Clinical summary:

Osmose study, multinational evaluation of the peristomal condition in new ostomates using moldable skin barriers

Maria Teresa Szewczyk, MD, PhD; Grazyna Majewska, RN, ETN; Mary V. Cabral, MS, FNP-BC, CWOCN-AP; and Karin Hölzel-Piontek, RN; The Effects of Using a Moldable Skin Barrier on Peristomal Skin Condition in Persons with an Ostomy: Results of a Prospective, Observational, Multinational Study, Ostomy Wound Management 2014;60(12):16-26.

INTRODUCTION

Peristomal skin problems are the most commonly experienced physical complication following ostomy surgery.[1] An estimated half of all ostomates develop skin complications around the stoma, and the majority of problems stem from bodily waste leaking in between the stoma and the seal.[1,2] A prospective, multicenter, observational evaluation was conducted in Germany, Poland, and the USA to assess the incidence of peristomal complications, evaluate peristomal skin condition and assess satisfaction levels with moldable skin barriers in patients with a colostomy, ileostomy or urostomy.[3]

ConvaTec Moldable Technology™ has been on the market for nearly two decades and its technology is still innovative. It is the only customizable skin barrier that is able to rebound and mold to individual stomas for a secure fit every time.

STUDY DESIGN

- 561 patients were included in the study population* comprised of two subsets; group A (277) used the moldable barrier as the first system after stoma creation; group B (284) replaced a traditional skin barrier with the moldable skin barrier.
- In Group A there were 195 Colostomates, 72 Ileostomates, and 10 Urostomates.
- Data was collected via case report forms at: baseline, 8-15 days, 1 month and 2 months after baseline.
- Peristomal skin condition was assessed using the SACS™ scale.
- Patients also assessed the comfort level, ease of preparing, ease of attaching, ease of removal, reliability, and overall perception of the moldable skin barrier in a satisfaction questionnaire at all follow-up visits.

*The intent to treat population

The results in this summary focus on the subset of new patients for whom moldable skin barriers were their first long-term ostomy care system following stoma creation.

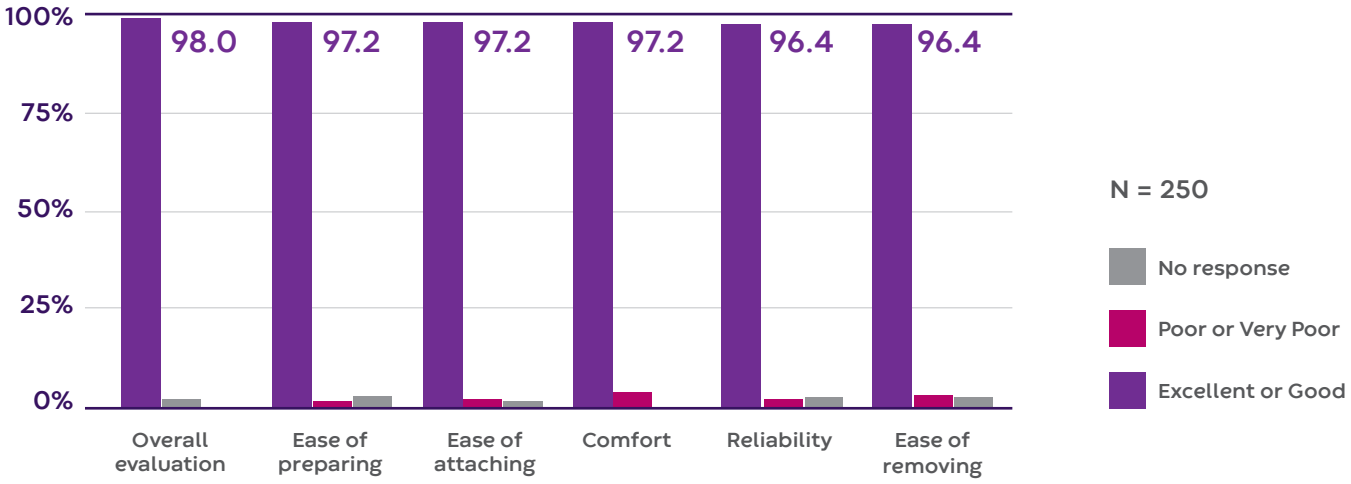
RESULTS

In Group A, 250 patients were included in the analyzable population; new patients who completed every follow-up visit. Of those new patients, **more than 95%** maintained normal peristomal skin after 2 months of using ConvaTec Moldable Technology™ skin barriers. The majority of new patients also rated the following categories as "GOOD" or "EXCELLENT":

- **Overall perception of the moldable skin barrier**
- **Ease of preparing**
- **Ease of attaching**
- **Comfort level**
- **Reliability**
- **Ease of removal**

PATIENT SATISFACTION

Analyzable population: new patients who completed every follow-up visit



CONCLUSION

- The results of this study demonstrate that moldable skin barriers helped maintain peristomal skin integrity in new ostomates for whom moldable skin barriers were their first long-term system following ostomy surgery.
- Comfort, ease of preparation, application, removal, and reliability were scored high by the majority of patients.
- Moldable skin barriers may provide multiple benefits to new patients.

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