Osmose Study: Multinational Evaluation of the Peristomal Condition in Ostomates Using Moldable* Skin Barriers

Mary V. Cabral, MS, RNP, FNP-BC, CWOCN-AP[1]; MT Szewczyk, Associate Professor, MD[2]; GM Majewska, RN, ETN[3]; K Hölzel-Piontek, RN[4]

[1]RI Colorectal Clinic, Pawtucket RI, USA; [2]Nicolaus Copernicus University Ludwik Rydygier Colegium Medicum and Clinic of Vascular Surgery and Specialist Center for the Treatment of Chronic Wounds, University Teaching Hospital of Dr Jurasz, Bydgoszcz, Poland mszewczyk@cm.umk.pl; [3]Ostomy Outpatient Clinic of Medical University of Bialystok, Poland; [4]RehaTechnik Jesse, Velbert Germany

Osmose Study

The OSMOSE study was an observational, prospective, multicenter, multinational evaluation of a moldable barrier in ostomates with a colostomy, ileostomy, or urostomy. Patients enrolled in group A used the moldable barrier as the first long-term system after stoma creation, and patients in group B replaced a traditional barrier with the moldable barrier. This study was conducted in Germany, Poland and USA and was approved by local regulatory authorities.

Study Objectives

The objectives of the study were to estimate the incidence and severity of peristomal skin lesions, evaluate the progression of peristomal skin condition, and assess the level of satisfaction in ostomates using a Moldable Technology Skin Barrier.

Materials and Methods

Data was collected via case report forms at baseline, and at follow-up visits 8-15 days, 1 month and 2 months after baseline. Peristomal skin condition was assessed at each visit using the SACS™ scale. The SACS™ scale classifies skin lesions in two dimensions: Lesion type (L) and the Topography (T). The progression of the peristomal skin condition was assessed comparing SACS™ values during the follow-up.

Patients evaluated the performance of the Moldable Technology Skin Barrier at each follow-up visit. Comfort, ease of molding, ease of application and removal, level of confidence and overall performance of the skin barrier were rated from poor to excellent. Patients also rated their satisfaction at 1 month and 2 months using the validated Mirror questionnaire.[1]

Results

623 patients were enrolled from 67 centers in Germany, Poland, and USA. 561 patients were included in the study population, with 277 patients in group A and 284 patients in group B. There were 369 colostomates, 160 ileostomates, and 32 urostomates. 511 patients were included in the analyzable population, with 250 patients in group A and 261 patients in group B.

Baseline Characteristics N (%)	Group A (N=277)	Group B (N=284)
Age (years)	64.7 + 12.86	66 + 12.62
Gender	Male: 160 (57.8%) Female: 117 (42.2%)	Male: 135 (47.5%) Female: 148 (52.1%)
Ostomy type	Colostomy: 195 (70.4%) Ileostomy: 72 (26.0%) Urostomy: 10 (3.6)	Colostomy: 174 (61.3%) Ileostomy: 88 (31.0%) Urostomy: 22 (7.7%)
Nature of stoma	Permanent: 174 (62.8%) Temporary: 96 (34.7%)	Permanent: 209 (73.6%) Temporary: 71 (25.0%)
Shape of stoma	Round: 166 (59.9%) Oval: 92 (33.2%) Irregular border: 15 (5.4%)	Round: 132 (46.5%) Oval: 89 (31.3%) Irregular border: 61 (21.5%)
Stool Consistency	Solid: 52 (18.8%) Semi-liquid: 144 (52.0%) Liquid: 64 (23.1%)	Solid: 74 (26.1%) Semi-liquid: 129 (45.4%) Liquid: 57 (20.1%)
Time between stoma creation to inclusion (mean, SD)	0.3 months (1.43)	18.2 months (44.35)
Associated treatments (chemotherapy, radiotherapy…)	Yes: 28 (10.1%) No: 239 (86.3%)	Yes: 52 (18.3%) No: 229 (80.6%)
Type of ostomy system with ConvaTec Moldable Technology™ Skin Barrier used	Esteem synergy™: 21 (7.6%) Combihesive®: 256 (92.4%)	Esteem synergy™: 24 (8.5%) Combihesive®: 259 (91.2%)
Type of device in use prior to study inclusion	NA	Two piece adhesive: 2 (0.7%) Two piece standard: 103 (36.3%) One piece: 168 (59.2%)

Table 1. Baseline Characteristics

Peristomal skin condition at baseline

In group A, 251 (90.6%) patients had normal skin and 26 (9.4%) had abnormal skin at baseline.

