

# Ostomy Bag Management: A Comparative Clinical Study of a New Drainable Bag for people with ileostomies

Katrin Schmitz<sup>1</sup>, Carola Seidenstricker<sup>2</sup>, Andrea Arnhold<sup>3</sup>, Petra Carstensen<sup>3</sup>, Antje Tillig<sup>4</sup>, Werner Droste<sup>5</sup>, Gertrud Brink<sup>6</sup>, Elke Fronhoffs-Schommen<sup>7</sup>, Alexandra Koch-Adolph<sup>8</sup>, Dorothea Müller<sup>9</sup>, Ebba Tautz<sup>10</sup>, and Kerstin Winkelmann<sup>11</sup>.

- 1: Stoma Care Nurse (SCN) and Health Economist, RN, Gesundheitszentrum Lang, Dinslaken, Germany  
 2: (SCN), RN, Almed GmbH, Zwickau, Germany  
 3: (SCN), RN, Nomamed Schütze/Schuster GbR, Harsum-Asel, Germany  
 4: (SCN), RN, Keimed GmbH, Dresden, Germany  
 5: (SCN), RN, Publicare GmbH, Köln, Germany  
 6: (SCN), RN, Sanitätshaus Beuthel, Wuppertal, Germany  
 7: (SCN), RN, Sanitätshaus Kelz, Mönchengladbach, Germany  
 8: (SCN), RN, Rodamed GmbH, Saarlouis, Germany  
 9: (SCN), RN, Nobaymed GmbH, Ottensooos, Germany  
 10: (SCN), RN, Medicare GmbH, Neubrandenburg, Germany  
 11: (SCN), RN, Visé Vital Service, GmbH, Magdeburg, Germany

## INTRODUCTION

- The effluent from an ileostomy is usually collected in a drainable ostomy bag and disposed of through an outlet as needed.
- Improvements of current bags are needed to minimise bag-related complications and improve the quality of life of individuals with stomas<sup>1</sup>.

## AIM

- To compare the performance of a new one-piece drainable ostomy bag, SenSura, with that of a well-established bag, focusing on minimising problems related to use of ostomy bags.

## METHODS AND PARTICIPANTS

### Products

The test and reference bags were one-piece drainable ostomy bags with a hydrocolloid skin adhesive welded on to a pouch and provided with a filter. The test bag was the SenSura bag with a double-layer adhesive and a so-called "Hide-away" outlet (Coloplast A/S, Humlebæk, Denmark), introduced in Europe in 2006, Figure 1.

The reference bag was the Moderma Flex with Lock'n Roll outlet and a single-layer adhesive (Hollister Inc., Illinois, United States), introduced in Europe in 2002.

