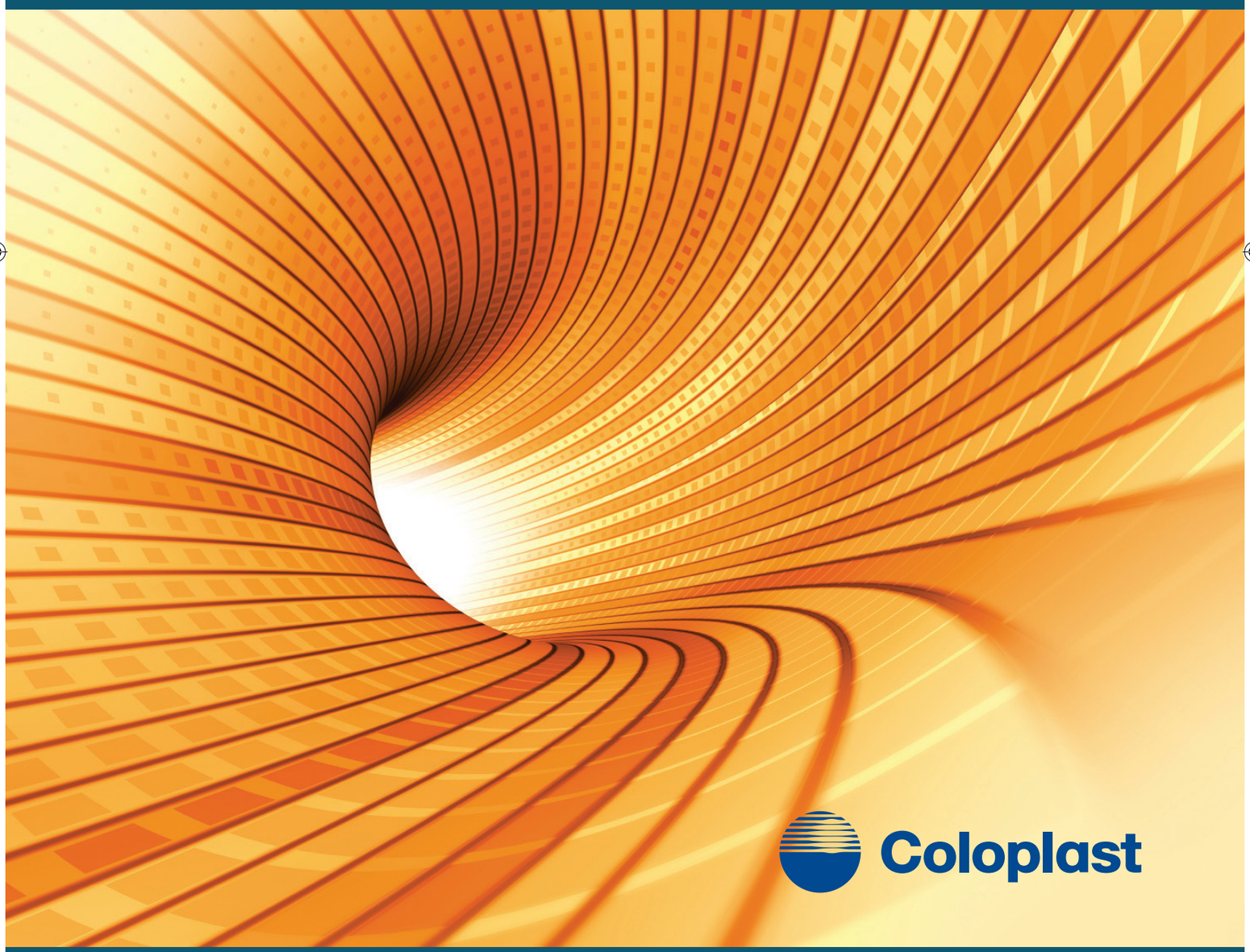
Gastrointestinal Nursing

THE ONLY UK JOURNAL FOR GASTROINTESTINAL AND STOMA CARE NURSES

DialogueStudy

An international real-life study of stoma care nursing using a new ostomy appliance



This supplement has been supported by Coloplast

DialogueStudy Supplement contents

Gastrointestinal Nursing

Consultant Editor Theresa Porrett
Editor Sophie Gardner
Subeditor Vicqui Stuart-Jones
Design Executive Peter Constantine
Production Jon Redmayne
Associate Publisher Stacy Schwarz
Publisher Liam Benison

This supplement has been supported by Coloplast

Gastrointestinal Nursing
St Jude's Church, Dulwich Road, Herne Hill, London SE24 OPB
Tel 020 7501 6714
sophie.gardner@markallengroup.com

www.gastrointestinalnursing.com

Printed in Great Britain by Pensord Press Limited, Blackwood, Gwent NP2 2YA

MA HEALTHCARE LIMITED is part of the MARK ALLEN GROUP

Coloplast's commitment to supporting ostomy care research

Coloplast is a global medical device company with an ongoing commitment to ostomy care. We aim to achieve new standards in ostomy care through effective collaboration with health professionals and people with a stoma.

We understand the importance of peristomal skin conditions to people with an ostomy through listening to our customers and reading the published literature. The OstomySkinStudy, supported by Coloplast, demonstrated that a peristomal skin condition although common, may not be recognized by affected people. The study also showed that a peristomal skin condition often has a negative impact on the person's quality of life. Other research suggests that peristomal skin conditions form a major part of the workload of the stoma care nurse (SCN) (Nybaek et al, 2009). We supported a group of expert SCNs to develop the Ostomy Skin Tool, a validated tool for objectively assessing peristomal skin.

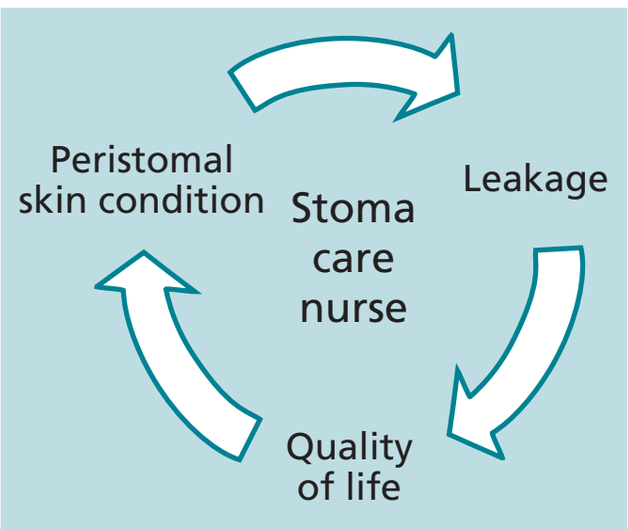
We designed the protocol for the DialogueStudy to focus on quality of life and peristomal skin conditions by working in partnership with the same expert SCNs. It was important to us and the SCNs that the DialogueStudy took place in a 'real-life' setting, and included a wide range of people with an ostomy, including those with an existing peristomal skin condition. The DialogueStudy allowed us to assess the impact of our newest product, SenSura, in combination with the intervention of an SCN, using evidence-based nursing tools. The results from the DialogueStudy will help to improve and refine the solutions we provide to people with an ostomy and to the SCNs who care for them.

Daniel Carter Director, Clinical Operations, Coloplast A/S, Denmark and **Mette Kaad Jensen** International Project Manager, Coloplast A/S, Denmark

What does the DialogueStudy mean for stoma care nurses?

The DialogueStudy is the largest study ever undertaken in ostomy care, with over 3000 people enrolled, and I am thrilled that Gastrointestinal Nursing journal is able to bring you this study results supplement. The results provide a wealth of data on quality of life, peristomal skin condition and ostomy appliance performance. The study also highlights the crucial role of the stoma care nurse (SCN) in optimising the management of the person with an ostomy. This supplement focuses on three key aspects: quality of life, peristomal skin conditions and leakage from the ostomy appliance; these aspects are inter-related (*Figure 1*).

As you will see, the results of the DialogueStudy show that the combination of evidence-based SCN intervention and the use of an appropriate ostomy appliance improved quality of life, peristomal skin conditions and ostomy appliance performance (leakage) in the real-life population. Some readers might be somewhat cynical; because the study is company sponsored and its single product brand SenSura (Coloplast A/S) was used throughout. In my view, such cynicism is misplaced: in a large study of this design (with quality of life and skin condition being measured pre and post stoma care nurse intervention), the use of a control product is essential. Without a control product there would be an additional external variable, which might make the statistical evaluation of outcomes almost impossible. These findings will support our day-to-day clinical practice, help us serve our patients better, and also justify our specialist role. I hope that you will see the potential use of this data to support the role of the SCN. I for one, will certainly be using this evidence in my 2011 Annual Report to help show the cost-effective and efficient service provided in the last year. There is continuing emphasis from the current UK government for private and public collaboration (Department of Health, 2010). This research is an example of the benefits of such collaborations to both the patients and the profession.



Theresa Porrett Homerton University Hospital NHS Foundation Trust, London, City University London, London, United Kingdom

Nybaek H, Lophagen S, Karlsmark T, Bang Knudsen D, Jemec GB (2009) Stratum corneum integrity as a predictor for peristomal skin problems in ostomates. *Br J Dermatol*, **162** (2):357-61

Department of Health (2010) Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry. 27 August. http://tinyurl.com/286hbb (accessed 21 January 2011)

Introduction to the DialogueStudy: methods and baseline demographic findings

Abstract

The DialogueStudy, an open-label, non-comparative, multinational post-marketing study, was set up to document real-life experiences of users of a new ostomy appliance, SenSura, manufactured by Coloplast A/S, with a focus on quality of life (QoL) and peristomal skin conditions. The largest study of its kind, the DialogueStudy involved more than 500 stoma care nurses (SCNs) from 379 sites in 18 countries and a total of 3017 participants with a colostomy, ileostomy or urostomy. During the study, participants completed two visits with an SCN and were given advice on maintaining healthy peristomal skin and provided with an appropriate ostomy appliance, SenSura. The primary endpoint was the difference in QoL between the first and second visit. Secondary endpoints included self-awareness of skin disorders, leakage and peristomal skin condition at the study start and then at the study end (6–8 weeks later). The mean QoL score increased significantly during the study ($P<0.0001$).

Birgitte Dissing Andersen is Stoma Care Nurse, Herlev Hospital, Denmark. **Paula van Keizerswaard** is Nurse Practitioner, VU Medical Centre, Amsterdam, Netherlands. **Maria Manuel Castro** is Specialized Stoma Care Nurse, Stoma Care Ward, Hospital São João, Porto, Portugal. **Elizabeth English** is Clinical Nurse Consultant, Stoma and Wound Care, Royal Adelaide Hospital, Adelaide, Australia. **Daniel Carter** is Director, Clinical Operations, Clinical Regulatory Development, Global R&D, Coloplast A/S, Denmark.
Email: birgitteda@oncable.dk

Key words

- Ostomy
- Peristomal skin
- Quality of life
- Evidence-based nursing
- Stoma

This article has been subject to double-blind peer review

Peristomal skin disorders are a common problem faced by people with an ostomy, their carers and health professionals. A literature review suggested that the overall rate of peristomal skin complications ranged from 18 to 55% (Colwell et al, 2001). In a Danish study, 45% of people with a permanent stoma were diagnosed with a peristomal skin disorder (Herlufsen et al, 2006). However, 67% of people in the study diagnosed with a mild skin disorder were not aware of their condition (Herlufsen et al, 2006). Even though it is difficult to estimate the precise scope of peristomal skin complications, they typically account for one third of visits to a stoma care nurse (SCN) (Nybaek et al, 2009a) and it is obvious that they are a major concern for many people with an ostomy.

Leakage from the ostomy appliance is also common, and a correlation between leakage and peristomal skin disorders has been demonstrated (Nybaek et al, 2009b). Other factors, such as obesity or a poorly sited ostomy, can also affect the fit of the ostomy appliance (Turnbull, 2002; Nybaek et al, 2009b). Sustained leakage causes skin disorders, and these disorders make it harder to attach the ostomy appliance properly, leading to more leakage and a worsening of existing skin problems. This 'vicious circle' can lead to decreased quality of life (QoL). Many factors can influence the QoL of the individual person with an ostomy. For example, some people fear their ostomy appliance might leak, feel embarrassed about their body, or worry about becoming a burden to family and friends. Concerns like these may stop the person with the ostomy from doing the things he/she enjoys and thus affect his/her QoL. Impaired QoL is a challenge not only for the individual person living with an ostomy, but also for society as a whole. It may be associated with an increased number of absences from work due to illness, or the need for early retirement, both associated with significant health-economic burdens.