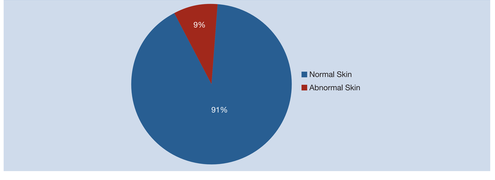

Figure 1. Peristomal Skin at Baseline in Group A

For patients in group A with baseline peristomal lesions, (n=26), they were mainly classified as L1 and L2. Some patients reported multiple lesions with differing types.

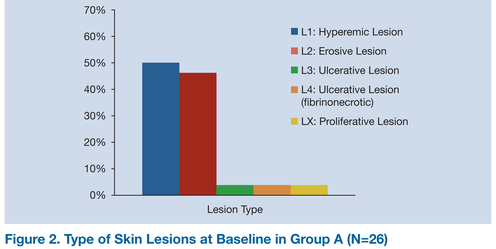

Figure 2. Type of Skin Lesions at Baseline in Group A (N=26)

In group B, all patients (284) had skin disorders at baseline; most were classified as L1 and L2 (Figure 3). Lesions in the lower quadrants around the stoma were more frequent than the upper quadrants, and 39.1% of patients had lesions in all quadrants (Table 2). Some patients reported multiple lesions with differing types and affected quadrants.

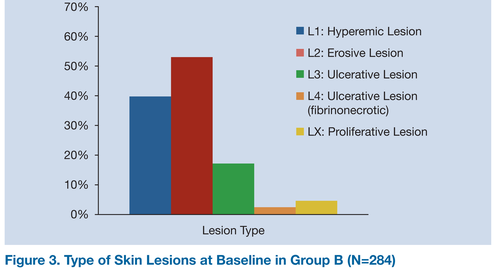

Figure 3. Type of Skin Lesions at Baseline in Group B (N=284)

Peristomal Quadrants Affected	% of Patients (N=284)
Upper Right	23.2%
Lower Right	40.1%
Lower Left	47.9%
Upper Left	21.5%
All Quadrants	39.1%

Table 2. Quadrants Affected at Baseline in Group B

Peristomal skin condition at follow-up

The number of patients (N) corresponds to the number of patients in each group who completed each of the follow-up visits: 8-15 day follow-up (V2), 1-month follow-up (V3) and 2-month follow-up (V4).

Group A:

Out of the patients completing all follow-up visits in group A, at baseline 228 patients (91.2%) had normal peristomal skin, and 22 (8.8%) had abnormal skin. At V2, V3, and V4 the percentages of patients with normal skin were 90.4%, 89.2%, and 95.6%.

Out of the patients completing V2 in group A, 5.2% of patients had new lesions or worsening of pre-existing lesions at V2 (Figure 4).

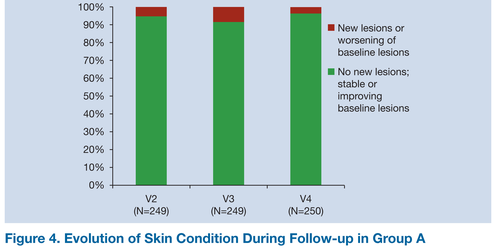

Figure 4. Evolution of Skin Condition During Follow-up in Group A

Group B:

All patients in group B had peristomal skin disorders at baseline. Out of the patients completing all follow-up visits, at V2, V3, and V4 the percentages of patients with normal skin were 39.5%, 77.4%, and 86.2% (Figure 5).

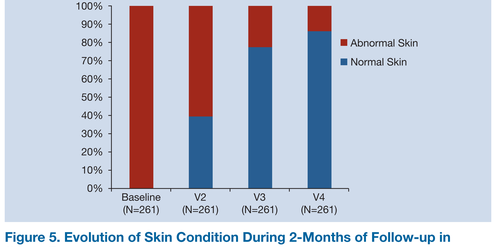

Figure 5. Evolution of Skin Condition During 2-Months of Follow-up in Group B

Out of the patients completing V2 in group B, 9.2% of patients had new lesions or worsening of pre-existing lesions at V2 (Figure 6).

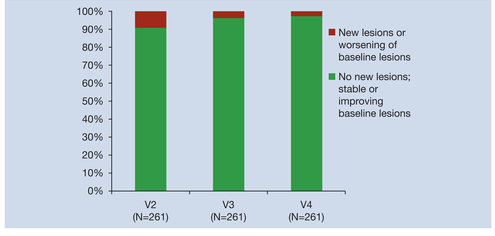

Figure 6. Evolution of Skin Condition During Follow-up in Group B

Patient Evaluation of Moldable Technology Skin Barriers

For all patients in groups A and B who completed all follow-up visits, all categories in the questionnaire (comfort, ease of preparing, ease of attaching, ease of removing, reliability, and overall evaluation) were rated as good or excellent by a combined percentage of over 96% at the 1-month and 2-month follow-up visits.

