

Management of Fistulas in the Abdominal Region

- A non-comparative, multi-center investigation

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Case Study no.4

For overall study information please refer to the backside

Medical History

This 66-year-old female has a history of multiple enterocutaneous fistula repairs since a partial colostomy in 2000. She has metabolic acidosis, a low urine output, and acute renal failure. The fistula is located in a mid-abdominal wound with the following dimensions: 10 (L) x 5,5 (W) x 2,5 (D) cm. Output quantity is moderate, the consistency is thick and it has a golden brown colour. Five small pouches were tested.

Questionnaire

Investigator's opinion:

- Would you prefer using this pouch in the future? **Absolutely**
- Is it more or less time consuming to use this pouch compared to pouches used before? **Much less time consuming**
- How did the pouch adapt to the body? **Very well**
- What did the Investigators think of the pouch with regard to:

Wear time	Adhesiveness	Flexibility	Management of odor/flatus	Skin friendliness	Ability to access Fistula
3.3	3.5	3.5	3.5	4	4

Scale: 1 (very poor), 2 (poor), 3 (reasonable), 4 (good), 5 (very good)

Patient's opinion

- Did you feel you were able to move around while wearing the product? **Yes**
- How did the patient experience the pouch with regard to:

Flexibility	General Comfort
4.6	4.6

Scale: 1 (very poor), 2 (poor), 3 (reasonable), 4 (good), 5 (very good)

Have you been bothered by odor or flatus?	Did you experience discomfort during removal?
5	4.6

Scale: 1 (very much), 2 (much), 3 (some), 4 (a little), 5 (not at all)

Wear time

Pouch 1	Pouch 2	Pouch 3	Pouch 4	Pouch 5	Average
53 hours 30 minutes [⊙]	64 hours 00 minutes [⊙]	48 hours 20 minutes [⊙]	41 hours 45 minutes [⊙]	118 hours 36 minutes [★]	65 hours 14 minutes

★ Routine change, ⊙ Changed because of leakage.

Investigator's comments

- "Great pouch"
- "The Tracing Guide helped to make a perfect fit"
- "I'm very pleased with the new pouch"
- "Keeps skin intact"

Patient's comments

- "Some previous used pouches only lasted a few hours"

Health Economics

The objective is to identify the health economic consequences by introducing the new Fistula and Wound Management System (FWMS) compared to standard treatment. The health economic analysis is carried out as a cost-effectiveness study with focus on cost improvements. The costs are based on usage of devices, accessories and labour costs and wear time is the effect measure.

Treatment Costs = (Device costs + Accessory costs + Labour costs) x (Number of Changes)

Standard treatment in this case is a fistula pouch including accessories.

For an average changing situation the cost improvement with FWMS is minus \$18 due to its higher unit price. But when wear time is taken into account over a ten day period, cost improvements compared to standard treatment increased dramatically.

Conclusion

The case study shows that the FWMS provides clear advantages for both the patient and the nursing staff and is proved to be a cost-effective solution.

The product is very innovative and less time consuming during application. It is also very skin-friendly and conforms well to the patient due to the flexibility in the adhesive barrier.

The patient felt safer with this product since it lasted much longer than previous pouches. Also, odor and flatus were not a bother for the patient, which contributed to patient dignity when being visited by relatives. Therefore the FWMS offers a more comfortable treatment option.

Economically, the FWMS provides substantial budgetary savings due to the increased wear time when compared to the standard treatment.



1. Fistula, wound and surrounding skin before application of pouch.



2. Pouch without Flexible Lid applied.



3. Pouch with Flexible Lid and Drain Port applied.

**Cost improvement
after 10 days
of treatment:
\$US 206**

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Background

Currently management of fistulas can be a very complicated and time-consuming process for the nursing staff. The lack of a functional pouch creates an inconvenience for patients and nurses relating to leakage, skin irritation, and mobility. Furthermore, the general wear time of existing pouching systems is considered to be inadequate.

Purpose

The purpose of this investigation is to investigate the performance of a new Fistula and Wound Management System (FWMS) and its ability to efficiently manage challenging fistula pouching situations.

Objective

The primary objective is to evaluate the nurse's preference, on a 4-point scale, to use the Fistula and Wound Management System in the future.

The secondary objectives, among others, are to evaluate the performance: wear time, adaptation of pouch to fit the fistula/wound, flexibility of the adhesive, accessibility of the fistula/wound and features: Wound Trace Sheet, Drain Port and Bed Drainage Bag.

Design

The investigation is designed as a non-comparative, multi-center investigation. A maximum of 25 patients from ten centers in the United States will be included. Patients included must be at least 18 years old, capable of giving informed consent, hospitalized, and have an abdominal fistula. Patients are excluded if pregnant, breast-feeding or receiving radiation- or chemotherapy. The goal is that each patient tests five products. During the investigation, the Investigator will fill in a questionnaire with regard to the objectives listed above.

Results

The investigation is ongoing

- The first patient was enrolled in January 2006.
- The last patient and conclusions are expected in spring 2007.

Financial Assistance/Disclosure

This investigation is initiated and sponsored by Coloplast A/S.

Product information

The Fistula and Wound Management System is developed and manufactured by Coloplast A/S.

