Intestinal stomas are created for a variety of reasons, including acute diverticulitis, trauma, and inflammatory bowel disease. However, cancer is by far the most prevalent reason for the formation of a stoma, and has been shown to account for more than half of the cases in a large post-marketing clinical study (Andersen et al, 2011). In Europe, survey results have indicated that approximately 700,000 people are living with a stoma, and in the US, more than 1 million people have a stoma (European Ostomy Association (EOA), 2012; United Ostomy Associations of America (UOAA), 2014).

A stoma operation causes profound changes in a patient's life because of the resulting physical damage, disfigurement, loss of bodily function, and change in personal hygiene (Persson et al, 2005). It can change the person's social life and make them feel different because they do not display the characteristics and attributes that society deems normal, due to their changed body (Brown and Randle, 2005). It may even lead to social isolation. The patient may feel overwhelmed by having a serious disease, and may find it difficult to understand the implications of a stoma (Carlsson et al, 2010). Nevertheless, the reaction to stoma surgery varies from person to person. For some, it will be a new lease of life, while for others it will be a devastating experience. The study by Pieper and Mikols, published almost 20 years ago, identified sudden leakage of stool, presence of odour, participation in sports, alteration in sleep habits and the need for further treatment to be of highest concern for people dependent on a stoma appliance (Pieper and Mikols, 1996). Since then, there have been significant advances in stoma appliances and an increase in nurses specialising in stoma care, yet a large proportion of people with a stoma continue to experience adjustment problems and are unable to live the life they want to live (Brown and Randle, 2005).

**Abstract**

The aim of the Ostomy Life Study was to get a better understanding of the challenges that people living with a stoma face in their everyday lives. With more than 4000 participants from 11 countries, the study provides a wealth of information covering all age groups, stoma types, stoma products and a variety of cultures. The result shows that the majority of ostomates have issues related to leakage and ballooning which, among other things, have a negative effect on sleep, or lead to unplanned appliance changes for approximately 40% of the respondents. Two-piece users are concerned specifically about coupling failure and the associated consequences. The results can be used to provide guidance in everyday stoma care and in development of new products.
that ostomates face as a result of using a stoma appliance, and evaluate the impact that these challenges have on their everyday life.

### Methods

**Survey design**

A total of 193 specialised stoma care nurses from 10 countries (Germany, the Netherlands, the UK, the US, Denmark, Slovakia, France, Sweden, Canada, and Belgium) were involved in designing and providing content for the survey. Two former market research studies, which included a total of more than 2400 people with a stoma, highlighted that leakage and the associated consequences, as well as the feeling of ‘standing out’, were of particular concern when living with a stoma and dealing with the challenges related to the everyday use of a stoma appliance (Coloplast, 2010; 2012).

Four main topics were chosen for purposes of the Ostomy Life Survey: leakage, ballooning, discretion and appearance of the stoma bag, and, for two-piece users, any challenges they may have with the coupling (a mechanical or adhesive connection between the baseplate and the stoma bag). For each topic, questions were asked relating to users’ experiences and worries, and the impact they have on their daily lives. Every question had a set of predefined response options, as well as the option to choose ‘other reason’ and write an individual answer. In addition to the questions on the four main topics, the survey also contained questions regarding demographics, description of the peristomal area (Box 1), use of appliances, and appliance-change routine.

The survey was primarily conducted online, and the participants received an introduction by email and a link through which they could give their consent to participate in the survey. Participants were recruited through an online market research database (only available in the UK, France, Germany and the US) or through customer databases or nurses. Participants were required to be a minimum age of 18 years to participate in the survey. No further exclusion criteria were needed, as the aim of the study was to obtain a snapshot of everyday life of people living with a stoma.

**Data collection and processing**

Data was collected and processed by a market research software system provided by Confirmit (based in Norway) and weighted by product brand used (according to market share in each country and country of the respondent, hence each country was set to weight equally. Additional statistical analysis was performed using SAS version 9.2 (SAS Institute Inc., North Carolina, US). All statistical tests were two-sided and carried out at the 5% level of significance, and were adjusted for confounding effects, such as product brand, gender, country, and age.

