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

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Osmose Study

The OSMOSE study was an observational, prospective, multicenter, multinational evaluation of a moldable barrier in ostomates with a colostomy, levoring, or unstromy. 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 Convatec Moldable Technology™ Skin Barrier.

Materials and Methods

Data was collected via case report forms at baseline, and at follow-up visits 0-15, 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.

The OSMOSE study was an observational, prospective, multicenter, multinational evaluation of a moldable barrier in ostomates with a colostomy, levoring, or unstromy. Patients evaluated the performance of the ConvaTec 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 Skin Barrier at each follow-up visit. Comfort, ease of molding, ease of application and removal, level of confidence and overall performance of Skin Barrier at each follow-up visit. Comfort, ease of molding, ease of application and removal, level of confidence and overall performance of Skin Barrier at each follow-up visit.

Results

623 patients were enrolled from 67 centers in Germany, Poland and USA. 541 patients were included in the study population, with 277 patients in group A and 284 patients in group B. There were 382 colostomates, 160 levorostomies, and 32 unstromies. 111 patients were included in the analysable population, with 230 patients in group A and 261 patients in group B.

In group B, all patients (294) had skin disorders at baseline; most were classified as L1 and L2 (Figure 5). Lesions in the lower quadrants around the stoma were more frequent than the upper quadrants, and 22.4% of patients had lesions in all quadrants (Table 2). Some patients reported multiple lesions with differing types and affected quadrants.

In group B, all patients (294) had skin disorders at baseline; most were classified as L1 and L2 (Figure 5). Lesions in the lower quadrants around the stoma were more frequent than the upper quadrants, and 22.4% of patients had lesions in all quadrants (Table 2). Some patients reported multiple lesions with differing types and affected quadrants.

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Patient Evaluation of Convatec 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 98% at the 1-month and 2-month follow-up visits.

In group A, patients rated the comfort of the device at V4 as good or excellent by a combined percentage of over 97% (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 6).

Conclusions

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. 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 psychologically.

The results of this global study demonstrated that Convatec 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.

The study confirms results of previous research indicating a very high level of satisfaction with Convatec 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 receive for new patients who have just received a new ostomy.

References

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