

# Ostomy Bag Management: Two comparative studies of one-piece bags

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## INTRODUCTION

Security is a major concern for Ostomy bag users, with a need for reduced problem-related changes. Generally, Ostomy users report that their quality of life depends on a number of issues related to the function or design of ostomy bags<sup>1</sup>:

- skin disorders in the peristomal area
- worries about bag-leakage, smell and odour
- interruption of sleep
- anxiety about a full bag
- noises from the bag
- indiscreetness of the bag

## AIM

Performance of a new ostomy bag, SenSura, was compared to two different well-established ostomy bags, Figure 1, with focus on problems related to the use of ostomy bags.



Figure 1: SenSura closed and drainable ostomy bags.

## METHODS

### Study design

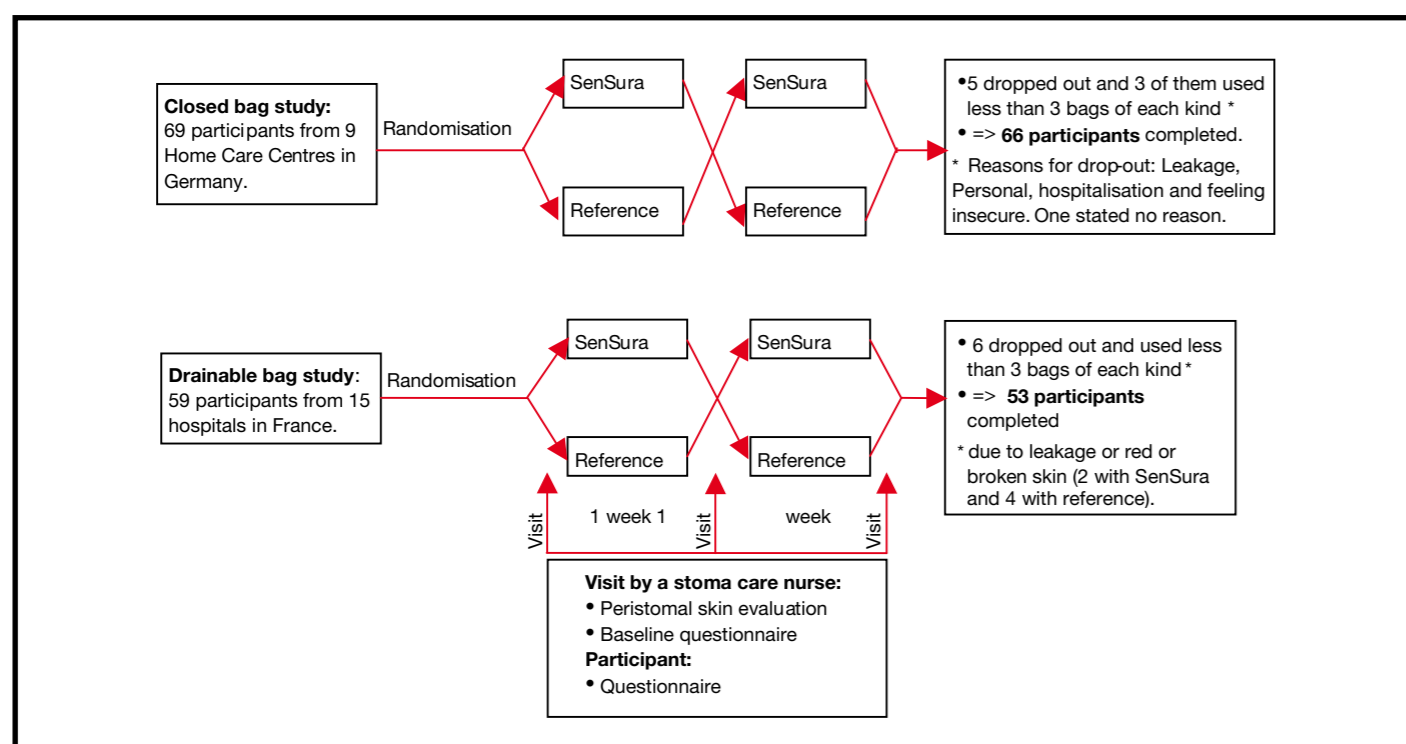


Figure 2: Study design. Two open, randomised, comparative, crossover multi-centre studies were conducted. Prior to the study, using 3 bags of each kind was defined as the minimum level for completion. For a complete description of the study design please see reference 2.

