*Ostomy Care*

# Publication Compendium

2nd edition

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

Jensen et al. 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 followingleakage 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.





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- **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.

## 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.

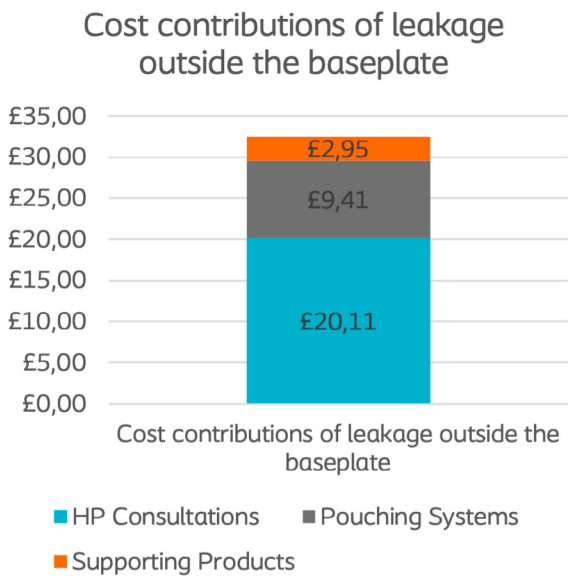


**Figure 1**: Data on cost contributions of leakage outside the baseplate visualised from table 9 of the publication. HP = Health Professional





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# Results of an audit of the Peristomal Body Profile Assessment Tool

Tonks N, Rolls N et al. 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,





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or postponed. As well as surgeries were cancelled. 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.

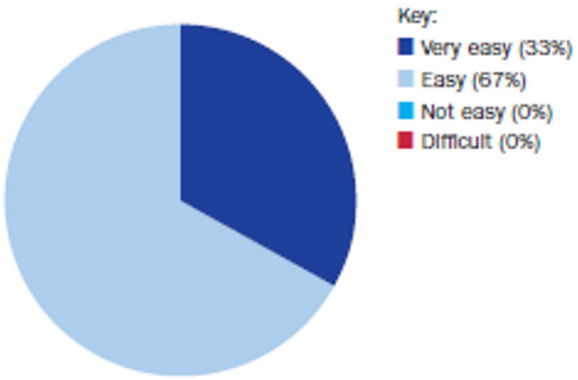
## Study strengths and weaknesses

- 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.

**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)




**Flure 1.** Ease of use





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# Perception of leakage: data from the Ostomy Life Study 2019

Down et al. 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.





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## 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.

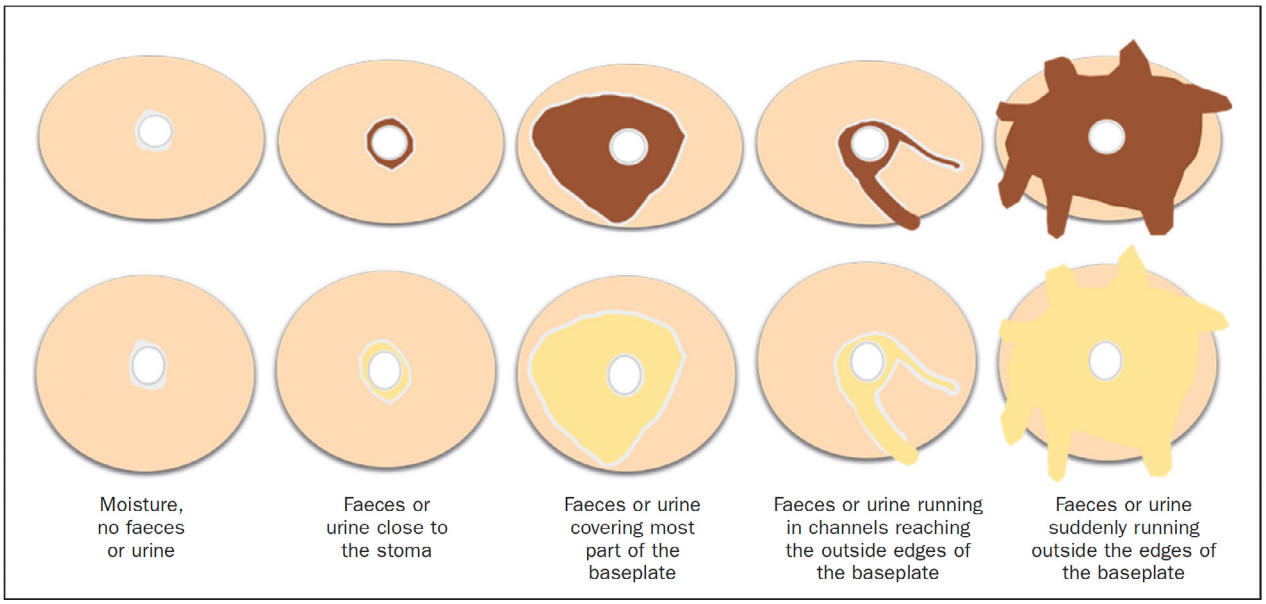


**Figure 1:** People with a colostomy, ileostomy or jejunostomy and stoma care nurses were shown pictures with different degrees of faecal leakage (top), while people with a urostomy were shown pictures with different degrees of urinary leakage (bottom).

