

*Ostomy Care*

# **Publication Compendium**

## **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 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.

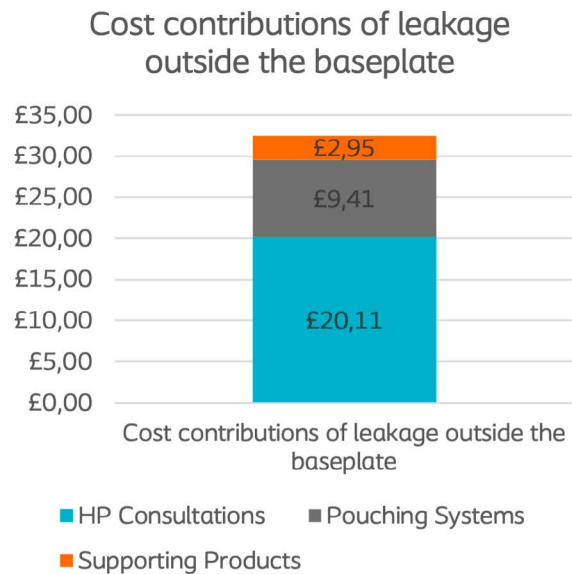
- **Healthcare resource use:** the cost of a single leakage event was estimated to be **£32.47 in the first 3 weeks following a leakage incident** (in a UK community care setting). The primary cost contributors were nurse and GP consultations (62%), with pouching systems accounting for 29% and supporting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

### 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

# 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 \(magonlinelibrary.com\)](https://magonlinelibrary.com)

## Objective

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

## Study design

- Survey with preferred 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%).

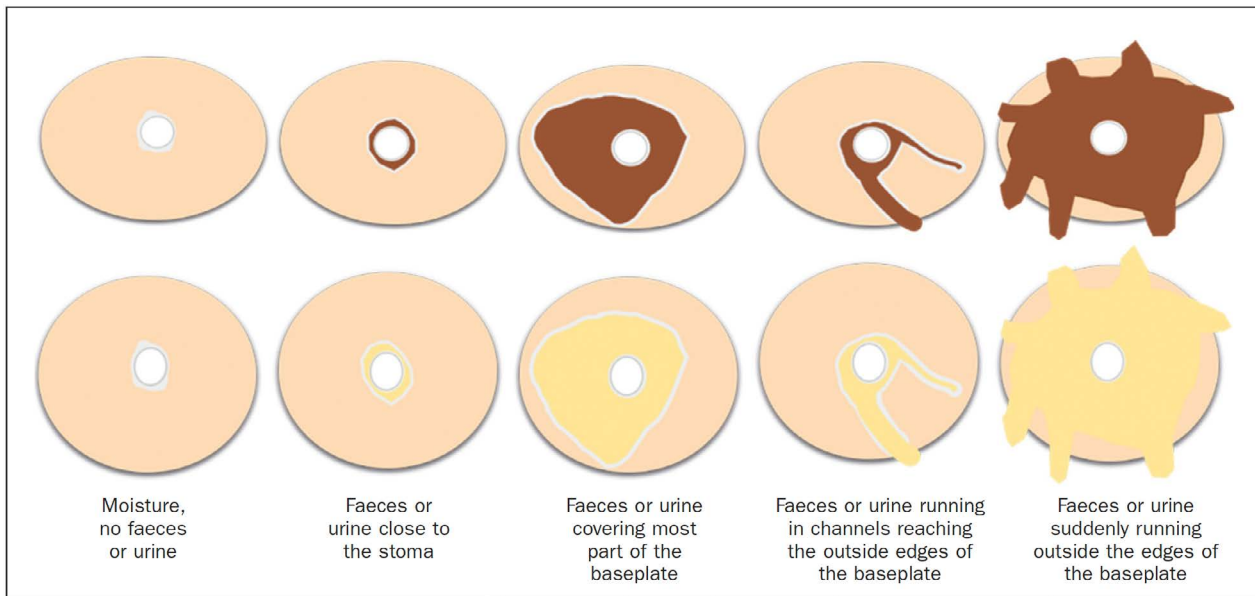
- Only 9–19% of the people with a stoma and 30% of the stoma care nurses considered stomal effluent close to the stoma as leakage.
- Body profile, stoma appearance and incorrect product usage were often considered by stoma care nurses as the reason for leakage.
- In the majority of cases, multiple interactions 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