## Products

In the first study two closed bags were compared, and in the second study two drainable bags were compared. All test and reference bags were one-piece ostomy bags with a hydrocolloid skin adhesive welded on to a pouch and provided with a filter. The test bags were the SenSura closed and drainable bags with a double-layer adhesive (Coloplast A/S, Humlebæk, Denmark).

## CONCLUSIONS

- The study revealed that the sense of security with the SenSura bags was greater than with the reference bags as well as fewer problem-related changes, a more hygienic outlet and a greater tack was experienced. This was reflected in the high percentage of participants who preferred the SenSura bag ( $\geq 75\%$ ) to the reference.
- Ballooning during the night may be difficult to avoid, in particular with an ileostomy; thus, developers of ostomy bags should focus on this issue.

The reference bag in the study with closed bags was the Moderma Flex closed bag with a single-layer adhesive (Hollister Inc., Illinois, United States). In the drainable bag study the reference bag was the Esteem drainable bag with InvisiClose integrated closure and a single layer adhesive (ConvaTec Ltd, Deeside, UK).

## Participants

### Closed bags study

- 34 men and 35 women (69 in total) with a colostomy and with a mean age of 62 years (range:19-85).

### Drainable bags study

- 26 men and 33 women (59 in total) with an ileostomy and a mean age of 54 years (range: 25-83).

They all had healthy peristomal skin at inclusion.

## RESULTS

The SenSura drainable bag was superior to the reference in all outlet performance outcomes, Figure 3.

- The SenSura bag had a significantly greater tack than the reference bag,  $p < 0.0001$ .
- The sense of security with the bag as a whole was significantly greater for SenSura ( $p < 0.005$ ), Figure 5, and there were fewer problem-related changes,  $p < 0.05$ , Table 1.
- 75% of the participants or more preferred the SenSura bags to the reference bags,  $p < 0.0001$ , Figure 4.
- Ballooning (overfilling with air) happened with 6% of the closed SenSura bags and with 23% of the closed reference bags. With the drainable bags it was around 45%, ( $p = 0.8$ ).
- Ballooning during the night was less with the SenSura closed bag (15%) than with the reference bag (26%),  $p = 0.05$ . 42% of the participants experienced ballooning with the drainable SenSura and reference bags at night, ( $p = 1.0$ ).

## REFERENCES

1. Prieto L, Thorsen H, Juul K. Development and Validation of a Quality of Life Questionnaire for Patients with Colostomy or Ileostomy. *Health Qual Life Outcomes*; 2005; 3:62.
2. Tenière P, Welser M and Martinet C. Ostomy Bag Management: Two comparative studies of one-piece bags. *J WCET* 2007; 27(2), in press.