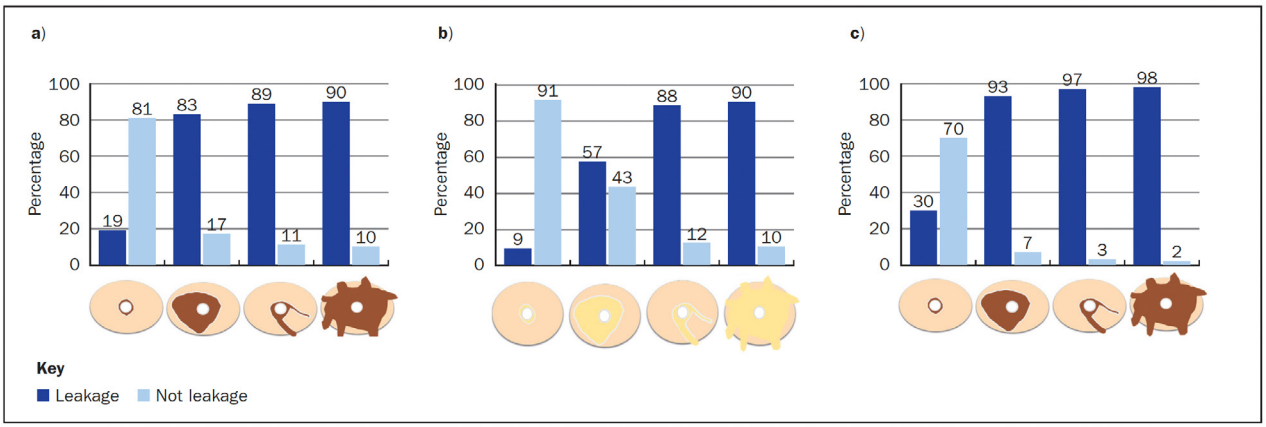


**Figure 2:** Perception of leakage among respondents with a stoma and stoma care nurses. a) People with colostomy, ileostomy or jejunostomy (n=3314), b) people with urostomy (n=847), c) Stoma care nurses (n=294 to 312).





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

Martins L et al. 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.
- n 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.





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### 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.





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# Use of a Convex Pouching System in the Postoperative Period. *A National Consensus*

Janice C. Colwell, Janet Stoia Davis, Krisztina Emodi, Jane Fellows, Mary Mahoney, Bethany McDade, Sima Porten, Elizabeth Raskin, Terran Sims, Holly Norman, Matthew T. Kelly, Mikel Gray.
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/methodology**
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





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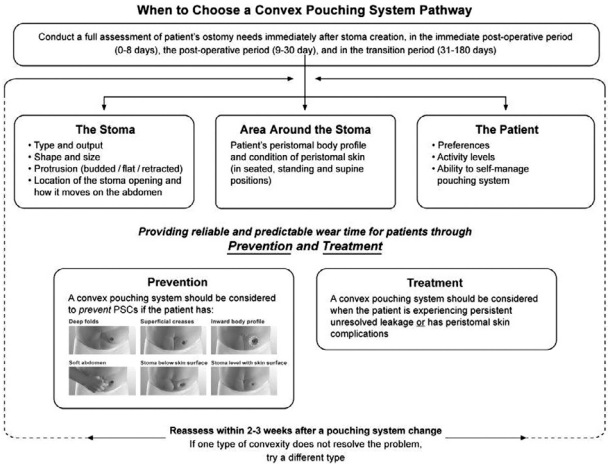
were defined to conform with current care patterns for patients undergoing ostomy surgery and broad time frames suggested in the scoping review. The expert panel reached consensus on eight statements (Figure 2) for the use of convex products immediately after surgery and throughout the first 6 months 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.




**Flure 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:<br>• Secure a reliable seal around the stoma to avoid leakage;<br>• Provide a *predictable* wear time; and<br>• 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:<br>• The patient is experiencing leakage.<br>• Peristomal skin complications due to leakage are present.<br>• The area around the stoma pulls or dips inward, recesses into the abdomen, is concave, or there is a moat around the stoma.<br>• The abdomen is soft and/or the peristomal area has creases, folds, or scars.<br>• 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:<br>• Type of ostomy;<br>• Characteristics of the stoma;<br>• Stoma effluent—type and volume;<br>• Patient's peristomal body profile;<br>• Topography of area around the stoma assessed in the sitting, standing, and supine positions (may need to consider lying on back and on side);<br>• Condition of peristomal skin;<br>• The ability of the patient to self-manage pouching system;<br>• Patient's physical activity levels; and<br>• 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. |

**Flure 2:** The eight consensus statements.





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

Down et al., WCET, 2023.

## 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) T

he 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

## Study design

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.

