A comparative, randomized, multi-center study of a new one-piece drainable pouching system

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INTRODUCTION

The frequency of problems related to using an ostomy pouching system can be relatively high[1]. This may affect the quality of life of a person with an ostomy[2] and there is a need to improve existing systems.

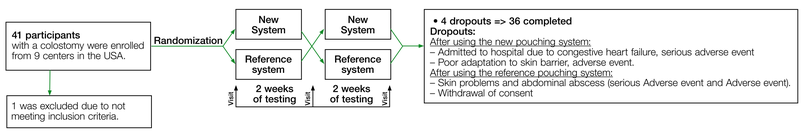
PURPOSE

To evaluate the performance and safety of a new one-piece drainable ostomy pouching system (new system) to a reference system already known to the market (reference system).

METHODS

The investigation was a comparative, open, randomized, crossover investigation and it included 9 centers in the United States of America (2006-2007), Figure 1.

Figure 1: Study design



Forty-one participants with a mean age of 63 ± 16 years (Mean ± Standard Deviation, SD) and with a colostomy (≥ 3 months duration) were enrolled. Each participant evaluated one of the pouching systems for two weeks and the other system for another two weeks in randomized order. The participants and the investigators completed a questionnaire with 29 comparative and two non-comparative parameters. The parameters were evaluated on a 5-point scale (e.g. 1: very poor; 2: poor; 3: reasonable; 4: good; 5: very good). Ordinal logistic regression was used to analyze the data (α=0.05).

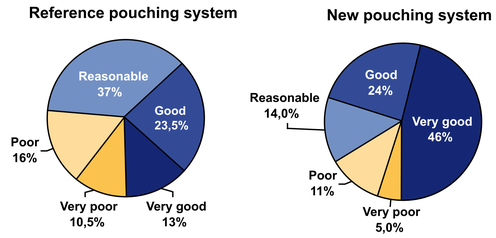
RESULTS

- The security of the new system was perceived significantly higher than that of the reference system, p=0.002, Figure 2.
- The outlet on the new pouch was superior to the reference outlet on all outcomes including handling, hygiene and security p<0.01, Figure 3.
- Overall performance outcomes for the pouching systems are presented in Table 1.
- The mean wear time was around 3 days for both pouching systems: 70 ± 37 hours for the new system and 67 ± 33 hours for the reference system, p=0.6.
- Approximately 50% of the pouches (new and reference system) could have been worn longer than they were, p=0.6. The pouches on the new system could have been worn significantly longer (2 ± 1.5 days, mean ± SD) than those on the reference system (1.5 ± 0.7 days), p<0.0001.
- There were significantly fewer problems with the filter on the new pouching system than the one on the reference system, p=0.015.
- The new pouching system performed significantly better than the reference system for approximately half of the parameters investigated in the study. The reference system was not significantly better than the new pouching system for any of the parameters.

CONCLUSION

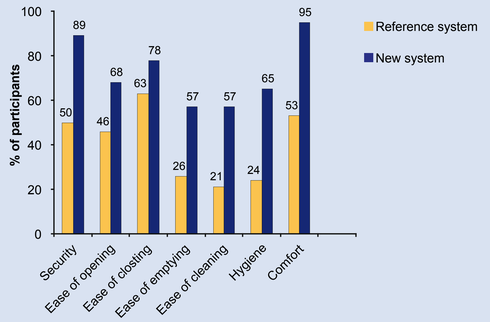
As a whole, the new pouching system was perceived as being better and more secure than the reference system. Both systems had an adequate wear time and were safe in use.

Figure 2: Feeling of Security with Regard to the Pouch



The feeling of security was perceived significantly better with the new pouching system than with the reference system, p=0.002.

Figure 3: Evaluation of outlets



The new pouching system was significantly more secure than the reference system (p<0.0001) and was more hygienic (p=0.0003) and comfortable (p<0.0001). It was also significantly easier to open (p=0.004) and close (p=0.022) and to clean (p=0.0006) and empty (p=0.0007).

Table 1: Performance outcomes

Outcome	Reply	Pouching System	Participants Number	Participants %	P-value
Overall performance of pouching system:	Good or Very good[1]	New	24	67	0.0003
		Reference	12	32	
Preference	I prefer this system	New	31	86	<0.001
		Reference	5	14	
Comfort of the pouch	Good or Very good[1]	New	32	86	0.002
		Reference	24	63	
Adhesion immediatly after application (tack)	Good or Very good[1]	New	30	81	<0.0001
		Reference	26	68	
Adhesion inner area	Good or Very good[1]	New	22	59	0.06
		Reference	16	42	
Flexibility	Good or Very good[1]	New	27	73	0.2
		Reference	23	61	

1: On a scale from 1 (Very poor) to 5 (Very good).

PRODUCTS

The new system was the SenSura® one-piece pouching system with EasiClose™, Coloplast A/S, Humlebæk, Denmark. The reference system was the Hollister Premier one-piece with Lock n' Roll™, Libertyville, Illinois, USA.

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