4th edition

Ostomy Care

Publication Compendium

Coloplast Professional

Welcome to the Ostomy Care Publication Compendium

At Coloplast, we listen to the perspectives of both healthcare professionals (HCPs) and the people who use our products every day. The insights we gain from understanding these respective clinical and personal experiences, combined with new scientific evidence, enables us to better respond to the needs of both. In doing so, our aim is to develop solutions that make users' lives easier, while helping you to initiate valid decision making in the care you provide as an HCP.

The Ostomy Care Publication Compendium provides one-page summaries of articles published within Ostomy Care with a direct link to the full article. The insights can relate to the physical and mental challenges faced by people living with a stoma, such as peristomal skin complications and leakage, evidence for preventive strategies to minimise potential risks and new clinical and scientific findings within different areas of Ostomy Care.

The Compendium is regularly updated with new knowledge within Ostomy Care. By sharing these new insights, we hope that together we can continue to improve care and, through this, make life easier – both for people with a stoma and for healthcare professionals like you.

To learn more, and to stay up to date with the latest information within Ostomy Care, you can download the Compendium in the evidence section of the dedicated Coloplast Professional website. And in order to help us ensure that knowledge is freely available, you are also welcome to share the link to the Ostomy Care Publication Compendium on the Coloplast Professional website with your colleagues and other healthcare professionals in your network

Thank you.

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The effect of frequency of leakage and a novel digital leakage notification system on sleep in people living with an intestinal stoma

Brady RRW, Ambé PC, Boisen EB, Hansen HD, Ajslev TA, Vestergaard M,
Br J Nurs. 2024 Dec 5;33(22):S18-S25.

Link to article: Please access through Open Access here

Objective
The study aimed to assess the impact of stoma leakage on sleep quality and to evaluate whether a digital leakage notification system, Heylo™, could alleviate sleep disturbances in individuals living with an intestinal stoma.

Study design
The research combined data from three sources: a large cross-sectional survey (Ostomy Life Study, OLS 2019) and two prospective, multi-centre clinical trials (CP340 and CP345). The CP340 was a single-arm, open-label study conducted in the UK, while CP345 was a randomized, controlled, crossover trial conducted in Germany. Both trials included evaluation of the impact of Heylo on sleep-related outcomes.

Population
The OLS survey included 4,209 individuals with various types of stomas from 17 countries. The CP340 enrolled 92 newly operated stoma patients, and the CP345 included 139 participants with a history of frequent leakage and concern about leakage. All participants had intestinal stomas and were assessed for sleep-related issues.

Results
The study found a clear association between the frequency of leakage incidents and sleep disturbances. Participants who experienced leakage at least once per week were significantly more likely to report sleep problems and nighttime awakenings to check their pouching system. Use of Heylo system led to statistically significant improvements in sleep outcomes across both clinical trials. Participants using Heylo reported:

- Fewer instances of being unable to sleep (Table 1)
- Reduced frequency of waking up at night to check their stoma (OR=0.195; p<0.001)
- Increased likelihood of waking up feeling fresh and rested; 66.3% of the participants reported that they woke up feeling fresh and rested 'more than half of the time', 'most of the time' or 'all the time' when using Heylo, compared to 49.5% who stated this at baseline.

In CP340 study, the proportion of participants who "rarely or never" experienced sleep disruption increased from 36.3% at baseline to 57.5% after using Heylo. Similar improvements were observed in the CP345 trial with an increase from 40.6% to 58.2% (Table 1).

Conclusion
Frequent leakage incidents are strongly associated with sleep disturbances in people with stomas. Heylo digital leakage notification system significantly improved sleep quality by reducing both the physical and psychological burden of leakage. It may be a valuable tool for individuals experiencing leakage-related sleep problems.

Clinical trial	Time	I could not sleep *n* (%)			
		All the time	Often	Sometimes	Rarely or never
CP340	Baseline	6 (6.6)	17 (18.7)	35 (38.5)	33 (36.3)
	Week 12 (Heylo)	1 (1.3)	8 (10.0)	25 (31.3)	46 (57.5)
CP345	Standard of care	6 (4.7)	23 (18.0)	47 (36.7)	52 (40.6)
	Heylo	5 (4.1)	12 (9.8)	34 (27.9)	71 (58.2)

Table 1. Use of Heylo has a positive impact on the ability to sleep

Study strengths and weaknesses
A major strength of the study is its use of both large-scale survey data and clinical trial evidence, providing a comprehensive view of the issue. The consistency of findings across different study designs strengthens the validity of the conclusions. However, limitations include the post-hoc nature of the sleep-related analyses, lack of blinding in the trials, use of three different data sources, and the use of single-item questions rather than full and validated sleep assessment tools. Additionally, the studies were not originally powered to assess sleep outcomes, so findings should be interpreted as exploratory.

A pilot study of a digital ostomy leakage notification system: Impact on worry and quality of life

Brady RRW, Fellows J, Meisner S, Olsen JK, Vestergaard M, Ajslev TA.
British Journal of Nursing 2023. 32(6): S4-12

Link to full-text article: A pilot study of a digital ostomy leakage notification system: impact on worry and quality of life | British Journal of Nursing (magonlinelibrary.com)

Objective
To evaluate the performance of a novel digital ostomy leakage notification system performance, users' experience of the system, the system's ability to prevent leakage progressing onto clothes, and the impact on worry about leakage and QoL.

Study design
The study was a single arm, open-label, exploratory investigation comprising 25 subjects assigned to use of the test product (HeyloTM) (Figure 1) for 21±3 days. Subjects completed questionnaires at baseline and termination of study evaluating leakage episodes, leakage worry and quality of life (QoL).

Population
Adults aged >18 years who had a colostomy or an ileostomy for ≥3 months and had mushy to liquid output (Bristol scale 6 or 7) were included. Subjects could use a flat, convex, or concave one-piece or two-piece pouching system of a Coloplast A/S brand. Subjects had to have a minimum of three episodes of leakage underneath the baseplate within the previous 14 days and had to worry about leakage. Subjects undergoing radio- or chemotherapy, receiving topical or systemic steroid treatment or with severe peristomal skin complications were excluded from participation. A total of 25 patients were included. Mean age was 56 years, 60% had an ileostomy, and 40% were females.

Results
Mean episodes of leakage outside the baseplate decreased significantly from 2.8 to 0.5 episodes after 21 days' use of the test product (P<0.001) corresponding to an 82% decrease (Figure 2).

Seventy-eight % of subjects felt that the test product provided a higher feeling of leakage control compared with their usual product.

Subjects' level of worry about leakage decreased significantly from baseline to termination of the study (P<0.001). After the test period, most subjects (70%) worried to a 'low' or 'very low' degree.

Product related quality of life improved significantly (P<0.01) after the test period and the increase was also clinically significant.

Performance accuracy was 78%, suggesting high concordance between messages conveyed to the user and baseplate pictures.

Limitation
Due to COVID-19 pandemic healthcare providers were unable to complete the audit within the intended 6-week timeline. Patients' appointments were often shortened, expanded, or postponed.

As well as surgeries were cancelled. The original target was 400 patients, which was not possible during the planned period.

Conclusion
This study showed that a novel digital leakage notification system can support users in their daily ostomy care by notifying them of a potential leakage and thus informing the decision of when to change the baseplate and providing people with a feeling of leakage control, less worry of leakage, and a reduction in leakage episodes.

Figure 1: The Heylo system comprises a sensor layer to be applied underneath the user's baseplate. The sensor layer continuously monitors for moisture between the skin and baseplate, and the status of the baseplate is conveyed to the user via a Bluetooth transmitter to an application on a smartphone. The transmitter charger is not shown here. The user has access to technical support when needed.

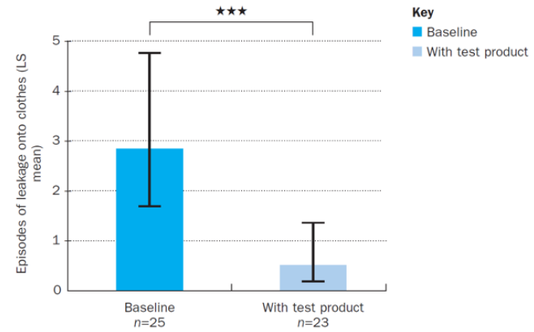

Figure 2: Episodes of leakage onto clothes. Subjects were asked at baseline and termination of study to recall the number of episodes of leakage onto clothes in past 21 days.

Study strengths and weaknesses
This was the first ever study to test a leakage notification system within ostomy care, and it provided very strong results in favour of the test product, e.g. reduction in leakage onto clothes by 82%. This study and test product addresses leakage, which is the main concern of people living with a stoma. Reducing leakage has been proven to increase quality of life[1].

Drawbacks include that single arm studies do not include a control group that receives standard of care or alternative intervention. Hence, it can be difficult to make comparisons.

1. Hedegaard C, Ajslev T, Zeeberg R, et al. Leakage and peristomal skin complications influences user comfort and confidence and are associated with reduced quality of life in people with a stoma. WCET Journal. 2020;40(4):23–29.

Evaluating the effect of a novel digital ostomy device on leakage incidents, quality of life, mental well-being, and patient self-care: An interventional, multicentre clinical trial

Brady RRW, Sheard D, Alty M, Vestergaard M, Boisen EB, Ainsworth R, Ajslev TA.
Journal of Clinical Medicine 2024, 13(19), 5673

Link to full-text article: Evaluating the Effect of a Novel Digital Ostomy Device on Leakage Incidents, Quality of Life, Mental Well-Being, and Patient Self-Care: An Interventional, Multicentre Clinical Trial

Objective
To investigate the effect of the digital leakage notification system (Heylo) on leakage, quality of life (QoL), and other health outcomes.

Study Design
An interventional, single-arm, multi-centre study was undertaken in the United Kingdom to evaluate a novel digital leakage notification system for ostomy care, including a support service (=test product) for 12 weeks in patients with a recent stoma formation (≤9 months). Patients completed questionnaires at baseline and after 4, 6, 8, 10, and 12 weeks, evaluating leakage episodes, Ostomy Leak Impact (OLI) (a tool containing three domains), and patient self-management (PAM-13). Additionally, mental well-being (WHO-5) and health-related quality of life (QoL) (EQ-5D-5L) were assessed. Outcomes between baseline and final evaluation were compared using generalised linear and linear mixed models. An overview of the study design is shown in Figure 1.

Population
Ninety-two patients (ITT population) with a mean age of 49.4 years (range 18–81 years) were recruited, of whom 53% were female. In total, 80% had an ileostomy, and 20% had a colostomy. Reasons for stoma formation included cancer (34%), ulcerative colitis (22%), Crohn's disease (13%), or other causes. On average, patients had their stoma surgery 140.9 days (range 21–275; SD = 77.7) prior to enrolment. Two-third of patients used Coloplast brand products as their regular ostomy solution, and 95% of patients used 1-piece products. Moreover, two-third of patients used a convex product type.

Results
After 12 weeks of using the test product, a significant decrease in mean episodes of leakage outside the baseplate (1.57 versus 0.93, $p<0.046$) was observed. Ostomy Leak Impact scores improved across all three domains ($p<0.001$), indicating less embarrassment, increased engagement in social activities, and increased control. Patient self-management also improved significantly (PAM-13 score: Δ6.6, $p<0.001$), as did the WHO-5 well-being index (Δ8.0, $p<0.001$). Lastly, EQ-5D-5L profile scores tended to improve ($p = 0.075$).

Conclusion
Patients experienced significantly fewer leakage incidents outside the baseplate when using the test product and experienced significant improvements in QoL and mental well-being. Besides improving users' QoL, patients also became more knowledgeable, pro-active, and engaged in managing their own health

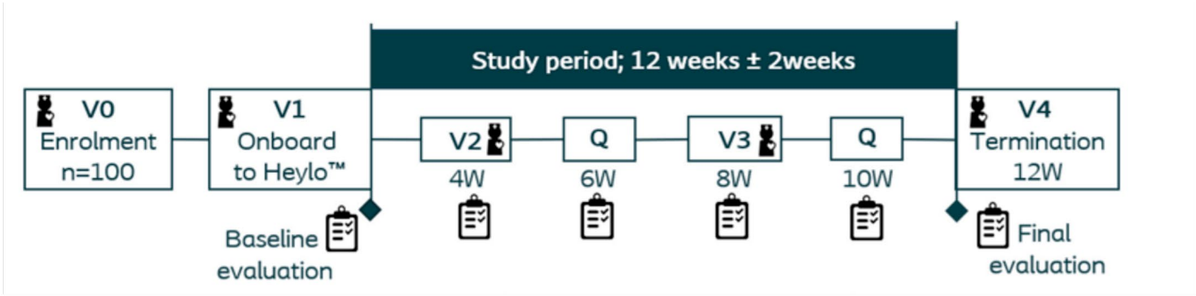

Figure 1: Overview of study design.

Study strengths and weaknesses
The study's design has limitations, including being non-blinded and single arm, which may affect subjective evaluations of the test product. Improvements seen could stem from the product, natural recovery post-surgery, or study effects. However, since no endpoints correlated with time since discharge, the improvements are likely from the test product. Recall bias may have influenced baseline values, as patients were not initially tracking leakage episodes. The observed reduction in leakage was lower than expected, possibly due to patients having recently formed stomas, making them more prone to sudden leaks.

Effect of a novel digital leakage notification system (Heylo) for ostomy care on quality of life and burden of living with an intestinal ostomy: The ASSISTER Trial, a randomized controlled cross-over trial

Ambe PC, Brunkhorst, E, Hansen HD, Gotfredsen JL, Vestergaard M, Ajslev TA.
Mayo Clin Proc Digital Health 2023. 1(3):438-449

Link to full-text article: Effect of a Novel Digital Leakage Notification System (Heylo) for Ostomy Care on Quality of Life and Burden of Living With an Intestinal Ostomy: The ASSISTER Trial, A Randomized Controlled Cross-Over Trial

Objective
To investigate the effect of a novel digital leakage notification system (Heylo) on quality of life (QoL) and burden of living with an intestinal ostomy. The hypothesis was that the use of Heylo as a stand-alone solution would be associated with positive care effects in people with intestinal ostomies by enabling detection of an imminent leakage and thereby reduce the worry hereof.

Study Design
The study was a randomized, controlled, open-label, cross-over trial with two test periods, enrolling 144 participants to use the test product for two test periods of 8 weeks; one period with Heylo and one period on standard of care (SoC). The order of test period was randomised.

Population
Adults aged >18 years who had a colostomy or an ileostomy and had mushy to liquid output (Bristol scale 5 or 7) were eligible. Participants should have experienced leakage underneath the baseplate at least 3 times in the past 2 weeks and should worry about leakage to some, high or very high degree on a 5-point Likert scale. Exclusion criteria included those having a pacemaker, those with known hypersensitivity to any components of the product, females being pregnant or breastfeeding, and failure to provide written consent. Mean age of participants was 50.7 years and 51% were female. Sixty-three percent had an ileostomy, and 37% had a colostomy.

Results
All 3 domain scores of the OLI tool (including the primary endpoint: Emotional Impact) were significantly higher when using Heylo for 8 weeks. Emotional impact increased from 62.0 to 73.4 (p<0.001) (Figure 1). The positive impact of Heylo on the Emotional impact domain score significantly improved already after 2 weeks of use compared with SoC and remained stable during the first test period.
Five out of the 6 domain scores on WHODAS 2.0 and the total score improved significantly when using Heylo compared with SoC (Figure 2). Only the Self-care domain did not change significantly. Number of leakage incidents outside the baseplate decreased significantly from 2.26 leakage incidents with SoC to 1.56 leakage incidents per 2 weeks with Heylo (p<0.001) corresponding to a 31 % reduction.

