An Evaluation of the Peristomal Skin Condition in Ostomates Using Moldable Skin Barriers

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Introduction

This poster presents some of the data from the OSMOSE study, an observational, prospective, multicentre study of two groups of ostomy patients:

- Group A: Patients who used a moldable skin barrier* as their first ostomy system after stoma creation
- Group B: Patients who used a moldable skin barrier* as a replacement for another skin barrier due to reported peristomal skin problems

The study objectives were to estimate the incidence and severity of peristomal skin lesions and to evaluate the change in the condition of the peristomal skin while using a moldable skin barrier over a 2 month period. In addition, patients evaluated the skin barrier's performance and rated their satisfaction with the device.

Materials & Methods

This study was conducted in France and approved by local legal authorities. Data was collected by case study reports completed by the stoma care nurse at:

- Baseline assessment (V1)
- 15 days (V2)
- 1 month (V3)
- 2 months (V4)

Peristomal Skin Assessment

A skin disorder classification instrument[1#] developed in Italy, was utilized to classify any skin lesions into two dimensions: Lesion type (L) and the Topography (T). The change in the condition of the peristomal skin over time was assessed comparing the values throughout follow-up.

Patient Evaluation of Device Performance

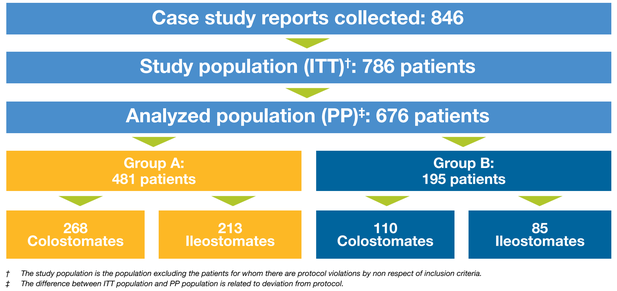
The performance of the moldable skin barriers was evaluated by the patient at each clinical visit by rating its comfort, ease of molding, ease of application and removal, level of confidence and overall performance of the skin barrier on a scale from 1=poor to 4=excellent.

Patient Satisfaction Questionnaire

Patient satisfaction was evaluated through the analysis of patient mirror questionnaires completed at 1 and 2 months. The questionnaire, which focused on satisfaction regarding comfort, ease of use, confidence, and overall assessment has been validated previously in Spain[2]. The questionnaire is composed of 13 items related to comfort, ease of use, and confidence, followed by 2 questions that involved ranking the importance of different factors. The 13 items were each rated using a 4-point scale ranging from 0='very satisfied' to 4=not at all satisfied, leading to a total score ranging from 0-'Very satisfied' to 52-'Not at all satisfied' with lower scores indicating higher satisfaction. At each visit, patients were also asked if they would recommend the device to another ostomy patient.

The questionnaire also included 2 questions for which the patient had to rank the importance of 5 items, one question focused on characteristics of the device (ease of changing, adherence, frequency of changing, security and skin protection) and one focused on information provided by the medical staff (stoma care, diet, training on instruction on device usage and how to contact medical staff).

Results



† *The study population is the population excluding the patients for whom there are protocol violations by non respect of inclusion criteria.*
‡ *The difference between ITT population and PP population is related to deviation from protocol.*

Baseline Characteristics

Baseline Characteristics N (%)	Group A (N=481)	Group B (N=195)
Age (years)	65.4 (± 14.26)	67.3 (± 13.93)
Gender	Male: 288 (60.3%) Female: 190 (39.7%)	Male: 77 (39.9%) Female: 116 (60.1%)
Ostomy type	Colostomy: 268 (55.7%) Ileostomy: 213 (44.3%)	Colostomy: 110 (56.4%) Ileostomy: 85 (43.6%)
Nature of stoma	Permanent: 143 (30.3%) Temporary: 329 (69.7%)	Permanent: 101 (52.6%) Temporary: 91 (47.4%)
Shape of stoma	Round: 219 (45.9%) Oval: 165 (34.6%) Irregular border: 93 (19.5%)	Round: 99 (51%) Oval: 55 (28.4%) Irregular border: 40 (20.6%)
Stool consistency	Solid: 56 (11.9%) Semi liquid: 229 (48.6%) Liquid: 186 (39.5%)	Solid: 48 (24.6%) Semi liquid: 91 (46.7%) Liquid: 56 (28.7%)
Time between stoma creation to inclusion (mean, SD)	7.4 days (12.33)	24.6 months (60.81)
Associated treatments (chemotherapy, radiotherapy…)	Yes: 60 (12.5%) No: 421 (87.5%)	Yes: 55 (28.2%) No: 140 (71.8%)
Type of ostomy system with moldable skin barrier used	Adhesive coupling 2-piece**: 402 (84.3%) Standard 2-piece##: 75 (15.7%)	Adhesive coupling 2-piece: 152 (77.9%) Standard 2-piece: 43 (22.1%)

In Group B, the device in use prior to the date of inclusion was:

- 2-piece device: 79.4% (n=154) [45.4% (n=88) standard, 34.0% (n=66) adhesive coupling]
- 1-piece device: 20.6% (n=40)

Peristomal Skin at Baseline

Figure 1. Type of Skin Lesions at Baseline in Group A (N=55)

In Group A, 426 (88.6%) patients had normal skin and 55 (11.4%) had abnormal skin at the baseline. For patients with skin lesions present at baseline (n=55), the majority (72.8%) were classified as L1 and L2 (Figure 1).