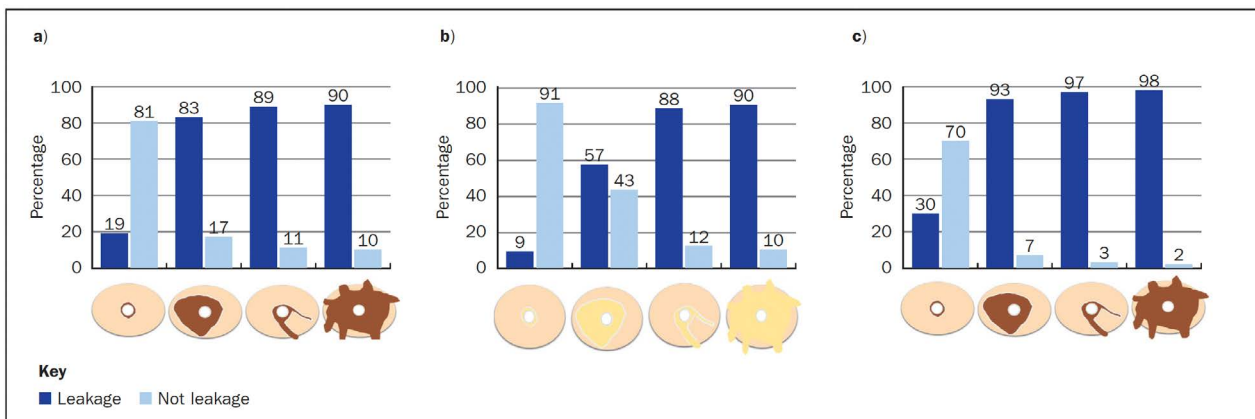
This study revealed that effluent reaching outside the baseplate is generally perceived as leakage, whereas effluent present next to the stoma is generally not perceived as leakage, by both people living with a stoma and stoma care nurses. The psychological aspects, such as embarrassment following leakage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

## 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).

# 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 \(magonlinelibrary.com\)](https://doi.org/10.1111/bjn.15444)

## 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 with a 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.

# 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)

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

## 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.

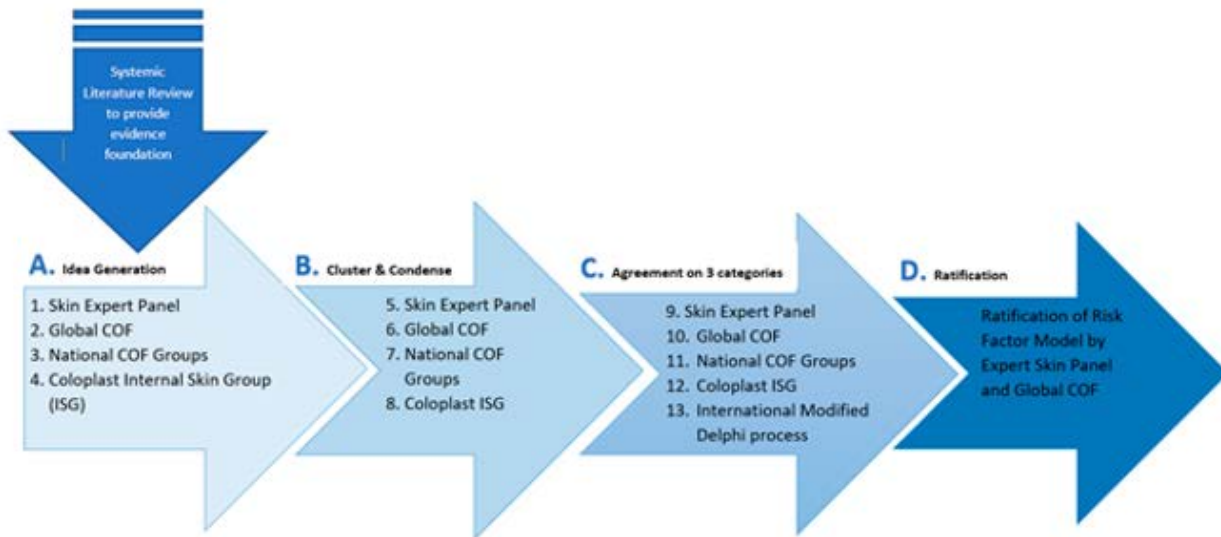
The risk factors were categorized under three headings: **Individual with a stoma, Healthcare system, and Ostomy products.**