Conclusion
Overall, Heylo showed great potential in increasing QoL in people with an ostomy who used to struggle mentally and being at risk of isolating themselves. Use of Heylo improved participants' capability to participate in society and to engage in everyday life activities. Furthermore, Heylo reduced the number of leakages outside the baseplate with 31%.

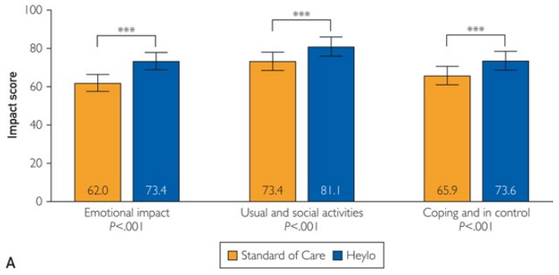

Figure 1: The three domains on the OLI score all increased significantly.

Figure 2: Five out of six domains on the WHODAS 2.0 improved significantly.

Study strengths and weaknesses
The randomized cross-over design is a key strength of this study. Performing a cross over allows participants to serve as their own control group, removing between subject variability. Also, this investigation was carried out in a real-world setting, so this study will likely reflect how Heylo will perform in real life. A limitation was that the participants were not blinded to the investigational product, which may influence their perception of the product.

A Concave Shaped Skin Barrier Provides Improved Clinical Outcomes for People Living With an Ostomy Who Have an Outward Peristomal Body Profile

St-Cyr D, Gilbert D, Dionne I, Kelly M, Kameka N.
J Wound Ostomy Continence Nurs 52(2):p 119-125

Link to article: Please access through Open Access here

Objective
The study aimed to evaluate the clinical performance of a concave-shaped ostomy skin barrier (baseplate) in individuals with an outward peristomal body profile (OPBP). Specifically, it compared the concave barrier to the flat or convex barriers the participants were using prior to the study, focusing on outcomes such as leakage, peristomal skin health, fit, usability, and patient satisfaction.

Study design
This was a single-arm, open-label, multicentre, prospective study conducted in three outpatient clinics in Quebec, Canada. Participants acted as their own controls, comparing their experience with their previous ostomy system to the concave system over a 4–6 weeks period. Data were collected through questionnaires, clinical assessments, and validated tools such as the Ostomy Skin Tool (OST) and the Peristomal Body Assessment Guide (PBAG).

Population
The study enrolled 20 adult participants with an OPBP, of whom 17 completed the study. The cohort was evenly split by gender, with 60% having a colostomy and 40% an ileostomy. Most participants had end stomas and semi-liquid or pasty output. Prior to the study, 55% used flat barriers and 45% used convex barriers, with the majority using products from Hollister.

Results
The study found a significant reduction in leakage when participants switched to the concave pouching system. At baseline, only 35% of participants reported no leakage, whereas 88% reported no leakage after using the concave system (Figure 1). Participants also perceived the concave system as significantly better at preventing leakage, with 71% rating it as good or very good, compared to just 21% at baseline. Peristomal skin health improved, as evidenced by a decrease in the average DET score from 2.05 to 1.19. Reports of skin problems dropped from 65% to 18% (Figure 2). Fit and comfort were also enhanced; 88% of participants said the concave system avoided wrinkles and folds, compared to only 25% with their previous system. The concave barrier was also rated better at conforming to body movements and providing a secure fit. Wear time increased from 4.1 to 5.0 days, and participants reported greater ease of application and less confusion about accessory use. Satisfaction was high, with 88% of participants expressing satisfaction and intent to continue using the concave system.

Conclusion
The study concluded that the concave skin barrier significantly improved clinical outcomes for individuals with an OPBP. It reduced leakage and peristomal skin complications, improved wear time, and enhanced user comfort, security, and satisfaction. These findings support the use of concave barriers as a tailored solution for this specific patient population.

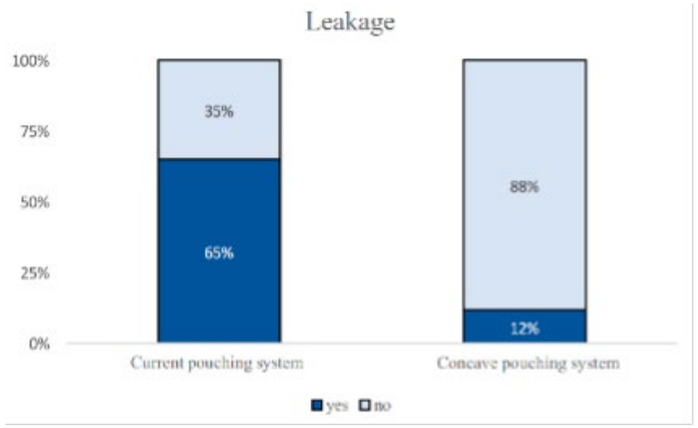

Figure 1. Participants experiencing challenges with leakage related to their ostomy pouching system.

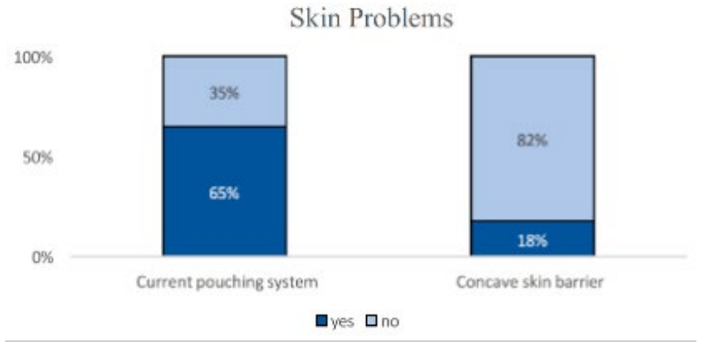

Figure 2. Participants experiencing challenges with skin problems related to their ostomy pouching system.

Study strengths and weaknesses
A major strength of the study is its prospective design and use of validated assessment tools, which provided a comprehensive evaluation of the concave barrier's performance. The holistic approach to measuring multiple dimensions of ostomy care added depth to the findings. However, the study was limited by its small sample size, lack of a control group, and potential bias due to the open-label design. Most outcomes were based on subjective self-report or non-validated tools, and the study was conducted only in private clinics within a single Canadian province, which may limit generalizability.

Evaluation of a pouching system with a concave contour for people with an outward peristomal body profile

Vestergaard M, Hansen MF, Boisen EB, Dambæk MR
Br J Nurs. 2024 Dec 5;33(22):S18-S25.

Link to article: Please access through Open Access here

Objective
The primary objective of the study was to evaluate how the use of a one-piece concave pouching system (SenSura® Mio Concave) affects wear time in individuals with an outward peristomal body profile1 who previously used flat pouching systems. Secondary objectives included assessing the impact on unplanned changes of the pouching system and the use of accessories.

Study design
This was a 4-week product evaluation conducted in the UK, consisting of two test periods of approximately 14 days each. Participants first underwent a screening phase to determine if they could and wished to continue using the concave pouching system. Only those who met the criteria and chose to proceed were included in the second evaluation phase. Data were collected through online questionnaires and phone interviews.

Population
A total of 110 participants were enrolled, all of whom had an ileostomy or colostomy for at least three months and an outward peristomal body profile. The average age was 65.9 years, and 77.3% were male. Most participants (79%) used one-piece open/drainable pouches before the study. After the screening phase, 87 participants continued to the second test period, and 84 completed the final evaluation.

Results
The study found no statistically significant difference in wear time between the concave and the usual flat pouching systems. However, significantly fewer participants reported unplanned changes when using the concave system (52.4%) compared to the flat system (36.9%). Leakage was the most common reason for unplanned changes in both groups. Additionally, the use of accessories dropped significantly from 69.9% with the flat system to 41.7% with the concave system. Specific accessories like adhesive removers, tape, and rings/seals were used less frequently with the concave system.

Conclusion
Selecting the right stoma-care product can be challenging but it is very important to obtain a secure seal between peristomal skin and baseplate. For people with an outward peristomal body profile, use of a concave pouching system led to fewer unplanned changes of pouching systems, and less use of accessories compared with use of flat pouching systems

	Usual flat pouching system (*n*=103)	Concave pouching system (*n*=84)	*P*-value
Q. Do you use accessories with your usual flat/concave pouching system?			
Yes	72 (69.9%)	35 (41.7%)	0.0001***
No	31 (30.1%)	49 (58.3%)	
Q. If you use any accessories, which do you use?			
Adhesive remover (spray/wipes)	57 (55.3%)	26 (31.0%)	0.0008***
Skin barrier (spray/wipes/cream)	35 (34.0%)	19 (22.6%)	0.0881
Tape	19 (18.4%)	2 (2.4%)	0.0005***
Rings/seals	26 (25.2%)	10 (11.9%)	0.0214*
Belts	9 (8.7%)	6 (7.1%)	0.6896
Paste	4 (3.9%)	3 (3.6%)	0.9110
Powder	14 (13.6%)	3 (3.6%)	0.0177*
Cleansing spray/wipes	22 (21.4%)	8 (9.5%)	0.0283*
Deodorant	13 (12.6%)	3 (3.6%)	0.0278*

Table 1. Differences in accessory use between flat and concave pouching systems.
* P<0.05; ** P<0.01;*** P<0.001

Study strengths and weaknesses
A key strength of the study was its real-world design, allowing participants to assess the product in their daily lives and continue only if they found it suitable. This approach provided insights into user-driven outcomes. However, this design also introduced a positive bias, as only those who could and chose to use the concave system were included in the final evaluation. Additionally, the lack of a formal sample size calculation and the absence of a control group limit the generalizability of the findings.

1. Colwell JC, Bain KA, Hansen AS, Droste W, Vendelbo G, James-Reid S. International Consensus Results: Development of Practice Guidelines for Assessment of Peristomal Body and Stoma Profiles, Patient Engagement, and Patient Follow-up. J Wound Ostomy Continence Nurs. 2019;46(6):497-504.

A retrospective chart review of ostomy pouching systems in new ileostomy patients: a sub-analysis

Zamarripa C, Craig A, Mathews C, Small L, Folk A
Nurs. Rep. 2025 15(6), 206.

Link to article: Please access through Open Access here

Objective
The study aimed to evaluate the prevalence of leakage and peristomal skin complications (PSCs) in patients with newly created ileostomies. It specifically compared the performance of two types of ostomy pouching systems—elastic tapeless border (ETB)(Coloplast) and ceramide-infused tape-border (CIB)(Hollister)—to determine their impact on leakage and PSCs in this high-risk population.

Study design
This was a retrospective sub-analysis of a previously published chart review conducted at two University of Pittsburgh Medical Center hospitals reviewing medical records of 214 patients who had recently undergone surgery to have either a colo- or an ileostomy. The present study reviewed electronic medical records of 98 patients with new ileostomies, analyzing data from 479 pouch changes including up to five pouch changes. The analysis focused on leakage and PSCs, using generalized linear mixed models to assess the risk of leakage while controlling for confounding demographic and surgical variables.

Population
The ileostomy cohort consisted of 98 patients, predominantly white (84.7%) and male (53.1%), with a mean age of 59.6 years and average BMI of 27.9 kg/m². Most surgeries were elective (76.5%) and performed via open procedures (87.8%). The majority of patients had chronic conditions such as cancer or inflammatory bowel disease. Compared to the full study population of 214 patients, the ileostomy group was younger, had longer surgeries, and more frequently underwent emergent procedures.

Results
All individuals with ileostomies left the operating room wearing a flat pouching system and the majority had a pouching system with a tapeless border (ETB) or tape border (CIB) [61.2%, n=60; 38.8%, n=38)], respectively. The overall leakage prevalence in the ileostomy cohort was 19%, with leakage instances increasing over successive pouch changes. ETB barriers were associated with a significantly lower leakage risk (13.7%) compared to CIB barriers (29.3%), representing a 53.2% reduction in risk (p = 0.03; OR = 2.45) (Table 1). PSCs were observed in 25% of ileostomy patients, higher than the 17% in the full study population. PSC prevalence also increased with length of stay and was highest at the fifth pouch change.

Conclusion
The study concluded that ETB barriers significantly reduce the risk of leakage in patients with new ileostomies compared to CIB barriers. This finding is clinically important given the higher risk of PSCs in this population due to the liquid and caustic nature of ileostomy effluent. Evidence-based selection of ostomy barriers can improve patient outcomes, reduce complications, and lower healthcare resource utilization.

Barrier Pouching System	Risk of Leakage—Total Study Population	Risk of Leakage—Ileostomy Patients
All barrier types	19%	18%
Ceramide-infused tape-border barrier (CIB) *	26%	29%
Elastic tapeless border barrier (ETB) *	15%	14%

* denotes statistical significance between CIB and ETB, $p < 0.05$.

Table 1. Risk of leakage in the total study population and in the ETB and CIB sub-groups.

Study strengths and weaknesses
A major strength of the study is its real-world setting, providing practical insights into ostomy management in acute care. The use of standardized data collection tools and assessments by certified WOC nurses enhanced data reliability. However, the retrospective design limits causal inference, and inter-rater variability among nurses may have influenced data consistency.

Pouching System Leakage and Peristomal Skin Complications Following Ostomy Surgery in the Immediate Postoperative Period

Zamarripa C, Craig A, Kelly MT, Mathews C, Folk A
J Wound Ostomy Continence Nurs. 2024;51(6):478-483.

Link to article: Please access through Open Access here

Objective
The purpose of this study was to explore the performance of barrier pouching systems, with respect to leakage and development of Peristomal Skin Complications (PSCs), in a hospital setting immediately following ostomy creation.

Study design
The study was designed as a retrospective chart review of all patients who were admitted for ostomy-creation surgery between February 2022 and June 2023. Chart reviews were conducted at 2 campuses of the University of Pittsburgh Medical Center (UPMC) Presbyterian Shadyside.
Leakage and PSCs were captured as dichotomous outcomes (present vs absent) in the data collection form. The authors did not capture the severity of leakage in this retrospective chart review. Information was also collected regarding products used for barrier pouching systems (barrier product number) and manufacturer.

Population
The study included a sample comprised of 214 patients who were admitted for ileostomy, colostomy, and urostomy surgery. Their mean age was 64 years (SD 13; range 26-94) and 50% (n = 107) were male. Most patients (66%, n = 142) stayed in hospital for less than the 2-week observation period, and their mean hospital length of stay was 7.33 days (SD 4; range 1-13). The average number of barrier pouch system changes was 3.9 (SD 1.2; range 1-5).

Results
Of the 214 patients whose charts were reviewed, 43.5 % (93) had 1 or more leakage events during the review period and 17% (n = 36) had 2 or more. Specifically, 57 patients had a single leakage event, 23 had 2 leakage events, 5 had 3 leakage events, 7 had 4 leakage events, and 1 patient had 5 leakage events. 36 of the 214 patients whose charts were reviewed (17%), developed at least 1 PSC and 5 of 36 (14%) developed 2 PSCs. Most PSCs (78%, n = 28) developed at pouch change 3 or later. There were 5 types of PSCs which occurred during the study; the most common documented was irritant contact dermatitis (n = 24; 59%) followed by cutaneous blisters (n = 8, 19%), medical adhesive-related skin damage of the peristomal skin (PMARSI; n = 5, 12%), and fungal dermatitis (n = 4, 10%). When the risk of leaking was examined for the two most frequently used barrier designs (Ceramide Infused Barrier (CIB) (Hollister) vs Elastic Tapeless Border barrier (ETB) (Coloplast), study findings indicate that the probability of the CIB barrier leaking was 26% (95% CI 24%-28%) (Table 1). In contrast, the probability of an ETB barrier leaking was 15% (95% CI 14%-16%). Thus, the likelihood of leakage is 41% lower for patients using the ETB as compared to CIB (P = 0.011).