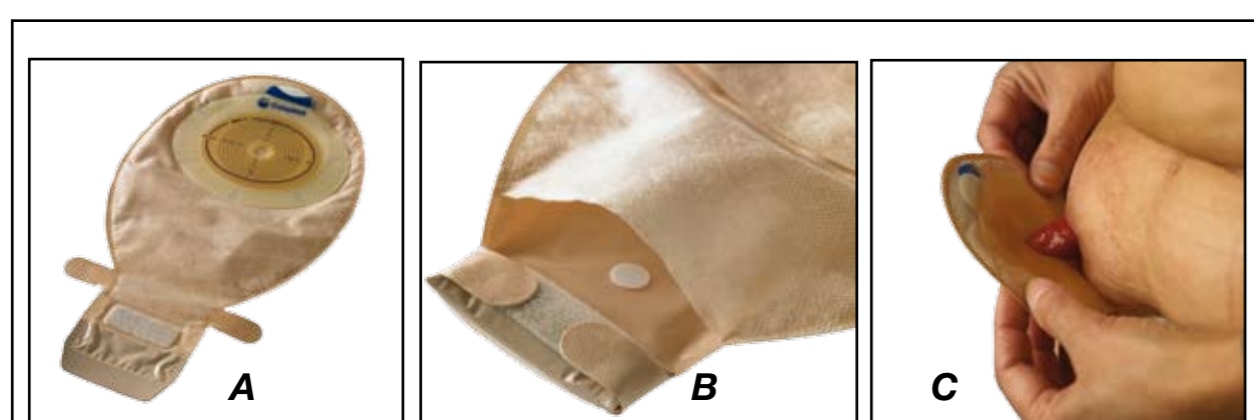


Figure 1: Open-ended ostomy bag. A: The outlet can be folded down and the effluent disposed of through the outlet. B: The outlet is folded up and can be hidden away. C: The bag is applied on the peristomal skin to collect effluent from an ileostomy.

### Participants

- 27 men and 37 women (64 in total) participated.
- Their mean age was 53 years (in the range: 21-84).
- They normally used a one-piece open ostomy bag and managed the bags themselves.
- It was a requirement that on inclusion they did not suffer from bleeding or broken skin in the peristomal area.

## CONCLUSIONS

- Individuals with an ileostomy can expect greater sense of security with SenSura. The experience of greater security with SenSura could be associated with the decreased erosion and improved tack
- Ballooning at night was not solved with any of the stoma bags in the present study. A solution to this problem remains to be found.

## Study design

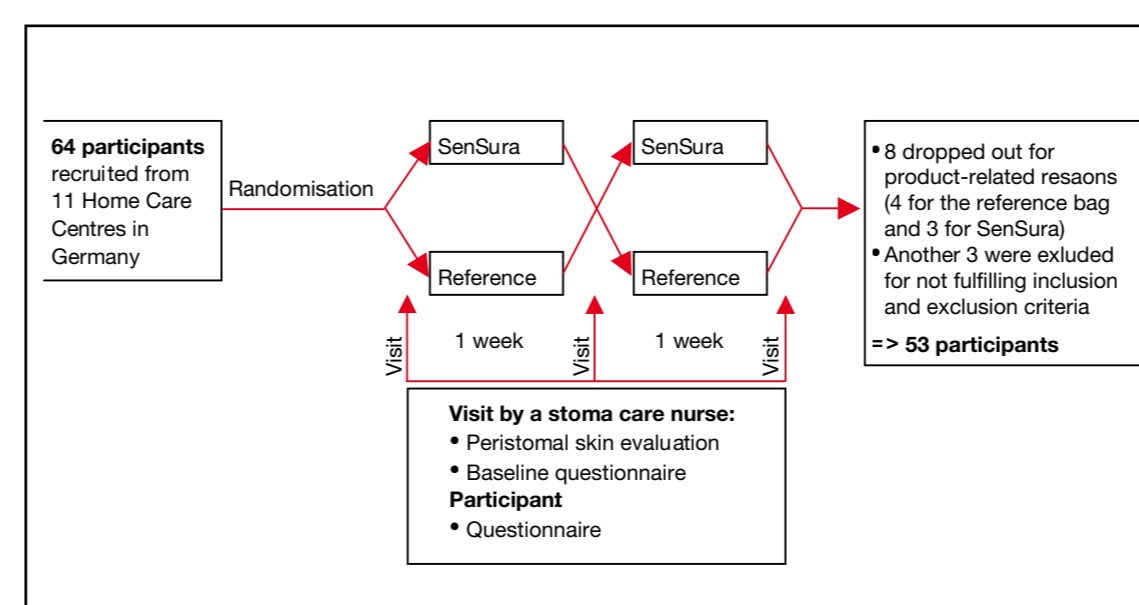


Figure 2: Study design. The investigation was an open, randomised, comparative, crossover multi-centre study. The Freiburger Ethical Committee in Germany approved the study. For a complete description please see reference 2.