Patients in group A rated the comfort of the device at V4 as good or excellent by a combined percentage of 97.2% (Figure 7). Patients in group B rated the ease of attaching the moldable barrier at V4 as good or excellent by a combined percentage of 98.1% (Figure 8).

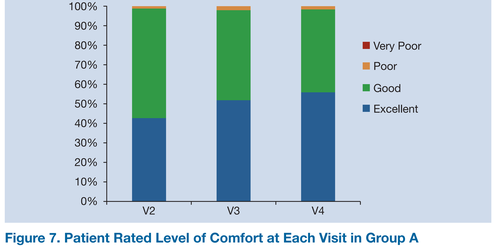

Figure 7. Patient Rated Level of Comfort at Each Visit in Group A

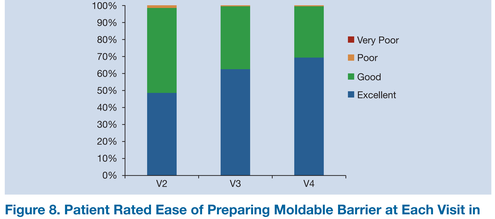

Figure 8. Patient Rated Ease of Preparing Moldable Barrier at Each Visit in Group B

Patient satisfaction with Moldable Technology Skin Barriers using the Mirror Questionnaire

Patient satisfaction was evaluated at 1 month and 2 months using the Mirror satisfaction questionnaire. The questionnaire is composed of 13 items regarding comfort, ease of use, secureness, and information provided by the medical staff, with each item rated on a scale of 0=Very Satisfied to 4=Not At All Satisfied. Overall total scores range from 0 to 52, with lower scores indicating better satisfaction.

For group A (N=250), the mean Mirror satisfaction score was 18.9 at 2 months, and for group B (N=261) was 18.1. In both groups A and B, patient satisfaction was higher at month 2 than at month 1, for group B the difference was statistically significant (P<0.001).

The Mirror questionnaire also includes two questions on patient preference regarding the relative importance from 1 to 5 (1 being most important) of characteristics of the ostomy system, and relative importance of the type of information provided by the medical staff. Patients in both groups A and B combined rated 'Secureness of the skin barrier or pouch (so that it does not leak)' (V3: 1.9 ± 1.17; V4: 1.9 ± 1.16), and 'Information on training and instruction on how to handle the skin barrier or pouch' (V3: 1.7 ± 0.95; V4: 1.8 ± 0.97) as the most important items.

Conclusion

Patients adapting to an ostomy can encounter physical issues such as skin lesions or leaks, as well as psychosocial challenges of altered body image or quality of life.[2,3] A properly fitted skin barrier and intact peristomal skin are required to avoid a cycle of leakage and erosion, which can impact the patient both physically and psychosocially.[4]

The results of this global study demonstrated that Moldable Technology Skin Barriers helped to maintain peristomal skin integrity, and helped improve the condition of the peristomal skin for patients with baseline skin lesions.

This study confirms results of previous research[5] indicating a very high level of satisfaction with Moldable Technology Skin Barriers, both in patients with a new ostomy as well as in patients changing from another type of barrier.

The patient feedback showed the importance of the security of the device and the trainings they received from caregivers on the stoma care.

References

1. Arias-Alvarez ME, Fernández MA, González A, et al. En nombre del grupo Espejo. Cuestionarioespejo. Valorar la satisfacción de pacientesostomizados con la atención sanitaria y el dispositivo. *Rev ROL Enf* 2010;33(4).
2. Brown H, Randle J. Living with a stoma: a review of the literature. *J Clin Nurs* 2005;14:74-81.
3. Berg K, Seidler H. Randomized crossover comparison of adhesively coupled colostomy pouching systems. *Ostomy Wound Management* 2005;51:30-36.
4. Herlufsen P, Olsen AG, Carlsen B et al. Study of peristomal skin disorders in patients with permanent stomas. *Br J Nurs*. 2006 Sep 14-27;15(16):854-62.
5. Hoeflok J, Guy D, Allen S, et al. A prospective multicenter evaluation of a moldable stoma skin barrier. *Ostomy Wound Management*. 2009;55(5):62-69.

The authors thank all centers who participated in this OSMOSE study.

The OSMOSE study was sponsored by ConvaTec Inc with DZS Clinical Services as partner.

Funding provided by ConvaTec Inc. There are no other conflicts of interest to declare.

"Moldable Technology" Skin Barrier used.

©2013 ConvaTec Inc Esteem synergy, Combihesive, ConvaTec Moldable Technology are trademarks of ConvaTec Inc.

*Moldable technology skin barrier: ConvaTec Moldable Technology Skin Barriers™

Poster presented at WOCN, Nashville, TN, June 21-25, 2014 AP-014483-US