Conclusion
The rate of leakage was 19% for all WOC nurse supervised pouching system changes. Analysis revealed no significant differences in PCSs between pouching systems. In contrast, when the 2 most common pouching system designs, an ETB and a CIB were analysed, the risk of leakage for the CIB was 26% as compared to a 15% risk when the ETB was used. The difference in these risks, based on statistical modelling, yielded a 41% reduction in the risk of leakage for ETB when compared to CIB.

Risk of leakage—barrier pouching system	Risk of barrier leakage (%)[a]
Total population	19
Ceramide-infused tape border (CIB) barrier	26
Elastic tapeless border (ETB) barrier	15
2+ leakage episode population	58
Multi-leakers CIB barrier	72
Multi-leakers ETB barrier	50

[a]The risk of leakage was calculated utilizing a statistical model based on 214 patient charts and 832 pouch change observations during the study period.

Table 1: Risk of leakage with different barrier types.

Study strengths and weaknesses
A major strength of this study is that it generated real world evidence without bias or interference by research staff. This study setting was an internationally recognized hospital system with an experienced group of ostomy nurse specialists. Moreover, both hospitals have consistent leadership, standardized documentation, and ostomy care training, combined with a specialized WOC nursing team performing pouching system changes and documentation.
Data were collected by multiple WOC nurses raising the possibility of less-than-optimal inter-rater reliability. Severity of leakage was not measured, but could have provided additional insights into the influence of various pouching systems on leakage and PSCs.

Body fit with a pouching system with concave contour for people with an outward peristomal body profile

Rolfsen T, Vestergaard M, Hansen MF, Boisen EB, Dambæk MR.
J Wound Ostomy Continence Nurs. 2024;51(4):303–311.

Link to article: Journal of Wound Ostomy & Continence Nursing

Objective

The primary objective of the study was to compare the body fit of a two-piece pouching system with a concave skin barrier to a two-piece pouching system with a flat skin barrier in individuals with an outward peristomal body profile. The secondary objectives were to compare the concave and flat comparator pouching systems regarding the degree of leakage, wear time, and Quality of Life (QoL).

Study design

The study was designed as a randomized, controlled, open-label, cross-over trial involving 53 subjects with outward peristomal body profiles. Conducted in Denmark, Norway, Germany, and the Netherlands, participants used either a concave two-piece pouching system or a flat comparator for three weeks, then switched to the other system for another three weeks. The primary endpoint was the fit of the skin barrier to body contours, evaluated on a 5-point Likert scale. Secondary endpoints included leakage, wear time, and QoL, assessed using the Ostomy-Q questionnaire.

Population

The study included participants with an outward peristomal body profiles who experienced leakage of ostomy effluent. Participants were aged 50 to 91 years, with an average age of 70.9 years. The majority (79%) were male. Thirty-seven percent had an ileostomy, and 63% had a colostomy, with the most common reasons for surgery being cancer (50%), ulcerative colitis (21%), and Crohn's disease (8%). Participants had lived with an ostomy for an average of 8.4 years. The outward peristomal area had a mean diameter of 12.5 cm and a mean height of 5.9 cm, and all participants used flat two-piece pouching systems before the study.

Results

The study found that the concave pouching system provided a significantly better fit to body contours compared to the flat comparator ($P < .001$). Eighty-six percent of participants rated the concave skin barrier as "good" or "very good" at fitting body contours, vs. 38% for the comparator (Figure 1). Additionally, the concave system reduced the degree of leakage underneath the skin barrier, with a mean difference of -1.84 (95% CI -3.31 to -0.37; $P = .016$). Leakage was observed underneath 87.8% of the comparator skin barriers upon change, compared to 74.1% of the concave skin barriers. Furthermore, participants experienced fewer episodes of leakage outside the skin barrier with the concave system (13.0% vs. 26.7%).

Participants also reported significant improvements in quality of life (QoL) when using the concave system, with a mean difference of 14.3 (95% CI 9.4 to 19.2; $P < .001$). This improvement was reflected across all four domains of the Ostomy-Q tool: confidence, comfort, discreetness, and social life.

No significant differences were observed in wear time between the barriers

Conclusion

Findings of this trial indicate that a skin barrier with a concave profile was perceived to provide a better fit to the peristomal area of people with an outward peristomal body profile. Specifically, the concave skin barrier reduced the risk of the skin barrier to fold or wrinkle upon application compared with a flat skin barrier. The concave skin barrier also reduced leakage, and participants reported concomitant improvements to QoL related to using an ostomy product.

No significant difference in wear time between skin barrier shapes was reported.

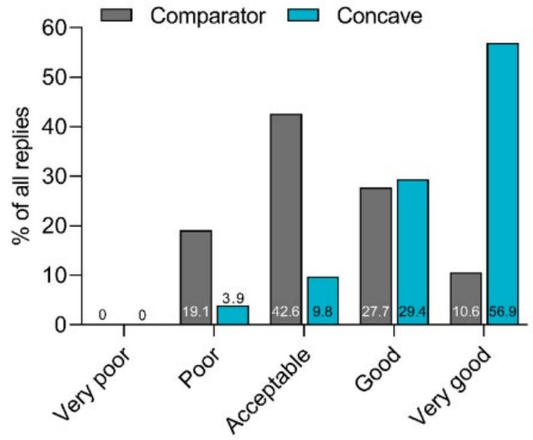

Figure 1: Subjective evaluation of body fit of concave and flat comparator skin barriers

Study strengths and weaknesses

The study's strengths include its robust randomized controlled cross-over design, which minimizes bias and allows participants to serve as their own controls. It clearly demonstrates that the concave skin barrier significantly improves body fit, reduces leakage, and enhances QoL. The use of validated tools like the Ostomy-Q questionnaire adds credibility to the findings. However, the open-label design introduces potential bias in subjective evaluations. The overrepresentation of male participants (79%) may limit the generalizability of the results. Additionally, the study's duration may not capture long-term effects, and reliance on self-reported data could introduce subjective bias.

Leakage of stomal effluent outside the baseplate leads to rise in product usage and health professional interactions

Jensen LdF, Rolls N, Russell-Roberts P, Vestergaard M, Jensen ML, Boisen EB.
Br J Nurs. 2023 Jan 12;32(1):8-19

Link to full-text article: Leakage of stomal effluent outside the baseplate leads to rise in product usage and health professional interactions | British Journal of Nursing (magonlinelibrary.com)

Objective

To understand behavioural changes regarding the usage of pouching systems, supporting products and interactions with health professionals for people experiencing faecal leakage outside the baseplate.

Study design

- Online survey with recall questions on leakage frequency and its consequences: use of consultations with health professionals (nurses and general practitioners) and changes in the use of pouching systems and supporting products.
- The cost per event of leakage outside the baseplate was estimated based on the reported increase in healthcare resource use (HCRU) related to experiencing leakages outside the baseplate with UK health-related costs.

Population

n= 602 people with ileostomy or colostomy from the UK, USA, France, Germany, and Denmark.
Inclusion:

- People with a faecal stoma
- Age 18 years or above
- Consented to participate Population
- People with urostomies
- Participant did not complete the questionnaire

Results

Number of leakage incidents outside baseplate: Respondents reported a mean of 1.1 and 3.8 incidents in the past 2 weeks and 3 months, respectively.

Worry about leakage outside the baseplate: 89% worried about leakage to a different degree. Most (84%) who worried reported that this was due to the risk of soiling clothes or bedsheets; concerns about odour, embarrassment, skin issues and waking up at night.

Interactions with health professionals following leakage issues: Of the 384 who reported leakage outside baseplate at least once during the past 3 months, 9.9% had had physical consultation with a stoma care nurse (SCN), 2.9% had had physical consultation with a home care nurse, and 1.8% with a GP. Furthermore, 15.4% of them had remote consultations with a SCN via the telephone or online.

Usage of pouching systems following incidents of leakage outside the baseplate: 45.6% reported making changes to their usage pattern by increasing the number and/or changing the type of pouching system, which lasted on average 4.2 days after leakage episode.

Use of supporting products following leakage outside the baseplate: 25% increased their use of existing supporting products and 21% added supporting products to their change routine.

Healthcare resource use: the cost of a single leakage event was estimated to be **£32.47 in the first 3 weeks following a leakage incident** (in a UK community care setting). The primary cost contributors were nurse and GP consultations (62%), with pouching systems accounting for 29% and supporting products for 9% of the cost (figure 1).

Conclusion

Many people living with a stoma struggle with leakage outside the baseplate, despite having had a stoma for several years, and most worry about it. Experiencing leakage outside the baseplate promoted behavioural changes for about half the respondents, leading to increased use of stoma care products, and consultations with health professional.

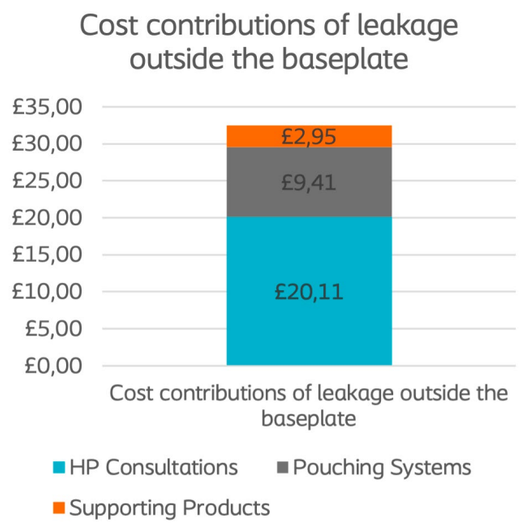

Figure 1: Data on cost contributions of leakage outside the baseplate visualised from table 9 of the publication. HP = Health Professional

Study strengths and weaknesses

The survey included respondents from 5 countries, the majority of whom used Coloplast products. Hence, the study results may not necessarily represent the global stoma population.

This research is solely based on user-reported recall data, which could bias the results.

Some assumptions were made in costing the increases in HCRU relating to leakages outside the baseplate, which would have impacted the estimate to some degree.

Results of an audit of the Peristomal Body Profile Assessment Tool

Tonks N, Rolls N, Bain K, Russell-Roberts P, Bain M.
Br J Nurs. 2022 Nov 31;22; 4-12

Link to full-text article: https://www.magonlinelibrary.com/doi/full/10.12968/bjon.2022.31.22.S4

Objective

A low-interventional, clinical investigation was designed to assess the use of a six-step "Peristomal Assessment Tool" for nurses to help patients choose the appropriate stoma product, and possibly decrease incidents of leakage, peristomal skin complications assessed by the DET® Score, and increase Quality of life assessed by the OLI (Ostomy Leakage Impact tool) score.

Study design

A UK multicentre – 33 sites with 147 patients.

- 111 were new stoma Patients.
- 29 were established stoma patients.
- 7 Patients did not answer.

Population

- Patients had 2-3 visits at the clinic.
- Clinicians measured the Peristomal Body Profile and retrieved information on leakage and peristomal skin health at each visit.
- Patients reported incidents of leakage and answered the OLI at each visit.
- A focus group of 16 participating clinicians was established to evaluate the ease of use of the Peristomal Assessment Tool in clinical practice.

Results

All 147 patients had two visits and 74 patients had a third visit. When using the Peristomal Body Profile Assessment tool at the first visit, 50% (74 patients) were recommended a flat pouching type, 37% (55 patients) a convex and 12% (18 patients) a concave. At same time patients with healthy peristomal skin (DET>3) and few leakages combined with high quality of life (OLI<40) were most often recommended a flat pouching system (46 patients). Patients found with deep folds or superficial creases in the peristomal skin at first visit had a significant impact on both the peristomal skin complications (higher DET score) and leakage combined with decrease in quality of life (Low OLI score) (Table 1). During the audit 18 patients had a recorded change in Peristomal Body Profile between visit one and two.

There was reported fewer leakages, healthier skin, and an improved quality of life for the patients in general.

The focus group evaluated the Peristomal Body Assessment Tool to be easy or very easy to use (Figure 1) Majority of the focus group indicated that it took between 2 – 5 minutes to perform the assessment. In the focus group (15 responders), 46,67% indicated they would save time, while 53,33% indicated it added time to use the tool. However, it reduced number of patients returning and improved clinicians' ability to advice about best product solution from the start and hereby potential could save money.

Limitation

Due to COVID-19 pandemic healthcare providers were unable to complete the audit within the intended 6-week timeline. Patients' appointments were often shortened, expanded, or postponed, and surgeries were canceled as well. The original target was 400 patients, which was not possible during the planned period.

Conclusion

The audit acknowledges that use of Peristomal Body Profile Assessment Tool supports clinicians in choosing the best fitting appliance the first time, resulting in better peristomal skin conditions. Fewer leakages and higher quality of life for people living with a stoma.
At same time the audit indicated a decrease in healthcare cost

Table 1. Average DET and OLI scores at first visit by Peristomal Body Profile

Peristomal Body Profile	DET	OLI
Regular area around stoma	1.39	44
Inward area around stoma	3.68	42
Outward area around stoma	2.31	40
Uniform area around stoma	1.69	44
Variable area around stoma	3.00	41
Soft abdomen	2.15	42
Firm abdomen	1.94	46
Superficial creases	2.08	44
Deep folds	3.94	30
Stoma above bending line	2.10	39
Stoma at bending line	2.94	38
Stoma under bending line	1.97	45
Stoma opening above skin surface	1.62	42
Stoma opening level with the skin	1.85	45
Stoma opening below skin surface	5.50	39
Thick stool output	1.48	49
Liquid stool output	2.33	40
Urine output	3.60	36

Key: = poor score: >3 DET score or <40 OLI score
DET score=0 (normal); 9 (severe injury)
OLI score=80 (highest quality of life); 20 (lowest quality of life)

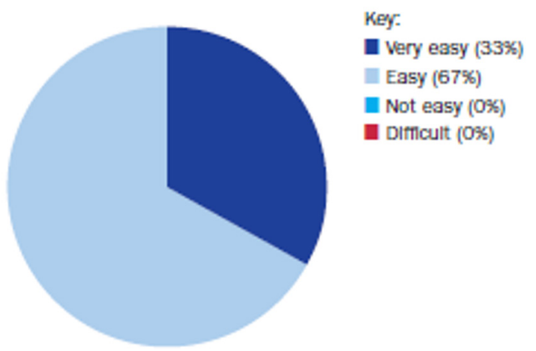

Figure 1. Ease of use

Study strengths and weaknesses

Show a high acceptance from clinicians in use.

Neither the clinicians nor the patients were compensated for their time or participation which indicate exclusion of bias.

The audit was solely performed in UK, which can make it difficult to adapt to other countries with different healthcare systems.

The COVID-19 pandemic has had an impact on the study negatively in the planning of clinic visits.

There was a high level of variability in DET score in between audit centres, which could indicate different approaches to the scoring tool.

Lack of data for visit two and three.

Perception of leakage: data from the Ostomy Life Study 2019

Down G, Vestergaard M, Ajslev TA, Boisen EB, Nielsen LF.
Br J Nurs. 2021 Dec 9;30(22):4-S12.

Link to full-text article: Perception of leakage: data from the Ostomy Life Study 2019 (magonlinelibrary.com)

Objective
To investigate how people with a stoma and stoma care nurses perceive different patterns of effluent under the baseplate.

Study design
Suvery with prefered response options.
Participants were randomly selected from local Coloplast A/S databases with stratified sampling to reflect each country's market size.
Participants were shown pictures of baseplates with different patterns of effluent to investigate the degree of effluent perceived as leakage (Figure 1).