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

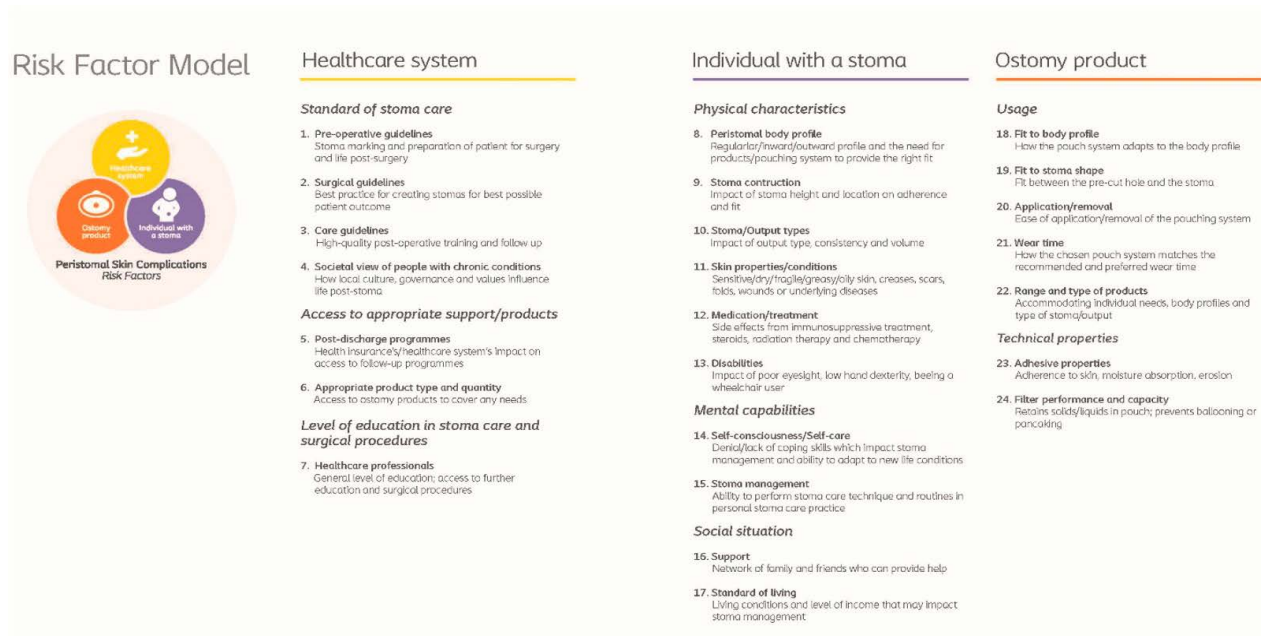
## Study strengths and weaknesses

- 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

**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



# 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.

## 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 wear time?

#### 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

# 