## 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





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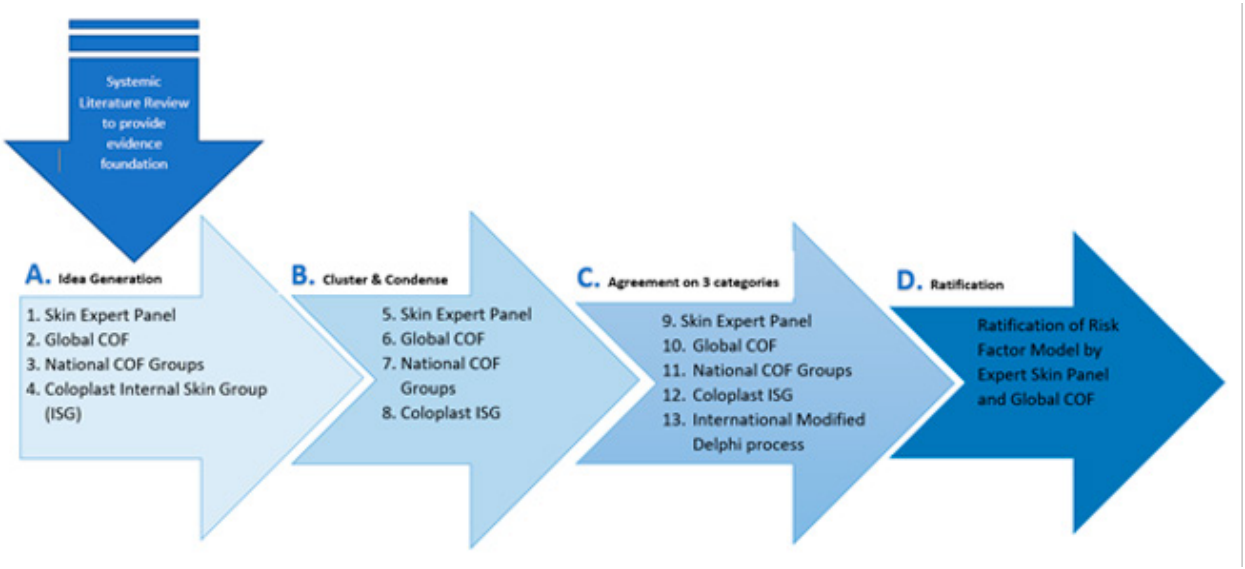


**Figure 1:** Method for development of the risk factor model – using both literature evidence and experiential evidence. **A.** Idea generation and risk factor identification. **B**. Condensation of risk factors into 10 overall categories. **C.** Condensation of risk factors into 3 categories and international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

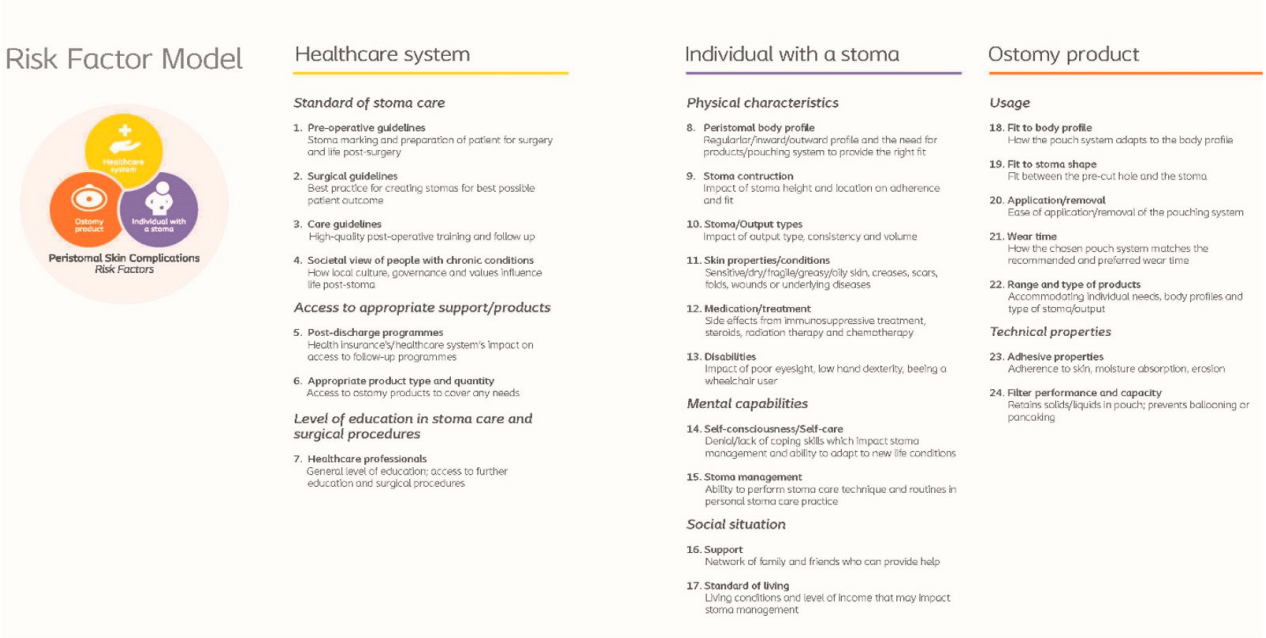


**Figure 2:** The final Risk Factor Model





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# A risk factor model for peristomal skin complications

Steen Hansen et al. 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.

## 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.





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# 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





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

Martins et al., 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.

## Study strengths and weaknesses

- Methods triangulation (interviews and consensus) make outcomes more credible





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- 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.