### Results

Respondents from 11 different countries, namely the UK, France, Germany, the Netherlands, Italy, Belgium, Sweden, the US, Canada, Australia and Japan, completed the survey, with a response rate of 30%. Canada and the US accounted for 34% of the respondents, Europe for 47%, and Australia and Japan for 19%. Figure 1 shows the exact number and distribution of respondents in the different countries.

Of the respondents, 55% were male and 45% were female. The majority of the respondents (82%) were aged 50 years or above, and one third had had their stoma for 10 years or more. Of these ostomates, 43% had a colostomy, 37% had an ileostomy, and 18% had a urostomy. The respondents used stoma appliances from a wide range of manufactures; 49% used a one-piece appliance and 51% used a two-piece appliance. The majority of respondents (85%) using a two-piece appliance attached the bag to the baseplate using a mechanical coupling. The appliance-change routine varied greatly from country to country. Notably, people from the US, Canada and Japan changed their appliance less frequently than people from Europe and Australia. However, on average, 62% of one-piece users changed their appliance one or more times per day. Out of the two-piece appliance users, 48% changed their bag one or more times per day.

### Box 1. Definitions

- **Leakage or seepage** under the adhesive: output comes in contact with the skin and/or clothing.
- **Ballooning**: air gathering in the bag.
- **Peristomal area**:
  - **Regular**: the area around the stoma is more or less level with the abdomen, although the skin surface may be uneven.
  - **Inward**: the area around the stoma sinks into the abdomen creating a dip.
  - **Outward**: the area around the stoma rises from the abdomen, creating a peak.
Leakage: experience, worries and the impact on everyday life

According to a five-level scale, ranging from ‘to a very high degree’ to ‘not at all’, as well as the option to answer ‘don’t know’, the participants were asked to what degree they had experienced leakage within the past 6 months and to what degree they worry about leakage (definition in Box 1). Results showed that 76% of the respondents had experienced leakage on some level ranging from a very high degree to a low degree, and 91% said they worried about leakage (Figure 2, Graph A). People with an ileostomy worried significantly more (p=0.001) about leakage than people with a colostomy. Of those who worried about leakage, 69% answered that their main reasons for worrying was their knowledge of the consequences of leakage. Their concerns led to more frequent appliance changes (43%) and use of accessories (42%). When the participants were asked how their concerns surrounding leakage affected their everyday life, a large proportion (40%) responded that they woke up at night, one out of three limited their physical and social activities, and for 12% of the respondents, their concerns about leakage led to the unfortunate consequence of the ostomates isolating themselves. Only 19% of the respondents did not feel that their concerns influenced their daily life (Figure 3).

Ballooning: experience, worries and the impact on everyday life

Using the same five-level scale, 91% of the respondents (excluding people with a urostomy) answered that they had experienced ballooning on some level ranging from a very high degree to a low degree within the past 6 months, and 94% worried about ballooning (Figure 2, Graph B). Of those that had experienced ballooning, three out of four experienced ballooning particularly during night, which led 46% of them to wake...
up at night (Figure 3, Graph B). To solve the problem of ballooning, 68% of the respondents manually let the air out of the bag and one out of five handled the problem by changing their appliance more frequently. This was supported by an analysis showing that significantly more people ($p<0.01$) experienced ballooning in the group of respondents that changed their stoma appliance less often than once every 1–2 days. Those who had an inward or outward stoma area also experienced ballooning more frequently compared with those with a regular stoma area ($p<0.0001$). Because of ballooning, 39% worried about leakage and one out of three were afraid that people would notice the bag profile and/or smell/odour. Significantly more people with an ileostomy experienced ballooning compared to people with a colostomy ($p<0.01$).

Appearance of stoma appliance: worries and impact on everyday life
The results of the survey also revealed that the majority (74%) of ostomates worry about the appearance of the stoma appliance on some level ranging from a very high degree to a low degree (Figure 2, Graph C). Of these respondents, one out of three said that their worries were related to the product being visible through their clothing. Consequently, 57% limited their choice of clothing (Figure 3, Graph C), and 68% primarily worried about the appearance of the stoma appliance in social situations. The respondents that were younger than 70 years worried significantly more ($p<0.0001$) about the appearance of the stoma appliance than those above 70 years. It was also evident that respondents who had had their stoma for less than 12 years worried significantly more ($p≤0.01$) about the appearance than those who had had their stoma for 12 years or more.

