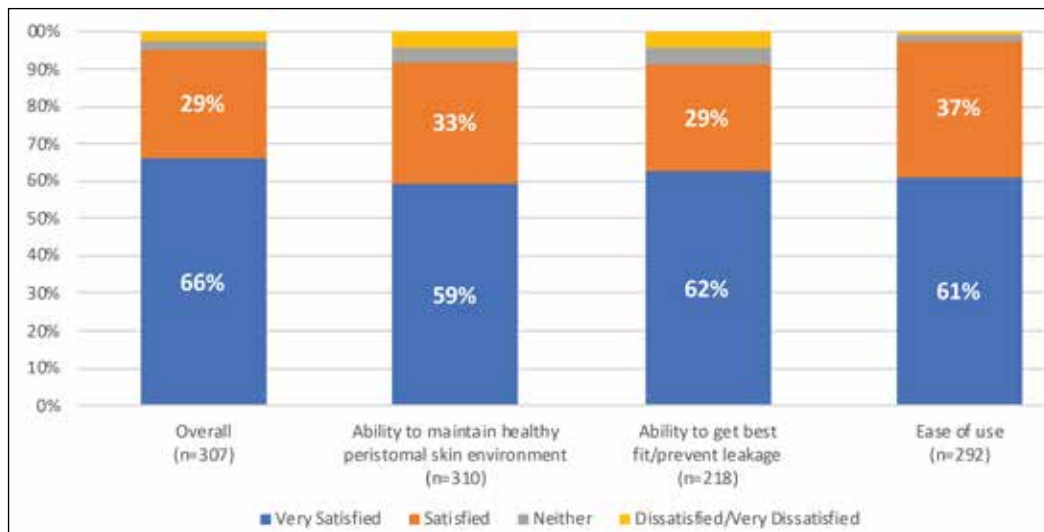


Figure 3. Very positive clinician satisfaction with more compressible convex skin barriers

flexible, more compressible convex products immediately out of the operating room to help improve the fit of the pouching system. Some clinicians are now opting to use these types of products within the operating room and removing flat products as the postoperative pouching system based on this newer evidence.¹⁵

Evidence continues to build, encouraging clinicians caring for people with ostomies to use more compressible convex products immediately after surgery, discharge to home with them, and encourage continued use while caring for themselves at home. Most abdominal topographies are not flat once the patient is at home and active, which poses the question, why should a flat barrier be the first go-to solution? Given the high prevalence of PSCs and their impact on QoL, the increased economic burden, and the clinicians' additional time taken caring for patients with PSCs, we must continue to challenge current clinical practices and provide solutions to ensure healthy peristomal skin using evidence-based principles. Based on all the newer evidence, it does appear that the world is no longer flat.

CONFLICT OF INTEREST

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