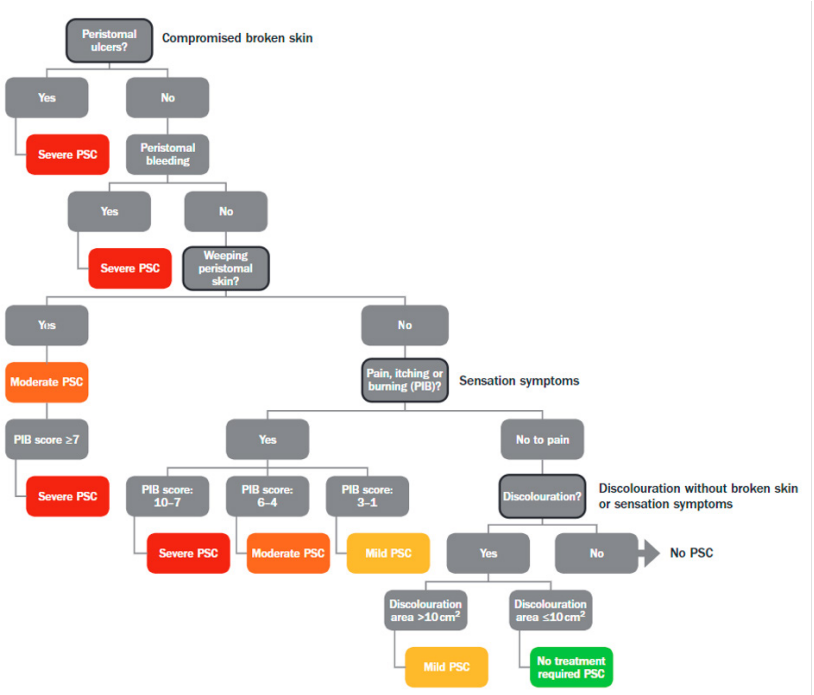


**Figure 1:** Hierachy of the decision tree model

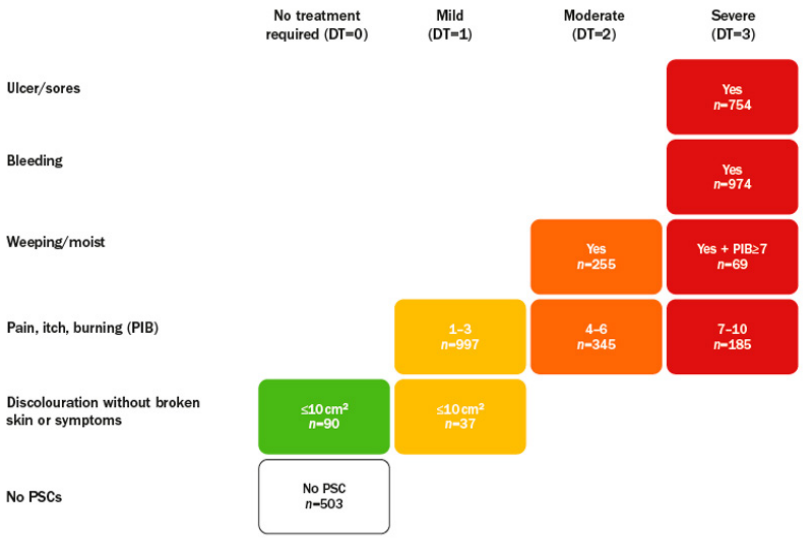


**Figure 1:** Decision tree model applied to a data set from the Ostomy Life Study '19.





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

Fellows J et al., 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.