Coupling failure: concerns and impact on everyday life
Half of the respondents using a two-piece stoma appliance (all using different types of coupling combinations) had experienced coupling failure within the past 6 months, and the majority

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**Figure 2. Leakage, ballooning, appearance, and coupling failure are unresolved issues in stoma care**
(81%) worried about the bag not being securely fastened to the baseplate (Figure 2, Graph D). Coupling failure was mainly experienced while asleep (30%), when bending (24%), and when doing physical activities (20%), and 50% felt a constant need to check the connection between the bag and the baseplate. The consequences of coupling failure and the concerns relating to it had a huge range of implications on the ostomates’ daily life: 42% woke up at night, and 24% and 34% respectively limited their social and physical activities (Figure 3, Graph D).

**Discussion**

The results from the Ostomy Life Study confirm that stoma formation has an impact on everyday life, with several physical, mental and social impairments. The daily dependence on a stoma appliance and the challenges it may present can lead to additional troubles, concerns and a feeling of standing out. The main questions raised in the present study relate to experiences and concerns about leakage, ballooning, bag appearance and coupling. Of the respondents, 76% had experienced leakage to a certain degree during the past 6 months and a concerning 91% of the respondents worried about leakage. The high percentage that worry about leakage may reflect the fact that one devastating experience of leakage could have a long-lasting emotional impact (Simmons et al, 2007). The experience of leakage, and how it affects people with a stoma, emotionally and physically, has been of focus in other studies. In a large multinational post-marketing study (Porrett et al, 2011), which included more than 3000 ostomates, it was shown that the frequency of leakage had a significant correlation with the severity of the peristomal skin condition as well as the stoma-related quality of life. The study also showed that those experiencing leakage carried out more unplanned appliance changes (Porrett et al, 2011). Hence, the consequences of leakage may have a number of negative effects, and leakage prevention is necessary. It is especially important to break the potential vicious circle of leakage and skin erosion, which may lead to more serious peristomal skin problems (Rolstad and Erwin-Toth, 2004). High priority should therefore be given to ensuring that resources, in terms of assistance provided by professional stoma care nurses, are available and that everyone is supplied with an adequate number of appropriate stoma appliances and stoma care accessories, to prevent leakage and keep the peristomal skin healthy.

In the present study, ballooning was a huge challenge for the majority of the respondents; 91% had experienced ballooning during the past 6 months and 94% worried about it. Digestive precautions may help to reduce ballooning. In particular, people with an ileostomy could benefit from adding fibre to their diet, depending on
their reason for having an ileostomy, and be careful with food that causes a lot of gas, such as broccoli, cabbage and onions. (EOA, 2012). The filter of the stoma bag and how often the bag is changed is important. Anecdotally, changing the bag just before bedtime may be beneficial, as while lying down, the filter may become blocked due to stool not falling down in the pouch. The results from the survey also revealed that, for approximately 40% of the respondents, problems with ballooning and leakage had a negative effect on sleep or led to unplanned appliance changes.

Many factors contribute to an ostomate’s sense of feeling different, once such factor being the appearance of the stoma appliance. Only 25% of the respondents did not worry about the appearance of the stoma appliance and there was a significant correlation (P<0.001) between age and concern about appearance, with a higher percentage of people below 70 years of age worrying about appearance than people over the age of 70. Similarly, people who have had their stoma for more than 12 years worried significantly less about its appearance compared with those who have had their stoma for a shorter time.

Campaigns on social networks and other media, where ostomates share their life stories and show pictures of themselves using a stoma bag, have created more awareness and understanding around living with a stoma and being dependent on a medical device (Frohlich and Zmydlsinski-Seeling, 2014). Nevertheless, as everyone is different, it is also important to recognise when someone would prefer to be private and not share such personal details about themselves and their life (Frohlich and Zmydlsinski-Seeling, 2014; Queensland Stoma Association, 2015).

Conclusion

According to the results of the present study, too many people with a stoma are living with concerns relating to the use of a stoma appliance, such as leakage, ballooning, and coupling failure. Among other aspects, these concerns can limit their social and physical activities, but also have a negative impact on their sleep. More resources in terms of experienced stoma care nurses should be allocated to ensure that ostomates get the necessary care and guidance. The development of new products that will fulfil the unmet needs of ostomates must also be prioritised and acknowledged, to allow them to live a life without worrying about leakage, ballooning and feeling insecure in social situations.