The first intervening step to improve the situation for the person with an ostomy is to identify whether he/she has a poor QoL. However, QoL can be difficult to measure. Generic QoL instruments such as the World Health Organization WHOQOL-BREF scale (http://www.who.int/mental_health/media/en/76.pdf) and the Short Form-36 scale (www.sf-36.org) are widely used, but do not specifically address the concerns of the person living with an ostomy. In 2005, a QoL questionnaire specifically for people with an ostomy, the Stoma-QoL, was developed and validated (Prieto et al, 2005; Nybaek et al, 2010).

The DialogueStudy

Peristomal skin disorders, leakage from the ostomy appliance and QoL are important, interrelated concepts in ostomy care. The DialogueStudy, an open label, non-comparative, multinational post-marketing study, was set up to document real-life experience of a new ostomy appliance, SenSura (Coloplast A/S) with a focus on QoL and peristomal skin conditions. The target population in the DialogueStudy was people with a colostomy, an ileostomy or a urostomy. The Stoma-QoL was used to assess QoL, with the validated Ostomy Skin Tool (Prieto et al, 2005; English et al, 2008; Martins et al, 2010; Jemec et al, 2011) used to assess peristomal skin condition. The primary endpoint was the difference in QoL between the first and last visit. Secondary endpoints included self-awareness of skin disorders, leakage and peristomal skin condition before (baseline data) and after a study-related visit to a stoma care clinic and the use of an appropriate stoma appliance. The DialogueStudy also allowed correlations between these different factors to be investigated.

This article describes the methodology of the DialogueStudy and presents the baseline demographic findings. Results for QoL, peristomal skin conditions and ostomy appliance performance (including leakage) are reported in the other articles in this supplement (Davis et al, 2011; Martins et al, 2011; Porrett et al, 2011).

Methods

The DialogueStudy protocol was developed with input from a global panel of expert SCNs. All of the procedures were performed in compliance with relevant laws and institutional guidelines and the appropriate approvals. The study was conducted by investigators who were enterostomal therapists, SCNs or (in some cases) doctors (collectively 'SCNs'). Some investigators will have received sponsorship or payment from Coloplast in relation to activities such as conference attendance or consultancy outside the DialogueStudy.

Study population

Potential participants were selected from the patient records at participating sites and were contacted either by phone or mail by the designated study personnel. People interested in participating in the study received further verbal and written information about the study.

To be eligible for inclusion in the DialogueStudy, participants were required to provide signed informed consent. They also had to have a colostomy, ileostomy or urostomy (people with a urostomy were not enrolled in all countries). Participants had to have their stoma for at least 6 months, because this is the population for which the Stoma-QoL questionnaire has been validated. Participants had to be at least 18 years of age, and have the mental capacity to understand the study and questionnaires.

People with more than one ostomy were excluded from the study because it may be impossible for them to use a normal ostomy appliance, depending on the positioning of the ostomies. People who used an ostomy plug (except occasionally in special circumstances such as during sports, swimming, or travelling) were also excluded as these people usually irrigate their ostomies. Women who were pregnant or breast-feeding were excluded. Participation in other studies at the same time or previous participation in the DialogueStudy was also a reason for exclusion.

Procedures and assessments

The study included two visits 6–8 weeks (±4 days) apart. At visit 1, QoL and peristomal skin conditions were measured and demographic

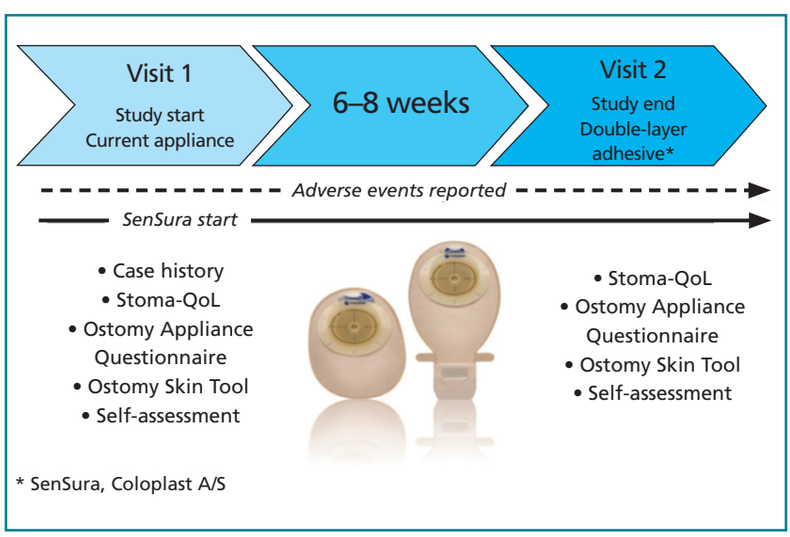


Figure 1. Short overview of the assessments performed at the two visits in the DialogueStudy. The case history at visit 1 included demographic data and information about the ostomy. The Ostomy Appliance Questionnaire captured information about the ostomy appliance and use of accessories. The 'self-assessment' recorded the participant's opinion about whether they had a peristomal skin disorder.

data were recorded, including information about the ostomy (e.g. type, reason for creation, time since surgery) and participants' pre-study ostomy appliance (e.g. type, use of accessories). Participants were provided with an appropriate ostomy appliance, a double-layer adhesive appliance, SenSura, and instructed on how to use it by the SCN. At visit 2, QoL and peristomal skin conditions were measured again. Participants were also asked about their experience using SenSura. At both visits, participants were asked whether they thought they had a peristomal skin disorder (self-assessment) (*Figure 1*).

The DialogueStudy used two assessment tools, the Stoma-QoL questionnaire and Ostomy Skin Tool, developed by nurses for nurses with support from Coloplast.

Stoma-QoL questionnaire

The Stoma-QoL questionnaire was developed and validated specifically for people with a colostomy or ileostomy (Prieto et al, 2005; Nybaek et al, 2010). It is a suitable instrument for use in clinical practice as well as in clinical research. The 20 items in the questionnaire cover four domains:

Table 1. Number of participants from each country

Country	Number of participants
USA	701
France	522
Poland	261
Germany	166
United Kingdom	140
Portugal	136
South Korea	132
Spain	131
Italy	115
Japan	110
Argentina	104
Denmark	100
Netherlands	94
Czech Republic	92
Iceland	73
Slovakia	61
Canada	43
Australia	36
Total	**3017**

- Sleep
- General activity (including ostomy appliance factors)
- Relations to family and close friends
- Social relations to people other than family and close friends.

The Stoma-QoL generates a score of 0 (worst QoL) to 100 (best QoL).

In the DialogueStudy, the Stoma-QoL was administered at visits 1 and 2. To minimize bias, the participants were asked to complete the Stoma-QoL questionnaire themselves in privacy at the clinic after thorough instruction from the SCN. If a participant was physically unable to complete the questionnaires, he/she was allowed assistance from a private caregiver (e.g. a spouse). The completed questionnaire was put in a sealed envelope, without interference from the SCN.

Ostomy Skin Tool

Until relatively recently, there was a need for a standardized tool to diagnose and assess peristomal skin and associated disorders to help health professionals improve the care of people with an ostomy (Ratliff et al, 2005; Bosio et al, 2007). Accordingly, the Ostomy Skin Tool was developed and evaluated to help health professionals evaluate and monitor the condition of peristomal skin with high reliability and accuracy (Martins et al, 2008, 2010; Jemec et al, 2011; http://www.coloplast.com/OstomyCare/Topics/EducationTools/TheOstomySkinTool/About/Pages/MoreAbouTtheTool.aspx).

The Ostomy Skin Tool generates an objective score based on clinical observation of three domains: discolouration, erosion/ulceration and tissue overgrowth (DET). This composite measure represents the increasing severity of skin problems with scores based on clinical observations (English et al, 2008; Martins et al, 2008). The three domains (i.e. discolouration, erosion/ulceration and tissue overgrowth) are scored according to the extent of the peristomal area they cover (maximum score 3) and the severity of change in the skin (maximum score 2). A score of 0 represents normal skin; a maximum score of 15 represents the greatest severity and extent. The skin on the other side of the abdomen acts as a control. The Ostomy Skin Tool was administered by the SCN at visits 1 and 2.

Results

More than 500 SCNs from 379 sites in 18 countries participated in the study. A total of 3017 participants were recruited. The largest groups of patients came from the USA, France and Poland (*Table 1*).

Of the 3017 participants, 2796 attended visit 2, which represents a discontinuation rate of 7%. The main reasons for discontinuation included adverse events (1.5%; 44/3017) and non-compliance (1%; 33/3017).

The majority of participants had a colostomy (67%) or an ileostomy (31%); 2% had a urostomy (people with a urostomy were not enrolled in all countries). The mean age of the participants was 63.2 years (±14.3 years) and the average time since their surgery was 5.9 years (±7.9 years) (*Table 2*).

The majority (58%) of the study participants had their ostomy created because of cancer (1759/3017) (*Figure 2*). The creation of the ostomy was planned in 72% of participants (2177/3017). For 86% of participants, the ostomy was considered to be permanent rather than temporary (2608/3017).

Forty-six per cent of participants were using a Coloplast product before joining the study (1398/3017) and 54% were using products from other manufacturers. The characteristics of the appliances and accessories used during the study period are discussed elsewhere in this supplement (Porrett et al, 2011).

The time since the participants' last visit with the SCN ranged from less than 1 month to more than 12 months (*Figure 3*). The majority of participants in the study (52%) reported visiting the stoma care clinic only when they needed to (1578/3017), compared with 33% who had regular appointments (984/3017) and 15% who never visited the clinic (451/3017).

Overall, 74 participants (2.5%) reported an adverse event, of which 17 were judged to be serious. None of the serious adverse events were related to the use of the double-layer adhesive, SenSura. Of the remaining non-serious events, 49 were considered to be 'possibly related' or 'related' to the double-layer adhesive, SenSura. The majority of these events (47%) were irritant contact dermatitis, corresponding with published literature (Herlufsen et al, 2006).

The mean score on the Stoma-QoL increased during the study from 58 to 60 (P<0.0001).

Table 2. Demographic findings from participants in the study at baseline

		Number of participants	% of participants
Gender			
	Males	1474	49
	Females	1541	51
Type of ostomy			
	Colostomy	2015	67
	Ileostomy	954	31
	Urostomy*	46	2
Mean age (years)		63.2 ± 14.3	
Time since surgery (years)		5.9 ± 7.9	

*People with urostomies were not enrolled in all countries.

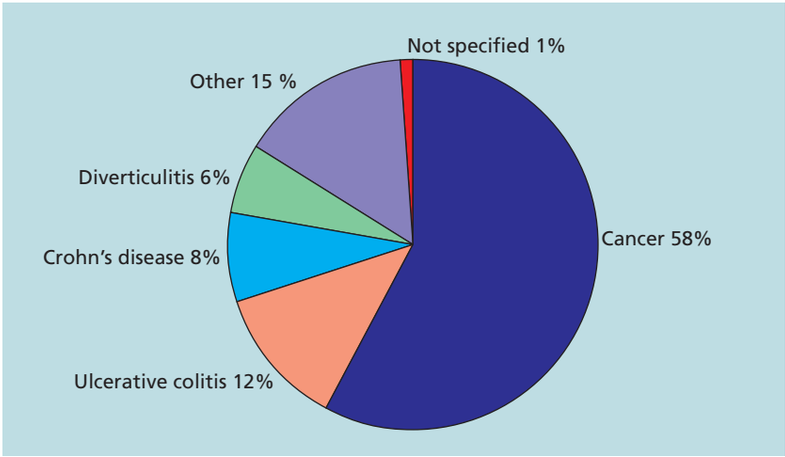


Figure 2. Reasons for ostomy creation

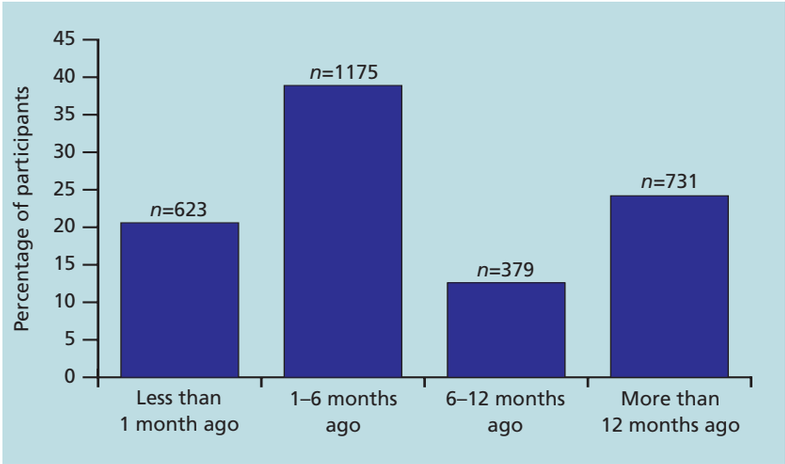


Figure 3. Time since the participants' last visit with a stoma care nurse

This result and the results for the secondary endpoints, including the factors influencing QoL and skin condition, are discussed elsewhere in this supplement (Davis et al, 2011; Martins et al, 2011).