### 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.

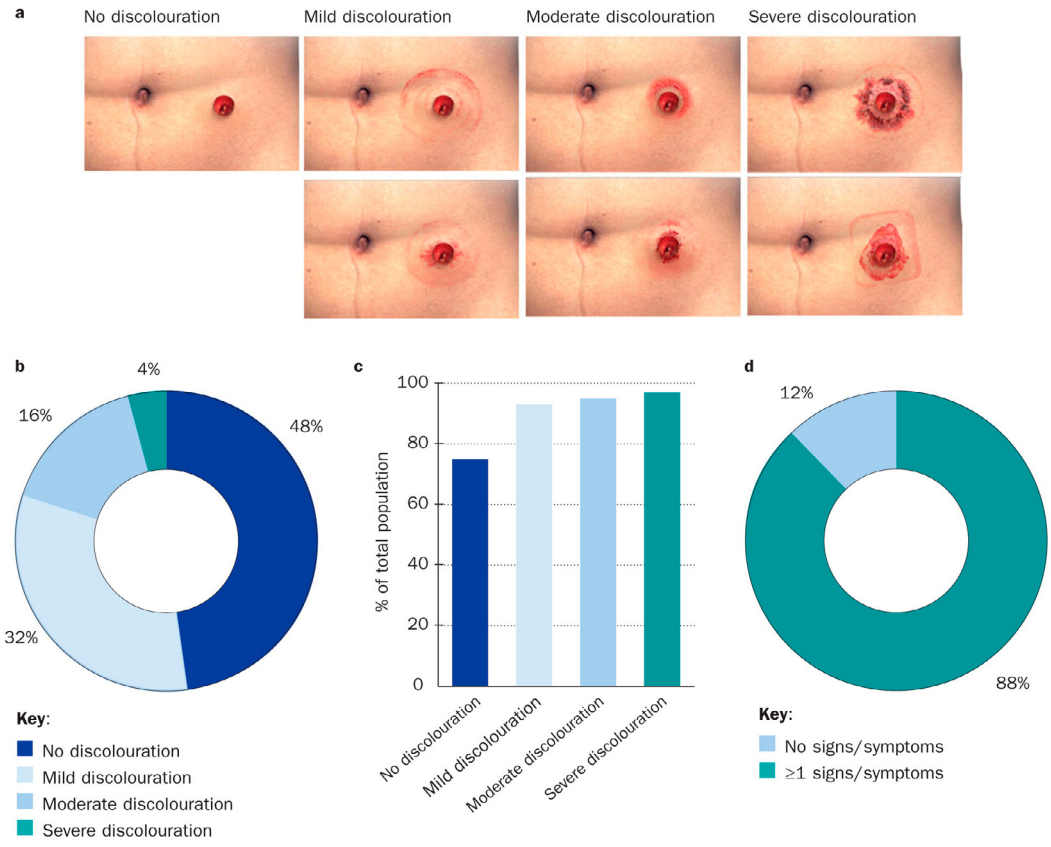


**Figure 1:** Self-assessed visual and non-visual signs of peristomal skin complications.

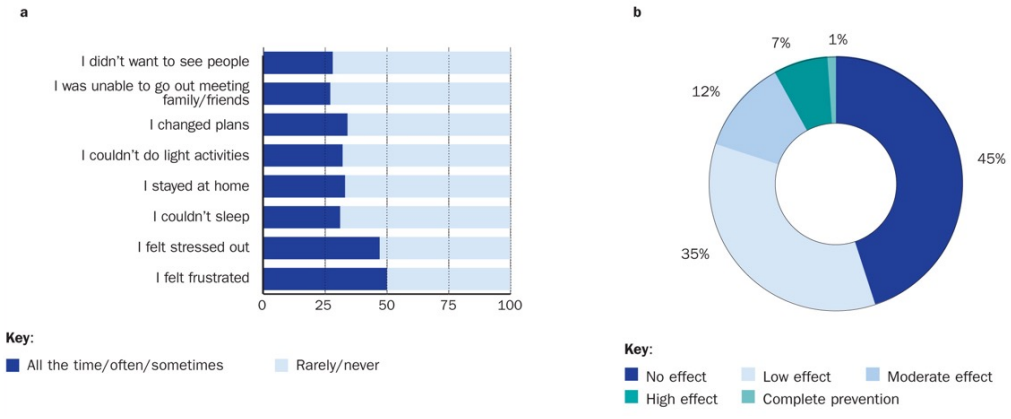


**Figure 2:** Self-assessed impact of having peristomal skin complications..





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# 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 et al. 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.





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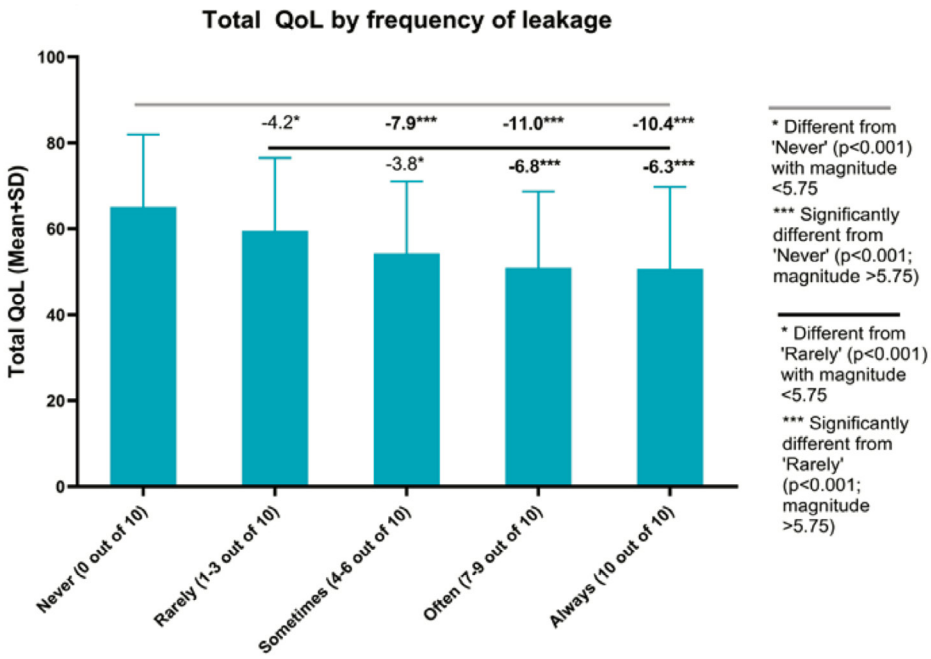


**Figure 1**: The influence of output under baseplate (leakage) on total QoL. Respondents reported output underneath their baseplate during the last ten baseplate changes (n=3,638). Levels compared to 'Never observing leakage' and 'Rarely observing leakage'. *Statistically significant difference observed (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).

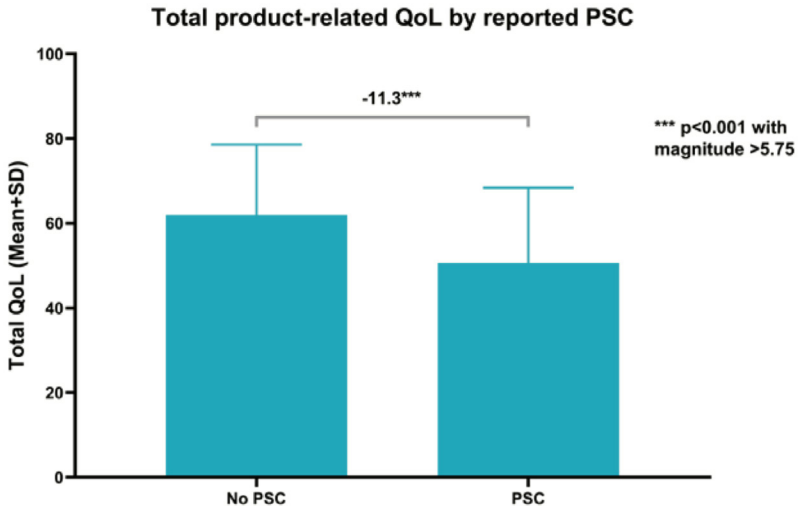


**Figure 2:** The influence of PSC on total QoL. Respondents reported PSC (no/yes) during the previous 6 months (n=3,638). Levels (PSC no/yes)
compared to each other. ***Difference observed is statistically significant (p<0.001) and greater that the clinically relevant MID (>5.75).