## RESULTS

- 79% preferred the SenSura bag to the reference bag, Figure 3.
- Key performance outcomes for the bags as a whole and for the outlet are shown in Table 1, Table 2 and Figure 4. For more details, please see 2.
- The adhesive was very positively evaluated for the SenSura bag: 77% experienced little or no erosion with the SenSura bag whereas it was 55% for the reference ( $p=0.02$ ); 83% experienced good or very good tack with the test bag, whereas it was 55% for the reference ( $p<0.0001$ ). There was no difference between the bags in flexibility and adhesion during use ( $p<0.3$ ).
- The sense of security was significantly greater with the SenSura filter (80% of participants stated it was "good" or "very good") than with the reference filter (70%),  $p<0.05$ .
- 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 reference bag ( $p=0.4$ ).

Parameter	Reply	Reference % of participants	SenSura % of participants
Overall evaluation	Good/Very good <sup>1</sup>	34***	68***
Overall security	Good/Very good <sup>1</sup>	32*	70*
Comfort	Cornfortable/Very cornfort <sup>2</sup>	55***	87***
Discretion	Good/Very good <sup>1</sup>	64*	79*

<sup>1</sup> On the following scale: 1: Very poor, 2: Poor, 3: Reasonable, 4: Good, 5: Very good.  
<sup>2</sup> On the following scale: 1: Very uncomfortable, 2: Uncomfortable, 3: Reasonable, 4: Comfortable, 5: Very comfortable.  
 \*\*\*: significantly different,  $p<0.0005$ ; \*: significantly different,  $p<0.05$ .

Table 1: Key performance outcomes for the SenSura and reference bag as a whole. The outcomes are evaluated on a scale from 1 to 5.

Parameter	Reply	Reference <sup>2</sup> % of participants	SenSura <sup>2</sup> % of participants
Security of outlet	Good or Very good <sup>1</sup>	51	92
Handling of outlet	Easy or Very easy <sup>2</sup>	26	72
Cleaning of outlet	Easy or Very easy <sup>2</sup>	21	66
Emptying through outlet	Easy or Very easy <sup>2</sup>	30	62

<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> significantly different,  $p<0.0005$ .

Table 2: Key performance outcomes for the SenSura and reference outlet, in addition to Figure 4. Handling, security, cleaning and emptying of the outlet was rated significantly higher for the SenSura bag,  $p<0.0005$ , ordinal logistic regression.

