

# Ostomy Bag Management: A comparative study of a new 1-piece closed bag

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## INTRODUCTION

- Ostomy bag users regularly experience problems such as peristomal skin disorders, leakage of stoma effluent onto the peristomal skin, excess air in the bag (ballooning) and odour<sup>1,2</sup>.
- Good performance of ostomy bags is important for the quality of life of individuals with a stoma<sup>3</sup>.
- This investigation was the first comparative study of one-piece closed ostomy bags to be published<sup>4</sup>.

## AIM

The performance of a new one-piece closed ostomy bag (SenSura bag) was compared to an already established bag (reference bag), with the focus on testing differences related to the use of ostomy bags.

## PARTICIPANTS AND METHODS

### Products

The test bag was the new SenSura ostomy bag with a double layer adhesive and a filter (Coloplast A/S, Humlebæk, Denmark), *Figure 1*. The reference bag was the established ostomy bag, Nova 1, with a single-layer graduated adhesive and a filter (Dansac A/S, Fredensborg, Denmark).

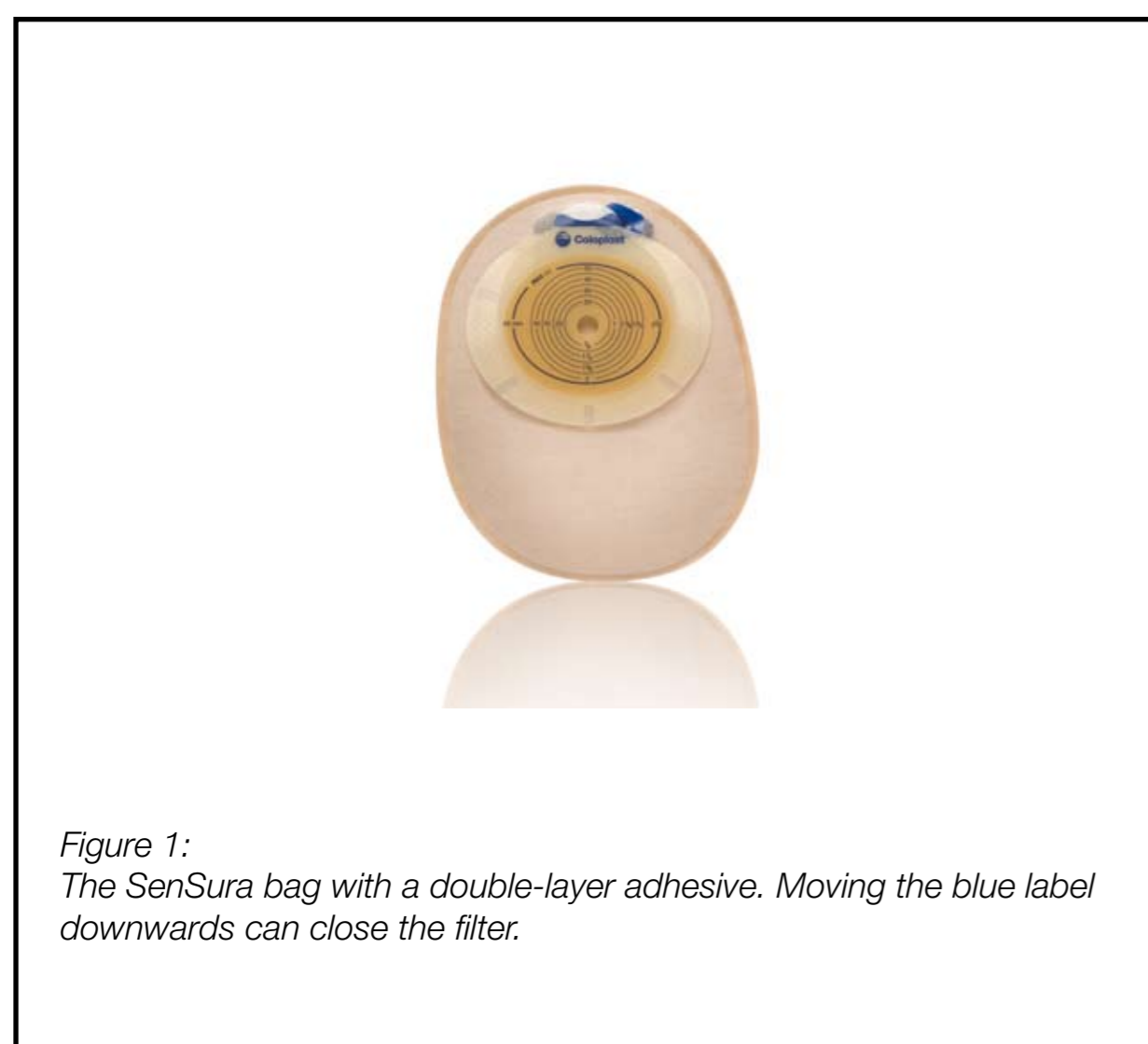


Figure 1:  
The SenSura bag with a double-layer adhesive. Moving the blue label downwards can close the filter.