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

Jeppesen BJ et al. Br J Nurs. 2022 Mar 24;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.

## 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





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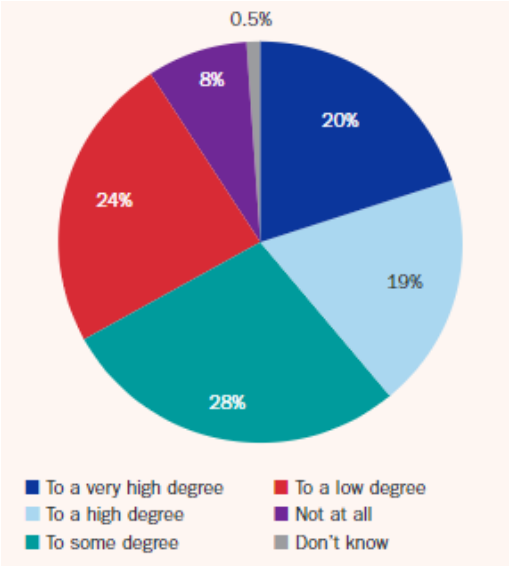


**Figure 1:** If and to what degree people with a stoma worry about leakage of stomal effluent.

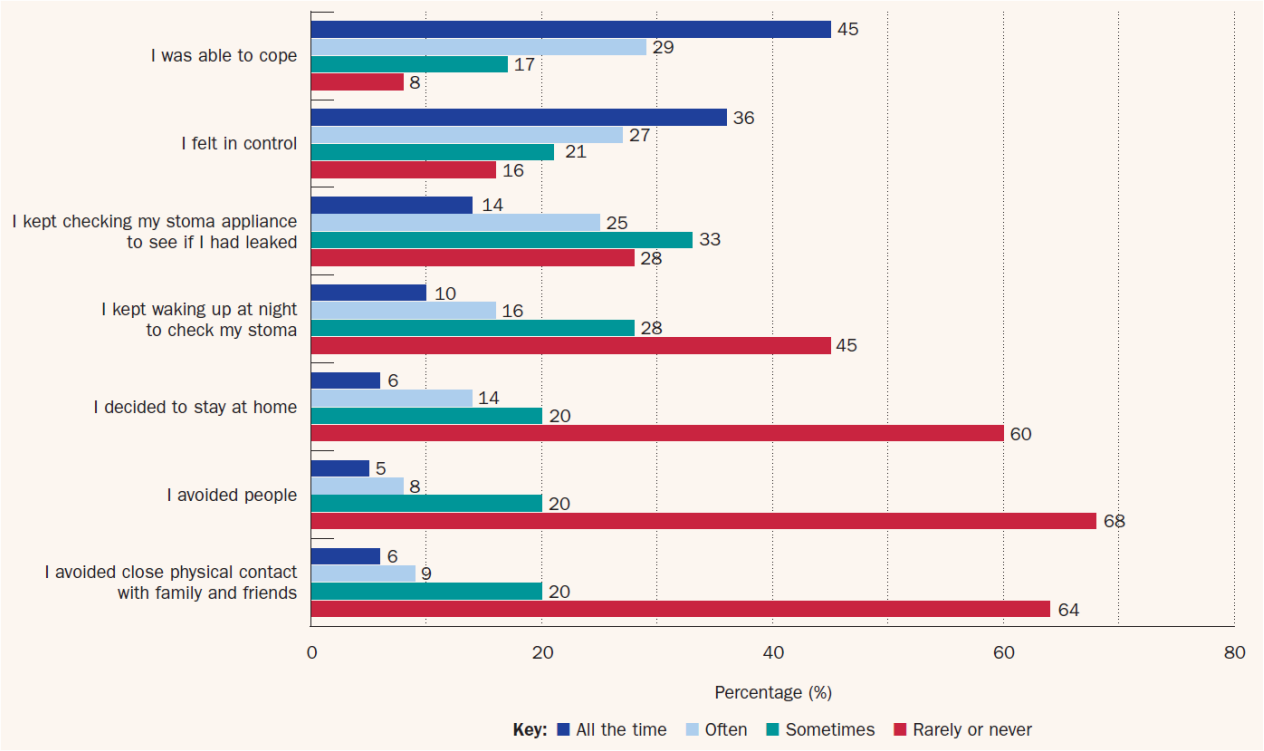


**Figure 2:** How the risk of leakage affects different emotional aspect of life and everyday activities.





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# 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. British Journal of Nursing. 2023; Vol 32, No 4

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.