Discussion

The DialogueStudy is the largest study ever undertaken in ostomy care with more than 3000 participants from 18 countries. The study provided real-life data that could help inform day-to-day clinical practice due to the wide range of participants and the real-life clinical setting. The use of validated tools—the Stoma-QoL and Ostomy Skin Tool—makes this an important contribution to evidence-based nursing. The findings on people with a urostomy, while from a small sample compared to those with a colostomy or ileostomy, are valuable because there is little published literature in this area.

Limitations

The real-life setting in a number of countries may have led to a variation in the populations recruited. Differences in ostomy care standards, including the types of appliance and accessories available, are likely to have affected baseline parameters such as QoL and peristomal skin condition. In addition, this study does not distinguish between the effect of the SCN and the use of the new ostomy appliance. The DialogueStudy could not account for all the factors that influence QoL and skin condition, such as obesity (Nybaek et al, 2009b).

Conclusions

As will be discussed elsewhere in this supplement, the results from the DialogueStudy showed that evidence-based nursing, combined with the use of a double-layer adhesive appliance, SenSura, improved leakage, peristomal skin condition and QoL for people with an ostomy.

Conflicts of interest: *Some investigators will have received sponsorship or payment from Coloplast in relation to activities, such as conference attendance or consultancy, outside the DialogueStudy. Daniel Carter is an employee of Coloplast A/S. No particular conflicts of interest were reported by the other authors.*

Acknowledgments: *The authors thank Helle Aaes and Mette Kaad Jensen from Coloplast A/S and Drs Barbara Byth and David Collison from AXON Communications who provided medical writing services on behalf of Coloplast.*

Bosio G, Pisani F, Lucibello L, Fonti A, Scrocca A, Morandell C et al (2007) A proposal for classifying peristomal skin disorders: results of a multicenter observational study. *Ostomy Wound Manage* **53**(9): 38–43

Colwell JC, Goldberg M, Carmel J (2001) The state of the standard diversion. *J Wound Ostomy Continence Nurs* **28**(1): 6–17

Davis JS, Svavarsdottir MH, Pudlo M, Arena R, Lee Y, Jensen MK (2011) Factors impairing quality of life for people with an ostomy. *Gastrointestinal Nursing* **9**(2 Suppl): 14–18

English E, Claessens I, Martins L, Tavernelli K, Serrano JLV, Perrin A et al (2008) The Ostomy Skin Tool: a peristomal skin assessment tool. *WCET Journal* **28:** 1–20

Herlufsen P, Olsen AG, Carlsen B, Nybaek H, Karlsmark T, Laursen TN et al (2006) Study of peristomal skin disorders in patients with permanent stomas. *Br J Nurs* **15(16):** 854–62

Jemec GB, Martins L, Claessens I, Ayello EA, Hansen AS, Poulsen LH, Sibbald RG (2011) Assessing peristomal skin changes in ostomy patients: validation of the Ostomy Skin Tool. *Brit J Dermatol* **164**(2): 330–5

Martins L, Tavernelli K, Serrano JLC (2008) Introducing a peristomal skin assessment tool: The Ostomy Skin Tool. *WCET Journal* **28:** 8–13

Martins L, Ayello EA, Claessens I, Hansen AS, Poulsen LH, Sibbald R et al (2010) The Ostomy Skin Tool: tracking peristomal skin changes. *Br J Nurs* **19**(15): 932–4

Martins L, Samai O, Fernandez A, Urquart M, Hansen AS (2011) Maintaining healthy skin around an ostomy: peristomal skin disorders and self-assessment. *Gastrointestinal Nursing* **9**(2 Suppl): 9–13

Nybaek H, Lophagen S, Karlsmark T, Bang Knudsen D, Jemec GB (2009a) Stratum corneum integrity as a predictor for peristomal skin problems in ostomates. *Br J Dermatol* **162**(2): 357–61

Nybaek H, Bang Knudsen D, Norgaard Laursen T, Karlsmark T, Jemec GB (2009b) Skin problems in ostomy patients: a case-control study of risk factors. *Acta Derm Venereol* **89**(1): 64–7

Nybaek H, Knudson DB, Laursen TN, Karlsmark T (2010) Quality of life assessment among people with peristomal skin disease. *Eur J Gastroenterol Hepatol* **22**(2): 139–43

Porrett T, Novakova S, Schmitz K, Klimekova E, Aaes H (2011) Leakage and ostomy appliances: results from a large-scale, open-label study in clinical practice. *Gastrointestinal Nursing* **9**(2 Suppl): 19–23

Prieto L, Thorsen H, Juul K (2005) Development and validation of a quality of life questionnaire for patients with colostomy or ileostomy. *Health Qual Life Outcomes* **3:** 62

Ratliff CR, Scarano KA, Donovan AM, Colwell JC (2005) Descriptive study of peristomal complications. *J Wound Ostomy Continence Nurs* **32**(1): 33–7

Turnbull GB (2002) The position on preoperative stoma site positioning. *Ostomy Wound Manage* **48:** 22–4

Maintaining healthy skin around an ostomy: peristomal skin disorders and self-assessment

Abstract

Problems affecting the peristomal skin are common in people with an ostomy and are an important area of stoma care nurse intervention. The DialogueStudy documented the experiences of more than 3000 people with an ostomy, with a focus on quality of life (QoL) and peristomal skin condition. These factors were assessed using the Ostomy Skin Tool. At visit 1, 60% of participants had a skin disorder, with irritant contact dermatitis (48%) and mechanical trauma (21%) being the most common causes cited. Only 58% of participants with a skin disorder were aware of it. The mean DET score had improved (decreased) from 2.5 (±2.8) at visit 1 to 1.6 (±2.1) at visit 2, 6–8 weeks later (P<0.0001). The factors affecting peristomal skin included age, time since surgery, ostomy type, choice of appliance and leakage. The results demonstrate that the combination of evidence-based nursing practices and the use of a double-layer adhesive, SenSura (Coloplast A/S) improved peristomal skin condition in people with an ostomy.

In people with an ostomy, problems affecting the peristomal skin are common and can have a negative impact on quality of life (QoL) (Jemec et al, 2007). Stoma care nurses (SCNs) play an important role in the management of peristomal skin with an estimated one third of all patient visits to an SCN directly related to peristomal skin disorders (Nybaek et al, 2009). Leakage of ostomy effluent beneath the adhesive of an ostomy appliance is one of the main causes of peristomal disorders (Herlufsen et al, 2006). Other causes include (Herlufsen et al, 2006):

- Mechanical injuries (e.g. the stripping of the skin during removal of the ostomy appliance barrier)
- Infections
- Underlying skin diseases and immunological disorders (e.g. allergic contact dermatitis).

A mild peristomal skin disorder can quickly deteriorate into a more serious condition requiring medical attention if left unattended (Herlufsen et al, 2006). It is imperative that people with an ostomy regularly check the peristomal skin and seek professional advice in a timely manner if a deterioration in skin condition is observed.

Despite the prevalence of peristomal skin disorders and their impact on QoL, many people with an ostomy do not recognize that they have a peristomal skin disorder. In a Danish study, the OstomySkinStudy, researchers observed that 45% of participants (n=202) had a peristomal skin disorder; however, only 38% of those diagnosed by an SCN agreed they had a skin disorder (Herlufsen et al, 2006).

The DialogueStudy provided the opportunity to investigate the extent and types of peristomal skin problems, as well as participants' self-awareness of having a skin problem. During the study, SCNs used the Ostomy Skin Tool (discolouration, erosion, tissue overgrowth (DET)) to objectively record skin condition (Jemec et al, 2011).

Methods

Detailed descriptions of the DialogueStudy and the Ostomy Skin Tool are provided in this supplement by Andersen et al, 2011. Peristomal skin was assessed using the Ostomy Skin Tool (Martins et al, 2008). Two statistical analyses were carried out: the first on the factors that affected peristomal skin at visit 1 (baseline) and the second on the factors influencing the degree of change in peristomal skin condition between visits 1 and 2. The baseline analyses included clinically relevant factors such as:

- Personal information (e.g. age and gender)
- Ostomy characteristics (e.g. type of ostomy and reason for ostomy creation)

Lina Martins is clinical nurse specialist, advanced practice nurse, enterostomal therapy nurse, London Health Sciences Centre, London, Ontario, Canada. **Oirda Samai** is enterostomal therapist, Exern Consultations, Jean Marcel General Hospital, Traverse des Capucins, Brignoles, France. **Adelina Fernández** is enterostomal therapist nurse, Complejo Hospitalario Universitario de Vigo - CHUVI Vigo, Spain. **Mary Urquhart** is colorectal nurse specialist, Queen Margaret Hospital, Whitefield Road, Dunfermline, Fife, UK. **Anne Steen Hansen** is international senior project manager, Medical Marketing, Coloplast A/S, Denmark. **Email: lina.martins@lhsc.on.ca**

Key words

- Peristomal skin
- Ostomy
- Self-assessment
- Evidence-based nursing

This article has been subject to double-blind peer review

- Ostomy appliance (e.g. 1-piece or 2-piece and frequency of leakage)
- Health care-related factors (e.g. frequency of clinic visit before visit 1).

The analyses of the change in peristomal skin during the study period included two additional factors: Stoma-QoL value and DET score at baseline. An additional analysis of factors affecting the participant's peristomal skin self-assessment (how he/she perceived the health of his/her skin) included additional ostomy appliance-related items (e.g. feeling of confidence, pain at removal, erosion).

Results

Peristomal condition at baseline

At visit 1, 40% of participants had normal skin and 60% had a skin disorder. The most common cause of skin disorder was irritant contact dermatitis (48%) followed by mechanical trauma (21%) (*Figure 1*).

Peristomal skin disorder differed by type of ostomy (*Table 1*). People with an ileostomy had more skin disorders than those with a colostomy or urostomy. In the ileostomy group, 34.0% had normal skin compared with 42.8% of participants with a colostomy. Irritant contact dermatitis was the most common type of skin disorder for participants with an ileostomy, occurring in 35.4% of participants compared with 22.7% of participants with a colostomy.

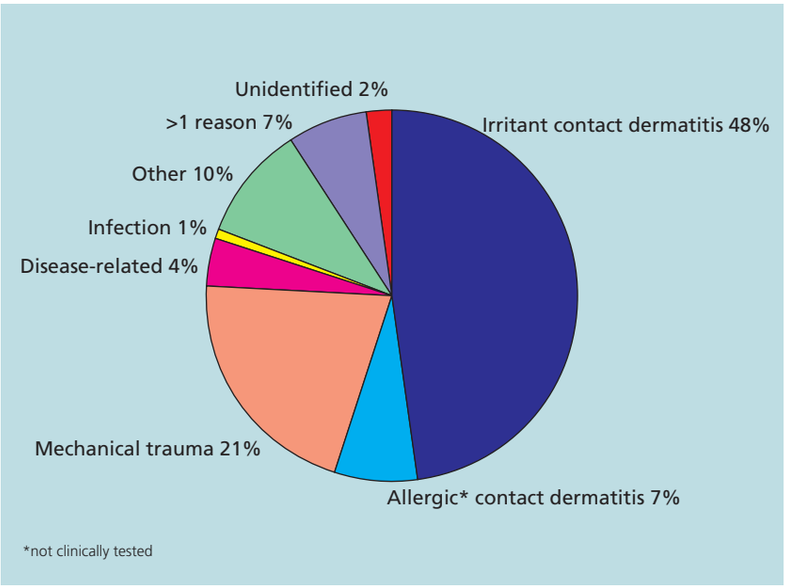


Figure 1. Distribution of peristomal skin disorders at visit 1.