Population
n=4209 people with stoma, 328 stoma care nurses
Inclusion:
- People with a stoma or stoma care nurse
- Consented to participation
- Exclusion:
- People irrigating their stoma
- Answered all questions within 15 minutes (survey should take 30 minutes to complete).
- Answered 'don't know' to more than 30% questions
- Participant did not finish the survey

Results
88–90% of people with a stoma and 97-98% of stoma care nurses perceived effluent reaching outside the baseplate as leakage.
Effluent covering major parts of the baseplate was perceived as leakage by most respondents with a colostomy or ileostomy (83%), whereas fewer respondents with a urostomy perceived this as leakage (57%).
Only 9-19% of the people with a stoma and 30% of the stoma care nurses considered stomal effluent close to the stoma as leakage.
Body profile, stoma appearance and incorrect product usage were often considered by stoma care nurses as the reason for leakage.
In the majority of cases, multiple interactions between stoma care nurses and patients were needed to resolve leakage issues.
Stoma care nurses of the advised patients having problems with leakage to use supporting products.

Conclusion
This study revealed that effluent reaching outside the baseplate is generally perceived as leakage, whereas effluent present next to the stoma is generally not perceived as leakage, by both people living with a stoma and stoma care nurses. The psychological aspects, such as embarrassment following leakage on to clothes, may be more apparent to patients, whereas the link to PSCs may be less obvious to patients.

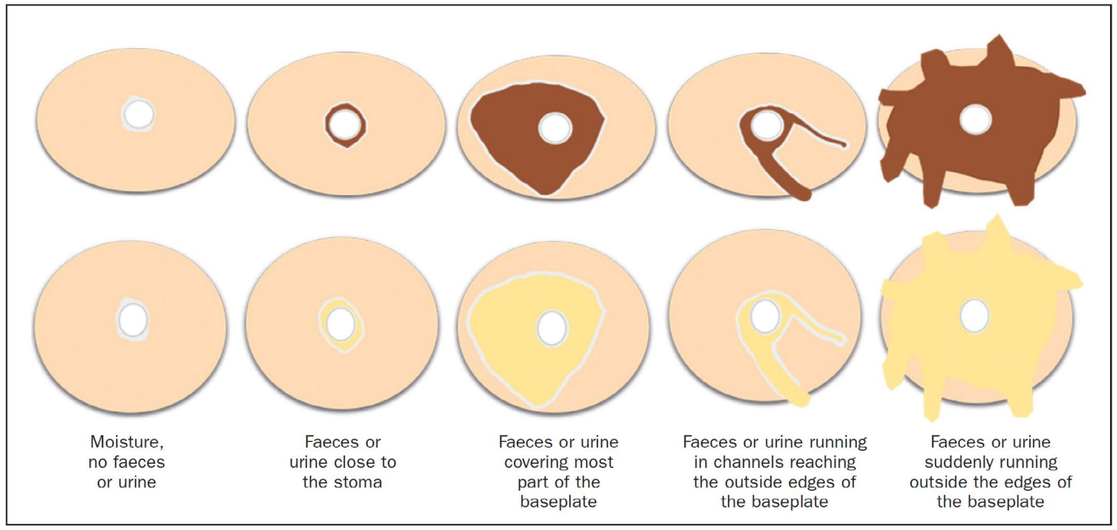

Figure 1: People with a colostomy, ileostomy or jejunostomy and stoma care nurses were shown pictures with different degrees of faecal leakage (top), while people with a urostomy were shown pictures with different degrees of urinary leakage (bottom).

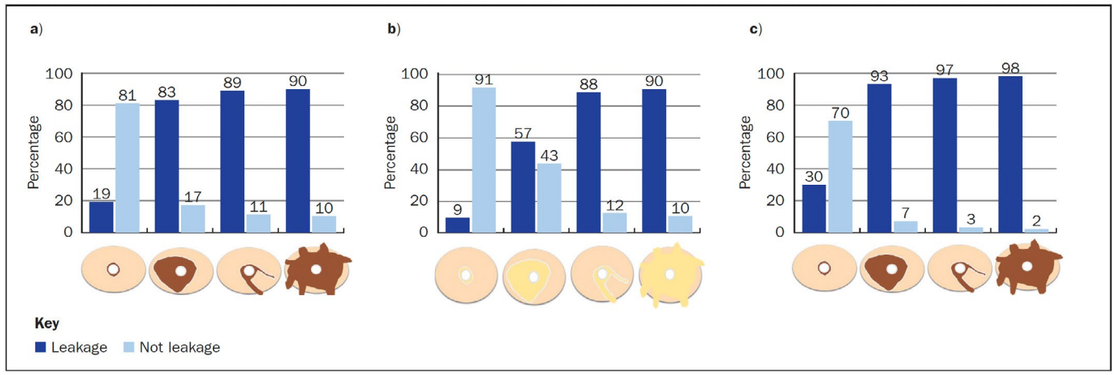

Figure 2: Perception of leakage among respondents with a stoma and stoma care nurses. a) People with colostomy, ileostomy or jejunostomy (n=3314), b) people with urostomy (n=847), c) Stoma care nurses (n=294 to 312).

Study strengths and weaknesses
The survey included 17 countries, which gives a good representation of the global population in ostomy care.
The study did not investigate national differences.
Online survey may not be representative of all people living with a stoma.

Challenges facing people with a stoma: Peristomal and body profile risk factors and leakage

Martins L, Andersen BD, Colwell J, Down G, Forest-Lalande L, Novakova S, Probert R, Hedegaard C, Hansen AS. Br J Nurs. 2022 Apr 4;31(7):376-385.

Link to full-text article: Challenges faced by people with a stoma: peristomal body profile risk factors and leakage | British Journal of Nursing (magonlinelibrary.com)

Objective
To obtain a better understanding of the challenges that people living with a stoma face in their everyday lives and their experiences and worries, including data on peristomal body profiles, leakage, peristomal skin complications, physical and social activities and access to a stoma care nurse.

Study design
Online survey with predefined response options (Ostomy Life Study 2019).
Participants were randomly selected from local Coloplast A/S databases with stratified sampling to reflect each country's market size.
Participants were asked questions relating to their experiences and worries regarding the shape of the stoma and peristomal body profile of the respondents, leakage prevalence and peristomal skin complications, physical and social activities, and access to a stoma care nurse.

Population
n=5187 people with stoma
Inclusion:
- People living with a stoma
- Consented to participation

Exclusion:
- Participant did not finish the survey

Results
- 62% of respondents avoided physical and social activities due to their stoma
- 37% of respondents had never consulted their stoma care nurse to have the fit of their stoma product checked.
- In a subgroup of 4209 respondents receiving questions about leakage, detection of output under the baseplate and leakage onto clothes were common, with 76% and 26% of respondents, respectively, reporting each incidence within the previous month.
- The odds (risk) of leakage appeared to be associated with an irregular stoma shape, a stoma level with or below the skin surface, an inward peristomal body profile, changes in the shape of the peristomal area, and creases and folds in the peristomal area.

Conclusion
Leakage under the baseplate of the stoma product and onto clothes remain important concerns for individuals with a stoma. Leakage, which can cause peristomal skin complications, was associated with stoma types and peristomal body profiles and changes in the area around the stoma. The study highlights the need for optimal access to a stoma care nurse and/or validated assessment tools to minimise the leakage of stomal effluents and to provide the necessary care and guidance to improve the quality of life for people witha stoma.

Study strengths and weaknesses
- The survey included 17 countries, which gives a good representation of the global population in ostomy care.
- The study did not investigate national differences.
- Online survey may be not representative of all people living with a stoma.

Use of a convex pouching system in the postoperative period. A national consensus

Colwell JC, Davis JS, Emodi K, Fellows J, Mahoney M, McDade B, Porten S, Raskin E, Sims T, Norman H, Kelly MT, Grey M. J Wound Ostomy Continence Nurs. 2022;49(3):240-246.

Link to full-text article: Use of a Convex Pouching System in the Postoperative Period: Journal of Wound Ostomy & Continence Nursing (lww.com)

Objective
To conduct a scoping review identifying research-based evidence and gaps in present knowledge of the safety and effectiveness related to the use of a convex pouching system and develop consensus statements guiding the use of a convex pouching system following ostomy surgery.

Study design
A scoping review was conducted using PRISMA scoping review guidelines to identify current best evidence related to the use of convexity following ostomy surgery and to identify gaps in knowledge.

Sixteen inclusion criteria included articles published between 1996 and 2021. Exclusion criteria were articles that did not include the use of convex pouching systems and those written in a language other than English. An electronic database search included PubMed, EMBASE, and CINAHL.

A group of 10 nurses and physicians with expertise in caring for patients with an ostomy completed the scoping review identifying research-based evidence and gaps. Consensus statements guiding best practice related to the use of convexity were generated using a modified Delphi process (Figure 1). An expert panel was convened, comprising 10 healthcare providers with experience in managing patients with an ostomy in inpatient, outpatient, and home care settings.

Due to the COVID-19 global pandemic, the consensus was conducted virtually using online meeting platforms and asynchronous online collaboration boards.

Population
This study did not include a traditional study population as it was literature review and consensus work, but healthcare professionals with expertise in patients with an ostomy were involved in the work.

The review part of the study included publications on the use of convexity following stoma surgery.

Results
Outcomes of the scoping review revealed a paucity of evidence related to the use of convexity following ostomy surgery, and a particular lack of evidence regarding its use for the first month following surgery. Therefore, consensus statements guiding best practice related to the use of convexity were generated.
Due to a lack of standardization of care periods following ostomy surgery highlighted by the scoping review, the panellists reached consensus on 3 postoperative time periods: (1) immediate postoperative period, days 0 to 8; (2) postoperative period, days 9 to 30; and (3) transition phase, days 31 to 180. These periods were defined to conform with current care patterns for patients undergoing ostomy surgery and broad time frames suggested in the scoping review.
The expert panel reached consensus on eight statements (Figure 2) for the use of convex products immediately after surgery and throughout the first 6 months after stoma creation, as well as describing goals in choosing the best pouching system for the patient with an ostomy.

Conclusion
The statements described in this article provide best practice guidance for the use of convexity in the postoperative period. Panellists resided in the United States, and consensus statements reflect practice experiences and practice patterns among this group.

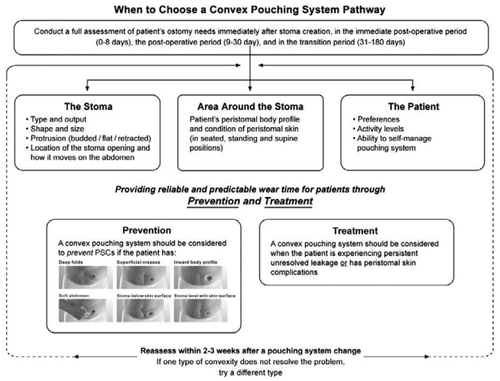

Figure 1: Overview of the Delphi process

TABLE 2.
Convexity Consensus Statements

1	The primary goals when working with a patient to choose an ostomy pouching system are to: • Secure a reliable seal around the stoma to avoid leakage; • Provide a *predictable* wear time; and • Contribute to an optimal quality of life for the patient.
2	A convex ostomy pouching system can be safely used regardless of when the stoma was created.
3	Convexity should be considered in the immediate postoperative period to ensure a secure, consistent, predictable seal and reduce the risk of leakage. The type and characteristics of the convexity used should be based upon the ability to provide a secure seal and exert the least amount of pressure on the mucocutaneous junction.
4	A convex pouching system may be necessary if any of the clinical findings are present: • The patient is experiencing leakage. • Peristomal skin complications due to leakage are present. • The area around the stoma pulls or dips inward, recesses into the abdomen, is concave, or there is a moat around the stoma. • The abdomen is soft and/or the peristomal area has creases, folds, or scars. • The position of the stoma opening is level with or below the peristomal skin, allowing the effluent to undermine the seal.
5	A pouching system belt should be introduced when convexity alone does not provide a secure seal. The group acknowledged that using a belt in the immediate postoperative period may increase pressure on the mucocutaneous junction.
6	Follow-up by an ostomy nurse specialist should occur within the first 2 wk after hospital discharge following stoma creation or stoma revision.
7	A full assessment of the patient's ostomy needs should be conducted in each stage of the postoperative periods: immediate postoperative period (days 0-8), postoperative period (days 9-30), and transition phase (day 31-6 months) and should include: • Type of ostomy; • Characteristics of the stoma; • Stoma effluent—type and volume; • Patient's peristomal body profile; • Topography of area around the stoma assessed in the sitting, standing, and supine positions (may need to consider lying on back and on side); • Condition of peristomal skin; • The ability of the patient to self-manage pouching system; • Patient's physical activity levels; and • Patient's preferences.
8	If a change in the pouching system is made, reassessment should be conducted by an ostomy nurse specialist within 2-3 wk after the change to assess the seal, wear time, and patient acceptance of the new system.

Figure 2: The eight consensus statements.

Clinical preventive-based best practices to reduce the risk of peristomal skin complications – an international consensus report

Down G, Bain K, Andersen BD, Martins L, Karlsmark T, Jemec G, Bain M, Nielsen LF, Bechshoeft CJL, Hansen AS. WCET Journal. 2023;43(1):11-19

Link to full-text article: Clinical preventive-based best practices to reduce the risk of peristomal skin complications – an international consensus report : Cambridge Media Journals

Objective
The objective of the work was to gain international consensus supporting the development of a model to guide health care providers in assessing the risk factors for developing peristomal skin complications (PSC).

Study design
A modified Delphi process was utilized to develop the consensus: Elements of Delphi survey methodology, nominal group techniques (NGT-R) and process facilitation were used. All elements that were used as input to the Delphi process were based on a comprehensive literature review and two large scale HCP surveys (Figure 1)

Population
A total of 4285 responses were received from HCPs worldwide (2262 from survey 1 and 2023 from survey 2)

An expert panel consisting of 15 dermatologists and ostomy care nurse specialists from eight countries ratified the list of risk factors deducted from the literature review, surveys, and facilitated dialogues

Results
Of the survey respondents, 93% agreed that peristomal skin health is very important to patient overall health and well-being, 99% agreed that preventing peristomal skin complications should be the aim of health care providers.

Respondents identified main risk factors for developing PSCs (Figure 1) The risk factors were categorized under three headings (Figure 2): the individual with a stoma (body profile, capabilities, social situation). The healthcare system (standard of care, access, and education). ostomy products (usage and technical properties).

International consensus was reached on the Risk Factor Model

Conclusion
The Modified Delphi Process resulted in a strong consensus around the importance of maintaining peristomal integrity and the risk factors that must be considered in the prevention of peristomal skin complications.

The risk factors were categorized under three headings: **Individual with a stoma, Healthcare system, and Ostomy products**.

The Peristomal Skin Complication Risk Factor Model was unanimously ratified by the expert panel.

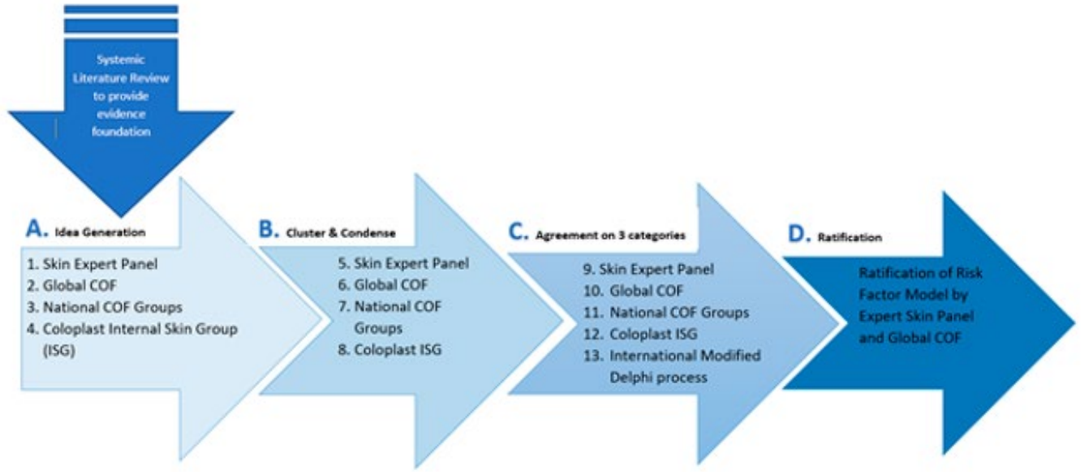

Figure 1: Method for development of the risk factor model – using both literature evidence and experiential evidence. **A.** Idea generation and risk factor identification. **B**. Condensation of risk factors into 10 overall categories. **C.** Condensation of risk factors into 3 categories and international modified Delphi process **D.** Ratification of the model. COF: Coloplast Ostomy Forum & Expert Panel.