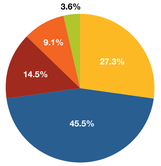
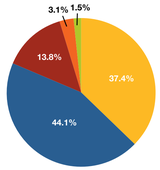


Figure 2. Type of Skin Lesions at Baseline in Group B (N=195)

In Group B, all patients (n=195) had skin disorders at baseline, the majority of which were classified as L1 and L2 (81.5%) with 13.8% of lesions L3 (Figure 2). The majority of these lesions (54.2%) were located in the lower quadrants around the stoma with 35.9% of the patients with lesions surrounding the stoma (4 quadrants affected).

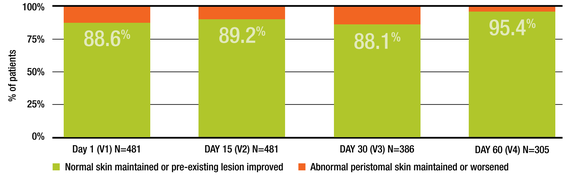


Change in Condition of Peristomal Skin over Time

For each group, the number of patients (N) corresponds to the number of patients who have completed each of the follow-ups. The 2 parameters of the peristomal skin assessment instrument were combined in order to obtain the change in condition of both lesion type (L) and topographical location (T).

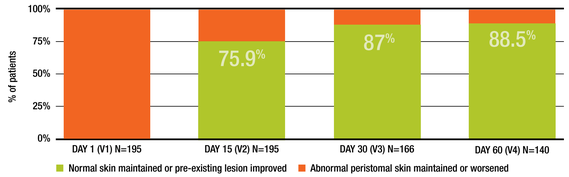
Group A: At baseline, 426 (88.6%) patients had normal skin and 55 (11.4%) had abnormal skin. At V2, V3, and V4, the percentages of patients with normal skin or improved pre-existing lesions were 89.2%, 88.1% and 95.4%, respectively (Figure 3).

Figure 3. Group A: Percent of Patients with Normal or Improved Peristomal Skin Conditions over Time



Group B: At first visit (V1), all patients had peristomal skin disorders (abnormal skin). At V2, 75.9% of patients recovered a normal skin or improved pre-existing lesions. At V3 and V4, the percentages of patients with normal skin or improved pre-existing lesions were 87% and 88.5%, respectively.(Figure 4).

Figure 4. Group B: Percent of Patients with Normal or Improved Peristomal Skin Conditions over Time

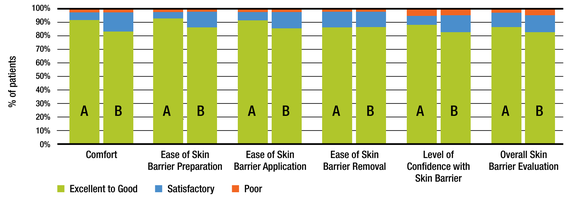


Patient Evaluation of a Moldable Skin Barrier

For Group A, the overall device was rated as good or excellent by 85.1% at V2, 89.2% at V3 and 90.8% at V4. At V4 the rates of good or excellent ranged from 86.1% to 94.9% for the various criteria (Figure 5). For Group A the highest ratings were associated with comfort and ease of preparation and application.

For Group B, the overall device was rated as good or excellent by 80.9% at V2, 85.9% at V3 and 85% at V4. At V4 the rates of good or excellent ranged from 84.4% to 86.5% for the various criteria (Figure 5). For Group B, the highest ratings were associated with ease of use (similar ratings for ease of preparation, application and removal).

Figure 5. Patient Ratings of Moldable Skin Barrier Performance (V4)



Patient Satisfaction with a Moldable Skin Barrier

Patient's satisfaction was evaluated using the mirror satisfaction questionnaire at 1 and 2 months.

Mean satisfaction scores	Group A (N=247)	Group B (N=121)
1 month (V3)	7.5	8.7
2 months (V4)	6	7.8

0-'Very satisfied' to 52-'Not satisfied'

For both groups, the mean satisfaction scores were very high and the scores improved between 1 and 2 months.

For the 2 items in the mirror questionnaire related to patients' ranking of importance:

- Most important item for patient concerning the device: "Security of the device"
- Most important item for patient concerning information provided by medical staff: "…training and instruction on how to handle the device"

At V4, 95.2% of patients from Group A and 90.3% of patients in Group B would recommend the moldable skin barrier to other ostomy patients.

Conclusions

Peristomal skin disorders are a relevant issue for ostomates and are common in patients with ileostomies or colostomies[3]. Maintaining peristomal skin integrity plays an important role in stoma management and patient satisfaction.

Key study results:

- The use of a moldable skin barrier helped to maintain or improve peristomal skin condition
- The performance of the moldable skin barrier was rated highly by patients for ease of use, security, and comfort
- Patients rated their overall satisfaction with the moldable skin barrier as very high
  - Satisfaction scores increased over time illustrating a learning curve as expected for new ostomates for whom acceptance and autonomy with their stoma care are essential.
- Patients would recommend the moldable skin barrier to another ostomy patient

References

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* ConvaTec Moldable Technology™ skin barriers
\# SACS™ Scale
** Esteem *synergy*® ostomy system
\#\# SUR-Fit Natura® ostomy system

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