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
- 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.

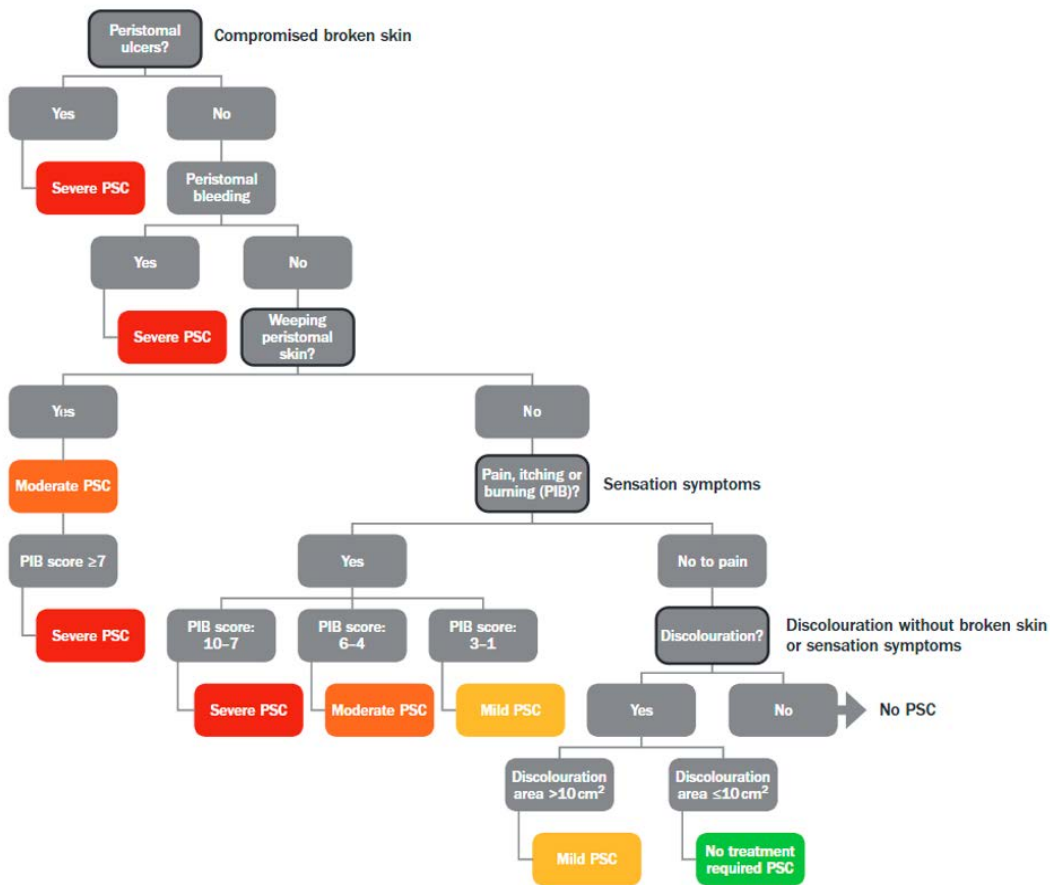


Figure 1.: Hierarchy of the decision tree model



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

# 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.



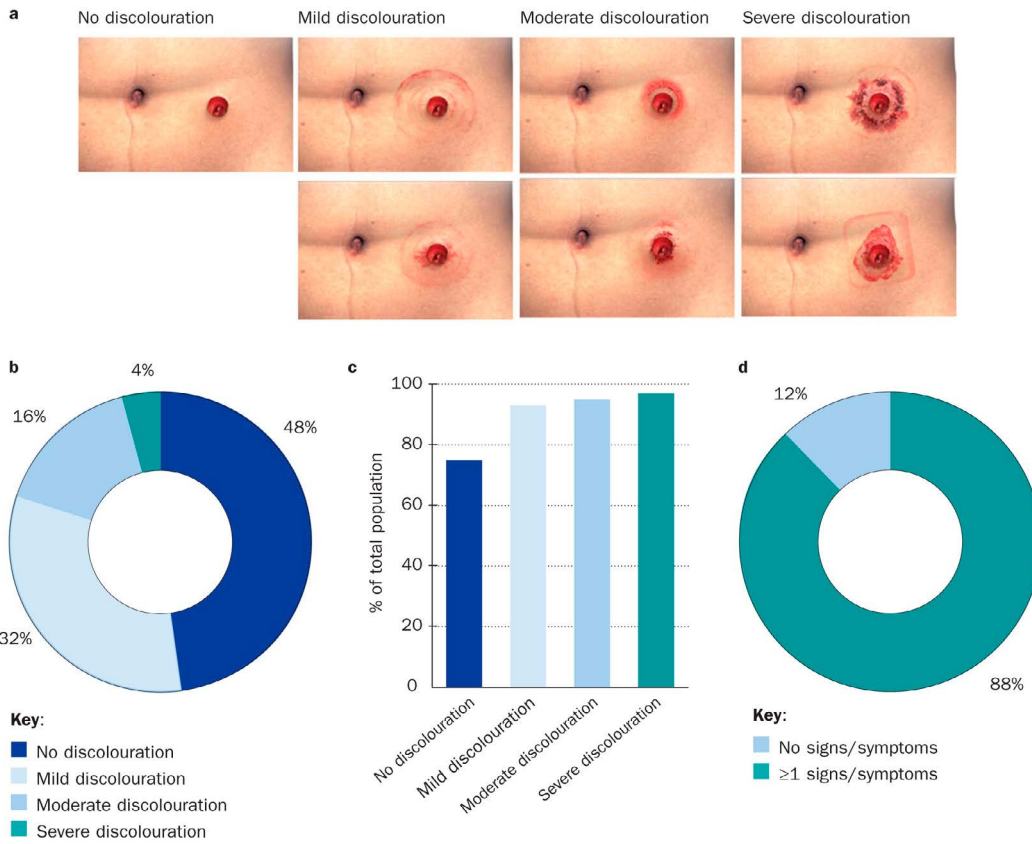


Figure 1: Self-assessed visual and non-visual signs of peristomal skin complications.

