

# An Innovative Combination Ostomy Barrier Seal and Spout to Reduce Peri-Stomal Skin Complications

Catherine T. Milne MSN, APRN, ANP/ACNS-BC, CWOCN-AP • Connecticut Clinical Nursing Associates, Bristol, Connecticut

## INTRODUCTION

- An Ostomy is a surgery to create an opening (i.e., stoma) in the abdomen to allow stool or urine to leave the body.
- Ostomy surgery is essential to treat certain conditions of the digestive and urinary systems, but it can also lead to adverse events in up to 80% of patients.<sup>1</sup>
- 75% of ostomy-related adverse events are considered peristomal skin complications (PSCs).<sup>2</sup>
- Most PSCs are caused by peristomal moisture-associated dermatitis (PMASD), which often results from exposure of the skin to stoma effluent.<sup>3</sup> PSCs can also be caused by mechanical device-related skin injuries, such as medical adhesive-related skin injury (MARS).<sup>3</sup>
- Barrier rings/seals are the most common intervention to prevent and manage PSCs. These products protect the skin from stoma output, as well as keep the ostomy pouch in place.<sup>2</sup>
- Despite recent advances in PSC management strategies,<sup>4-6</sup> PSCs remain a serious and costly health burden,<sup>2</sup> thus emphasizing the need for significant product innovation.

The case series discussed here evaluated the use of a newly available barrier seal on patients with or at risk for PSCs.

**This novel barrier seal\* was designed with an assisted flow mechanism (i.e., spout) to direct effluent away from the skin and into the ostomy pouch.**

## METHODS

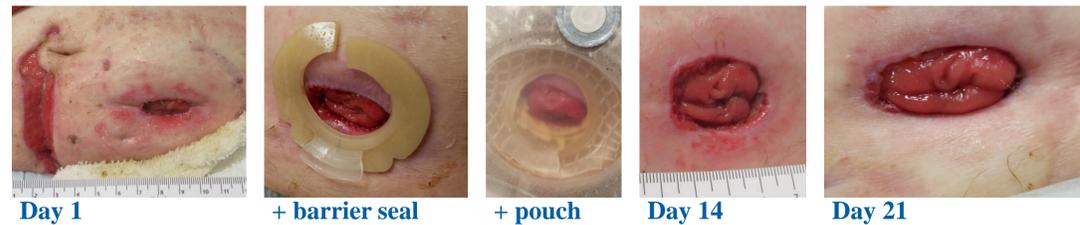
This case series included three patients with PSCs or at risk for PSCs due to peristomal topography or stomal construction.

- All patients suffered comorbidities and/or had undergone prior treatments.
- All patients had a history of stool leakage onto skin and peristomal skin issues.
- A novel barrier seal with a spout was provided to each patient.
- Wound assessment was performed at every visit.
- The patients', significant others', and healthcare providers' experiences with the new barrier seal were evaluated using a 1-5 Likert scale alongside additional comments to assess ease of use and peristomal skin condition. The Likert scale was completed at the first follow-up visit after a barrier seal with a spout was initiated and weekly for four weeks.

## RESULTS

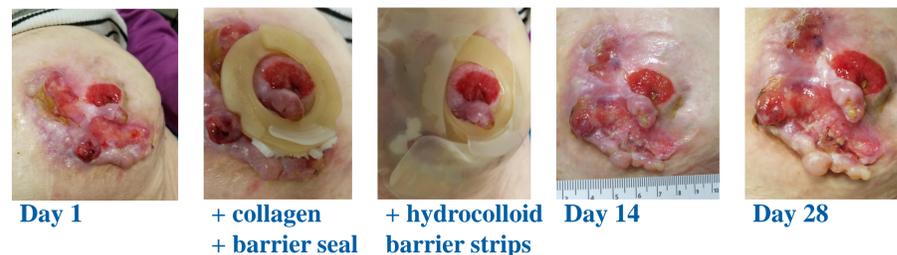
**Case #1** was a 63-year-old male with a history of left lower quadrant diverting colostomy and partial colectomy for ruptured diverticulum six weeks prior to evaluation.

