A STUDY OF A NEW DRAINABLE BAG FOR PEOPLE WITH ILEOSTOMIES

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This randomised, comparative crossover study compared the performance of a new one-piece drainable ostomy bag (SenSura) with that of a well-established bag to identify whether problems related to the use of ostomy bags improved. Sixty-four people with an ileostomy tested each bag for a week. SenSura was preferred by 79% of the participants and was superior to the control bag with regard to the key performance parameters. Individuals with an ileostomy preferred the SenSura. This is a summary: the full paper and reference list can be accessed at nursingtimes.net.

The aim of the study was to compare the performance of a new one-piece drainable ostomy bag, SenSura, with a well-established bag, focusing on minimising problems related to the use of ostomy bags. The primary aim was to find out if preference was for the control bag or the SenSura bag; secondary aims were to ascertain parameters relating to the adhesive, outlet, filter and the bag in general. To our knowledge this is the first comparative study investigating the performance of one-piece drainable ostomy bags. There is a lack of evidence within the area of stoma care and there have been numerous requests in the literature for more research involving pouch selection.

METHOD
The test and control bags were one-piece drainable ostomy bags with a hydrocolloid skin adhesive welded onto a pouch and provided with a filter.

The test bag was the SenSura bag with a double-layer adhesive and a ‘hideaway’ outlet (Coloplast). The outlet is equipped with a closure made of plastic material to ease handling and cleaning. The bag can be folded to half-size to make it more discreet.

BACKGROUND

An ileostomy is a surgically created opening of the ileum (small intestine) on the abdominal skin surface, allowing the elimination of stoma effluent (output from a stoma) (Wound, Ostomy and Continence Nurses Society, 2006). It is created when there is a need to remove the colon, usually to treat colon carcinoma and inflammatory bowel diseases such as Crohn’s disease or ulcerative colitis (Burch, 2005; Taylor, 2005). The effluent is usually collected in a drainable ostomy bag and disposed of through an outlet as needed.

A number of problems in connection with the use of a stoma bag have been identified as being related to quality of life (Prieto et al, 2005), including skin disorders in the peristomal area, sleep disturbance, anxiety about a full bag and bag leakage, smell and odour.

Although ostomy bags have improved since the first was introduced in 1957, further improvements are needed to minimise bag-related complications and improve quality of life (Nugent et al, 1999).

Stoma effluent leakage appears to be the main bag-related problem for people with ileostomies (Bourgois et al, 2001). It mainly occurs due to the liquid consistency and high amount of effluent from an ileostomy, and results in eroded skin with subsequent reduced adhesion of the ostomy bag.

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Study design
The investigation was an open, randomised, comparative, crossover multicentre study conducted in Germany. Each participant tested the SenSura bag for one week and the control bag for one week in randomised order. The bags were changed in line with the participant’s normal changing frequency.

RESULTS
The bag as a whole
On the whole 79% preferred the SenSura bag to the control bag. SenSura had a median rating of 4 or 5 – equivalent to ‘good’ or ‘very good’ – in all parameters measured, whereas the control bag in eight cases was evaluated with a median rating of 2 or 3, equating to ‘poor’ or ‘reasonable’.
There were no differences between the bags with regard to the number of problem-related changes (p=0.8). The mean wear time was 24 hours for both bags. In total, 40% of participants wanted to use the SenSura bag in the future instead of their own bag, whereas 11% wanted to use the control bag. Evaluations of the peristomal skin after use of the two bags were not significantly different (p>0.7).

Outlet, adhesive and filter performance
SenSura was superior to the control in all outlet performance parameters (security, hygiene, handling, cleaning and emptying) (p<0.0005). As it could be folded to half its normal size, participants were asked whether they liked that feature; 56% answered ‘a lot’ or ‘very much’. It was not possible to fold the control bag in this way.

The participants experienced less adhesive erosion with the SenSura bag than with the control – 77% experienced a little or no erosion with SenSura whereas 55% did with the control bag (p=0.02). Also, the adhesion immediately after application was deemed significantly better with SenSura – 83% experienced ‘good’ or ‘very good’ tack with the SenSura compared with 55% for the control (p<0.0001). Flexibility and adhesion during use were not significantly different for the two bags, however, 34% experienced ‘very good’ flexibility and adhesion with the SenSura bag, whereas only 21% did so with the control bag (p=0.3).

The sense of security was significantly greater with the SenSura filter compared with the control filter – 80% of participants stated the SenSura filter was ‘good’ or ‘very good’ versus 70% for the control (p=0.05). Some 90% of participants considered the discreetness of the SenSura filter to be ‘good’ or ‘very good’ against 75% for the control filter (p=0.004). The filter stopped functioning during wearing of the bags on 17.5% of all SenSura bags and on 22% of all control bags (p=0.11). For both bags, ballooning (excess air in the bag) was reported as the main reason for dysfunction of the filter. The percentage of participants who woke up at least once at the night due to ballooning while testing the bags was 33% for the SenSura bag and 41% for the control bag (p=0.4).

**DISCUSSION**
An ostomy bag that functions well is crucial to individuals with stomas as it makes daily life easier and has a positive impact on their overall quality of life (Prieto et al, 2005). A high degree of security seems to be the most important issue related to ostomy bags for people with ileostomies – security or reliability of the bag were among the main reasons for being satisfied with their usual ostomy bag in 64% of the cases in the present study. Also, leakage and insufficient sealing of the stoma were the main factors explaining the high frequency (45%) of anxiety about the ileostomy mentioned in a previous study investigating the quality of life of people with stomas (Nugent, 1999).

With the SenSura bag, the participants experienced a more hygienic outlet that was easier to clean, handle and empty. This may be due to the fact that it is sealed like an envelope when the outlet is folded up, preventing effluent from being squeezed out onto the outlet exterior, making cleaning easier and improving hygiene. Easier handling and emptying associated with the SenSura outlet ensures that older people with reduced finger mobility can handle the bag.

**CONCLUSION**
This study revealed that people with an ileostomy can expect a greater sense of security when wearing the SenSura bag than they would from the control bag. This is likely to be related to the good adhesion, reduced adhesive erosion, better hygiene, and easier handling and emptying of the SenSura bag.

**IMPLICATIONS FOR PRACTICE**

- The study revealed a greater sense of satisfaction with the SenSura bag for all security parameters. The significantly lower degree of adhesive erosion and the better grip of the SenSura adhesive are, most likely, the aspects that contributed to this.

- ‘Silent leakages’ (when effluent leaks underneath the adhesive without resulting in a change of bags) were not recorded but it has been demonstrated that leakage of stoma effluent underneath the adhesive is related to peristomal skin disorders (Herlufsen et al, 2006). Therefore, studies in the future should record silent leakages and should include participants who have peristomal skin disorders.

- The problem of ballooning is very difficult to solve, as the liquid stoma effluent blocks the filter when the patient is lying in a horizontal position. A solution to this issue is required from future product development programmes.

**REFERENCES**