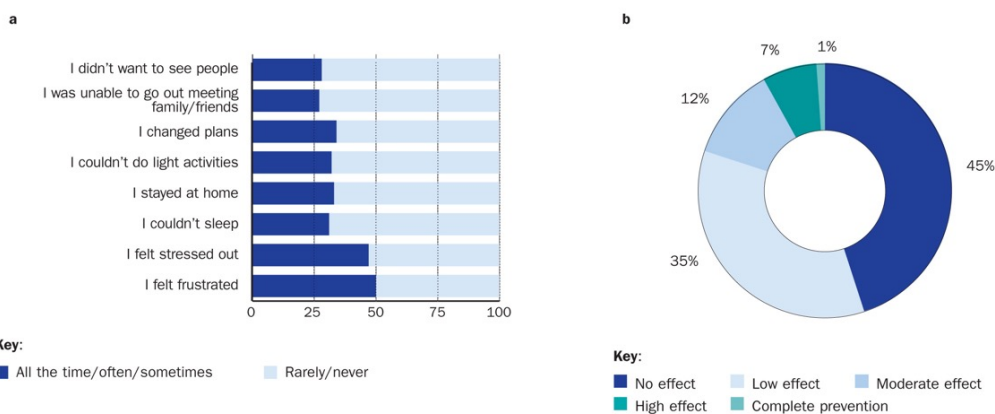


Figure 2: Self-assessed impact of having peristomal skin complications..

# 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](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:

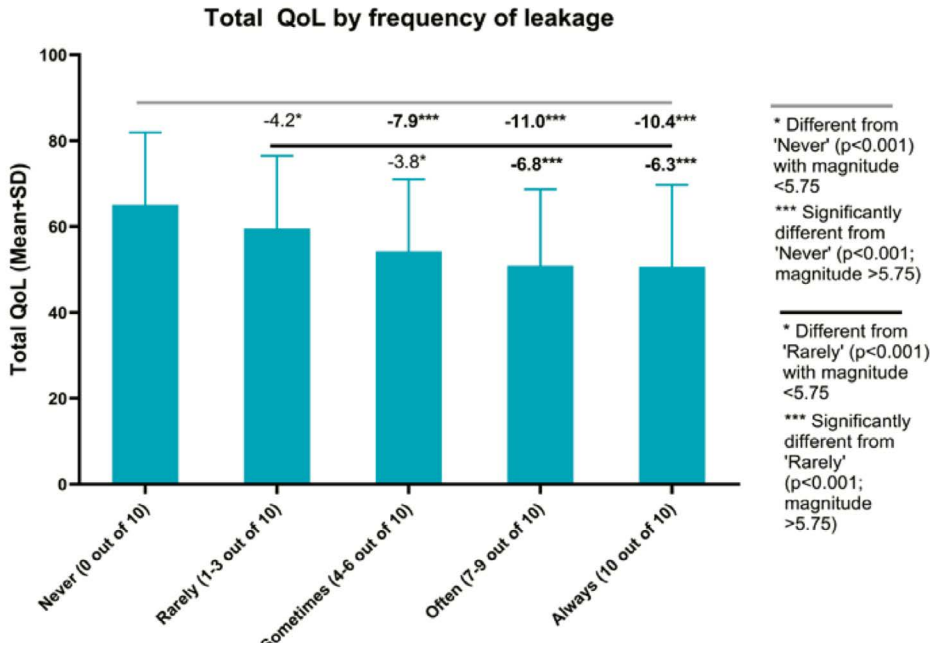
- Answered all questions within 15 minutes (survey should take 30 minutes to complete)
- Answered “don’t know” to more than 30% questions
- Participant did not finish the survey

