Management of Fistulas in the Abdominal Region

– A non-comparative, multi-center investigation

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BACKGROUND

- Currently management of fistulas can be a very complicated and time-consuming process for the nursing staff and it is inconvenient for the patient as well as the nurse, *Figure 1*.
- The wear time of existing pouching systems is considered to be inadequate.

Figure 1:
A fistula in an abdominal wound.

PURPOSE

- To evaluate the performance of a new Fistula and Wound Management System, *Figure 2*, and its ability to efficiently manage challenging fistula pouching situations.

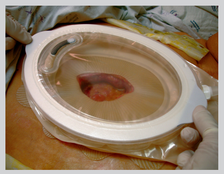

Figure 2:
The new Fistula and Wound Management System in use.

METHODS

Design

Six centers in the United States were involved. The study was non-comparative and the intention was that each patient tested five pouches.

Patients

Five males and 17 females participated in the study. They were 53.2 ± 10.7 years of age (mean ± SD).

Patients were included if they:

- were at least 18 years old
- were capable of giving informed consent
- were hospitalized
- had an abdominal fistula

Patients were excluded if they were:

- pregnant
- breast-feeding
- receiving radiation- or chemotherapy

RESULTS

In average, each subject tested 3.4 pouches and a total of 75 pouches were tested.

Baseline data

- 73% of patients had folded, uneven or scarred skin around the fistula or wounds; 18% had flat or normal skin. 81% of the fistulas were placed in a wound.

Performance outcomes

- 85% of the nurses thought that the Fistula and Wound Management system was “good” or “very good”.
- The nurses thought that the Fistula and Wound Management System was less time consuming than the pouch normally used, *Figure 3*.
- The majority of nurses answered that they would prefer to use this pouch for fistula and wound management in the future, *Figure 4*. The nurses evaluation of the pouch performance was very positive, *Figure 5*.
- With 96% of the tested pouches, the subjects answered that they were able to move around while wearing the product. The patients evaluated the overall pouch performance very positively, *Figure 6*.
- The overall mean wear time of the 75 tested pouches was 66 hours and 46 minutes. According to the nurses, 95% of the tested pouches delivered an adequate wear time.
- Residue is often a problem related to long wear times. Only 55% of the pouches produced residue, and 78% thought it was “reasonable”, “easy” or “very easy” to remove them again.
- Health Economic Analysis showed that an average pouch change with the Fistula and Wound Management System costed US$ 24.05 less than a pouch change with the standard treatment. Over a 10-day period, the cost improvement with the Fistula and Wound Management System was US$ 866.97.

CONCLUSIONS

- The majority of nurses answered that they would prefer to use this pouch for fistula and wound management in the future. Furthermore, the majority of nurses also felt that is was less time consuming to use this pouch compared to those normally used.
- The evaluation was very positive on wear time, adhesiveness, flexibility, odor/flatus management, skin friendliness and fistula/wound accessibility. This most likely explained why the majority of nurses would prefer to use the Fistula and Wound Management System when treating patients in the future.
- The subjects were very satisfied with the comfort level and overall product performance. With 96% of the tested pouches, the subjects felt able to move around while wearing the product. This would be expected to improve their quality of life significantly.
- From the Cost-Effectiveness Analysis it was clear that the Fistula and Wound Management System offers value for money in terms of budgetary savings due to the longer weartime and shorter application time.

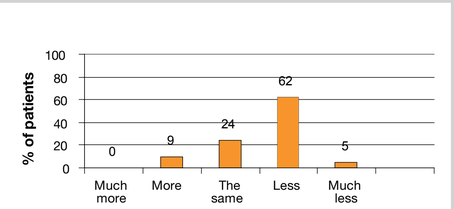

Figure 3:
Nurses evaluation of time spent when changing the Fistula and Wound Management System, compared to the pouches normally used.

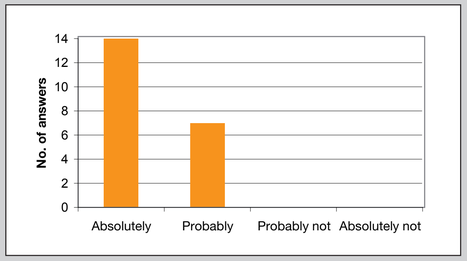

Figure 4:
The nurses' future product preference.

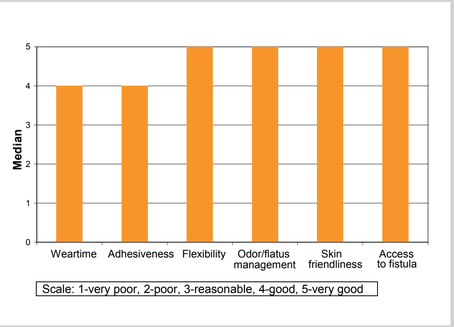

Figure 5:
Nurses evaluation of product features and wear time (medians).

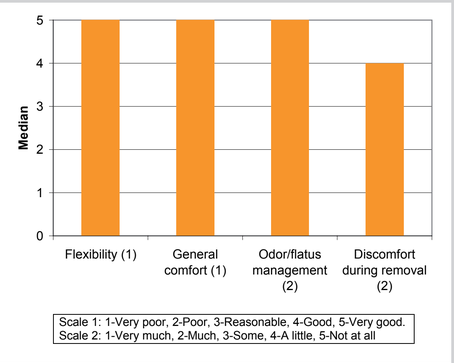

Figure 6: Patients experience with the pouch.

Presented at the WOCN Conference in Salt Lake City, USA, June 9-13, 2007.
Supported by Coloplast A/S.