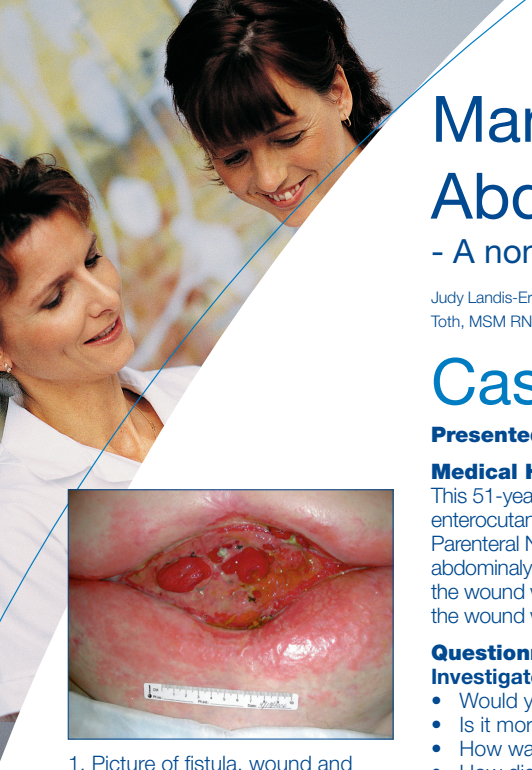

Management of Fistulas in the Abdominal Region

- A non-comparative, multi-center investigation

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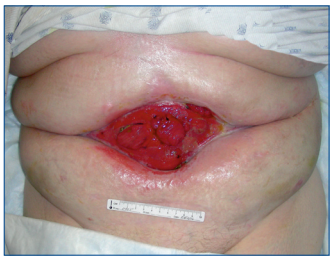
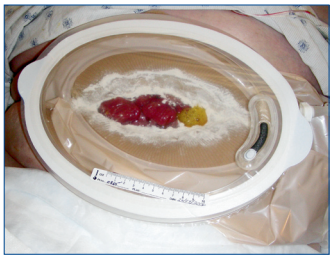
Case Study no.2

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

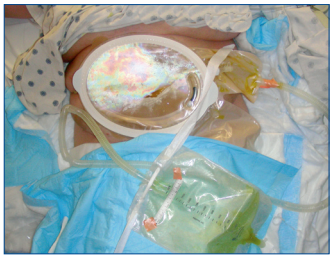
1. Picture of fistula, wound and surrounding skin before first pouch was applied.



2. Picture of same area three days later. Notice the improvement of surrounding skin.



3. Pouch fully applied.



4. Pouch fully applied with Bed Drainage Bag attached.

Cost improvement after 10 days of treatment: $US 834

Medical History

This 51-year-old female has a history of Crohn's disease and has undergone multiple abdominal surgeries. An enterocutaneous fistula developed post operatively in November 2005. During this time the patient was receiving Total Parenteral Nutrition (TPN), was obese, and was suffering from type 2 Diabetes Mellitus. The fistula was located in the mid-abdominaly area along a waistline crease. It had a granular wound bed with eight exteriorized bowel openings. Dimensions of the wound were 3 ¼" x 6 ¾". The fistula output consistency was watery and the type was small bowel. The skin surrounding the wound was uneven and creased. The patient tested four medium pouches before she was discharged from the hospital.

Questionnaire

Investigator's opinion:

- Would you prefer using the pouch in the future? ***Absolutely***
- Is it more or less time consuming to use this pouch compared to pouches used before? ***Less time consuming***
- How was it to adapt the adhesive to the fistula/wound area? ***No difficulties***
- How did the pouch adapt to the body? ***Easily***
- How was the flexibility of the pouch? ***Excellent – molded to deep creases immediately***
- 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
4	4.5	4.75	4.75	5	5

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
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	3

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	Average
65 hours 10 minutes ⊙	51 hours 55 minutes ⊙	67 hours 25 minutes ⊙	51 hours 50 minutes ⊙	59 hours 5 minutes

★ Routine change, ⊙ Changed because of leakage.

Investigator's comments

"Excellent flexibility; comfort level for patient was very good"
"Liked spout/drainage bag connection" "Used constant drainage – was easy to empty bag"
"Did not have to wedge as much"

Patient comments

"Very good comfort, until it leaked"
"Were able to move around, except when pouch leaked"

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 VAC system including accessories.
For an average changing situation the cost improvement with FWMS is $154 due to the high costs of VAC. When wear time is taken into account over a ten day period, cost improvements compared to standard treatment increases even more.

Conclusion

Staff found it easy to apply the pouch on this patient given its high moldability. They stated that less wedging was needed to fill in crevices and that it was less time consuming to apply compared to other products. Staff furthermore stated that they would absolutely prefer this pouch in the future. Given the challenges of the large abdominal crease the pouch had a satisfactory wear time. This patient was also very pleased with the comfort the pouch provided and was not bothered by odor and flatus. Last but not least, the patient was able to move around while wearing the pouch.

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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.

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