Factors affecting peristomal skin condition at visit 1

A number of factors affected peristomal skin condition at visit 1 (*Table 2*). Of the personal factors tested, age had a small, but statistically significant effect on DET score (P=0.025). For every year of increasing age, the DET score at baseline was estimated to be 0.009 higher. Time since surgery also influenced peristomal skin condition at baseline, with an estimated increase in DET score of 0.017 (P=0.021) for each year since surgery was performed.

Three ostomy-related factors affected skin condition at visit 1: type of ostomy, reason for surgery and permanent versus temporary ostomy.

The mean DET score at baseline was significantly higher for participants with an ileostomy than for those with a colostomy (P=0.0042). Those with a urostomy had the highest DET score at baseline (3.27 compared with 2.38 for colostomy and 2.77 for ileostomy); however, this study was not powered to test for statistical significance in this group. The reason for surgery also had a significant influence: participants who had surgery because of diverticulitis had a significantly higher DET score at baseline (P=0.0196) than those with other reasons for surgery. The DET score at baseline was greater in participants with a temporary ostomy (P=0.0121).

Appliance-related factors also had an influence on DET score. Participants using a 2-piece ostomy appliance at visit 1 had a significantly higher DET score compared with people using a 1-piece appliance (P=0.0236). Similarly, participants using a convex baseplate had a higher DET score than those using a non-convex baseplate (P=0.0016). The frequency of leakage also had a significant influence on DET score at baseline (P<0.0001).

Other factors tested, including gender, Stoma-QoL scores at baseline, and frequency of clinic visits before visit 1, had no significant influence on DET score at baseline.

Change in peristomal skin condition from visit 1 to visit 2

Peristomal skin condition, as measured by the DET score, improved significantly during the study period. The mean DET score improved from 2.5 (±2.8) at visit 1 to 1.6 (±2.1) at visit 2 (P<0.0001). The mean DET score included participants with normal skin (DET=0). A similar, statistically significant reduction in DET score was observed in

people with a colostomy, ileostomy and urostomy (P<0.001). The largest reduction was seen in those with a urostomy (–2.4); however, this study was not powered to detect statistical significance in this group alone.

The improvement in DET score was greater for those participants who changed the type of ostomy appliance baseplate at visit 1. Participants who changed from a flat to a convex baseplate (n=129) had the greatest improvement in DET score (–2.3 points). Those who used a flat baseplate for the duration of the study (n=1884) exhibited a DET score reduction of 0.7.

At the end of the study, there was a significant improvement in the mean DET score with all types of peristomal skin disorders (P<0.0001) (*Figure 2*).

Table 1. Skin disorder at visit 1 by ostomy type

	Type of ostomy					
	Colostomy		Ileostomy		Urostomy*	
Skin problem	Participants	%	Participants	%	Participants	%
Normal	862	42.8	324	34.0	18	39.1
Irritant contact dermatitis	457	22.7	338	35.4	4	8.7
Allergic (not verified) contact dermatitis	81	4.0	37	3.9	4	8.7
Mechanical trauma	243	12.1	98	10.3	5	10.9
Disease related	31	1.5	28	2.9	–	–
Infection	11	0.5	4	0.4	–	–
Other skin disease, more than one reason, unidentified	323	16.0	121	12.7	14	30.4

*The number of participants with a urostomy was too small for statistical analysis.

Factors affecting a change in peristomal skin condition from visit 1 to visit 2

Statistical analysis of the results showed that three factors influenced the degree of change in peristomal skin condition during the study period: time since surgery, type of ostomy and the DET score at baseline. Of the personal factors tested, time since surgery predicted a greater DET change at the study end (P=0.0291). For every year since surgery, the improvement in the DET score at study end was reduced by 0.01 (i.e. those participants with newer ostomies showed a larger improvement in DET score at visit 2). Participants in the DialogueStudy were required to have their ostomy for ≥6 months. Those people with a colostomy demonstrated a greater decrease in DET score (0.95) than the ileostomy group (0.72) (P=0.011). Worse skin conditions (higher DET scores) at visit 1 correlated with greater improvement in skin conditions at visit 2 (P<0.0001). For each increment of DET score at baseline, there was an improvement in DET score by 0.553 at visit 2. All other factors analysed (age, gender, Stoma-QoL score, permanent or temporary ostomy, reason for ostomy creation, 1-piece or 2-piece appliance and frequency of clinic visits), had no statistically significant effect on the degree of change in DET score during the study period.

Participant self-assessment of peristomal skin disorders

At visit 1, all participants were asked if they had a skin disorder: 32% said 'yes, I have a peristomal skin disorder' (self-assessment). Of the 60% diagnosed by the SCN with a skin disorder at visit 1, 53% considered themselves to have a skin disorder. At the end of the study (visit 2), 47% of participants had a skin disorder and, of these, 47% considered themselves to have a skin disorder. The change in self-assessment from study start to study end was not statistically significant.

A correlation between DET score and self-assessment was observed: participants with higher DET scores were more likely to recognize they had peristomal skin disorder. At DET score 9, 80% of participants recognized that they had a skin disorder, compared with 50% of participants at DET score 4. Other factors that had a positive influence on self-assessment included female gender, having an ileostomy, a convex appliance, recent surgery, lower baseline Stoma-QoL, more leakage, less confidence in ostomy appliance and painful removal.

Discussion

The results from the DialogueStudy showed that 60% of participants had a skin disorder at visit 1 and almost half of these (48%) had irritant contact dermatitis. These results are similar to the estimated frequency of perisomal skin disorders of 18–55% previously reported (Colwell et al, 2001;

Table 2. Factors with statistically significant influence on baseline DET score

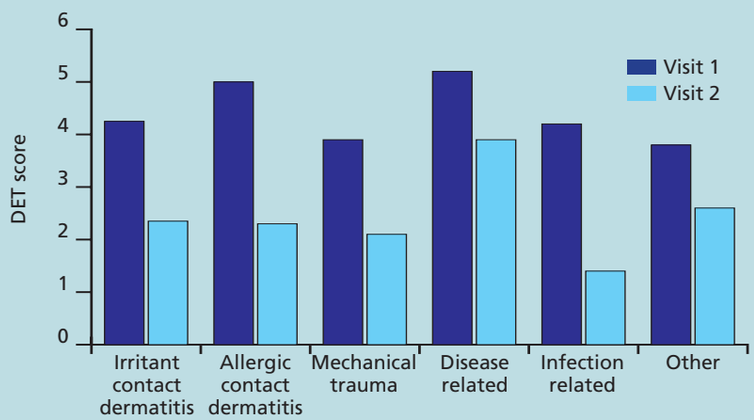
Continuous covariates

Factor	Increase in DET score	*P*-value
Per year since surgery	0.017	0.021
Per year of age	0.009	0.025

Categorical covariates

Factor	Category	DET score	*P*-value
Ostomy type	Colostomy	2.38	0.0042*
	Ileostomy	2.77	
	Urostomy	3.27	
Product type	1-piece	2.37	0.0236
	2-piece	2.64	
Convexity	Flat	2.43	0.0016
	Convex	2.80	
Leakage	Always	3.63	<0.0001†
	Often	3.80	
	Sometimes	2.71	
	Rarely	1.84	
	Never	1.73	
Reason for surgery	Ulcerative colitis	2.48	0.0196‡
	Cancer	2.44	
	Crohn's	2.85	
	Diverticulitis	3.02	
	Other	2.45	
Permanent versus temporary	Permanent	2.46	0.0121
	Temporary	2.84	

**P*-value refers to colostomy versus ileostomy; †*P*-value refers to all categories of leakage; ‡*P*-value refers to those with diverticulitis only.
DET= discolouration, erosion/ulceration, tissue overgrowth



Improvement was statistically significant (*P*<0.0001) for all categories.
DET=discolouration, erosion/ulceration, tissue overgrowth

Figure 2. The mean DET scores within each peristomal skin problem category at study start and study end.

Herlufsen et al, 2006) highlighting the magnitude of this problem for people with an ostomy.

Similar to the OstomySkinStudy (Herlufsen et al, 2006), the DialogueStudy also found that participants with an ileostomy had the highest proportion of peristomal skin disorders. Herlufsen et al (2006) suggested that this is due to the peristomal skin having increased contact with effluent that is more corrosive than colostomy effluent (Herlufsen et al, 2006). This correlates with the high proportion of cases of irritant contact dermatitis in people with an ileostomy, compared with a colostomy in the DialogueStudy.

During the DialogueStudy, participants visited an SCN twice and were provided with advice on maintaining healthy skin and using an appropriate ostomy appliance (SenSura). At the end of the study, results demonstrated a significant improvement in DET score, and more participants had healthy skin across all types of ostomies. Although only certain skin conditions might be expected to improve over a short study period (6–8 weeks) by active intervention, all types of peristomal skin disorders showed an improvement in the DialogueStudy. These data indicate the positive effect of nurse intervention and the appropriate appliance.

A number of factors were shown to significantly influence the DET score at visit 1. These included age, years since surgery, reason for surgery, ostomy type, ostomy appliance, leakage and whether the ostomy was temporary or permanent. The association of leakage and peristomal skin problems is well established, so it is not surprising to note that this was shown to be a highly significant (*P*<0.0001) factor influencing DET score at study start.

The importance of using an appropriate ostomy appliance for maintaining healthy peristomal skin is well established. Convex baseplates may be recommended when leakage is a problem, remaining mindful of the potential risk of pressure damage to the peristomal area that is sometimes seen with use of a convex baseplate. In this study, participants who switched from a flat to a convex appliance at visit 1 had the greatest improvement in DET score (–2.3) compared with other groups. This suggests that the SCN played an important role in assessing the care requirements and in selecting the appropriate type of appliance for the participant.

While several factors had a significant influence

on DET score at visit 1, only a few factors influenced the degree of change in DET score by visit 2. Participants with the highest DET score or the most severe skin disorders were more likely to have an improved DET score by the study end compared with those with mild skin conditions. This may be due to an increased room for improvement in severe skin disorders that score 11 or 12 with the Ostomy Skin Tool, compared with milder disorders that score 4 or 5.

In the DialogueStudy, 58% of participants with a skin disorder were aware they had a skin disorder at visit 1. This figure is higher than the 38% reported in the OstomySkinStudy (Herlufsen et al, 2006). Factors that increased the likelihood of a participant's awareness of a skin disorder by self-assessment included a lower quality of life score, increased ostomy leakage, less confidence in their ostomy appliance, and painful removal. Eighty eight per cent of participants with a severe skin disorder in the DialogueStudy recognized they had a problem compared with 44% in the OstomySkinStudy. Over 40% of participants with a skin disorder were not aware they had a problem and, therefore, would not have consulted the SCN. This finding suggests that SCNs need to continue to educate people with an ostomy about normal versus abnormal peristomal skin presentations and when to seek assistance from an SCN.

Conclusions

Peristomal skin conditions are common in people with an ostomy. By providing objective assessments of skin condition, the Ostomy Skin Tool is valuable in identifying peristomal skin disorders and in monitoring the effect of interventions. Other potential benefits of the Ostomy Skin Tool for clinical practice include provision of a common language to describe skin condition and support for collaboration between different health professionals, in different clinical settings (Martins et al, 2008).

The results of the DialogueStudy show that SCNs can help improve peristomal skin condition in people with an ostomy. This can be expected to minimize the negative impact of skin disorders on QoL, and may reduce health-care costs. The results highlight a possible gap in education for people with an ostomy around awareness of their peristomal skin condition and perhaps a need for a self-assessment tool. The DialogueStudy also indicated a requirement for periodic and ongoing follow-up assessments for people with an ostomy. Resources, in the form of expert SCNs and ostomy care clinics, may need to be augmented to meet this clinical requirement. Overall, these results show that evidence-based nursing practices in combination with a double-layer adhesive, SenSura, improved peristomal skin condition in people with an ostomy.

