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 onepage 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 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: <u>Leakage and peristomal skin complications influences user comfort and confidence and</u> are associated

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

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 predefined limit for a minimal important difference.

Conclusion

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

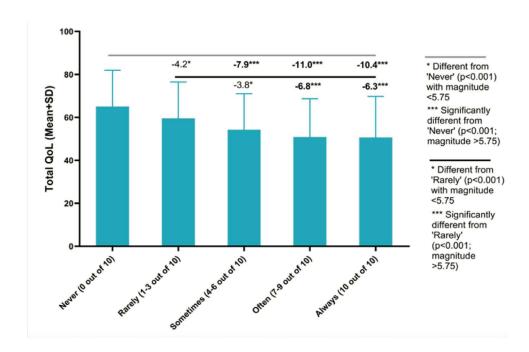


Figure 1: The influence of output under baseplate (leakage) on total QoL. Respondents reported output underneath their baseplate during the last ten baseplate changes (n=3,638). Levels compared to 'Never observing leakage' and 'Rarely observing leakage'. *Statistically significant difference observed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

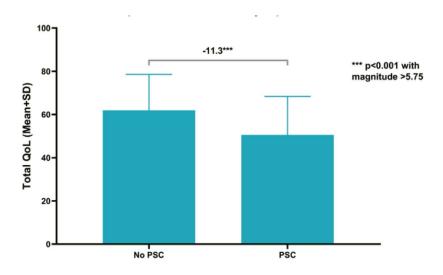


Figure 2: The influence of PSC on total QoL. Respondents reported PSC (no/yes) during the previous 6 months (n=3,638). Levels (PSC no/yes) compared to each other. ***Difference observed is statistically significant (p<0.001) and greater that the clinically relevant MID (>5.75).



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.

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.

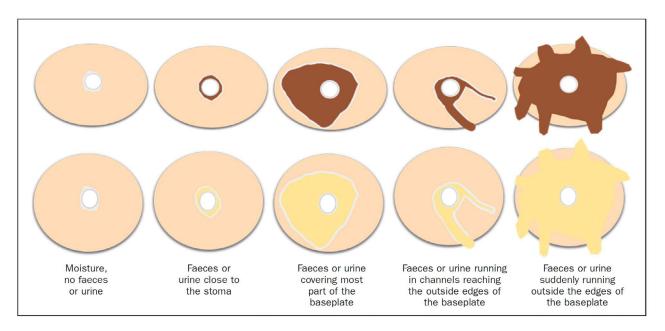


Figure 1. People with a colostomy, ileostomy or jejunostomy and stoma care nurses were shown pictures with different degrees of faecal leakage (top), while people with a urostomy were shown pictures with different degrees of urinary leakage (bottom).

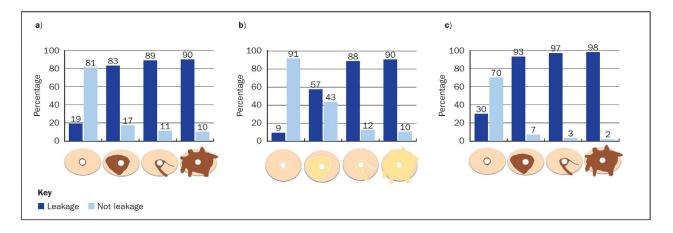


Figure 2. Perception of leakage among respondents with a stoma and stoma care nurses. a) People with colostomy, ileostomy or jejunostomy (n=3314), b) people with urostomy (n=847), c) Stoma care nurses (n=294 to 312).



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).

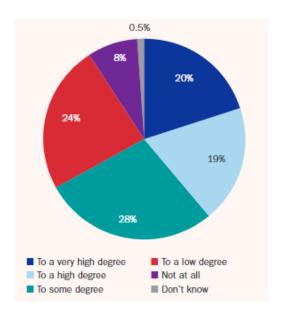
- 65% of employed people with a stoma were affected in their ability to work by leakage of stomal effluent or the worry hereof.
- People with a stoma who worried about leakage used more supporting products.
- The psycho-social impact of leakage increased with the frequency of leakage episodes.
- Leakage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

Conclusion

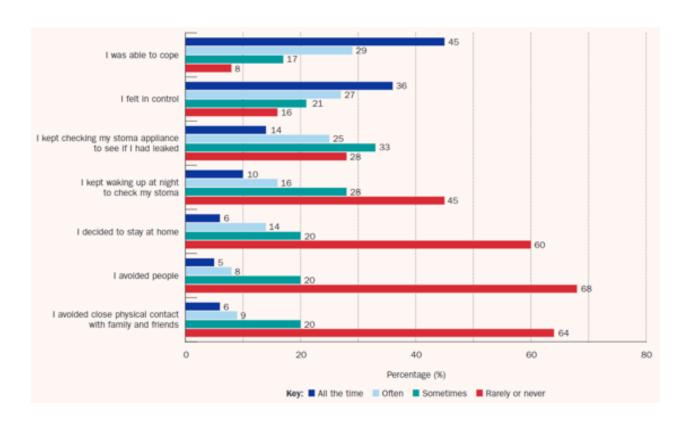
Most people with a stoma were emotionally impacted by leakage, especially by leakage outside the baseplate (those soiling clothes). New solutions are warranted that can help reduce the impact of leakage.

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



• 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.



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: <u>Challenges faced by people with a stoma: peristomal body profile risk factors and leakage</u> | 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 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.

Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare.

Our business includes Ostomy Care, Continence Care, Wound & Skin Care, Interventional Urology and Voice & Respiratory Care. We operate globally and employ about 14,000 employees.