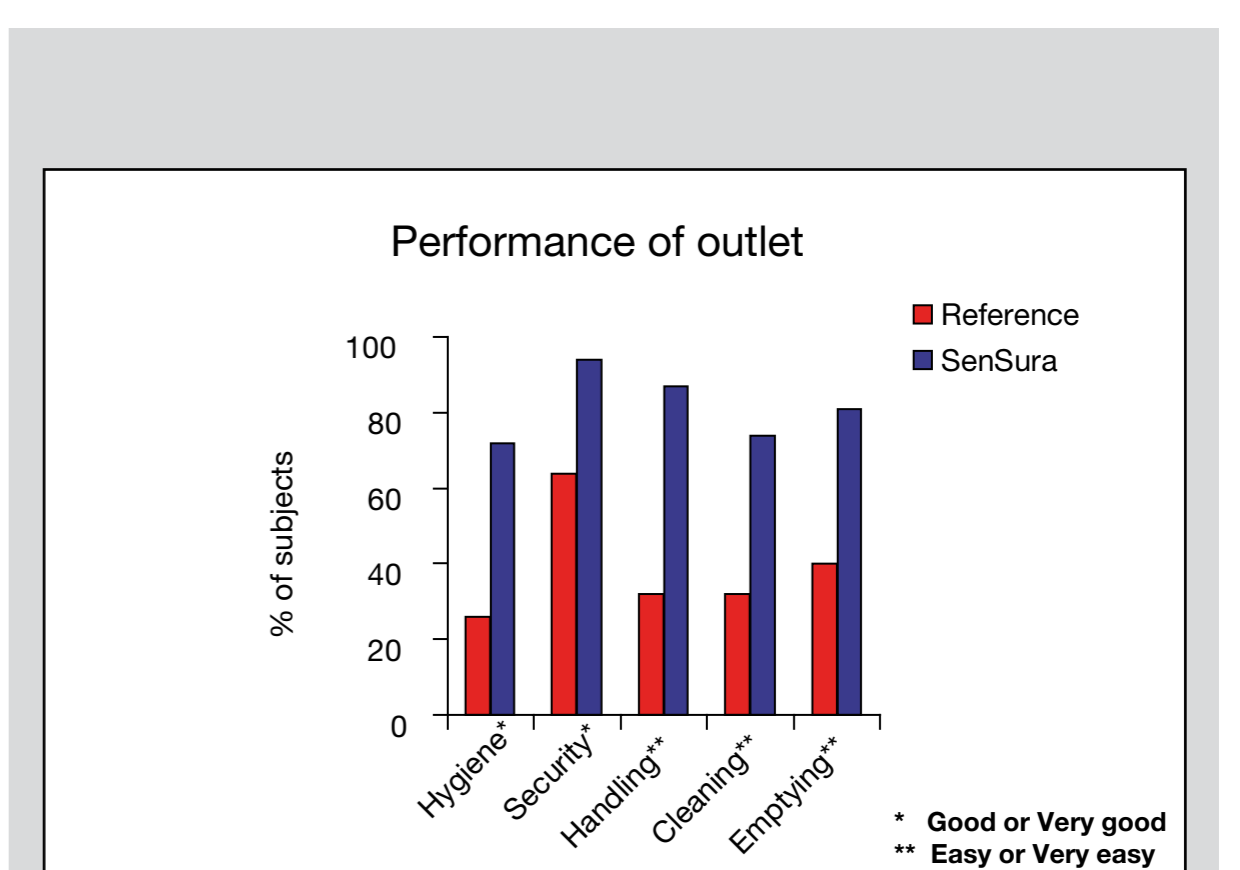


Figure 3: Performance of the drainable bag outlets. All outcomes were deemed significantly higher for the SenSura bag ( $p < 0.0001$ ).

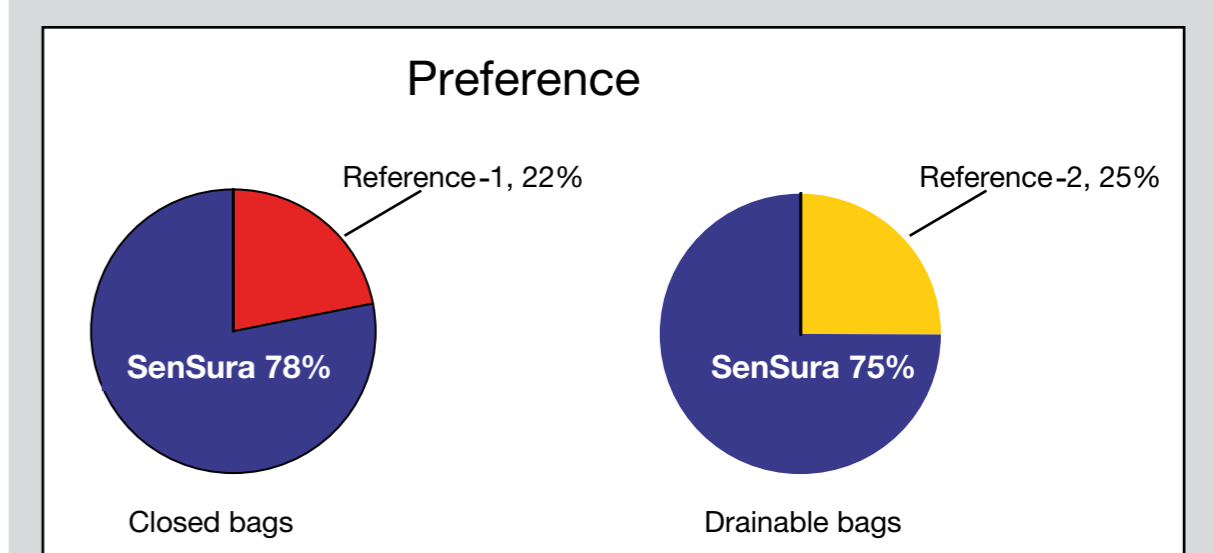


Figure 4: Of the 65 participants responding to the question "Which of the two bags do you prefer?", 78% preferred the SenSura bag in the closed bag study (95% confidence interval 68-88%) and 22% preferred the reference bag (12-32%), ( $p < 0.0001$ ). In the drainable bag study (52 answers), 75% preferred the SenSura bag (63-87%) and 25% preferred the reference bag (13-37%), ( $p < 0.0001$ ).