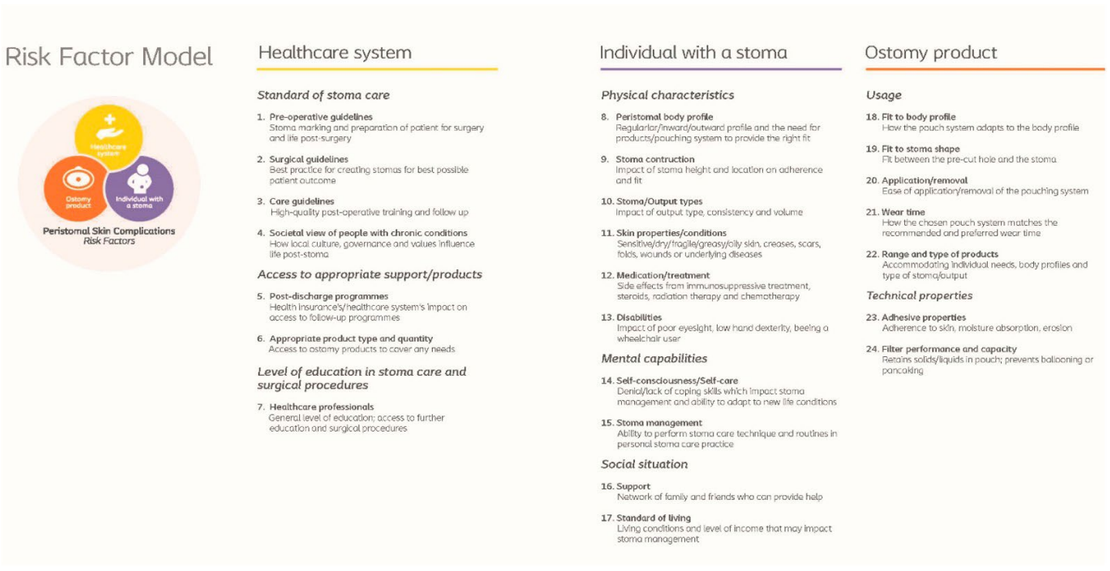

Figure 2: The final Risk Factor Model

Study strengths and weaknesses
Large and diverse population makes outcome more generalizable.
Method triangulation (questionnaire, review, and consensus) strengthens validity.
Self-reported outcomes leave questions to be interpreted by respondents. This may compromise validity.
Some respondents may have completed the questionnaire twice.

A risk factor model for peristomal skin complications

Hansen AS, Bechshoeft CJL, Martins L, Fellows J, Andersen BD, Down G, Karlsmark, Jemec G, Voegeli D, Størling Z, Nielsen LF. WCET Journal 2022;42(4):14-30

Link to full-text article: A risk factor model for peristomal skin complications: Cambridge Media Journals

Objective
To identify and develop consensus on the most important risk factors for peristomal skin conditions (PSC) and incorporate them in a risk factor model, while simultaneously identifying evidence and gaps in the literature pertaining to these risk factors.

Study design
A multistep process with 4 main stages; scoping, exploring, convergence, and ratification was used to develop the model. The process involved experts in the field of dermatology, wounds, and ostomy care. A systematic literature review was performed during the convergence stage, followed by a consensus process using the modified Delphi process (published in an individual article and described in a separate one-pager)

Population
- The Coloplast Global Skin Expert Panel, (dermatologists, professor in wounds, experts in ostomy care)
- The Global Coloplast Ostomy Forum (COF) of stoma care experts (experts in ostomy care)
- 15 national Coloplast Ostomy Forum boards of ostomy care nurses
- In total more than 400 ostomy care nurses

Results
Three overall risk factor categories/domains were identified: The Healthcare system, Individual with an ostomy, and Ostomy product (Figure 1) during step one and two. In step three (convergence stage), the content and nomenclature of the three categories were refined further, resulting in 24 risk factor subcategories/descriptors (Figure 1). In step four (ratification stage), these risk categories and subcategories were ratified by the Skin Expert Panel and the Global COF to constitute the final Risk Factor Model.
The systematic literature review conducted, demonstrated the evidence-base for the identified risk factors, further strengthening and consolidating the model. However, "Individual with an ostomy" had the most supporting evidence. The "Healthcare system" was the second most supported risk factor category. In the "Ostomy product" category, less supporting evidence was found.

Conclusion
With a personalized risk factor assessment, a trial-and-error approach should be avoided to save the individual patient from severe negative impact on health and quality of life.

Risk Factor Model on Peristomal Skin Complications

Health Care System

Standard of stoma care
- **Pre-operative guideline** Lack of stoma marking and preparation of patient for surgery and life post-surgery
- **Surgical guidelines** Lack of best practice for creating stomas that ensures best possible patient outcome
- **Care guidelines** E.g., high-quality post-operative training and follow up
- **Societal view of people with chronic conditions** E.g., how local culture, governance and values influence life post-stoma

Access to appropriate support/products
- **Post-discharge programmes** E.g., health insurance's / healthcare system's impact on access to follow-up programmes
- **Appropriate product type** E.g., access to appropriate products for output type/volume/body profile
- **Adequate product quantity** E.g., health insurance/reimbursement system's impact on product allowances
- **Cost considerations** E.g., impact of payer's financial policies on access to appropriate products and quantities

Level of education in stoma care
- **Healthcare professionals** E.g., general level of education; access to further education; ability to teach stoma management

Individual with a stoma

Physical characteristics
- **Peristomal body profile** E.g., regular/inward/outward profile and the need for products/pouching system to provide the right fit
- **Stoma construction** E.g., the impact of stoma height and location on adhesion and fit
- **Stoma/output types** E.g., impact of output type and consistency on peristomal skin integrity
- **Skin properties/conditions** E.g., sensitive/dry/fragile/greasy/oily, creases, scars, folds, psoriasis or other diseases
- **Medication/treatment** E.g., impact of immunosuppressive treatment, steroids, radiation therapy and chemotherapy
- **Handicaps** E.g., impact of poor eye-sight, low hand dexterity, wheelchair-bound, etc.

Mental capabilities
- **Self-consciousness** E.g., denial/lack of coping skills which impact stoma management
- **Self-care** E.g., ability to adapt to new life conditions in performing stoma care routines
- **Stoma management** E.g., technique and routines in personal stoma care practice

Social situation
- **Support** E.g., network of family and friends who can provide help
- **Standard of living** E.g., living conditions and level of income that impact stoma management

Ostomy Product Solutions

Usage
- **Fit to body profile** E.g., does the pouch system adapt to the body profile?
- **Fit to stoma shape** E.g., does the cutting size/pre-cut hole match the size of the stoma?
- **Application / removal** E.g., is the pouching system easy to apply and remove?
- **Weartime** E.g., does the adhesive's erosion resistance match the required weartime?

Technical properties
- **Adhesive properties** E.g., allows for safe adherence to skin and moisture absorption
- **Filter performance and capacity** E.g., retains solids/liquids in pouch; prevents ballooning or pancaking
- **Range of products** **Type of products** E.g., accommodates for individual needs, body profiles and type of stoma/output

Figure 1: The Risk Factor Model for peristomal skin complications

Study strengths and weaknesses
More than 400 stoma care nurses from 15 countries ensures high relevance.
Dermatologists plus experts in wounds and ostomy care validated the outcome.
Experience based knowledge may be perceived less consistent, hence validity is poorer.
Literature review showed a variable level of evidence in published studies.

The Ostomy Skin Tool 2.0:
A new instrument for assessing peristomal skin changes

Martins L, Down G, Andersen BD, Nielsen LF, Hansen AS, Herschend NO, Størling Z.
Br J Nurs 2022. 21;31(8):442-450.

Link to full-text article: The Ostomy Skin Tool 2.0: a new instrument for assessing peristomal skin changes

Objective
To develop a new tool that can capture a range of sensation symptoms together with visible complications and an objective assessment of discolouration in the peristomal area.

Study design
- This study partly consisted of qualitative interviews with people with an ostomy experiencing peristomal skin complications (PSC) and health professionals who managed or treated PSCs.
- Furthermore, data from a survey (Ostomy Life Study '19) including people with a stoma was conducted to demonstrate applicability of the skin tool.

Process and Results
Qualitative interviews about PSCs were conducted with ten people with an ostomy and 14 health care professionals (nine ostomy care nurses, four dermatologists, and one surgeon).
A patient-reported outcome (PRO) questionnaire was developed through a consensus process.
Overall, the PSC symptoms were divided into three groups: 'compromised broken skin' (ulcers, bleeding, weeping skin), 'sensation symptoms' (pain, itching, burning) and 'discolouration without broken skin or sensation symptoms'.
A decision tree model combining responses from the PRO questionnaire and objective peristomal skin analysis was constructed in collaboration with the Coloplast skin expert panel. Figure 1 shows the hierarchical structure of the model.
The decision tree model categories were verified by global and national Coloplast Ostomy Forum boards.
4209 people with an ostomy responded to a survey including the PRO questions and a simplified assessment of discolouration. Subsequently, the decision tree model was used to assess the distribution of peristomal skin status among the 4209 respondents (Figure 2). PSCs was identified in 3706 (88%) people with a stoma. Of those with a PSC, 1527 (41%) had sensation symptoms (pain, itching or burning) without any kind of visible signs such as broken compromised skin or discolouration.

Conclusion
The OST 2.0 captures both visible and non-visible PSCs and is based on a PRO questionnaire and an objective method to assess the area of discolouration. The tool can be used by people with an ostomy to follow their peristomal skin condition closely and provide a common language to be used in dialogues with their health professional. This will enable a better opportunity for early interventions to prevent severe PSC.

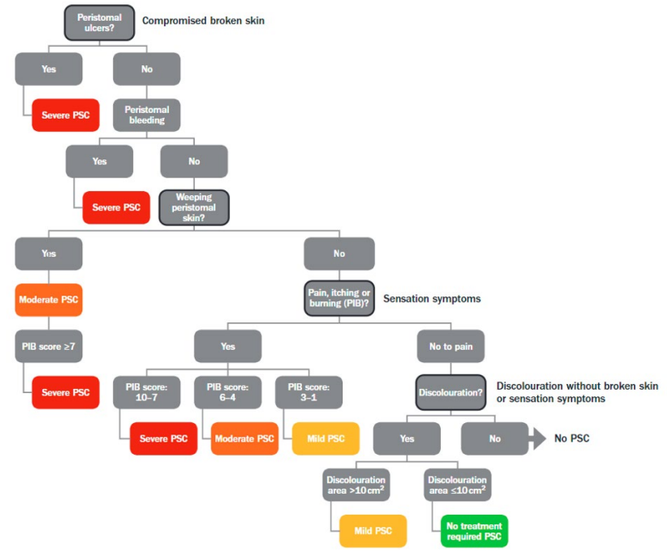

Figure 1: Hierachy of the decision tree model

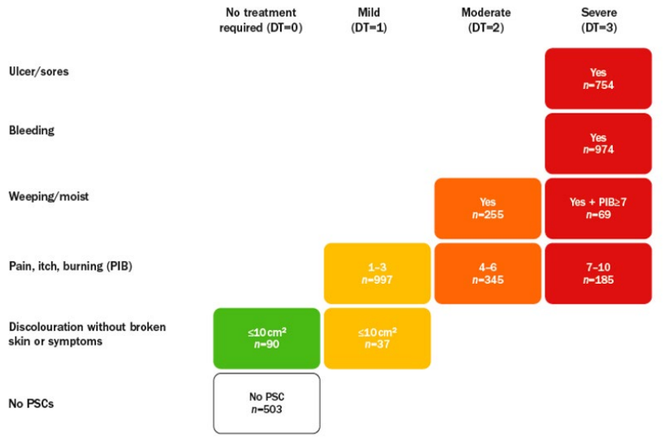

Figure 1: Decision tree model applied to a data set from the Ostomy Life Study '19.

Study strengths and weaknesses
Methods triangulation (interviews and consensus) make outcomes more credible.
No validation of the Ostomy Skin Tool 2.0 included in this paper. The validation is presented in a separate paper.
Included health care professionals and people living with a stoma ensures high relevance.

Multinational survey on living with an ostomy: Prevalence and impact of peristomal skin complications

Fellows J, Voegeli D, Håkan-Bloch J, Herschend NO, Størling Z.
Br J Nurs. 2021, 30(16): S22-30.

Link to full-text article: Multinational survey on living with an ostomy: prevalence and impact of peristomal skin complications | British Journal of Nursing (magonlinelibrary.com)

Objective
To provide insight and improved understanding of the current prevalence of PSCs and subsequent effect on the daily life of people living with an ostomy.

Study design
- Online and paper-based survey of people living with an ostomy and stoma care nurses across 17 countries worldwide

Population
- 5187 people with an ostomy answered the questionnaire.
- All respondents were above 18 years of age and consented to participation in the study.
- 328 stoma care nurses also answered the questionnaire

Exclusion:
Incomplete responses were removed.
Blank/"don't know"- responses were removed prior to data analysis.
Not enterostomal ostomy.

Results
- 88% of patients experienced PSCs and 75% experienced PSC symptoms despite absence of discolouration (Figure 1).
- Half of the participants (50%) felt frustrated to when experiencing PSCs, 47% felt stressed out, and for 31% it also affected their ability to sleep (Figure 2)
- 80% of nurses believed that the main reason for developing PSCs was ostomy-related
- Tendency towards a correlation between the severity of the skin complication and the number of consultations with a nurse needed to resolve the condition

Conclusion
The data revealed a high frequency of people with an ostomy without peristomal discolouration who still experienced sensation symptoms and/or observable symptoms. The emotional burden and restrictions on daily activities caused by PSCs heavily impair the life of the person living with the skin condition, and the society will experience increased treatment costs as PSCs may develop and progress into more severe stages.

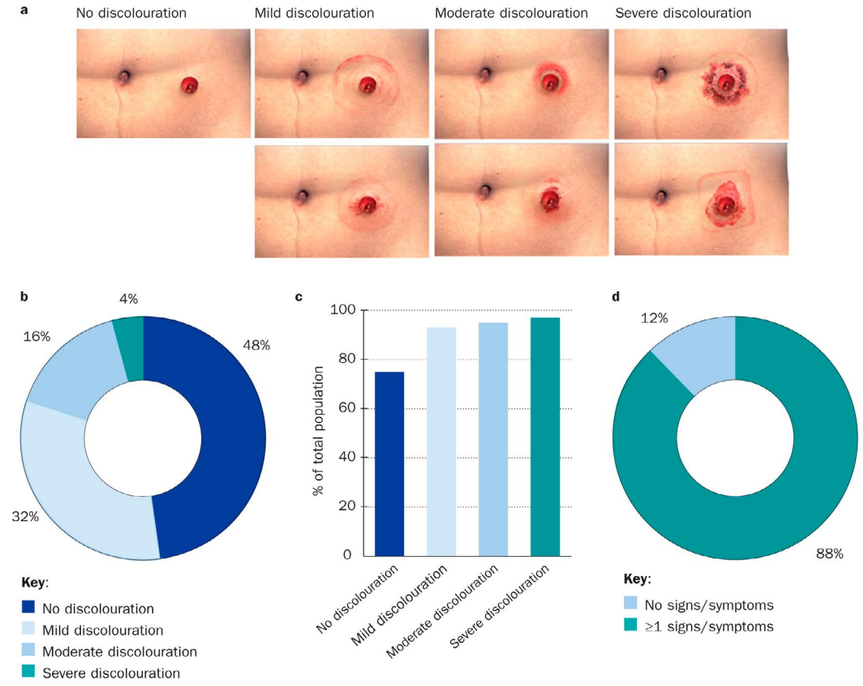

Figure 1: Self-assessed visual and non-visual signs of peristomal skin complications.