Conflicts of interest: *Some investigators will have received sponsorship or payment from Coloplast in relation to activities, such as conference attendance or consultancy, outside the DialogueStudy. Lina Martins is a member of the Global Coloplast Ostomy Forum. Anne Steen Hansen is an employee of Coloplast A/S. No particular conflicts of interest were reported by the other authors.*

Acknowledgments: *The authors thank Helle Aaes and Mette Kaad Jensen from Coloplast A/S and Drs Barbara Byth and David Collison from AXON Communications who provided medical writing services on behalf of Coloplast.*

Andersen BD, Van Keizerswaard P, Castro MM, English E, Carter D (2011) Introduction to the DialogueStudy: methods and baseline demographic findings. *Gastrointestinal Nursing* **9**(2 Suppl): 4–8

Colwell JC, Goldberg M, Carmel J (2001) The state of the standard diversion. *J Wound Ostomy Continence Nurs* **28:** 6–17

Herlufsen P, Olsen AG, Carlsen B, Nybaek H, Karlsmark T, Laursen TN et al (2006) Study of peristomal skin disorders in patients with permanent stomas. *Br J Nurs* **15:** 854–62

Jemec GB, Nybaek H, Karlsmark T, Herlufsen P, Olsen AG, Carlsen B (2007) Do peristomal skin disorders affect quality of life? Poster presented at the ECET Conference in Salzburg, Austria, 17–20 June

Jemec GB, Martins L, Claessens I, Ayello EA, Hansen AS, Poulsen LH, Sibbald RG (2011) Assessing peristomal skin changes in ostomy patients: validation of the Ostomy Skin Tool. *Brit J Dermatol* **164**(2): 330–5

Martins L, Tavernelli K, Serrano JLC (2008) Introducing a peristomal skin assessment tool: The Ostomy Skin Tool. *WCET* **28:** 8–13

Nybaek H, Lophagen S, Karlsmark T, Bang Knudsen D, Jemec GB (2009) Stratum corneum integrity as a predictor for peristomal skin problems in ostomates. *Br J Dermatol* **162:** 357–61

Factors impairing quality of life for people with an ostomy

Abstract

The DialogueStudy documented real-life experiences of the use of a double-layer adhesive ostomy appliance, SenSura (Coloplast A/S) with a focus on quality of life (QoL) and peristomal skin conditions. The overall mean QoL measured using the Stoma-QoL questionnaire improved from 58.1 ±10.2 at visit 1 to 59.9 ±9.9 at visit 2, 6–8 weeks later ($P<0.0001$). Factors correlating with QoL at visit 1 included leakage from the ostomy appliance, peristomal skin condition, age, gender and time since surgery. Three factors correlated with the improvement in QoL from visit 1 to visit 2: male gender, baseline leakage level and baseline Stoma-QoL value. As frequency of leakage influenced both the baseline QoL and the change in QoL, minimizing leakage is an important goal for stoma care nurses to improve the QoL for people with an ostomy.

Janet Stoia Davis is a wound ostomy continence nurse consultant, Stoia Consultants, CA, USA. **Margrét Hrönn Svavarsdóttir** is a lecturer, School of Health Sciences, Faculty of Nursing, University of Akureyri, Iceland. **Małgorzata Pudło** Bandagist, The Nicolas Copernicus State Hospital in Koszalin, Department of General, Oncological and Vascular Surgery, Poland. **Raimondo Arena** head nurse, Oncological Surgery, Nesima New Hospital - Catania, Italy **Yunjin Lee** is oncological and wound ostomy continence nurse, Colorectal Cancer Clinic, Severance Hospital Yonsei University Health System, Seodaemun-Gu, Seoul, Korea. **Mette Kaad Jensen** is international project manager, Coloplast A/S, Copenhagen, Denmark. **Email: janetsbc@sbcglobal.net**

Key words

- Ostomy
- Peristomal skin
- Quality of life
- Nursing practice
- Stoma

This article has been subject to double-blind peer review

Bodily function and emotional wellbeing are both affected following an ostomy. The person with an ostomy may have a number of concerns, including leakage, sexual problems, fear of odour (Pieper and Mikols, 1996; Nugent et al, 1999; Richbourg et al, 2007) and changes in body appearance (Pieper and Mikols, 1996). Sleep and mood may also be affected (Richbourg et al, 2007). Anxiety over ostomy complications could result in changes in lifestyle and affect quality of life (QoL) (Nugent et al, 1999).

Peristomal skin disorders may also have negative implications for QoL (Pittman et al, 2008; Nybaek et al, 2010). As well as discomfort and pain, deterioration of peristomal skin can cause the ostomy appliance to fail to adhere properly. This increases the risk of leakage and the necessity for frequent and unplanned appliance changes (Nybaek et al, 2010). Intervention from a nurse trained in ostomy care can improve QoL (Karadag et al, 2003; Marquis et al, 2003).

Methods

Detailed descriptions of the DialogueStudy and the Ostomy Skin Tool (discolouration, erosion, tissue overgrowth (DET) score) are provided in the article by Andersen et al (2011) in this supplement. QoL was measured using the Stoma-QoL (Prieto et al, 2006) and analysed using covariate analysis to assess the impact of clinically relevant factors on QoL. Two statistical analyses were carried out: the first on the factors that affected QoL at baseline (visit 1) and the second on the factors that influenced the change in the Stoma-QoL value over the study period. Twelve clinically relevant factors were analysed at baseline: time since surgery, age, gender, ostomy type, planned versus unplanned ostomy, reason for ostomy creation, 1-piece or 2-piece, convex versus non-convex, leakage level, DET score at baseline, time since visit to an SCN, and frequency of clinic visit prior to study. As is described below, nine of these factors were included in the analysis of change from visit 1 to visit 2, with the addition of Stoma-QoL score at visit 1.

Results

Mean QoL for the whole study population, improved from visit 1 to visit 2 (*Table 1*). Improvements in mean Stoma-QoL scores were observed in participants with the lowest (worst) mean scores at baseline (visit 1) (*Table 2*). Participants with the lowest Stoma-QoL scores at visit 1 had a mean improvement in Stoma-QoL score of 4.9 points at visit 2. Equivalent improvements were seen when participants were grouped by ostomy type (*Figure 1*). Participants with an intermediate (medium) baseline Stoma-QoL score showed an improvement of 2 points by visit 2. The participants with the highest (best) Stoma-QoL scores at baseline had an unchanged mean Stoma-QoL score of 66. Ten percent of all participants improved their QoL by more than 10 points (confidence interval 9%–11%).

Factors influencing quality of life at baseline

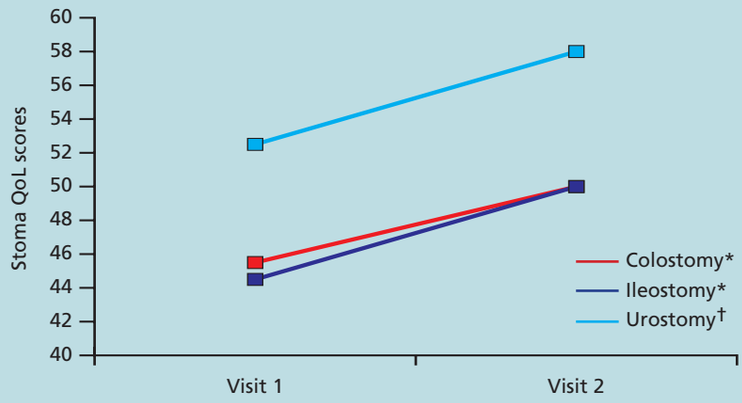
As is described below, eight of the twelve clinically relevant factors had a significant (*P*<0.001) influence on Stoma-QoL values at baseline (*Table 3*). Mean Stoma-QoL values for all factors, excluding the urostomy group, were within a limited range (55.6–59.8) except for leakage (52.6–62.5).

Age, gender and time since surgery all had a significant effect on QoL at baseline. For each year, the Stoma-QoL value increased by 0.053 (*P*=0.0004). Males had a higher Stoma-QoL value at baseline (59.6) than females (56.6) (*P*<0.001) (*Table 3*). For each year that had passed since surgery, the Stoma-QoL value increased by 0.088 (*P*=0.0017).

Ostomy factors also influenced QoL at visit 1. Participants whose ostomy creation was planned had a higher Stoma-QoL than those whose surgery was unplanned (*Table 3*). Participants whose ostomy was created because of ulcerative colitis were estimated to have a mean Stoma-QoL value 2.6 higher than the other groups (*P*=0.0018). In participants whose ostomy was created because of Crohn's disease, diverticulitis, cancer or other reasons, there were no significant differences in the Stoma-QoL value at baseline. Other ostomy factors (type, and permanent or temporary ostomy) did not influence QoL at baseline.

Leakage had a significant effect on Stoma-QoL at visit 1. For frequency of leakage, the mean Stoma-QoL at baseline differed by 9.9 points between the worst ('always') and best ('never') categories (*P*<0.0001) (*Table 3*). For every category of less-frequent leakage, the estimated Stoma-QoL score increased by 2.172 (*P*<0.0001). Of the other factors related to the performance of the ostomy appliance, only peristomal skin condition at visit 1 correlated with QoL. For each point that the discolouration, erosion/ulceration, tissue overgrowth (DET) score (measure of peristomal skin condition generated using the Ostomy Skin Tool) increased (i.e. more severe) at visit 1, the Stoma-QoL value decreased by 0.322 (*P*<0.0001). The type of ostomy appliance (1-piece or 2-piece) or level of convexity (convex or flat) did not influence QoL at baseline.

Factors related to the participants' health care also affected QoL at baseline. Participants who had visited an SCN less than 6 months ago were estimated to have a lower Stoma-QoL than participants who visited a SCN more than 1 year ago (*Table 3*). If the visit was less than 1 month ago, the Stoma-QoL was estimated to be 2.25 points lower (*P*=0.0007) and 1.298 points lower if the visit was 1–6 months ago (*P*=0.24). The time since the last visit did not have a statistically significant effect on the participants' peristomal skin condition or the frequency of leakage at visit 1. The regularity of clinic visits before visit 1 did not influence QoL at baseline.



* *P*<0.0001

† This group was too small for statistical analysis (n=9) and people with urostomy were not included in the validation of the Stoma-QoL questionaire

Figure 1. Change in Stoma-QoL scores for the participants with the lowest Stoma-QoL scorres at visit 1, grouped by ostomy type.

Table 1. Stoma-QoL at visit 1 and visit 2, entire population

	Stoma-QoL visit 1 Current appliance	Stoma-QoL visit 2 Double-layer adhesive*
Stoma-QoL	58.1 ±10.2	59.9 ±9.9
Range	11.5–89.0	18.5–89.0
N	2924	2710
P-value (visit 1 to visit 2)	*P*<0.0001	

* Double-layer adhesive = SenSura, Coloplast A/S

Table 2. Stoma-QoL at visit 1 and visit 2, divided into low, medium and high baseline QoL (mean Stoma-QoL values)

QoL at baseline *		Stoma-QoL visit 1 Current appliance	Stoma-QoL visit 2 Double-layer adhesive†
<25%	(low)	45.3 ± 6.2	50.2 ± 8.0‡
25%–50%	(medium)	55.3 ± 1.9	57.3 ± 5.9‡
≥50%	(high)	65.9 ± 8.8	66.0 ± 7.4

*Participants were grouped based on baseline Stoma-QoL scores into the 25% with the lowest scores, the 25% with intermediate scores and the 50% with the highest scores

†Double-layer adhesive = SenSura, Coloplast A/S

‡*P*<0.0001 visit 1 to visit 2

Table 3. Average QoL-score for each item in Stoma QoL at baseline

Factor	Number of participants	Mean Stoma-QoL, visit 1
Personal factors		
Age (years)		
18–30	84	56.5
31–50	447	56.6
51–70	1413	57.6
71–99	962	59.6
Gender		
Male	1430	59.6
Female	1492	56.6
Time since surgery (years)		
0–1	668	56.5
1–3	864	58.0
3–10	897	58.4
>10	495	59.8
Ostomy factors		
Planned ostomy		
Yes	2114	58.6
No	799	56.7
Reason for ostomy creation		
Ulcerative colitis	343	59.7
Cancer	1706	58.5
Diverticulitis	173	57.8
Crohn's disease	246	55.8
Other	421	56.4
Ostomy type		
Colostomy	1950	58.5
Ileostomy	928	57.0
Urostomy*	44	62.7
Permanent ostomy		
Yes	2527	58.4
No	389	55.6
Ostomy appliance factors		
Leakage level		
Always	118	52.6
Often	434	53.6
Sometimes	1115	57.8
Rarely	876	59.5
Never	369	62.5
Coupling type		
1-piece	1390	58.5
2-piece	1493	57.7
Convexity		
Convex	661	57.8
Non-convex	2202	58.2
Health-care factors		
Time since visit to with a stoma care nurse		
Less than 1 month	605	56.5
1–6 months	1137	58.7
6–12 months	367	58.2
More than 12 months	709	58.6
Frequency of clinic visit before study		
Never	438	57.5
Only when needed	1540	57.8
On regular basis	942	58.7

*People with urostomy were not included in the validation of the Stoma-QoL questionnaire

Factors influencing the change in quality of life from visit 1 to visit 2

Three factors had a significant influence on change in Stoma-QoL values from visit 1 to visit 2: gender, baseline leakage level and baseline Stoma-QoL value.