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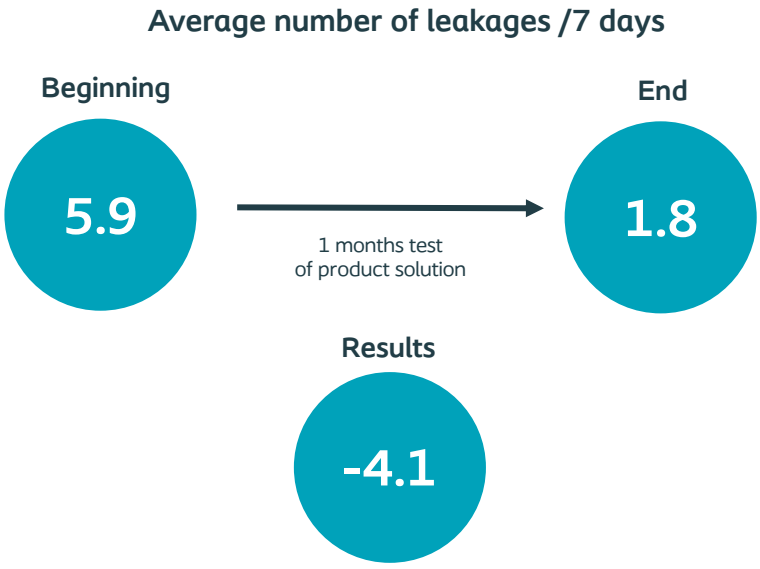
### Study strengths and weaknesses

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.




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

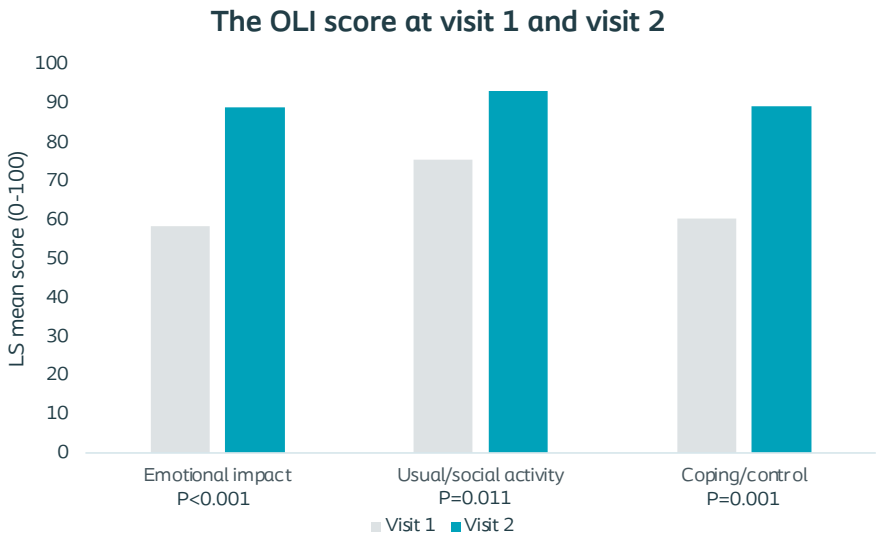



**Figure 2:** The OLI score at the Beginning and End of the study.





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# 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.






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## 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.

**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% |

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





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# 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, 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






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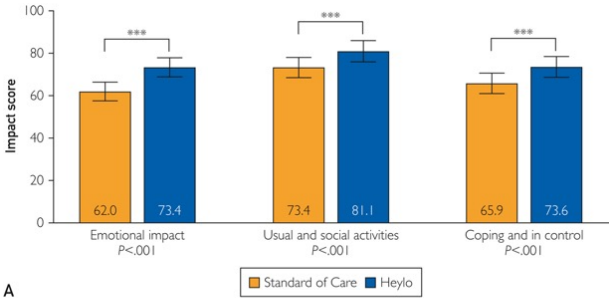
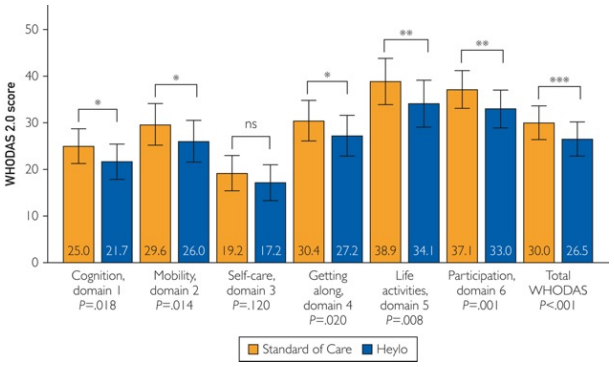
to participate in society and to engage in everyday life activities. Furthermore, Heylo reduced the number of leakages outside the baseplate with 31%.

## 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.




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




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





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# 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, 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.
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'






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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.

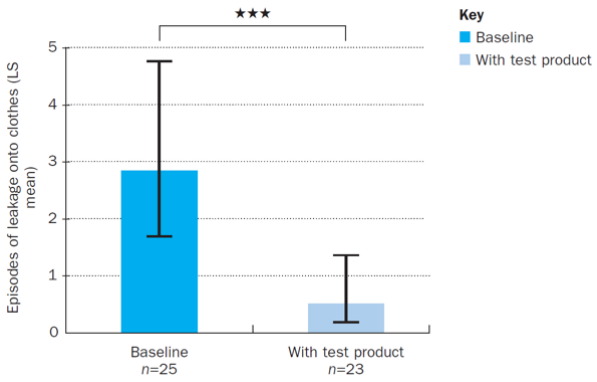
## Conclusion

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.