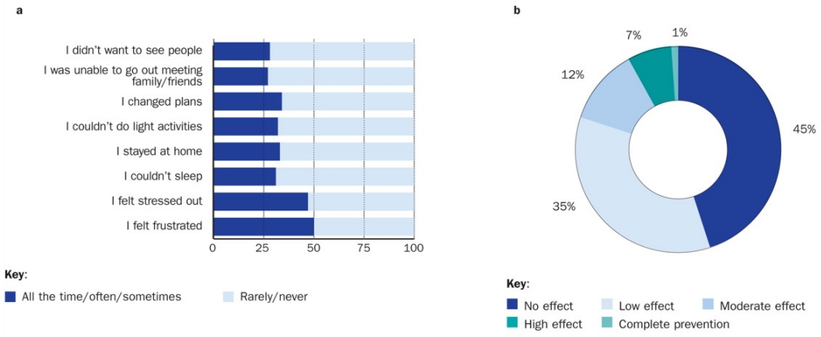

Figure 2: Self-assessed impact of having peristomal skin complications..

Study strengths and weaknesses
- Large population makes results more generalisable.
- Cross sectional study cannot conclude about causation between outcomes.
- Self-reported outcomes leave questions to be interpreted by respondents. This may compromise validity.

Utilities associated with stoma-related complications: Peristomal skin complications and leakages

Rolls N, Yssing C, Bøgelund M, Håkan-Bloch J, Jensen LdF.
Journal of Medical Economics. 2022. 25(1), 1005–1014.

Link to full-text article: Utilities associated with stoma-related complications: peristomal skincomplications and leakages

Objective
The primary objective of this study was to understand how leakages and peristomal skin complications (PSCs) impact health-related quality of life (HRQoL) in a UK population.

Study design
The study used time trade-off (TTO) methodology to quantify health state utilities associated with two stoma-related complications: PSCs and leakages. Respondents assessed 10 different health states with varying PSC severity levels (none, mild, moderate or severe PSC) and frequencies of leakage onto the clothes (2 per year, 1 per month or 4 per month, and no leakage due to a digital solution integrated into the stoma bag that warns the user to change the appliance before a leakage event occurs). The average disutility value for each health state was also assessed. The study was conducted via a web-based survey in the UK adult general population.

Population
In all 1017 respondents (93% of the target population) completed the questionnaire between April and May 2021. Of these, 758 respondents (70%) with an average age of 45 years (52% female, 48% male) were eligible for the final analysis, while 259 respondents (24%) were excluded because they indicated individual reasons for trading too much or too little (such as religious or ethical reasons) or because they did not understand the questions. Furthermore, 71 respondents (7%) did not complete the survey. Of the 758 respondents, 349 were presented with the PSC health states, and the remaining 409 were presented with the leakage health states.

Results
The analysis included 758 respondents. Respondents considered living with a stoma with no PSC to be more favourable than the other health states. Severe pain, itching and/or burning (PIB) was associated with the largest disutility compared to no PSC. The disutility (0–1 scale) compared to no PSC was 0.287 ($p < .0001$), 0.106 ($p < .0001$) and 0.025 ($p¼.0005$) for PIB scores of 8, 5 and 2, respectively, on a 1–10 scale (see Figure 1). More frequent leakage events were associated with lower utility. The utility decreases compared to no PSC were 0.114 ($p < .0001$), 0.057 ($p < .0001$) and 0.022 ($p < .0001$) for 48, 12 and 2 leakage events per year, respectively. The health state with a digital notification solution that notifies the user before a leakage event occurs was considered as good as no PSC.

Conclusion
Experiencing mild, moderate, and severe levels of PSC or leakage onto clothes is associated with a significant reduction in HRQoL compared to no PSC and/or no leakage. Stoma appliances that reduce the skin complications or keep leakage from reaching the clothes are likely to improve HRQoL. The utility values from this study express the relative health benefits for the specific health states and could be used in a cost utility analysis of different types of stoma appliances or stoma management options.

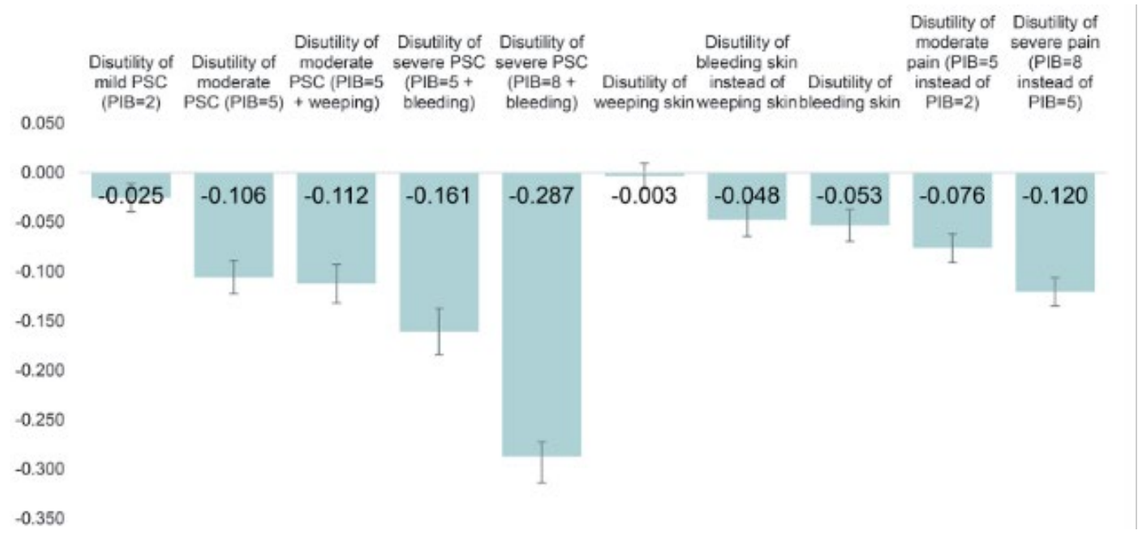

Figure 1: Utility differences associated with different levels of PSC. Error bars show 95% CI.

Study strengths and weaknesses
This online TTO survey has strengths, such as larger sample sizes and the ability to recruit a representative population. However, it includes only internet users, potentially introducing bias if their health state valuations differ from non-users. Given the UK's 98% internet penetration, this bias is minor. Another limitation is the lack of opportunity to explain health states in detail, though objective, validated descriptions were used to mitigate this. Results reflect the general population's views, not those with personal experience of the condition, though previous studies suggest utility differences are often minimal between these groups. Still, comparing with people living with a stoma would provide valuable insights.

Complications and healthcare costs associated with the first year following colostomy and ileostomy formation

Brady RRW, Scott J, Grieveson S, Aibibula M, Cawson M, Marks T, Page J, Artignan A, Boisen EB.
J Wound Ostomy Continence Nurs. 2023;50(6):475-483.

Link to article: Journal of Wound Ostomy & Continence Nursing

Objective
The primary objective of this study was to evaluate both the clinical and economic outcomes during the first year following the formation of an ileostomy or colostomy. The study aimed to provide an understanding of the burden of ostomy-related care, in people with a newly formed ostomy.

Study design
The study was designed as a single-center retrospective audit, focusing on patients who underwent surgery leading to the formation of an ileostomy or colostomy at large English NHS Trust. Patients included in the study were those living with an ileostomy or colostomy, aged 18 years or older, and had at least 12 months of follow-up care. Patients were excluded if they had stage 4 cancer, underwent ostomy surgery with palliative intent, had more than one ostomy, required revision of a previous ostomy, or had an open abdominal wound that could not be closed with surgery. Three types of outcomes were defined and investigated: (1) clinical compli¬cations; (2) pharmacotherapy related to the presence of an ostomy; and (3) interactions with the NHS.

Population
The study included 200 patients who underwent surgery leading to ileostomy or colostomy. Among these patients, 115 were male (57.5%), and 113 (56.5%) had a colostomy while 87 (43.5%) had an ileostomy. The median age of the patients was 61 years, with 55.5% being younger than 65 years. The most common indication for ostomy surgery was colorectal cancer (42.5%), followed by inflammatory bowel disease (16.5%) and diverticular diseases (16.5%). Common comorbid conditions included cancer (33.0%) and hypertension (25.0%). The patients spent a median of 11 days in the hospital after ostomy surgery.

Results
The study found that clinical complications were common among patients with newly formed ostomies. The most frequent surgical site complications included high output, which affected 35% of patients, moderate to severe peristomal skin complications in 24.5% of patients, and bleeding in 23.5% of patients (Figure 1). Additionally, ostomy management-related complications were prevalent, with 50% of patients experiencing general difficulties in managing their ostomy and 48.5% facing leakage-related mild peristomal skin issues. These complications were most frequent in the first quarter following surgery. Patients with ileostomies were more likely to experience high output, acute renal failure, and ostomy management-related complications compared to those with colostomies.
In terms of healthcare resource use, patients had a median of 13 inpatient admission days and 12 outpatient contacts within the first year post-surgery. The mean cost per patient was £20,444.60, with 90.5% of these costs attributed to ostomy-related factors. This indicates a significant economic burden associated with ostomy management and recovery. Please see Table 1 for more details.

Conclusion
The frequency and timing of ostomy-related complications and associated healthcare-related costs following ostomy for¬mation surgery in the UK are underreported. Ileostomy patients tend to have more frequent complications compared to colostomy patients, but healthcare costs remain equally high irrespective of stoma type. The findings highlight the importance of ongoing patient management and the potential to reduce costs through better management of complications.

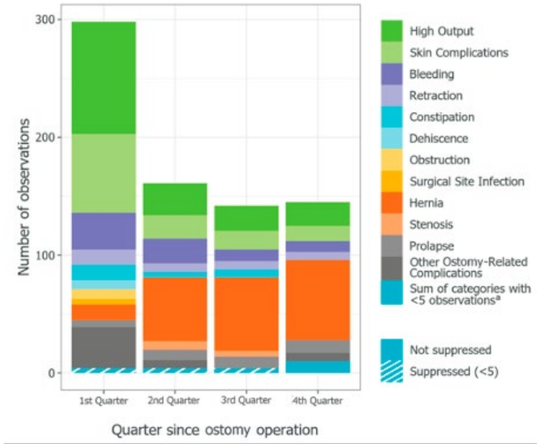

Figure 1: Ostomy-related complications by quarter.

Economic Costs of Interactions With the UK National Health Service (N = 200)

Variable	Unit Cost, £	Mean Cost per Patient			SD Cost per Patient		
		All	Ileostomy	Colostomy	All	Ileostomy	Colostomy
Ostomy							
Inpatient admissions and readmissions	9,332.00	16,331.00	17,698.62	15,278.05	16,385.34	13,123.15	18,499.21
Days inpatient admissions	NA	NA	NA	NA	NA	NA	NA
Outpatient contacts	118.00	1,677.37	1,925.98	1,485.96	1,476.75	1,727.92	1,223.62
Emergency A&E	182.00	41.86	62.76	25.77	138.61	189.93	76.40
All other reasons							
Admissions and readmissions	2,136.00	1,473.84	1,178.48	1,701.24	4,639.34	3,285.89	5,461.88
Days inpatient admissions	NA	NA	NA	NA	NA	NA	NA
Outpatient contacts	136.00	422.96	387.68	450.12	693.71	641.44	733.08
Emergency A&E	182.00	19.11	12.55	24.16	113.06	54.05	142.86

Abbreviations: A&E, accident and emergency; NA, not applicable; SD, standard deviation.

Table 1: Economic cost of interactions with UK NHS split by stoma type.

Study strengths and weaknesses
The study's strengths include comprehensive data collection from multiple databases, allowing for detailed analysis of clinical and economic outcomes. The large sample size and stratification by factors such as ostomy type and age enhance the generalizability and depth of the findings.
However, the study has weaknesses, including missing data on ostomy outpatient care contacts, which could lead to underestimation of adverse outcomes. The single-center design limits generalizability, and the retrospective nature may introduce biases related to data accuracy and completeness. Additionally, the impact of unmeasured covariates and the COVID-19 pandemic on care patterns was not accounted for.

Leakage and peristomal skin complications influences user comfort and confidence and are associated with reduced quality of life in people with a stoma

Hedegaard CJ, Ajslev TA, Zeeberg R, Hansen AS.
WCET Journal. 2020;40(4):23-29.

Link to full-text article: https://prod-professional.coloplast.com/globalassets/hcp/pdf-file/hedegaard_updated_-_eng-002.pdf

Objective

The purpose of the research was to investigate how leakage of stomal effluent and peristomal skin complications (PSC) affects the quality of life (QoL) of people living with a stoma. peristomal skin complications, physical and social activities, and access to a stoma care nurse.

Study design

- Online survey with questions on QoL, leakage frequency, and worry of leakage (Ostomy Life Study 2016).
- The Ostomy-Q scale was used to estimate product-related QoL, a scale which consists of four domains – confidence, comfort, discretion, and socialising.

Population

n= 4235 people with stoma

Inclusion:

- People living with a stoma
- Age 18 years or above
- Consented to participation

Exclusion:

- Answered all questions within 15 minutes (survey should take 30 minutes to complete)
- Answered "don't know" to more than 30% questions
- Participant did not finish the survey

Results

- More than 4,200 people from 13 countries completed the study between 30 August and 3 October 2016.
- Leakage had a statistically significant impact on the QoL for participants who experienced leakage four times (or more) out of ten baseplates changes (Figure 1).
- All four domains in the Ostomy-Q scale (confidence in stoma appliance, comfort, discretion, and socializing) were affected.
- People with PSC had a significantly lower QoL than those who had not experienced PSC in the 6 months before the survey. PSC impacted the confidence and comfort domains significantly (Figure 2).
- The discretion and socialising domains were also significantly affected but were below the pre-defined limit for a minimal important difference.

Conclusion

The data support that leakage has a significant physical and psychological impact on people living with a stoma. Thus, prevention of leakage incidents has the potential to improve QoL, including the domains of comfort and confidence, as well as reduce PSC. Moreover, as almost all respondents expressed a worry of leakage, and as leakage impacts confidence in stoma appliances, these results warrant for solutions that can enforce confidence by reducing the worry of leakage.