## Results

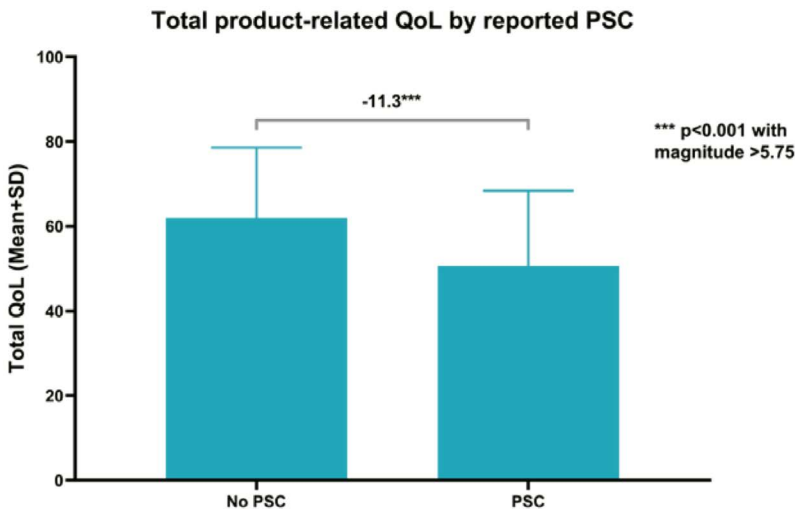
- More than 4,200 people from 13 countries completed the study between 30 August and 3 October 2016.
- Leakage had a statistically significant impact on the QoL for participants who experienced leakage four times (or more) out of ten baseplates changes (Figure 1).
- All four domains in the Ostomy-Q scale (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 than 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 than the clinically relevant MID (>5.75).

# 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 \(magonlinelibrary.com\)](https://www.magonlinelibrary.com/doi/10.1097/00006199-202203000-00008)

## 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).

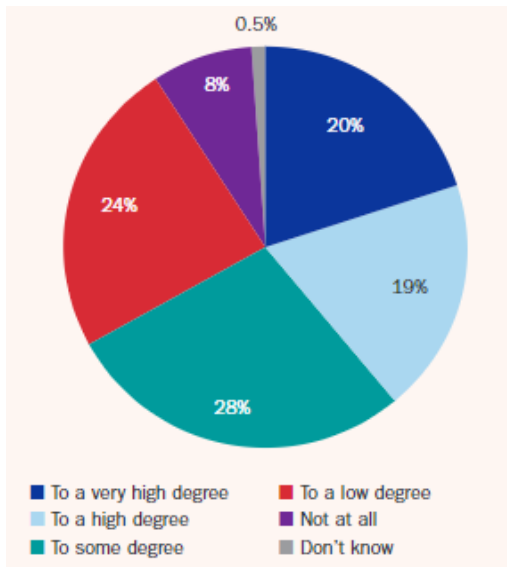
- 65% of employed people with a stoma were affected in their ability to work by leakage of stomal effluent or the worry hereof.
- People with a stoma who worried about leakage used more supporting products.
- The psycho-social impact of leakage increased with the frequency of leakage episodes.
- Leakage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

