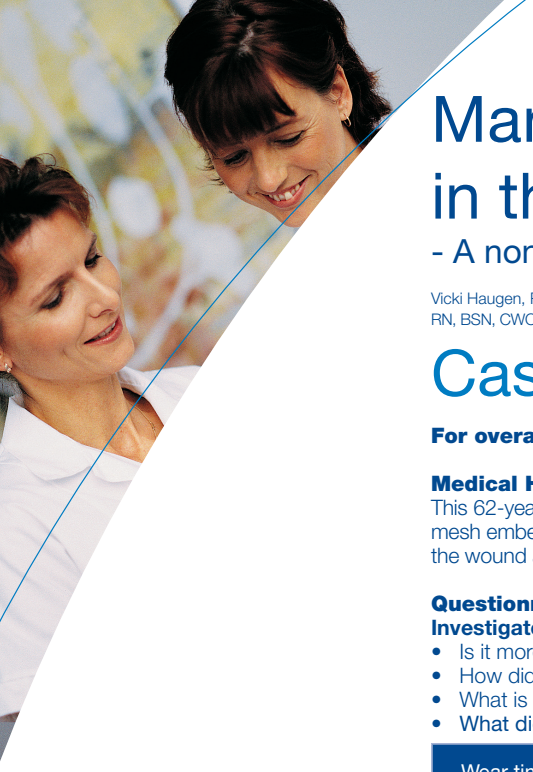


Management of Fistulas in the Abdominal Region

- A non-comparative, multi-center investigation

Vicki Haugen, RN, MPH, CWOCN, OCN [1], Julie Powell, RN, BSN, CWOCN [1], Sandra Griffin, RN, BSN, CWOCN [2], Lea Hietala, RN, BSN, CWOCN [2], Teri Garin, RN, BSN, CWOCN [2, 1] University of Minnesota Medical Center-Fairview, Minneapolis, MN, USA, [2] University of Minnesota Medical Center, Minneapolis, MN, USA

Case Study no.3

For overall study information please refer to the backside

Medical History

This 62-year-old female has a history of multiple abdominal surgeries. Her fistula developed as a result of an infected hernia mesh embedded in the bowel. The fistula is embedded in a midline, lower abdominal non-infected wound. Dimensions of the wound are 9 x 7 cm. Furthermore, she has a colostomy in the right upper quadrant. Five small pouches were tested.

Questionnaire

Investigator's opinion:

- Is it more or less time consuming to use this pouch compared to pouches used before? ***Less time consuming***
- How did the pouch adapt to the body? ***It conformed very well***
- What is your general evaluation of the pouch? ***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
3	4.25	4.5	4.2	5	5

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

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

Patient's opinion:

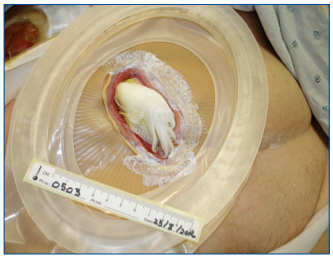
- Did you feel you were able to move around while wearing the product? ***Yes***
- How did the patient experience the pouch with regard to:

Flexibility	General Comfort
4.6	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?
4.2	3.2

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



2. Pouch applied on patient – Flexible Lid is not applied yet.

Wear time

Pouch 1	Pouch 2	Pouch 3	Pouch 4	Pouch 5	Average
72 hours 05 minutes ⊙	70 hours 10 minutes ★	46 hours 50 minutes ⊙	51 hours 30 minutes ★	70 hours 30 minutes ⊙	62 hours 13 minutes

★ Routine change, ⊙ Changed because of leakage.

Investigator's comments

- "The Tracing Guide is easy to use and allows creating a precise opening"
- "I like the flexibility and adhesive wafer – it's very effective, skin friendly and less painful"
- "The benefit with this pouch is I can pouch patient's with dynamic abdomens and deep creases which I may not have been able to pouch otherwise"

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 wound manager pouch including accessories.
For an average changing situation the cost improvements with FWMS is minus $26 due to its higher unit price. But when wear time is taken into account over a ten day period, cost improvement compared to standard treatment increased dramatically.

Cost improvement after 10 days of treatment: $US 699

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 upon application. It is also very skin-friendly and conforms well to the patient due to the flexibility in the adhesive barrier.
The patient felt freer and was able to move around which was not possible with the standard treatment. 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.

Coloplast

Management of Fistulas in the Abdominal Region

- A non-comparative, multi-center investigation

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.

Coloplast