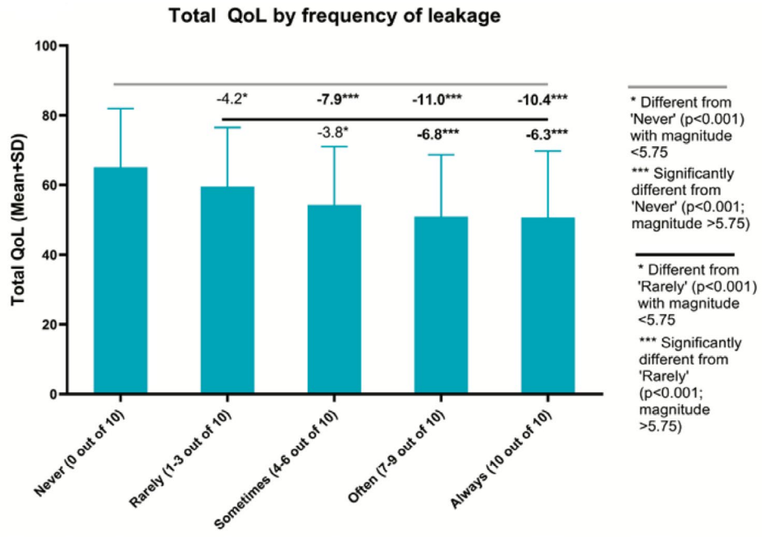

Figure 1: The influence of output under baseplate (leakage) on total QoL. Respondents reported output underneath their baseplate during the last ten baseplate changes (n=3,638). Levels compared to 'Never observing leakage' and 'Rarely observing leakage'. *Statistically significant difference observed (p<0.001), with a magnitude less than the clinically relevant MID (<5.75). ***Difference observed is statistically significant (p<0.001) and greater that the clinically relevant MID (>5.75).

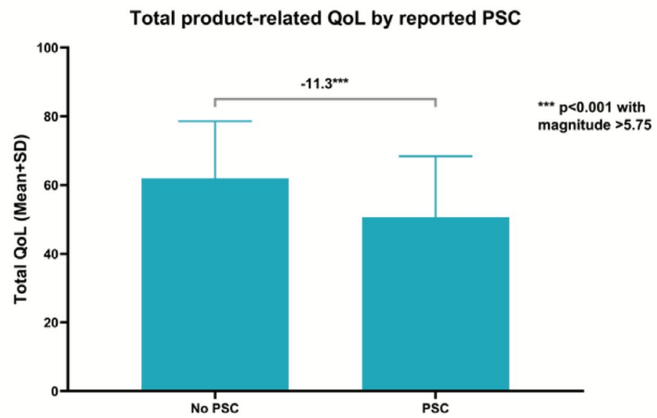

Figure 2: The influence of PSC on total QoL. Respondents reported PSC (no/yes) during the previous 6 months (n=3,638). Levels (PSC no/yes) compared to each other. ***Difference observed is statistically significant (p<0.001) and greater that the clinically relevant MID (>5.75).

Impact of stoma leakage in everyday life: data from the Ostomy Life Study 2019

Jeppesen PB, Vestergaard M, Boisen EB, Ajslev TA.
Br J Nurs. 2022. 31(6):48-58

Link to full-text article: Impact of stoma leakage in everyday life: data from the Ostomy Life Study 2019 | British Journal of Nursing (magonlinelibrary.com)

Objective
To investigate how people with a stoma were impacted in their everyday life following incidents of leakage (underneath the baseplate or onto clothes) and the worry thereof.

Study design
- Online survey with questions on QoL, leakage frequency, and worry of leakage.
- The Ostomy Leak Impact (OLI) tool was used to investigate the impact of leakage to everyday life for people with a stoma

Population
n= 4209 people with stoma
Inclusion:
- People with a stoma
- Age 18 years or above
- Consented to participation

Exclusion:
People irrigating their stoma.
Answered all questions within 15 minutes (survey should take 30 minutes to complete).
Answered 'don't know' to more than 30% questions.
Participant did not finish the survey.

Results
- 92% of people with a stoma worried about leakage (Figure 1).
- The risk of leakage affected different emotional and social aspects of life and everyday activities (Figure 2).
- 65% of employed people with a stoma were affected in their ability to work by leakage of stomal effluent or the worry hereof.
- People with a stoma who worried about leakage used more supporting products.
- The psycho-social impact of leakage increased with the frequency of leakage episodes.
- Leakage outside the baseplate (onto clothes) had greater impact on psycho-social well-being than leakage underneath the baseplate only.

Conclusion
Most people with a stoma were emotionally impacted by leakage, especially by leakage outside the baseplate (those soiling clothes). New solutions are warranted that can help reduce the impact of leakage.

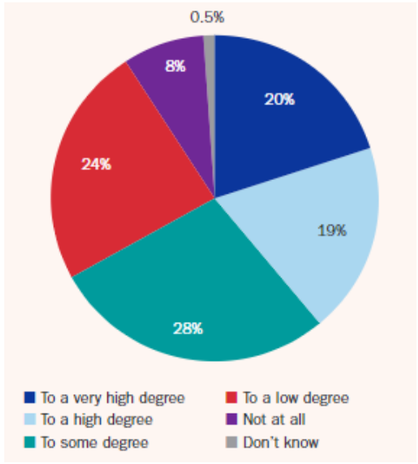

Figure 1: If and to what degree people with a stoma worry about leakage of stomal effluent.

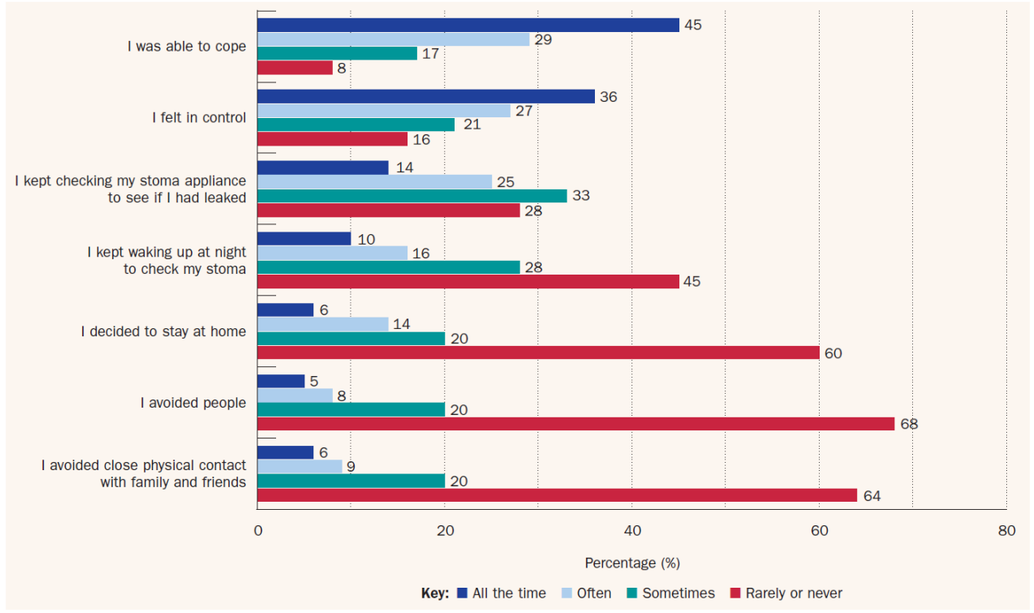

Figure 2: How the risk of leakage affects different emotional aspect of life and everyday activities.

Study strengths and weaknesses
The survey included 17 countries, which gives a good representation of the global population in ostomy care.
The study did not investigate national differences.
Online survey may be not representative of all people with a stoma: 62% of respondents were above 60 years and only 27% were employed.

Using peristomal body profile assessment to improve leakage-related quality of life for individuals with an ostomy – The Nordic Consensus Study

Vendelbo G, Carlsson E, Toril Tøndel L, Myller E, Sternhufvud C, Starup Simonsen K, Munch P, Petersen B.
Br J Nurs. 2023. 32(4):173-181

Link to full-text article: Using peristomal body profile assessment to improve leakage-related quality of life for individuals with an ostomy (magonlinelibrary.com)

Objective
To evaluate the clinical usability of the Body Assessment Tool and study how changing to the best product(s), based on peristomal body profile assessment, impacts number of leakages and quality of life.

Study design
A Nordic study, conducted in four countries: Denmark, Finland, Norway and Sweden, evaluated the usability and impact of the Body Assessment Tool in clinical practice. The impact was measured based on the self-reported answers to the questionnaires conducted among stoma care nurses and patients living with an ostomy. The study period lasted for 4-5 weeks and the participants visited the stoma care clinic at the beginning of the study and returned questionnaires at the beginning and end of the study. The questionnaires focused on number of leakage and quality of life – measured by the OLI score.

Population
22 stoma care nurses participated in the study and 68 patients constituted the study population. Patients had to be at least 18 years of age, living with an ostomy for at least 3 months and have leakage issues.

Results
21 out of 22 stoma care nurses recommended the use of the Body Assessment Tool.
The participants with an ostomy had a mean age of 68 years and the 61% were female.. The number of leakages per 7 days declined significantly by a mean of 4.1 (from 5.9 to 1.8) during the study period (Figure 1). Concomitantly, the OLI score increased significantly in all 3 domains: by 17.9 for emotional impact, 16.2 for coping and control and 10.7 for usual and social activity, (Figure 2). The most significant reduction in number of leakages (mean change of 7.0) was found for participants changing from a flat to a convex product

Conclusion
The study supported the use of the Body Assessment Tool in clinical practice to objectively assess the peristomal body profile when choosing ostomy product(s) for people with leakages.
The use of ostomy product(s) selected based on the evaluation of peristomal body profile using the Body Assessment Tool resulted in significant reduction in numbers of leakages and improved quality of life.

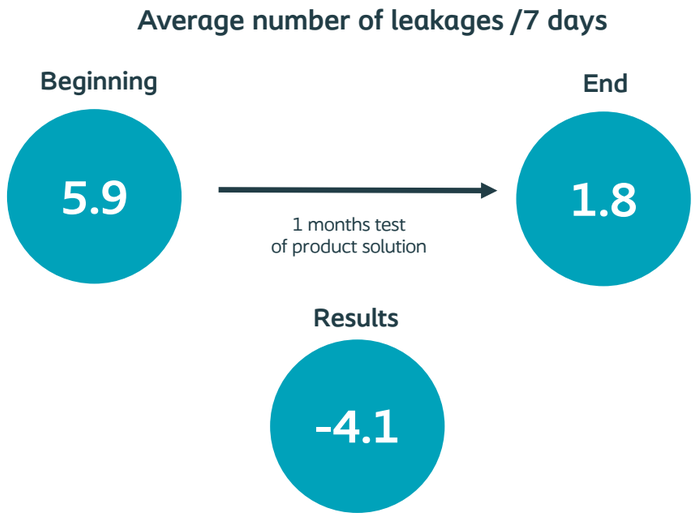

Figure 1: Average number of leakages reported in the previous 7 days.

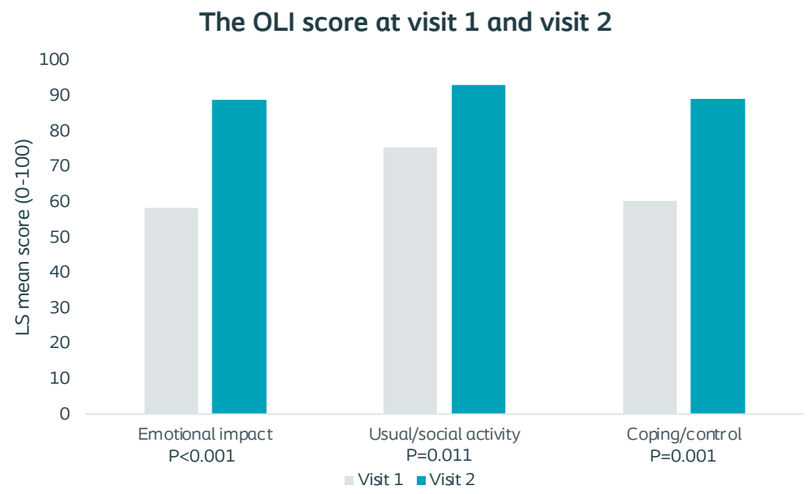

Figure 2: The OLI score at the Beginning and End of the study.

Study strengths and weaknesses
The strength of the study was that it was based on patient reported outcome that reflects the participants' own experience and that a validated tool (OLI) was used in the self-reported questionnaires. A methodological limitation was that 19 of initial 99 patients dropped out there was also a lack of information around supporting ostomy products.

Importance of stoma care nurses in preparing patients for stoma surgery and adjustment to life with a stoma

Rolls N, Gotfredsen JL, Vestergaard M, Hansen AS, Koblauch H
British Journal of Nursing 2023. 32(16): S32-41

Link to full-text article: Importance of stoma care nurses in preparing patients for stoma surgery and adjustment to life with a stoma | British Journal of Nursing (magonlinelibrary.com)

Objective

To explore and quantify the successes, choices, and challenges faced by stoma care nurses (SCNs) and patients undergoing stoma surgery in the pre-operative phase, during hospital admission and after hospital discharge.

Study Design

The Ostomy Life Study 2022 consisted of two online, retrospective, self-reported questionnaires. One questionnaire was designed for people living with a stoma and the other for nurses working within stoma care services. The questionnaires were sent out to the participants via email.

Population

A total of 6500 people with a stoma from 12 countries completed the patient-specific survey. Of these, 45% were female and most (86%) were aged 50 years or older. In total, 64% of participants were veterans, 29% were experienced users and 7% were new users. In terms of stoma type, 47% had a colostomy, 36% had an ileostomy and 18% had a urostomy. The nurse specific survey was completed by 250 nurses from 15 countries. The majority (88%) identified as SCNs and 73% had more than 10 years of experience working as an SCN. Most nurses worked in inpatient settings (68%) and/or outpatient clinics (66%) and 16% worked as community nurses.

Results

Most patients (98%) with planned stoma surgery had pre-operative consultations with health professionals in contrast to 36% of patients with unplanned surgery, who did not (Table 1).
One third of patients with unplanned surgery did not feel prepared for life with a stoma based on the information provided during their hospital stay (Table 1).

A higher proportion of patients who had a preoperative consultation with an SCN felt that they had been very well or well prepared for life with a stoma (59%), compared with patients who had not had such pre-operative consultations with an SCN (43%).
Majority of patients responded that the SCN was in some way involved in choosing the first stoma product (83%) while only 15% responded that they made the decision without the involvement of an SCN.

Conclusion

This study revealed that SCNs are key in preparing patients for stoma surgery and in adjustment to a new life with a stoma. Furthermore, the study uncovered considerable variations in stoma care services experienced by patients having planned versus unplanned surgery, indicating that additional attention should be provided to patients undergoing unplanned stoma surgery to better prepare them for life with a stoma.quality of life.

Table 1. Patients' time with health professionals before stoma surgery

Question: Before having stoma surgery, did you have a pre-operative talk with one or more health professionals preparing you for surgery? If yes, please choose all that apply	Total	Planned	Unplanned
	n=6499	*n*=4451	*n*=1987
Yes, with a surgeon	76%	87%	52%
Yes, with a stoma care nurse	40%	49%	20%
Yes, with a doctor	14%	17%	8%
Yes, with a ward (general) nurse	9%	9%	7%
Yes, other	4%	4%	3%
No	13%	2%	36%
Don't remember	2%	1%	4%
When did the pre-operative talk(s) take place*	***n*=5136**	***n*=4003**	***n*=1104**
The same day of surgery	9%	3%	30%
Prior to day of surgery	91%	97%	70%

Figure 1: Patients' time with health professionals before stoma surgery.

Study strengths and weaknesses

This study included a large study population of both patients and nurses, which make the results more credible. Furthermore, the triangulation of respondents allows to uncover the shared perspectives from nurses and patients. Drawbacks include that data were self-reported and not collected by health professionals as part of a clinical study, the responses may have been affected by recall bias.