Males had a greater increase in the Stoma-QoL value (2.2) than females (1.5) (P=0.0059). Leakage had a significant influence on the change in QoL (*Table 4*). The highest baseline leakage frequencies had the lowest baseline Stoma-QoL values. The Stoma-QoL score improved significantly from visit 1 to visit 2 for all baseline leakage levels (P<0.001). The greatest increase was observed at the higher leakage levels (P<0.001): 4.8 points for the 'always', 3.3 for the 'often', 1.8 points for the 'sometimes' categories 1.1 for the 'rarely' and 0.8 for 'never'). The change in Stoma-QoL decreased (P=0.0267) for every category for which leakage became less frequent. The estimated decrease in Stoma-QoL score was an average 0.306 per leakage level. For those participants who experienced an improvement in the level of leakage between visit 1 and visit 2, the estimated Stoma-QoL improved by 1.090 (P<0.0001) (*Table 4*).

For each 1-point higher Stoma-QoL value at baseline, the change in Stoma-QoL value decreased by 0.271 (P<0.0001). Therefore, the more room there was for improvement at visit 1, the more the Stoma-QoL score improved between visits 1 and 2.

There were no significant influences on the change in QoL for the remaining factors. Although peristomal skin disorder influenced QoL at baseline, participants with and without a peristomal skin disorder at visit 1 experienced an improvement in QoL by visit 2.

Discussion

Over the 6–8 week study period, QoL, as measured by the Stoma-QoL, increased significantly for the participants with the lowest (worst) baseline Stoma-QoL scores. It is important to evaluate the clinical significance of Stoma-QoL improvements, because statistically significant differences are not necessarily equivalent to a clinically significant improvement (Kald et al, 2008). Of the clinically relevant factors, leakage was the most important. The Stoma-QoL baseline values for the different leakage frequencies differed by 9.9 points from 'always' to 'never'. Therefore a Stoma-QoL

improvement of even a few points could be considered as a clinically significant improvement. Participants with the lowest baseline QoL achieved this degree of improvement, indicating that the combination of SCN intervention, evidence-based nursing and an appropriate appliance can make a difference in QoL for some people with an ostomy over a short period. It is reasonable to conclude that participants entering the study with high Stoma-QoL scores would also have improved over a longer time than the 6–8 week study period.

The analysis considered a number of clinically relevant factors and explored their correlation with QoL at baseline and on the change in QoL. SCNs have long suspected from their clinical practice that leakage influences QoL. Pittman et al (2008) showed evidence of the role of leakage on QoL. In this study, leakage proved to be the most pronounced factor influencing QoL. A significant correlation between leakage and Stoma-QoL value was seen at visit 1. The lower the level of baseline leakage, the higher the mean Stoma-QoL score at visit 1. The influence of leakage was substantially greater than any of the other clinically relevant factors analysed in the study. Leakage level also influenced the change in Stoma-QoL value from visit 1 to visit 2. The greatest improvement in Stoma-QoL value was observed in participants who reported the highest leakage levels, and who represents the group with the greatest room for improvement. Participants who experienced less leakage at visit 2 than visit 1 experienced a significant mean improvement in QoL of 1 point per leakage level improvement. Leakage is influenced by many factors, including stool characteristics (in turn influenced by, for example, chemotherapy or short bowel syndrome), body contours and physical characteristics of the ostomy.

Two other factors had a statistically significant influence on the change in QoL: male gender and baseline Stoma-QoL score. Male participants had a greater increase in the Stoma-QoL value (2.2) than female participants (1.5) (P=0.0059) and also had higher scores at baseline. The poorer QoL in females with an ostomy compared with males has been reported elsewhere and is consistent with sex differences observed in adaptation to chronic illness (Krouse et al, 2009). As noted above, participants with lower QoL at visit 1, those most in need of improvement, showed the greatest increase in Stoma-QoL scores.

Table 4. Mean Stoma-QoL values at visits 1 and 2 by leakage level at baseline

Leakage level at visit 1 (baseline)	Stoma-QoL, visit 1	Stoma-QoL, visit 2	Change in Stoma-QoL
Always			
Stoma-QoL	52.6 ±9.7	57.0 ±10.3	4.8 ±8.2
Range	28.2–74.6	28.2–89.0	-12.3–44.7
n	118	107	105
P-value	<0.001		
Often			
Stoma-QoL	53.6 ±10.4	57.3 ±9.4	3.3 ±6.9
Range	11.5–89.0	18.5–89.0	-16.0–40.1
n	434	396	392
P-value	<0.001		
Sometimes			
Stoma-QoL	57.8 ±9.5	59.4 ±9.6	1.8 ±6.5
Range	22.7–89.0	18.5–89.0	-18.6–35.6
n	1115	1036	1025
P-value	<0.001		
Rarely			
Stoma-QoL	59.5 ±9.9	60.6 ±10.1	1.1 ±6.8
Range	18.5–89.0	22.7–89.0	-39.2–28.7
n	876	812	800
P-value	<0.001		
Never			
Stoma-QoL	62.5 ±10.4	63.4 ±9.7	0.8 ±7.0
Range	18.5–89.0	30.3–89.0	-27.2–23.9
n	369	348	339
P-value	<0.001		

Poor peristomal skin condition at visit 1 correlated with decreased Stoma-QoL values. For each point the DET score at baseline was higher, the Stoma-QoL value decreased by 0.322 (P<0.0001). Peristomal skin conditions are often a result of leakage problems which, as discussed above, are strongly correlated with QoL. However, the degree of peristomal skin condition at visit 1 did not affect the degree of improvement seen at visit 2. These results suggest SCN intervention can play an important role. Future research may confirm the role of intervention, which may include any of several factors, such as choosing the right appliance, counselling and emotional support, and tips on managing an ostomy in daily life. The benefit of the combination of evidence-based nursing and double-layer adhesive, SenSura, in the DialogueStudy has further implications than improving peristomal skin condition.

Longer time passed since surgery was related

to better QoL at baseline, indicating that QoL increases over time as people adjust to having an ostomy. Each year of age at baseline corresponded to an increase in the QoL score. This is an important finding for individuals that have a new ostomy and can be an encouragement as they look into the future of living with an ostomy.

Of the ostomy-related factors, having planned stoma surgery predicted better QoL at visit 1 than having unplanned surgery. Haugen et al (2006) noted that people whose surgery is planned tend to have better adjustment to the ostomy, so would be expected to have better QoL. Ulcerative colitis was the only reason for ostomy creation with a significantly higher baseline Stoma-QoL. This is presumably because the participants no longer suffer from the disease.

The baseline Stoma-QoL value was lower for participants who had seen their SCN more recently. This could indicate that ostomy-related problems, which had a negative effect on QoL, prompted the participant to consult a SCN. However, the time since last consultation did not have a statistically significant effect on either peristomal skin condition or degree of leakage at visit 1.

Conclusions

The DialogueStudy showed that people with an ostomy and low baseline QoL experienced a clinically significant improvement in QoL over a 6–8 week period after consultation with a SCN and use of a double-layer adhesive ostomy appliance, SenSura. The Stoma-QoL includes 20 factors, including appliance-specific, personal and relationship factors. It is difficult to impact on relationship factors over the 6–8 week study period; however, a significant effect on QoL was observed over this short period of time and for people who have had their ostomy for 6 months or more. Of the clinically relevant factors affecting QoL, leakage was the most important. Frequency of leakage influenced baseline QoL and change in QoL. It is important for SCNs to consider all these factors as well as peristomal skin condition and the ostomy appliance to minimise leakage and to improve the QoL for people with an ostomy.

Conflicts of interest: *Some investigators will have received sponsorship or payment from Coloplast in relation to activities, such as conference attendance or consultancy, outside the DialogueStudy. Mette Kaad Jensen is an employee of Coloplast A/S. No particular conflicts of interest were reported by the other authors.*

Acknowledgments: *The authors thank Helle Aaes from Coloplast A/S and Drs Barbara Byth and David Collison from AXON Communications who provided medical writing services on behalf of Coloplast.*

Andersen BD, Van Keizerswaard P, Castro MM, English E, Carter D (2011) Introduction to the DialogueStudy: methods and baseline demographic findings. *Gastrointestinal Nursing* **9**(2 Suppl): 4–8

Haugen V, Bliss DZ , Savik K (2006) Perioperative factors that affect long-term adjustment to an incontinent ostomy. *J Wound Ostomy Continence Nurs*, **33**(5): 525-35

Kald A, Juul KN, Hjortsvang H, Sjodahl RI (2008) Quality of life is impaired in patients with peristomal bulging of a sigmoid colostomy. *Scand J Gastroenterol,* **43**(5): 627-33

Karadag A, Mentes BB, Uner A, Irkorucu O, Ayaz S, Ozkan S (2003) Impact of stomatherapy on quality of life in patients with permanent colostomies or ileostomies. *Int J Colorectal Dis*, 18(**3**): 234-8

Krouse RS, Herrinton Lj, Grant M, Wendel CS, Green SB, Mohler MJ, et al. (2009) Health-related quality of life among long-term rectal cancer survivors with an ostomy: manifestations by sex. *J Clin Oncol*, **27**(28): 4664-70

Marquis P, Marrel A, Jambon B (2003) Quality of life in patients with stomas: the Montreux Study. *Ostomy Wound Manage*, **49**(2): 48-55

Nugent KP, Daniels P, Stewart B, Patankar R, Johnson CD (1999) Quality of life in stoma patients. *Dis Colon Rectum*, **42**(12): 1569-74

Nybaek H, Knudson DB, Laursen TN, Karlsmark T (2010) Quality of life assessment among people with peristomal skin disease. *Eur J Gastroenterol Hepatol*, **22** (2):139-43

Prieto L, Thorsen H, Juul K (2005) Development and validation of a quality of life questionnaire for patients with colostomy or ileostomy. *Health Qual Life Outcomes*, **3**:62

Pieper B and Mikols C (1996) Predischarge and postdischarge concerns of persons with an ostomy. *J Wound Ostomy Continence Nurs,* **23**(2):105-9

Pittman J, Rawl SM, Schmidt CM, Grant M, Ko CY, Wendel C, et al (2008) Demographic and clinical factors related to ostomy complications and quality of life in veterans with an ostomy. *J Wound Ostomy Continence Nurs*, **35**(5): 493-503

Richbourg L, Thorpe JM & Rapp CG (2007) Difficulties experienced by the ostomate after hospital discharge. *J Wound Ostomy Continence Nurs*, **34**(1):70-9

Leakage and ostomy appliances: results from a large-scale, open-label study in clinical practice

Leakage from an ostomy appliance impairs peristomal skin integrity and quality of life (QoL). The proportion of participants who reported that they 'never' had leakage increased from 13% at visit 1 (i.e. with their pre-study appliance) to 36% at visit 2 (i.e. after using the double-layer adhesive appliance, SenSura (Coloplast A/S)) (P<0.0001). The proportion of participants reporting that they 'never' had unplanned changes increased from 12% at Visit 1 to 34% at visit 2 (P<0.0001). The double-layer adhesive appliance, SenSura, in conjunction with advice/intervention from a stoma care nurse (SCN), was superior to the pre-study appliance across all performance parameters (P<0.0001), including adhesion, flexibility and erosion. Higher leakage frequency at baseline correlated with worse peristomal skin (P<0.0001). Peristomal skin improved from visit 1 to visit 2, across all leakage frequencies. The use of an appropriate double-layer adhesive appliance in conjunction with SCN intervention, reduced leakage and improved peristomal skin conditions.