## Participants

- 27 males and 41 females (68 in total) participated in the study.
- Their mean age was 64 years (range: 42-84).
- They normally used a one-piece closed ostomy bag and managed the bags themselves.
- Only participants with healthy peristomal skin were allowed to enter the study.

## Study design

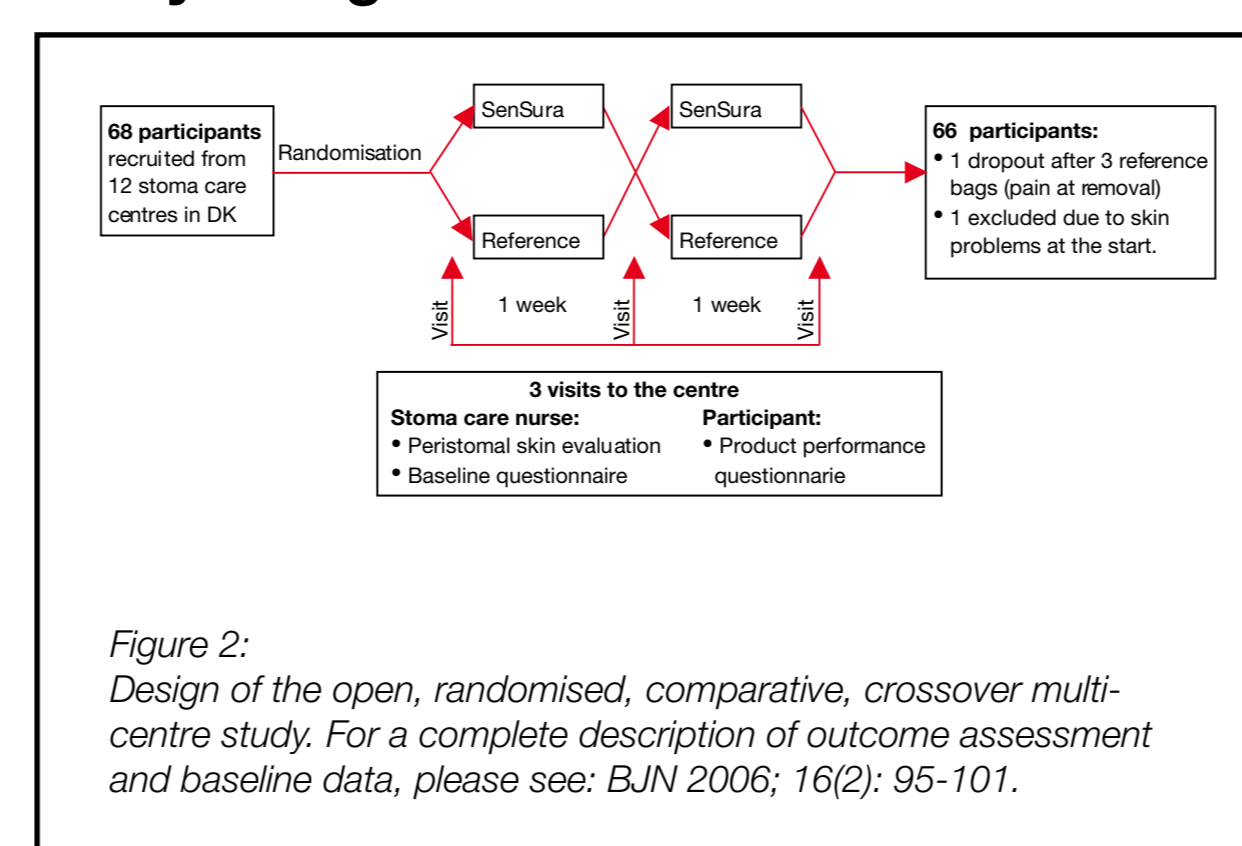


Figure 2:  
Design of the open, randomised, comparative, crossover multi-centre study. For a complete description of outcome assessment and baseline data, please see: *BJN* 2006; 16(2): 95-101.