## 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


**Flure 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 smartphate. The transmitter charger is not shown here. The user has access to technical support when needed.




**Flure 1:** 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.

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.





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# 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 et al. Healthcare. 11(3);369

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## 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.





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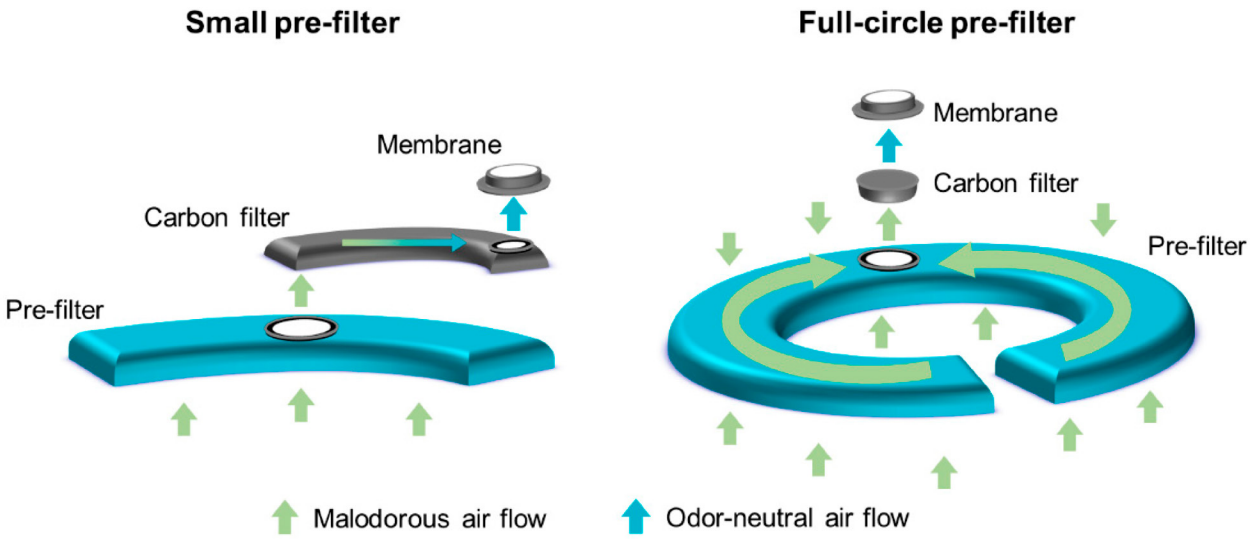
### Study strengths and weaknesses

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.




**Flure 1:** Schematic overview of the filter types

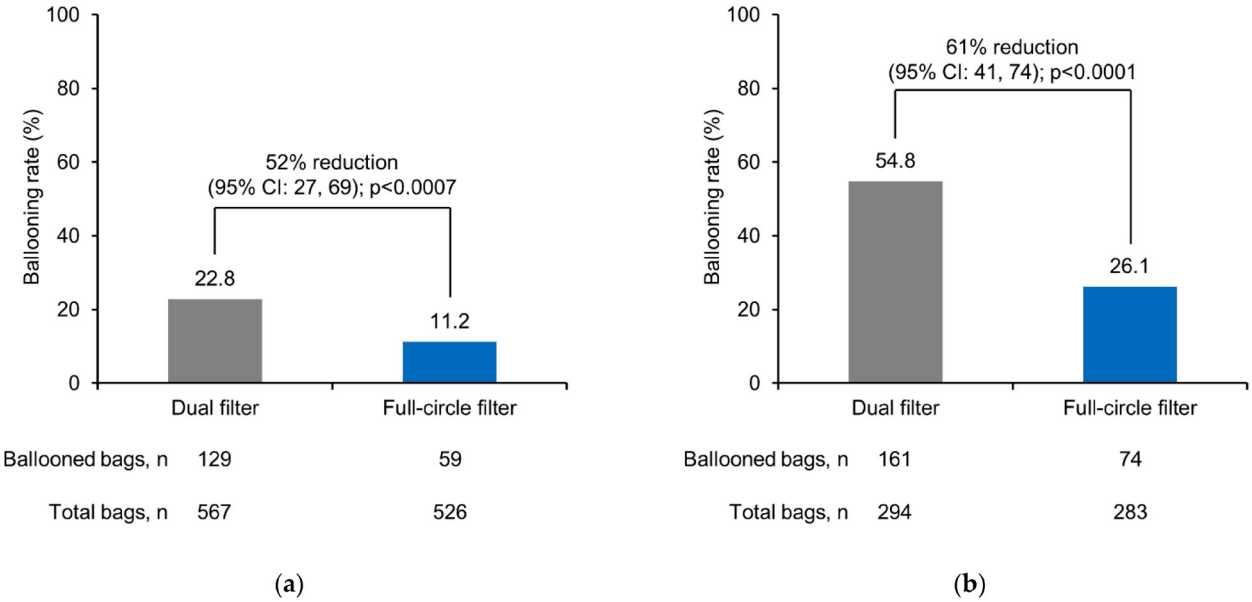



**Figure 2:** Results on frequency of ballooning with the dual filter and the full-circle filter. A) Colostomy group,





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