## Conclusion

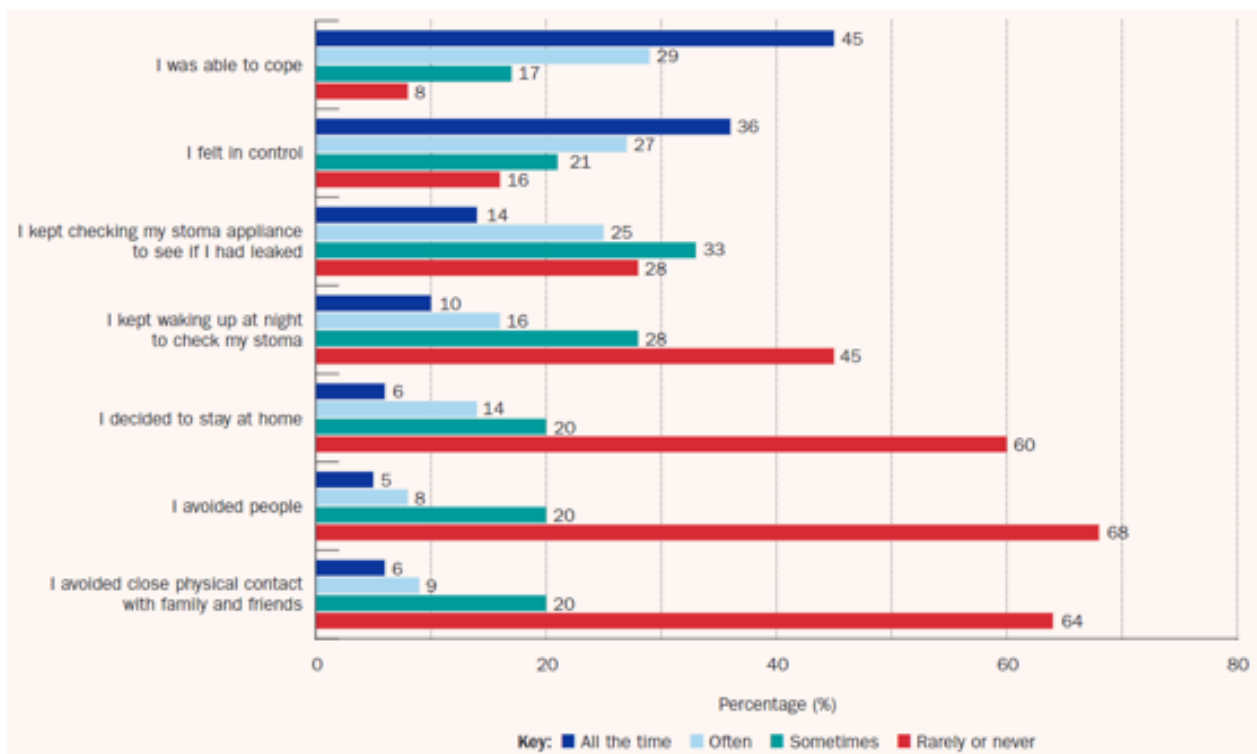
Most people with a stoma were emotionally impacted by leakage, especially by leakage outside the baseplate (those soiling clothes). New solutions are warranted that can help reduce the impact of leakage.

## 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



• **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.

# 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

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.

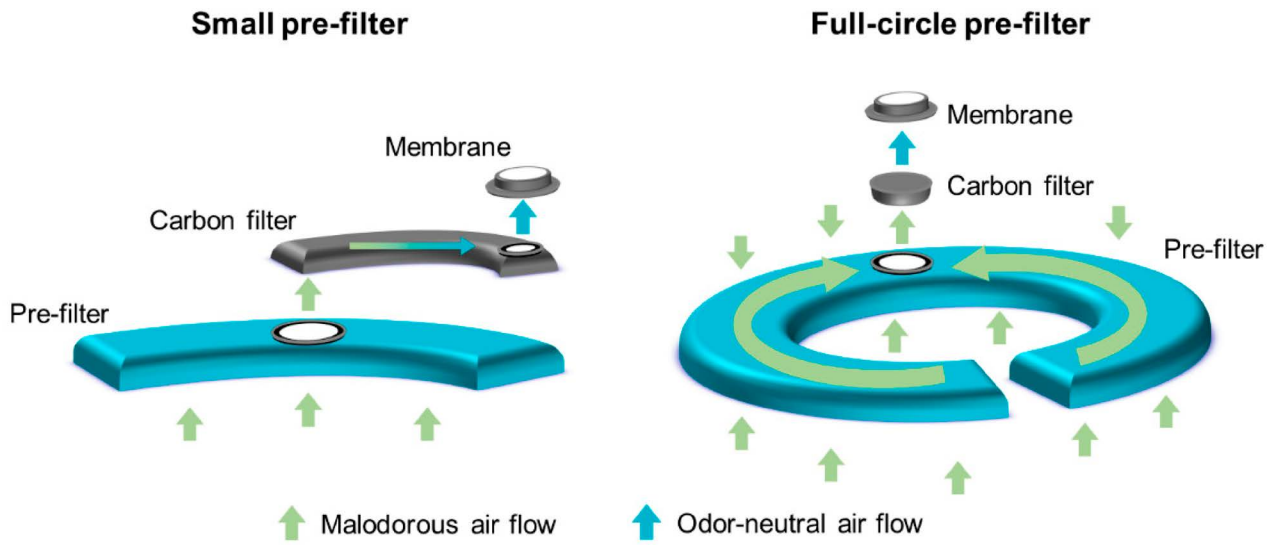
- Among participants with an ileostomy, ostomy solutions with the full-circle filter were, on average, worn for 3.3 h longer (20.5 [0.44] h) than ostomy solutions with the dual filter (17.3 [0.40] h) ( $p < 0.0001$ ). There was no significant difference in the colostomy group.
- Time to ballooning was 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.