The Prevalence of Leakage, Peristomal Skin Complications and Impact on Quality of Life in the First Year Following Stoma Surgery

Brady RRW, Sheard D, Howard K, Vestergaard M, Boisen EB, Mather R, Ainsworth R, Hansen HD and Ajslev TA
Nurs. Rep. 2025, 15(3), 107

Link to article: Please access through Open Access here

Objective
The study aimed to investigate the prevalence and impact of stoma-related complications—specifically leakage and peristomal skin complications (PSCs)—on health-related quality of life (HRQoL) and mental well-being during the first year following stoma surgery.

Study design
The study was designed as a cross-sectional, multi-center, observational study across three hospital sites in the United Kingdom. Data were collected through one-on-one nurse-led consultations with patients and an online patient questionnaire. Data we collected on Ostomy leakage impact (OLI tool), mental well-being (WHO-5), HRQoL (EQ-5D-5L), skin health (OST 2.0) and patient activation (PAM-13).

Population
This study included 114 adults who had undergone stoma surgery within the past year. The average age was 55.8 years, and 58% were male. Most participants had ileostomies (88%), with cancer being the most common reason for surgery (50%). All participants had been self-managing their stoma care for at least two weeks and were able to complete an online questionnaire. Nearly all (97%) used a one-piece pouching system, and baseplate shapes varied, with convex being the most common (55%).

Results
In the two weeks before the survey, 43% of participants reported experiencing leakage outside the baseplate, and 74% reported worrying about leakage 26% to a high or very high degree. Common concerns included soiling, embarrassment, and odour. Peristomal skin complications were found in 85% of participants, with 32% classified as severe. These issues were linked to lower scores in quality of life and mental well-being assessments (Figure 1). Participants with multiple leakages had significantly worse outcomes. Notably, no improvement in these measures was observed over time during the first year after surgery.

Conclusion
The study highlights a high burden of leakage and PSCs in the first year after stoma surgery, with significant negative impacts on QoL and mental well-being. These issues persist throughout the year, suggesting a need for targeted interventions to reduce complications and support patient self-management.

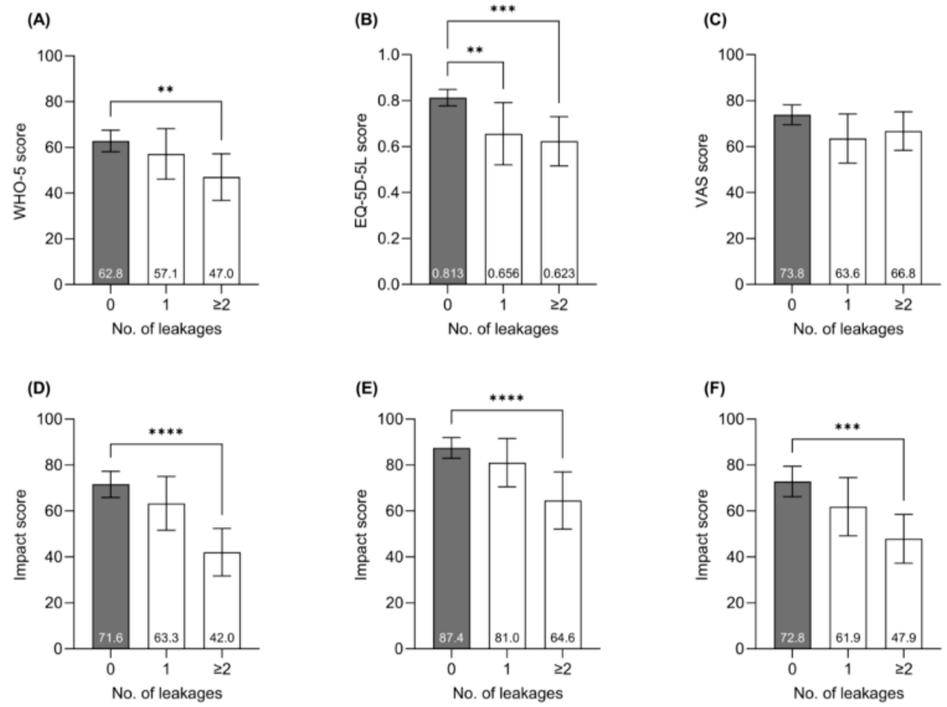

Figure 1. Influence of leakage on QoL-metrics. (A) WHO-5 mental well-being score, (B) EQ-5D-5L index score, (C) EQ-VAS score, (D) "Emotional impact" domain of OLI tool, (E) "Usual and Social activities" domain of OLI tool, and (F) "Coping and in Control" domain of OLI tool. Bars represent average outcome scores, and the error bars represent 95% confidence intervals. One-way ANOVA followed by Dunnett's multiple comparison tests were performed using the group with no leakages outside the baseplate as reference groups. $p < 0.01$ (**), $p < 0.001$ (***) and $p < 0.0001$ (****).

Study strengths and weaknesses
This study's strengths include its use of validated tools to assess leakage, PSCs, and HRQoL, as well as its multi-center design and focus on patient-reported outcomes, which enhance the relevance for people with a stoma and generalizability of the findings within the UK. However, its cross-sectional nature limits causal interpretation, and the small sample may not represent the broader stoma population. Exclusion of high-risk groups and lack of data on access to care or education further limit generalizability, and findings may not apply outside the UK.

Best practice guidelines for ostomy care in neonates, children, and adolescents: An executive summary

Forest-Lalande L.
J Wound Ostomy Continence Nurs. 2023;50(5):381-385

Link to article: Journal of Wound Ostomy & Continence Nursing

Objective
The purpose of developing best practice guidelines for ostomy care in neonates, children and adolescents are to provide a resource for best practices to health care professionals caring for paediatric patients with an ostomy.

Background
Due to relative infrequency of ostomy surgery in the paediatric population, and limited research and evidence in this population, students and less experienced ostomy care nurses have fewer opportunities to acquire skills and knowledge specific to paediatric ostomy care. To address this unmet need, an international group of paediatric ostomy care experts (table 1) was brought together to offer their expertise and develop guidelines for caring for children with an ostomy. These guidelines for paediatric ostomy care are based on clinical evidence when available and on consensus-based best practices when evidence supporting care was not available.

Methods
A structured and comprehensive review of PubMed and CINHAL electronic databases and the Google Scholar search engine for literature relevant to the keywords identified in table 2 was conducted by the board members. The project manager drafted the initial version of the literature synthesis for each of the 24 topics in table 2. Board members then collaborated on crafting content for each of the topics. Content was considered final when 100% consensus was reached among board members concerning each of the guidelines.
Whenever possible, related topics were grouped together, resulting in 13 final areas of guidance that comprise the best practice document summarised in the Executive Summary

Conclusion
A best practice guideline document was developed through a collaboration of international WCET-certified ostomy care nurses. This document provides a focused, evidence-based, and consensus-based resource to inform best practices in paediatric ostomy care. The full document, Global Best Practice Guidelines for Neonates, Children and Teenagers, was developed by the Global Paediatric Stoma Nurses Advisory Board (GPSNAB).

The GPSNAB recommend additional research focusing on ostomy care in the paediatric population.

The entire guideline is available as Supplemental Digital Content:

Paediatric stoma care guidelines

TABLE 1.
Advisory Board Members

Project Manager
Louise Forest-Lalande, MEd, RN, NSWOC (Canada), GPSNAB
Members, Advisory Board
June Amling, MSN, RN, CNS, CWON, CCRN (United States)
Claire Bohr, RSCN (United Kingdom)
Gail Creelman, RN, NSWOC, WOCC(C) (Canada)
Edith Ekkerman, RPN, ET, CT (the Netherlands)
Ester Sanchez Munoz, RN, SEECIR (Spain)
Sophie Vercleyen, RN, ET (France)

TABLE 2.
Selected Topics and Key Words

Topics	Key Words
Common pathologies and indications for a stoma in neonates and children	Neonate, children, adolescent, pediatric, ostomy, indications, pathologies
Therapeutic relationship	Therapeutic relationship, family, children
Types of stomas	Neonate, children, adolescent, pediatric, ostomy
Premature neonates, neonates, and children's skin characteristics	Skin, premature, neonate, children, characteristics, preemie
Stoma site marking	Neonate, children, adolescent, pediatric, ostomy, site, marking
Body profile	Babies, children, body profile
Use of convexity	Stoma, convexity, babies, children
Care of mucous fistula	Stoma, mucous fistula, skin, pouching
Multiple stomas	Necrotizing enterocolitis, management
Wear time of ostomy product	Stoma, pouching, babies, wear time
Cutting of the stoma opening	Skin barrier, opening, babies, children, measurement
Peristomal skin cleansing	Peristomal skin, babies, children, premature neonate
Flatus	Stoma pouch, emptying, breastfeeding
Rectal discharge	Colostomy, stoma, rectal discharge, loop ostomies
Mucous fistula refeeding	Enterocolitis, short bowel syndrome, mucous fistula refeeding
Vesicostomies	Urinary diversion, vesicostomy
Stoma care	Stoma, stoma care, preemie, neonate, child
Pediatric stoma care products and accessories	Stoma, pouch, babies, children
Prevention and management of stoma, peristomal skin, and systemic complications	Peristomal, skin, complications, prevention, management
Prevention and management of diaper dermatitis post–stoma closure	Stoma, colostomy, closure, baby, child, complications, diaper dermatitis, fungal, infection, diaper rash
Anal dilation, incision, and scar care post–stoma closure	Anal dilation, ostomy closure, babies, children, scar care, babies, children, complications, wound, Hirschsprung disease, anorectal malformation, imperforate anus, rectal stricture
Stoma care education according to the needs of the child and family	Stoma care, education, child, parents, developmental phases
Potential psychological impact of a stoma in children and teenagers and strategies to assist them with coping	Body image, socialization, peer relations, sexual identity, emotional, stoma, baby, childhood, adolescence, developmental phases
Activities of daily living with a stoma in children	ADL, stoma, children, teenagers, school, sleepover, sports

Abbreviation: ADL, activities of daily living.

Key points
Although similar to adult stoma care, caring for infants, children, and adolescents with an ostomy presents unique challenges.
Knowledge of the management of potential paediatric stomal and peristomal skin complications allows the ostomy nurse to deliver optimal care.
Paediatric ostomy nursing care must include physiological, physical, educational, and psychosocial aspects unique to this population.

Evaluating the performance and Perception of a stoma bag full-circle filter in people with a colostomy or an ileostomy — two randomized crossover trials

Virgin-Elliston T, Nonboe P, Boisen EB, Koblauch H.
Healthcare. 11(3);369

Link to full-text article: Healthcare | Free Full-Text | Evaluating the Performance and Perception of a Stoma Bag Full-Circle Filter in People with a Colostomy or an Ileostomy - Two Randomized Crossover Trials

Objective
To evaluate how a full-circle filter performs and is received by persons with a colostomy or an ileostomy as compared to a dual filter (Figure 1).

Study design
Two 4-week trials were conducted. They were identical in design - both were open-label, randomized controlled trials with a cross-over where participants tested both the full-circle filter and dual filter device in a randomised order. Both trials were conducted between January and May 2011.

Population
- Adults aged >18 years who had a colostomy or an ileostomy for ≥6 months and experienced more than one ballooning event per week were eligible for participation.
- A total of 40 people (20 in each trial) with a colostomy or an ileostomy were included in the trials.
- Mean age was 60 years and 66 years, and 11 and 13 participants were males in the colostomy and ileostomy groups, respectively.

Results
The frequency of ballooning was significantly lower with the full-circle filter compared with the dual filter in participants with a colostomy (52 % reduction, $p < 0.0007$) and in participants with an ileostomy (61 % reduction, $p < 0.0001$) (Figure 2).
The number of ballooning events per person was lower with the full-circle filter versus the dual filter for both the colostomy and ileostomy groups.
Among participants with an ileostomy, ostomy solutions with the full-circle filter were, on average, worn for 3.3 h longer (20.5 [0.44] h) than ostomy solutions with the dual filter (17.3 [0.40] h) ($p < 0.0001$). There was no significant difference in the colostomy group.
Time to ballooning was significantly longer in both colostomy (74% longer) and ileostomy (82% longer) groups.
There were no differences between the filter products regarding odor, discretion, or pancaking.
Participants in the ileostomy group preferred the full-circle filter over the dual filter. There was no specific preference in the colostomy group.

Conclusion
In conclusion, the results of these two randomized crossover trials show that use of the full-circle filter significantly reduced the frequency of ballooning events versus the dual filter in individuals with a colostomy or an ileostomy.

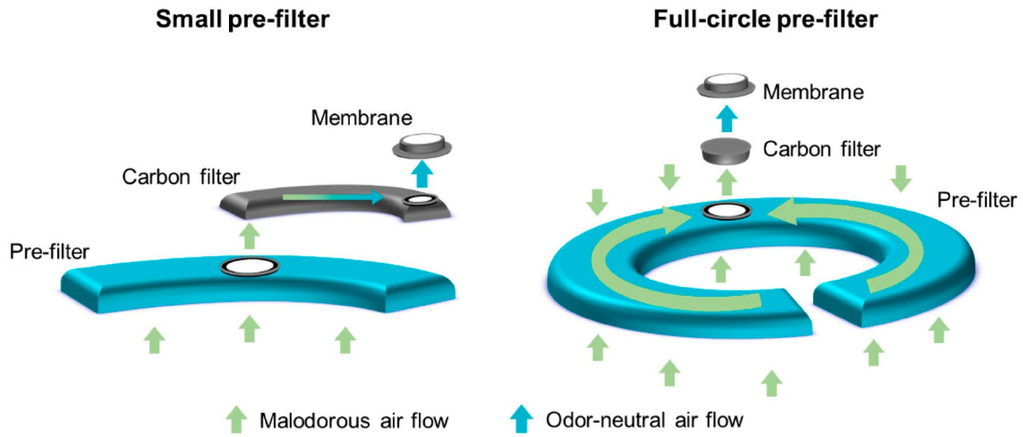

Figure 1: Schematic overview of the filter types

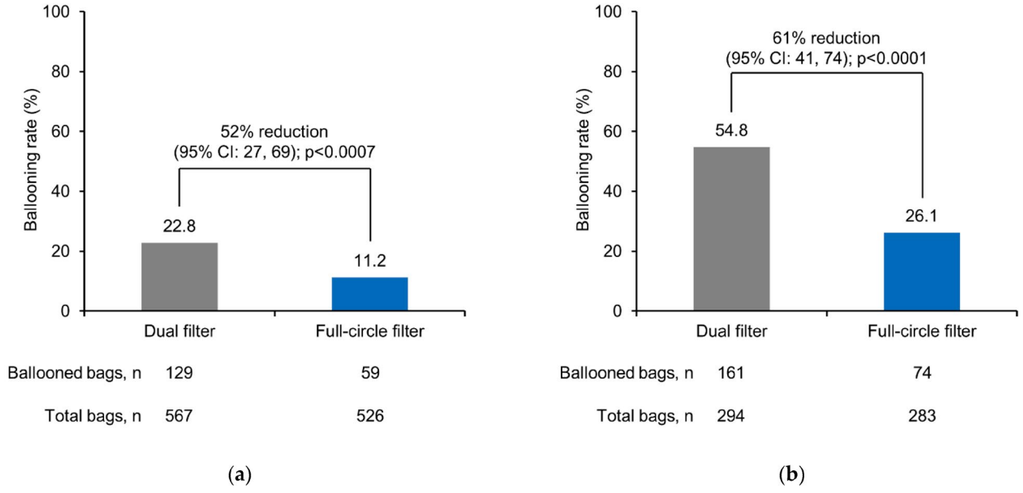

Figure 2: Results on frequency of ballooning with the dual filter and the full-circle filter. A) Colostomy group,

Study strengths and weaknesses
The crossover trial is a very strong design for evaluating product effects because participants act as their own control subjects.
Very strong results in favour of the full-circle filter with regards to ballooning. Participants were not blinded to which product they used, which may influence their perception the investigational product.

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