It is important for people with an ostomy to maintain healthy peristomal skin because problems associated with leakage and skin irritation can negatively affect quality of life (QoL) (Pittman et al, 2008). Risk factors for leakage include a higher body mass index (BMI) (Arumugam et al, 2003), an irregular body surface with folds and scarring (Redmond et al, 2009), and a poorly sited (Turnbull, 2002) or poorly created ostomy (Barr, 2004; English and Claessens, 2008).

An important aspect of ostomy care is the correct choice of ostomy appliance and accessories. In randomized clinical studies of people with a colostomy, the double-layer adhesive, SenSura's (Coloplast A/S) range of ostomy appliances compared favourably with established appliances in minimizing usage problems (Voergaard et al, 2007; Welser et al, 2009). SenSura was perceived to be more secure and had better adhesion and flexibility, less seeping, and necessitated fewer unplanned changes than the other appliances (Voergaard et al, 2007; Welser et al, 2009).

Methods

Detailed methodology is provided in the Introduction article in this supplement (Andersen et al, 2011). At visit 1, participants completed the Ostomy Appliance Questionnaire on their pre-study appliance. A stoma care nurse (SCN) performed an initial skin evaluation using the Ostomy Skin Tool (Martins et al, 2010). (measured by the discolouration, erosion, tissue overgrowth (DET) score). Participants were given an appropriate double-layer adhesive appliance, SenSura, and advice on skin care, correct product sizing and accessories. At visit 2 (6–8 weeks later), participants completed the Ostomy Appliance Questionnaire on the double-layer adhesive appliance, SenSura, and their skin was re-evaluated using the Ostomy Skin Tool.

The Ostomy Appliance Questionnaire was developed by Coloplast A/S, in collaboration with a global panel of expert SCNs, as part of the DialogueStudy case report form. It was used to assess different performance parameters: leakage, unplanned changes, confidence in security, pain at removal, adhesion during use, absorption of adhesive, erosion and flexibility.

Changes in leakage, appliance performance parameters, and the relationship between leakage frequency and peristomal skin conditions (Ostomy Skin Tool; Martins et al, 2010) were tested for statistical significance.

Results

Leakage-related product evaluation

The double-layer adhesive appliance used for this study was superior to the pre-study appliance on two leakage-related performance parameters: leakage and unplanned changes (P<0.0001)

Theresa Porrett is nurse consultant in coloproctology, Homerton University Hospital NHS Foundation Trust, London, City University London, London, UK. **Svatava Nováková** is head nurse, surgery department and stoma nurse, Regional Health Corporation, Masaryk Hospital, Ústí nad Labem, Czech Republic. **Katrin Schmitz** is key account manager, DZS GmbH - Gesundheitszentrum Lang, Dinslaken, Germany. **Emilia Klimekova** is head nurse, surgical department, Žilina Hospital and Clinic, Žilina, Slovakia. **Helle Aaes** is international senior scientific manager, Coloplast A/S, Humlebæk, Denmark. **Email: Theresa.Porrett@homerton.nhs.uk**

Key words
- Leakage
- Ostomy skin tool
- Peristomal skin complications
- Double layer adhesive appliance
- Stoma–QoL questionnaire

This article has been subject to double-blind peer review

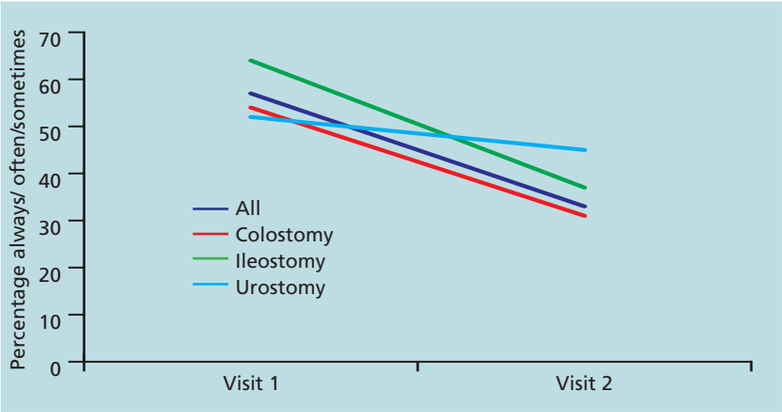


Figure 1. Proportion of participants with an ostomy reporting that they had leakage 'always', 'often' or 'sometimes' at visit 1 and visit 2. The change from visit 1 to visit 2 was statistically significant (P<0.0001) for all and the subgroups: colostomy and ileostomy. The urostomy group was too small for a statistical analysis.

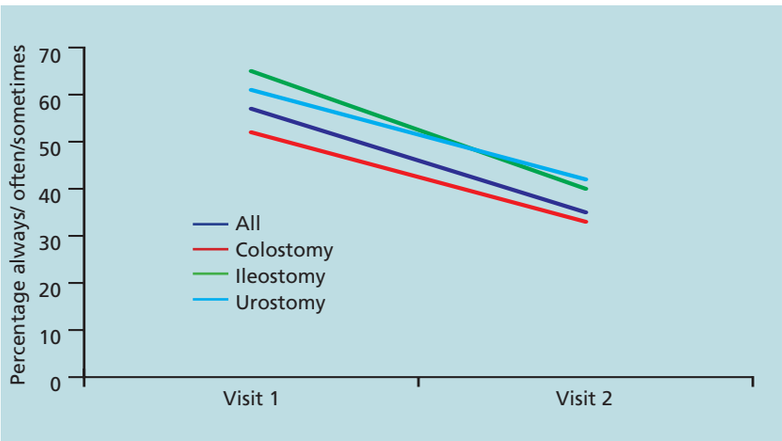


Figure 2. Proportion of participants with an ostomy reporting that they had unplanned changes 'always', 'often' or 'sometimes' at visit 1 and visit 2. The change from visit 1 to visit 2 was statistically significant (P<0.0001) for all and the subgroups: colostomy and ileostomy. The urostomy group was too small for a statistical analysis.

(*Table 1*). The proportion of participants who reported 'never' having had leakage increased from 13% at visit 1 with their pre-study appliance to 36% at visit 2 after using the study appliance (P<0.0001). The proportion of participants reporting that they 'never' had unplanned changes increased from 12% at visit 1 to 34% at visit 2 (P<0.0001).

Overall, the proportion of participants with an ostomy who reported that they 'always', 'often' or 'sometimes' had leakage decreased over the course of the study, from 57% at visit 1 to 32% at visit 2 (P<0.0001). The proportion of participants with an ostomy who reported that they 'always', 'often' or 'sometimes' had unplanned changes decreased from 56% at visit 1 to 35% at visit 2 (P<0.0001).

Extent of leakage and unplanned changes based on types of ostomy and base plate

At visit 1, participants with an ileostomy had more leakage and unplanned changes than those with a colostomy or urostomy (*Figure 1*); however, at visit 2, the ileostomy group had a slightly greater reduction in the frequency of leakage than the colostomy group (P<0.0001). Participants with a urostomy had only a modest reduction in the frequency of leakage from visit 1 to visit 2; however, the number of people in this group was relatively small (n=46) and therefore a statistical analysis was not performed. At visit 2, the frequency of unplanned changes had reduced by a similar amount across the three ostomy groups (*Figure 2*).

Before study entry, the majority of participants were using an appliance with a flat base plate

Table 1. Distribution of answers from all study participants to questions relating to the frequency of leakage and unplanned changes at visit 1 (pre-study appliance) and visit 2 (SenSura)

Question	Visit	'Always'	'Often'	'Sometimes'	'Rarely'	'Never'	*P*-value
'Did you experience output from the stoma under the adhesive' (i.e. leakage)	Visit 1	4%	15%	38%	30%	13%	P<0.0001
	Visit 2	2%	8%	22%	31%	36%	
'Did you need to replace the ostomy appliance before you expected or planned' (i.e. unplanned changes)	Visit 1	3%	15%	38%	31%	12%	P<0.0001
	Visit 2	3%	8%	24%	31%	34%	

(75%; 2271/3017) rather than a convex base plate (23%; 685/3017); data were unavailable for 2% (61/3017) of participants. At visit 1, a greater proportion of participants using an appliance with a convex base plate (67%) reported that they 'always', 'often' or 'sometimes' had leakage than those using a flat base plate (54%). At Visit 2, 39% of those using an appliance with a convex base plate reported that they 'always', 'often' or 'sometimes' had leakage, compared with 31% of those using a flat base plate. At visit 1, 63% of participants using an appliance with a convex base plate reported that they 'always', 'often' or 'sometimes' had unplanned changes compared with 55% of those using a flat base plate. At visit 2, 38% of those using an appliance with a convex base plate reported that they 'always', 'often' or 'sometimes' had unplanned changes, compared with 34% of those using a flat base plate.

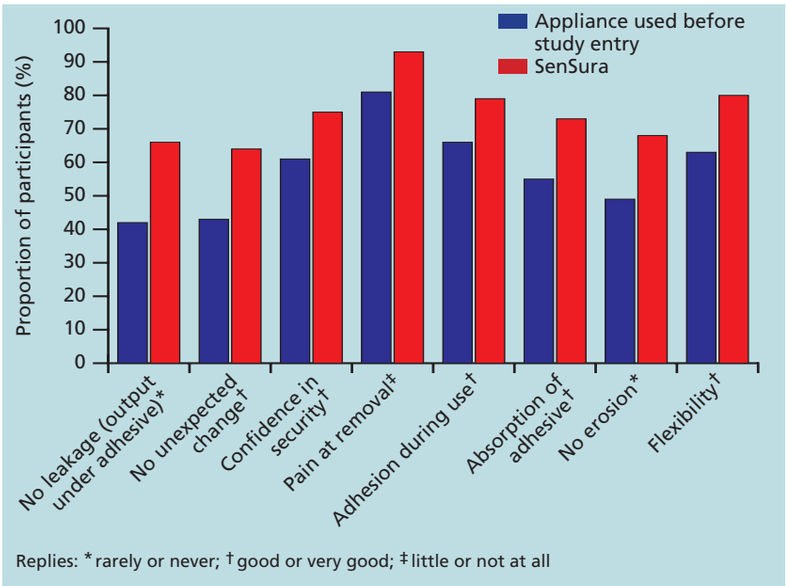


Figure 3. Evaluation of the ostomy appliances using performance parameters related to leakage and peristomal skin. The change in proportion of participants from visit 1 to visit 2 was statistically significant for all the performance parameters (P<0.0001).

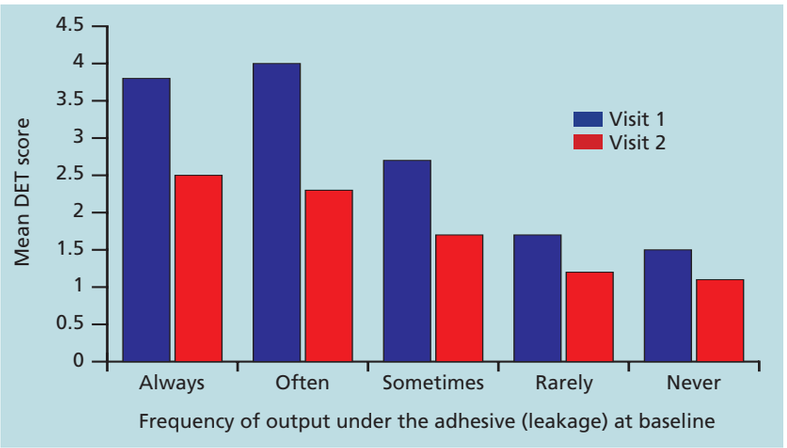


Figure 4. The severity of skin disorder (Ostomy Skin Tool) correlated with frequency of leakage at visit 1 (P<0.0001).

Product evaluation

The double-layer adhesive appliance, SenSura, was significantly superior to the pre-study appliance across all performance parameters related to leakage and peristomal skin (P<0.0001) (*Figure 3*). A greater proportion of participants reported less leakage, erosion, unexpected changes and pain during removal, as well as better adhesion during use, confidence in security, flexibility and absorption of adhesive with the double-layer adhesive appliance, than the pre-study appliance.