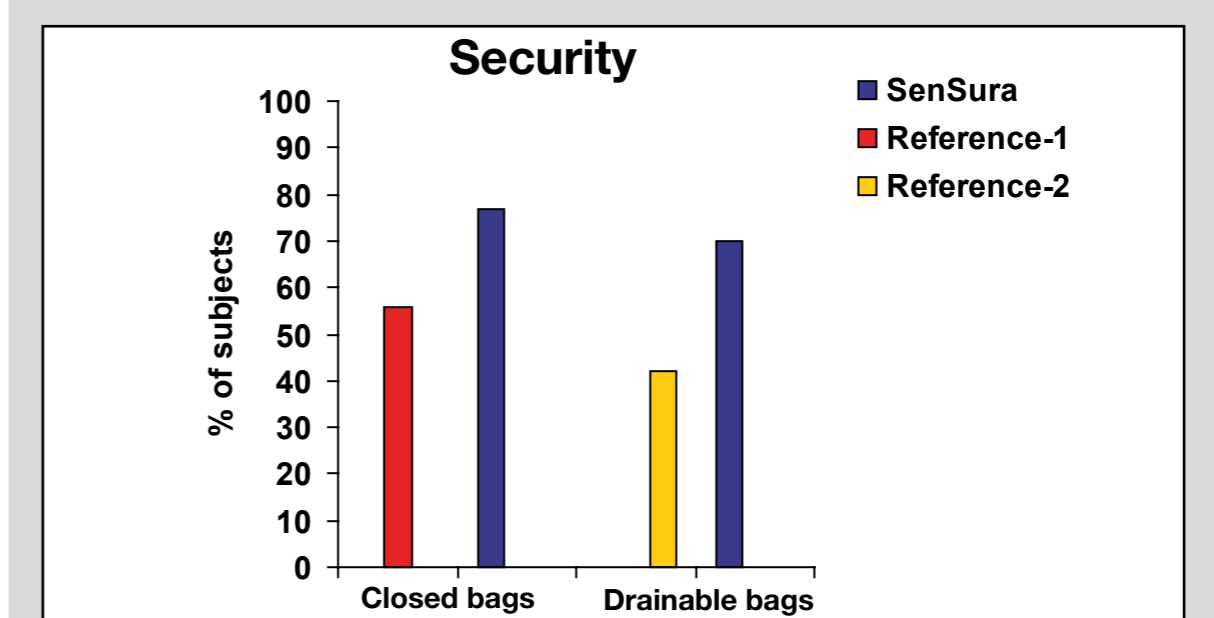


Figure 5: The overall sense of security was assessed by the question: "What is your assessment of security with regard to the bag as a whole?" 77% of the participants rated the security of the SenSura closed bags as "good" or "very good", whereas it was 56% for the reference.  $p = 0.001$ . For the drainable bags it was 70% (SenSura) as against 42% (reference),  $p = 0.0006$ .

Outcome	Assessment in questionnaire	Closed bags		Drainable bags	
		Reference-1	SenSura	Reference-2	SenSura
Wear-time <sup>1</sup>	The wear-time was the time from application to removal.	12.0 <sup>*</sup> (3.5-24)	12.4 <sup>*</sup> (5-24)	22.8 <sup>***</sup> (<1-71)	26.9 <sup>***</sup> (<1-89)
Overall evaluation	What is your general assessment of the bag?	40 <sup>***</sup>	71 <sup>***</sup>	25 <sup>***</sup>	74 <sup>***</sup>
Discretion	How was the discretion of the bag?	53 <sup>**</sup>	75 <sup>**</sup>	45 <sup>***</sup>	81 <sup>***</sup>
Problem-related changes	Was the bag changed due to a problem?	25 <sup>*</sup>	20 <sup>*</sup>	40 <sup>***</sup>	26 <sup>***</sup>
Future use	Would you use the bag in the future instead of your current ostomy bag?	20 <sup>**</sup>	53 <sup>**</sup>	19 <sup>***</sup>	60 <sup>***</sup>

1: Closed bags estimated means within a two-way analysis and the drainable bags were simple means.  
\*: The results for the reference and SenSura bag are statistically different,  $p < 0.05$ ; \*\* $p < 0.001$ ; \*\*\* $p < 0.0001$ .

Table 1: Overall performance outcomes for the reference and SenSura bags as a whole. Data are based on participants who fulfilled the evaluation criteria lined up prior to the studies.