- The patient also developed a midline abdominal wound infection.
- Home health services requested assistance for deteriorating peristomal skin and frequent pouch changes due to leakage.
- A **barrier seal with a spout** in combination with a convex skin barrier (i.e., convexity) was initiated. This was regarded as day 1 of treatment.
- By day 14, the peristomal skin had improved. Home health also reported a reduced need for unscheduled calls for pouch changes within one week and no unscheduled visits by day 14.
- By day 21, the peristomal skin was intact with post-inflammatory hyperpigmentation. The patient was learning self-care for stoma with the new treatment regimen.



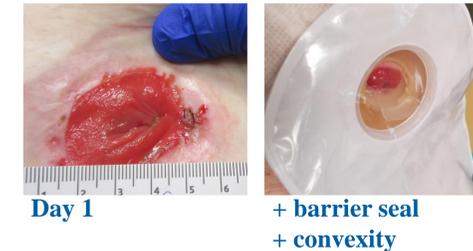
**Case #2** was a 58-year-old female with a 35-year history of left lower quadrant diverting colostomy for rectal cancer for which the patient was treated with adjunctive chemotherapy and pelvic radiation therapy.

- The patient also had a history of obsessive-compulsive disorder, depression, and anxiety.
- The patient and the significant other reported skin changes or “growths” that appeared near the stoma two years prior to an initial consultation with this provider. Biopsy of the lesion near the stoma revealed squamous cell cancer that was thought to be a Marjolin’s ulcer. The patient wanted no intervention and was sent by a colorectal surgeon for peristomal skin management.
- The patient and the significant other reported a greater than 5-year history of poor pouch adherence with pouch changes twice per day. The patient wanted to reduce stool leakage and the frequency of pouch changes, but she was resistant to change from her current pouching system, despite its contribution to skin ulceration.
- During the initial evaluation, a large parastomal hernia was noted. A **barrier seal with a spout** was initiated (day 1). Collagen was applied over Marjolin’s ulceration and other open areas prior to the barrier seal, and hydrocolloid barrier strips served as a secondary dressing.
- By Day 14, the patient and the significant other reported minimal leakage under the barrier seal. Both reported improved quality of life and wished home visits to be curtailed. The patient also reported less anxiety.
- By Day 28, the peristomal skin had improved. The patient was referred to colorectal surgery for follow-up.



**Case #3** was an 82-year-old female with a 4-year history of pruritis and “burning” at the edge of a diverting colostomy.

- The symptoms began after a failed ventral hernia repair with mesh. The patient experienced an infection following mesh implantation, which led to multiple surgical procedures that left her with a large peristomal hernia and flush stoma with lateral retraction and altered abdominal topography.
- The patient changed her pouch once every two days due to leakage of stool onto the skin and resulting pruritis.
- During the initial evaluation, stitch granulomas were noted, and the suture was removed. A **barrier seal with a spout** in combination with convexity was initiated (day 1).
- By day 7, early flattening of the granulomas was observed, and the patient no longer experienced pruritis/burning symptoms.
- By day 28, the patient had reduced pouch changes from every two days to every five days.



## OVERALL RESULTS

- All patients reported ease of use as 4.2 on a 1-5 Likert scale.
  - ❖ Positive comments highlighted an improved quality of life and reduction in PSCs
- The significant others assisting the patients rated ease of use at 4.8.
- Nurses initially rated ease of use as 3.9, improving to 4.3 after four weeks.
- Nurses rated high satisfaction (4.7) with the peristomal skin condition.

## CONCLUSION

The results from this case series support the use of barrier seals with spouts to prevent stool leakage, reduce pouch change frequency, and improve peristomal skin health. This novel device was relatively easy to use and received high marks for its impact on peristomal skin condition. Future studies could further help to confirm these results.

## ACKNOWLEDGEMENT

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\*OstoForm Barrier Rings with Flow-Assist Technology™, Ostoform LTD., Westmeath, Ireland

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