

Management of Fistulas in the Abdominal Region

- A non-comparative, multi-center investigation

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Case Study no.1

Presented at WOCN 2006. For overall study information please refer to the backside

Medical History

This 56-year-old female had an enterocutaneous fistula that developed following multiple abdominal surgeries including removal of infected hernia mesh. The patient's overall state of health was poor. She was receiving Total Parenteral Nutrition (TPN), and suffered from morbid obesity. She was admitted with line sepsis. The fistula was located in a wound in the mid-abdominal area. Dimensions of the wound were 4.7" x 5.9". Output quantity was approximately 1200 cc daily, consistency was liquid, and the type was small bowel. The skin surrounding the wound was scarred and uneven. The patient tested three medium size pouches before she was discharged to a long-term acute care facility.

Questionnaire

Investigator opinions:

- Would you prefer using the pouch in the future? **Absolutely**
- How did the pouch adapt to the body? **Excellent – did not use wedges or fillers** (in regards to test of pouch #3)
- The immediate adhesion of the pouch? **Very good**
- 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
5	5	5	5	5	5

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

Patient opinions:

- 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
5	4.5

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	4.7

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

Wear time

Pouch 1	Pouch 2	Pouch 3	Average
49 hours 5 minutes ★	70 hours 15 minutes ★	118 hours 15 minutes ◎	79 hours 11 minutes

★ Routine change, ◎ Changed because of leakage.

Investigator's comments

"The nurses really liked it – it was easy to empty + did not leak."

"Patient loved it – she found it comfortable, flexible – in a word: wonderful"

"Pressed into folds well and adhered quickly"

"The skin around the fistula was much improved. Decreased redness and moistness" (after removal of pouch 1)

Patient comments

"I just love this thing. This has made an unbearable situation bearable, almost pleasant"

"The "Cadillac" of all stoma devices – extremely comfortable, best pouch I have ever had"

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 drainable wound manager pouch including accessories.

For an average changing situation the cost improvement with FWMS is minus \$15 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.

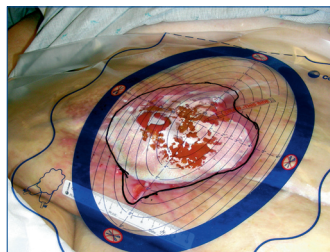
Conclusion

The Tracing Guide, Front Opening and the flexibility of the pouch made it easy for the staff to apply it on the patient and subsequently access the fistula and wound area. The long wear time of the pouch minimized the nursing time and thereby also the inconvenience for the patient of multiple pouch changes. At the initiation of the study the patient's peri-wound skin was red and broken - after the third and last pouch the skin was normal, intact and without redness. The patient was very pleased with the comfort level the pouch provided. She was not bothered by odor and flatus and experienced only minor to no discomfort during the removal.

Most importantly – the patient was able to enjoy the freedom of moving around while wearing the pouch.



1. Fistula, wound and surrounding skin before first pouch was applied.



2. Tracing Guide in use.



3. Tracing Guide applied to pouch adhesive and cut accordingly.



4. Pouch fully applied.

**Cost improvement
after 10 days
of treatment:
\$US156**

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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.