Effect of leakage and peristomal skin conditions on DET scores

There was a significant correlation between the severity of peristomal skin disorder and the frequency of leakage at baseline (P<0.0001). Participants who reported that they 'always' or 'often' had leakage at visit 1 had worse peristomal skin disorders (i.e. higher DET scores) than those who reported leakage 'rarely' or 'never' (*Figure 4*). Peristomal skin disorders improved from baseline levels to visit 2 across all frequencies; however, the greatest improvements were observed in those who reported leakage 'always' or 'often' at visit 1.

Baseline leakage frequencies and changes in DET score according to diagnosis

Overall, 60% of participants had a skin disorder; the most common disorders were irritant contact dermatitis (48%) and mechanical trauma (21%) (Martins et al, 2011).

A significant correlation was observed between the severity of irritant contact dermatitis and frequency of leakage at baseline (P<0.0001). Participants who reported that they 'always' or 'often' had leakage at visit 1 had worse irritant contact dermatitis (i.e. higher DET scores) than those reporting that they 'rarely' or 'never' had leakage (*Figure 5*). Irritant contact dermatitis improved from visit 1 to visit 2 across all baseline leakage levels, including participants who reported at baseline that they 'never' had leakage (P<0.0001)

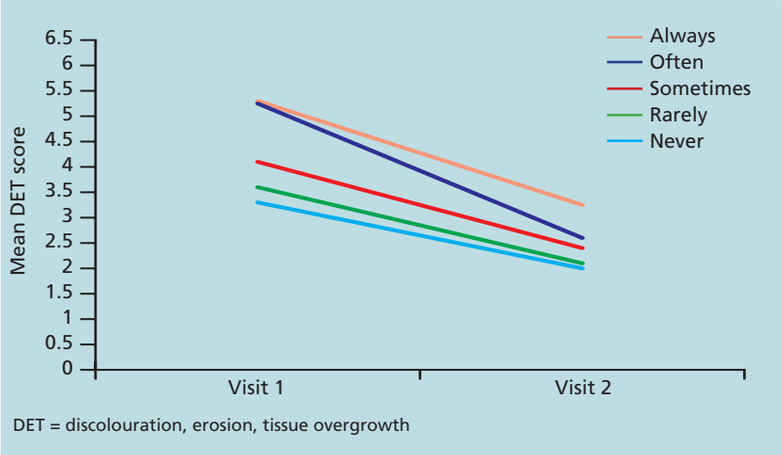


Figure 5. Change in leakage frequency and severity of irritant contact dermatitis from visit 1 to visit 2. Change in DET score from visit 1 to visit 2 was statistically significant for all the leakage subgroups: 'always', 'often', 'sometimes', 'rarely' and 'never' (P<0.0001).

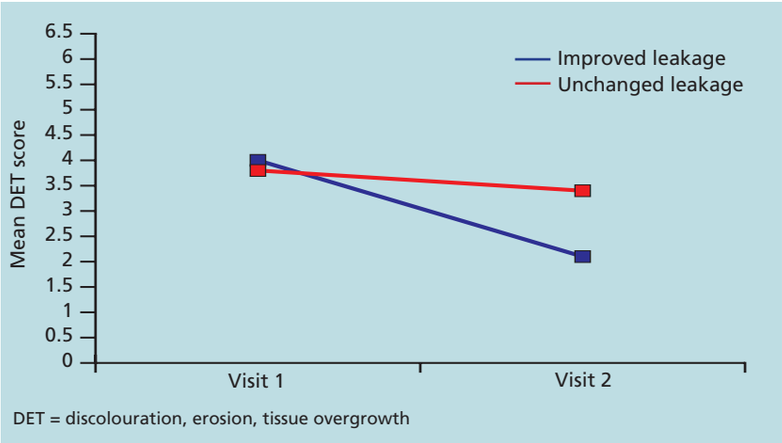


Figure 6. Change in DET score according to change in leakage (improved vs unchanged) for participants with a high frequency of leakage at baseline (i.e. 'always' or 'often'). Change in DET score at visit 2 for the 'improved' leakage group was statistically different from the change in DET score in the 'unchanged' leakage group (P<0.0001).

A similar magnitude of skin disorders caused by mechanical trauma was observed in participants across all baseline levels of leakage (mean DET scores at visit 1 were 3.5–4.2). Improvement in skin disorders caused by mechanical trauma was observed across all levels of leakage from visit 1 to visit 2 (mean DET scores at visit 2 were 1.9–2.6) (P<0.0001).

Participants with a higher frequency of leakage (i.e. 'always' or 'often') at baseline, who reported improved leakage at visit 2 showed a greater improvement in skin disorders than those who had no change in leakage at visit 2 (P<0.0001) (*Figure 6*).

The use of accessories

Overall, the number of accessories (excluding belts) used by participants significantly reduced from 4682 to 3214 from visit 1 to 2 (P<0.0001). The age and gender of participants did not influence use of accessories.

Discussion

Leakage problems, peristomal skin complications and overall QoL are interconnected (Herlufsen et al, 2006; Pittman et al, 2008). It is important to break the cyclical pattern of leakage and skin erosion to prevent peristomal skin problems (Rolstad and Erwin-Toth, 2004). If leakage occurs, action must be taken and the appliance changed to protect peristomal skin (Rolstad and Erwin-Toth, 2004). The results from the DialogueStudy demonstrated that leakage from an ostomy appliance is a critical factor in the development of peristomal skin conditions. There was a significant correlation between the frequency of leakage and the magnitude of peristomal skin conditions at baseline. Participants with high levels of leakage at baseline had moderate peristomal skin conditions (a mean DET score of more than 3.5) (Martins et al, 2010). Participants with low levels of leakage had mild peristomal skin conditions (DET scores of less than 2.0). Peristomal skin disorders improved (i.e. a decrease in DET score) across all levels of leakage over the course of the study, after participants had used SenSura and had study-related contact with an SCN. The greatest improvement in peristomal skin conditions was observed in those who reported a higher frequency of leakage at baseline.

The severity of irritant contact dermatitis and mechanical trauma correlated with leakage frequency at baseline—higher leakage levels had the highest DET score. There were marked improvements in irritant contact dermatitis and mechanical trauma over the course of the study, following the use of SenSura in conjunction with advice from an SCN on correct product use and skin care. Therefore, these improvements in leakage frequency relate to the product and the advice provided by the SCN.

Over the course of the study, the proportion of participants who reported that they 'always', 'often' or 'sometimes' had problems with leakage decreased from 57% to 33%. There was also a corresponding decrease in the proportion of participants requiring unplanned changes, from

57% at baseline to 35% at study end. Possible reasons for the observed decrease in leakage and unplanned changes include correct sizing of the appliance, management of skin conditions, and study-related contact with an SCN.

Participants with high leakage at baseline who had improved leakage over the course of the study showed a greater improvement in peristomal skin conditions (i.e. 50% reduction in DET score) than those with unchanged leakage. Improvement in peristomal skin conditions is possible, particularly in the more challenging cases that have high levels of leakage.

Participants with an ileostomy had greater frequency of leakage and unplanned changes at baseline than those with a colostomy or urostomy. Leakage is particularly important for patients with an ileostomy, because the condition of their skin is likely to deteriorate rapidly following leakage (Nybaek et al, 2009). It has been suggested that the absence of large bowel function leads to more frequent stool, thus resulting in more skin irritation compared with a colostomy (Hellman and Lago, 1990). Participants with a urostomy appeared to have less of a reduction in the frequency of leakage over the course of the study than those with a colostomy or ileostomy. However, it was not possible to determine statistical significance due to the small number of people in this group, which may have confounded findings on the beneficial effects of the double-layer adhesive appliance.

The double-layer adhesive appliance, in conjunction with SCN intervention, was superior to the pre-study appliance in terms of leakage, erosion, adhesion and flexibility. The management of leakage, the help of an SCN and the use of an appropriate double-layer adhesive appliance and accessories could potentially save money over the longer term. Less leakage equates to increased wear time and, therefore, less need to purchase new appliances, as well as less need for interventions and accessories to manage skin.

Conclusions

The DialogueStudy found that the use of an appropriate double-layer adhesive appliance, SenSura, combined with regular contact with an SCN using objective tools led to less leakage and improvement of peristomal skin conditions.

Conflicts of interest: *Some investigators will have received sponsorship or payment from Coloplast in relation to activities, such as conference attendance or consultancy, outside the DialogueStudy. The Homerton University Hospital NHS Foundation Trust was financially reimbursed by Coloplast A/S for participating as the lead study site in the United Kingdom, and Theresa Porrett as principal investigator of the DialogueStudy. No particular conflicts of interest were reported by other authors.*

Acknowledgments: *The authors thank Mette Kaad Jensen from Coloplast A/S and Drs Barbara Byth and David Collison from AXON Communications who provided medical writing services on behalf of Coloplast.*

Andersen BD, Van Keizerswaard P, Castro MM, English E, Carter D (2011) Introduction to the DialogueStudy: methods and baseline demographic findings. *Gastrointestinal Nursing* **9**(2 Suppl): 4–8

Arumugam PJ, Bevan L, Macdonald L, Watkins AI, Morgan AR, Beynon J et al (2003) A prospective audit of stomas--analysis of risk factors and complications and their management. *Colorectal Dis* **5:** 49–52

Barr JE (2004) Assessment and management of stomal complications: a framework for clinical decision making. *Ostomy Wound Manage* **50:** 50–6

English E, Claessens I (2008) How peristomal skin disorders impact on ostomy care. *WCET Journal* **28:** 3–7

Hellman J, and Lago CP (1990) Dermatologic complications in colostomy and ileostomy patients. *Int J Dermatol*, **29**(2): 129–33

Herlufsen P, Olsen AG, Carlsen B, Nybaek H, Karlsmark T, Laursen TN et al (2006) Study of peristomal skin disorders in patients with permanent stomas. *Br J Nurs* **15:** 854–62

Martins L, Ayello EA, Claessens I, Hansen AS, Poulsen LH, Sibbald R et al (2010) The Ostomy Skin Tool: tracking peristomal skin changes. *Br J Nursing* **19:** 960–4

Martins L, Samai O, Fernandez A, Urquart M, Hansen AS (2011) Maintaining healthy skin around an ostomy: peristomal skin disorders and self-assessment. *Gastrointestinal Nursing* **9**(2 Suppl): 9–13

Nybaek H, Bang Knudsen D, Norgaard Laursen T, Karlsmark T, Jemec GB (2009) Skin problems in ostomy patients: a case-control study of risk factors. *Acta Derm Venereol* **89:** 64–7

Pittman J, Rawl SM, Schmidt CM, Grant M, Ko CY, Wendel C et al (2008) Demographic and clinical factors related to ostomy complications and quality of life in veterans with an ostomy. *J Wound Ostomy Continence Nurs* **35:** 493–503

Redmond C, Cowin C, Parker T (2009) The experience of faecal leakage among ileostomists. *Br J Nurs* **18:** S12–7

Rolstad BS, Erwin-Toth PL (2004) Peristomal skin complications: prevention and management. *Ostomy Wound Manage* **50:** 68–77

Turnbull GB (2002) The position on preoperative stoma site positioning. *Ostomy Wound Manage* **48:** 22–4

Voergaard LK, Vendelbo G, Carlsen B, Jacobsen L, Nissen B, Mortensen J et al (2007) Ostomy bag management: comparative study of a new one-piece closed bag. *Br J Nurs* **16:** 95–101

Welser M, Riedlinger I, Prause U (2009) A comparative study of two-piece ostomy appliances. *Br J Nurs* **18:** 530–4

Trust in SenSura® double-layer security

Engineered for living

When it comes to your ostomy appliance, everything depends on trust. Trust that your bag won't come off or leak or let you down in any way. That's why SenSura's double-layer adhesive was engineered to provide maximum reliability and security. With SenSura you can be sure that your skin is protected and healthy, giving you the confidence to live life on your terms.

Ostomy Care
Urology & Continence Care
Wound & Skin Care

Coloplast

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, urology and continence care and wound and skin care. We operate globally and employ more than 7,000 people.

Coloplast A/S
Holtedam 1
3050 Humlebæk
Tel: +45 49111111

www.coloplast.com