## KEY RESULTS

- 85% preferred the SenSura bag to the reference bag, which is well-established on the European stoma care market, *Figure 3*.
- The sense of security was significantly higher with the SenSura bag, *Figure 4*.
- The SenSura bag was evaluated significantly better than the reference for 16 out of 28 secondary outcomes, *Table 1*. The reference bag was not rated better than the SenSura bag for any of the outcomes.
- Ballooning (excess air in the bag) was observed with 27% of all reference bag units and with 7% of the SenSura bags. Approximately 10% of the reference bags used were changed due to ballooning.
- 45% of the participants wearing the reference bag woke up in the middle of the night during the test period because of ballooning, ( $p < 0.0001$ ). This was 2.5 times more than with the SenSura bag.
- Both bags were safe in use and the skin was observed to be "normal skin without redness" or "normal redness and intact skin" for more than 90% of the participants throughout the duration of the study.

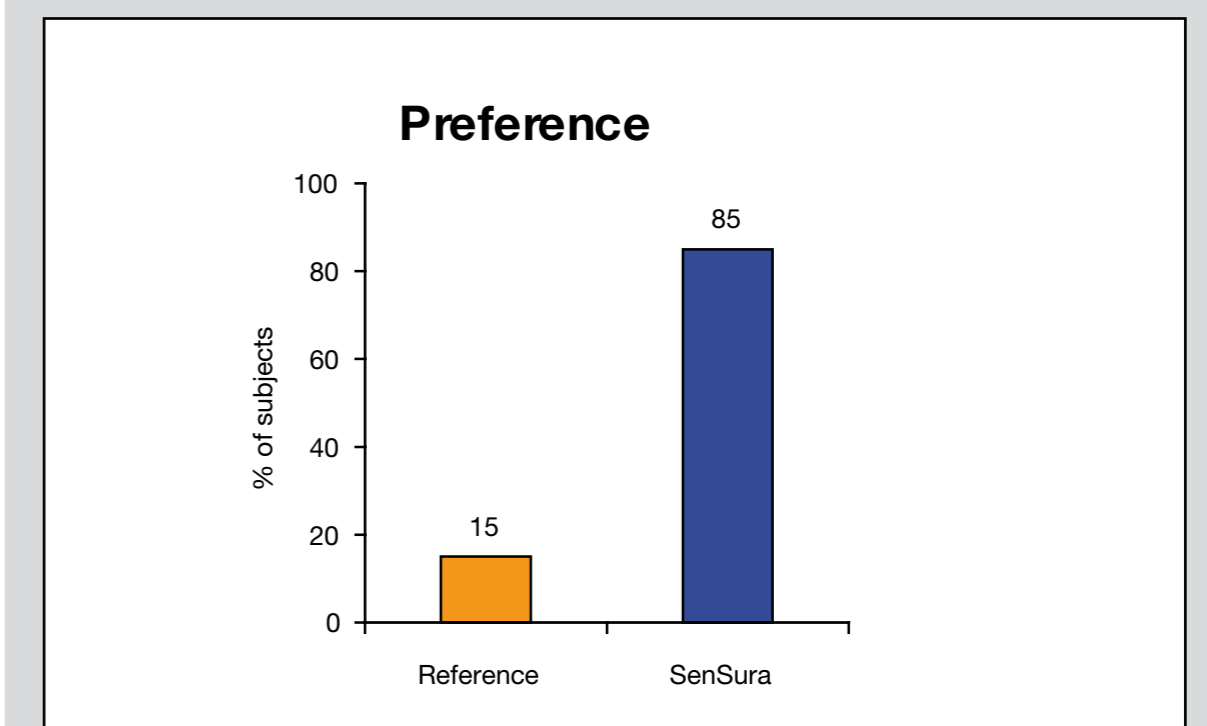


Figure 3:  
Of the 61 participants who responded to the question "Which of the two bags do you prefer?", 85% preferred the SenSura bag (95% confidence interval 76-94%) and 15% preferred the reference bag (95% confidence interval 6-24%) ( $p < 0.0001$ ).