## 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

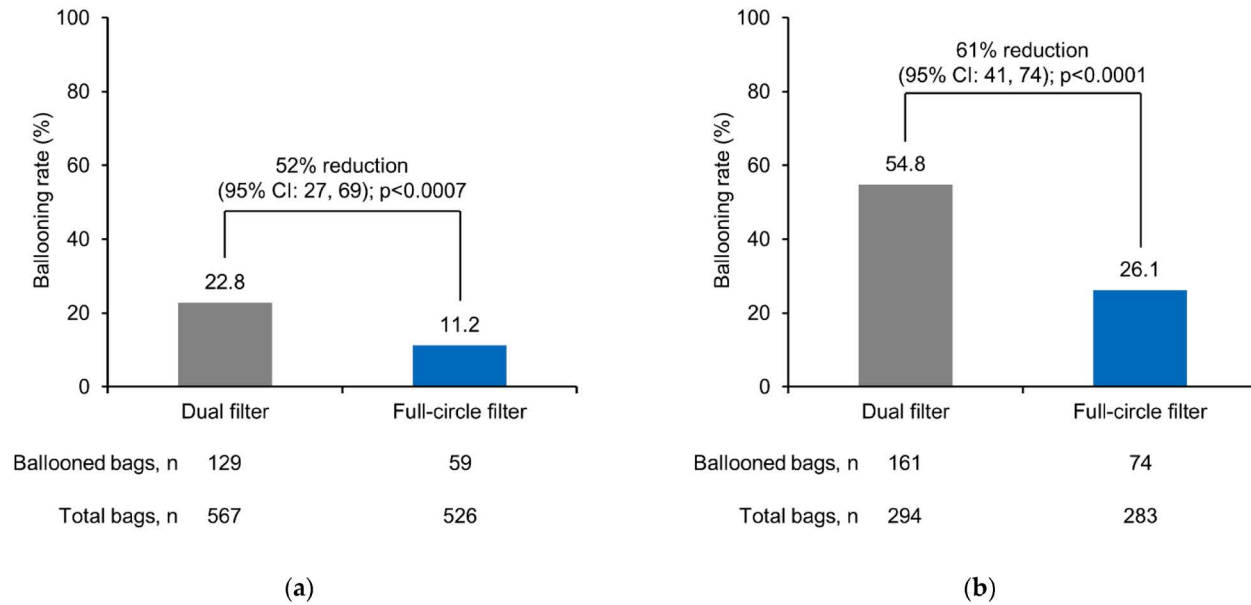


Figure 2. Results on frequency of ballooning with the dual filter and the full-circle filter. A) Colostomy group, b)

The Coloplast story begins back in 1954. Elise Sørensen is a nurse. Her sister Thora has just had an ostomy operation and is afraid to go out in public, fearing that her stoma might leak. Listening to her sister's problems, Elise conceives the idea of the world's first adhesive ostomy bag.

Based on Elise's idea, Aage Louis-Hansen, a civil engineer and plastics manufacturer, and his wife Johanne Louis-Hansen, a trained nurse, created the ostomy bag. An ostomy bag that helps Thora – and thousands of people like her – to live the life they want to lead.

A simple solution that makes a difference.

Today, our business includes Ostomy Care, Continence Care, Wound & Skin Care and Interventional Urology. We operate globally and employ about 12,000 employees.