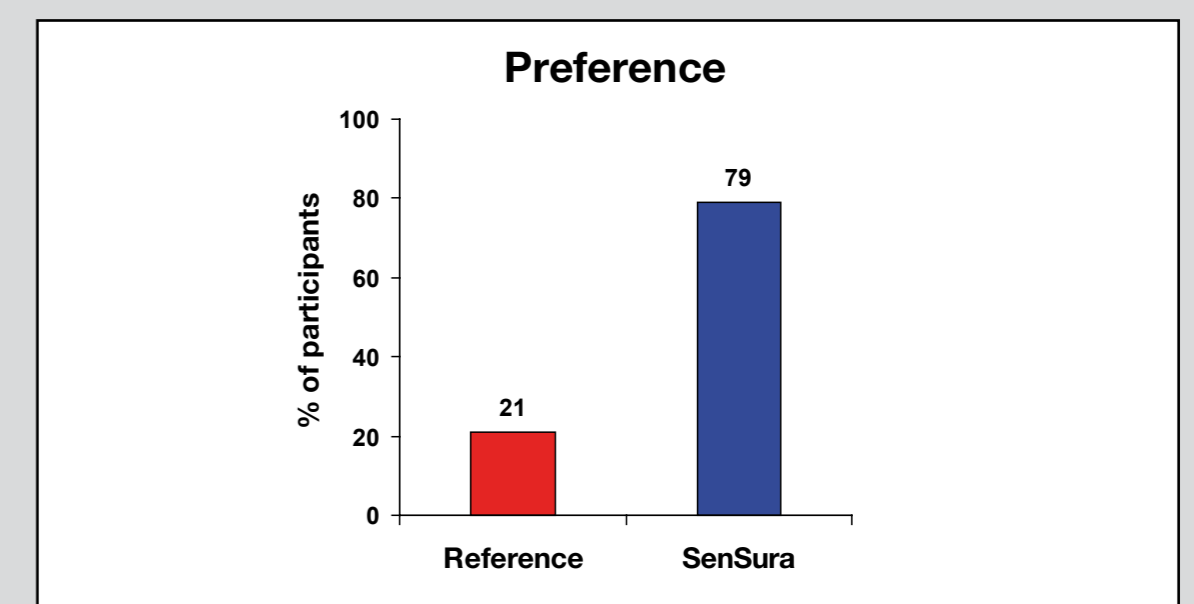


Figure 3: Of the 56 participants responding to the question "Which of the two bags do you prefer?", 79% preferred the SenSura bag and 21% preferred the reference bag, ( $p<0.0001$ ).

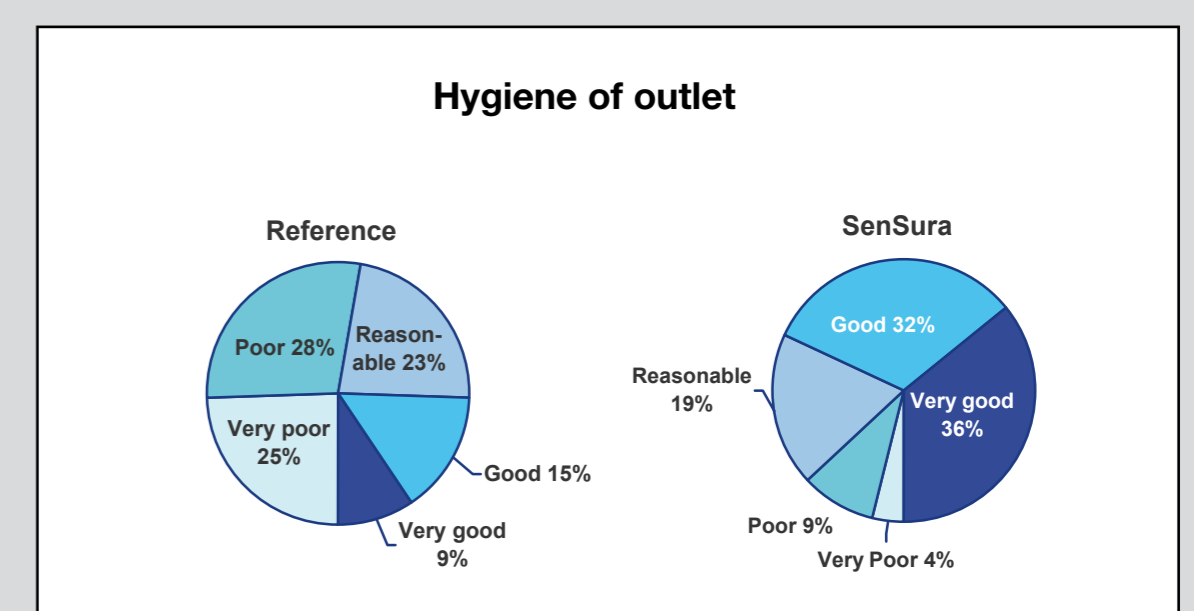


Figure 4: 68% found hygiene of the SenSura outlet to be "good" or "very good", whereas the equivalent was 24% for the reference bag ( $p<0.0001$ ). The results are based on the following question: "What is your assessment of the hygiene of the outlet".

## REFERENCES

- Nugent, K.P., Daniels, P., Stewart, B., Patankar, R., Johnson, C.D. Quality of Life in Stoma Patients. Diseases of the Colon and Rectum 1999; 42(12): 1569-74.
- Schmitz K, Seidenstricker C, Arnhold A et al. Nursing Times 2007; 103(9): 32-33.