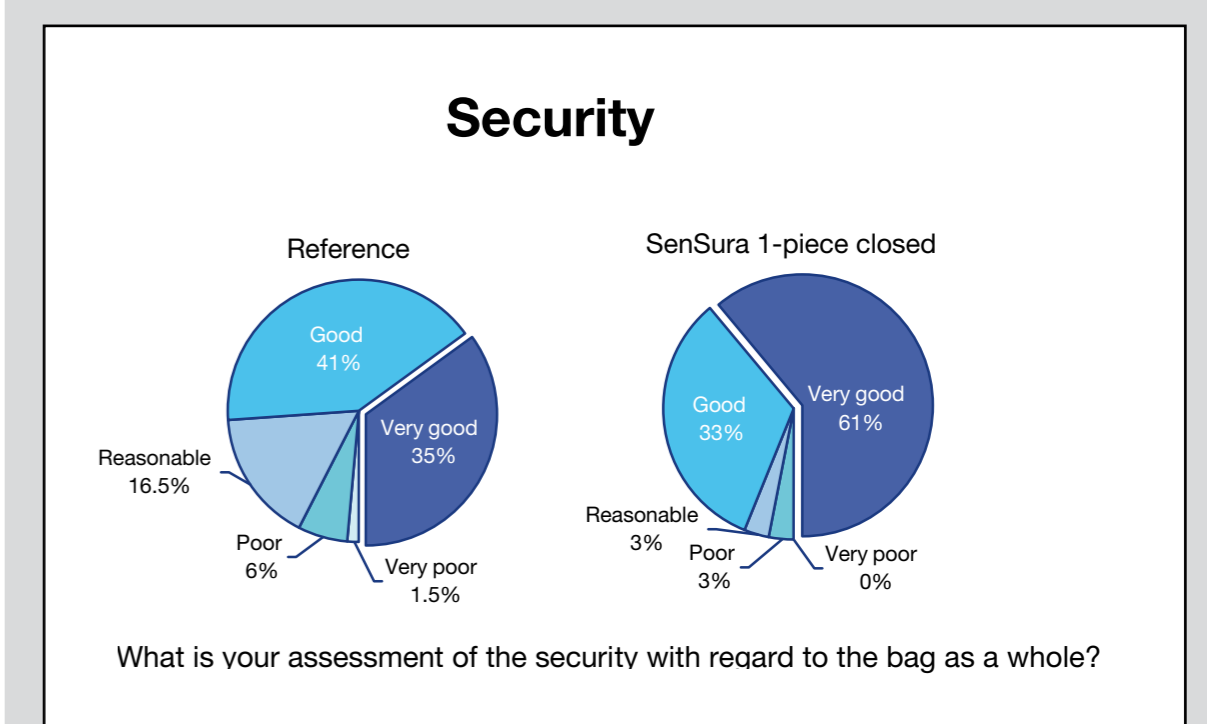


Figure 4:  
94% of the participants rated the security of the SenSura bag as "good" or "very good", compared to 76% for the reference bag. The reference bag was rated as "reasonable", "poor" or "very poor" by 24% of the participants compared to 6% for the SenSura bag, ( $p = 0.0006$ , logistic regression;  $n = 66$ ). The median on a scale from 1 (very poor) to 5 (very good) was 4.0 (reference) and 5.0 (SenSura).

Parameter	Reference	SenSura	P-value
	Median	Median	
Overall evaluation <sup>1</sup>	3.0	5.0	<0.0001
Comfort <sup>1</sup>	3.5	4.0	<0.0001
Tack <sup>1</sup>	4.0	5.0	0.0001
Flexibility <sup>1</sup>	4.0	5.0	0.001
Adhesion during use <sup>1</sup>	4.0	5.0	0.02
Ease of removal <sup>2</sup>	4.0	5.0	<0.0001
Design of adhesive <sup>1</sup>	3.0	5.0	<0.0001
Position of filter <sup>1</sup>	3.5	4.0	0.001
Ballooning (filter) <sup>3</sup>	3.0	4.0	0.0002

<sup>1</sup> 1: Very poor, 2: Poor, 3: Reasonable, 4: Good, 5: Very good.  
<sup>2</sup> 1: Very difficult, 2: Difficult, 3: Reasonable, 4: Easy, 5: Very Easy.  
<sup>3</sup> 1: Very much, 2: Much, 3: Some, 4: A little, 5: Not at all.

Table 1:  
Key performance endpoints in addition to those presented in *Figure 3* and *4*. The data is based on 66 participants fulfilling the evaluation criteria established before the start of the study.

## CONCLUSIONS

- The newly developed SenSura bag was determined to be significantly better than the reference bag with regard to the majority of key performance outcomes for the adhesive and for the filter. This was reflected in the high percentage of participants who preferred the SenSura bag (85%).
- Individuals with a colostomy can expect a higher sense of security with the SenSura bag than with the reference bag. The superior tack, adhesion and flexibility as well as less ballooning with the SenSura bag may explain this result.

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