Original Investigation

Evaluation of a Novel Ostomy Barrier Ring with Assisted Flow for Individuals with an Ileostomy

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ABSTRACT

OBJECTIVE: To determine the performance and user experience of a novel ostomy barrier ring over a 4-week period.

METHODS: This single-arm investigation conducted across three clinical sites included 25 adult participants with an ileostomy for 3 months or longer. The participants used their standard ostomy pouching appliance along with a novel barrier ring for a period of 4 weeks. Skin condition was assessed using the Ostomy Skin Tool. Change in skin condition over the study period was recorded for each participant. The participants' experience in using the novel barrier ring was measured using a five-point Likert-type scale.

RESULTS: Twenty of the 25 participants (80%) completed the trial. Of those participants, the median Ostomy Skin Tool score at both the beginning (range, 0–8) and end was 0 (range, 0–6). In terms of skin condition, 7 participants experienced an improvement in skin condition, 11 experienced no change, and 2 got worse. A median score of 5 out of 5 was recorded for all questions relating to user experience.

CONCLUSIONS: Although not statistically significant, there was a clear trend toward improvements in peristomal skin condition using the novel barrier ring, even for participants who were already using a barrier ring. User feedback was positive with respect to comfort, device handling, and the perception of the device's ability to protect the skin. Further, most participants who already used a barrier ring indicated that the novel barrier ring would result in a longer wear time.

KEYWORDS: barrier ring, ileostomy, ostomy appliance, ostomy accessories, ostomy care, peristomal skin

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INTRODUCTION

People who have a surgically created stoma are at risk of developing peristomal skin complications (PSCs), with incidence rates of up to 63% reported in literature.[1–4] As a result, it is estimated that PSCs are responsible for one in every three visits to ostomy nurses.[5] Peristomal moisture-associated skin damage (MASD) is the most common form of peristomal skin damage[6,7] and encompasses the spectrum of damage that occurs when the skin is overexposed to moisture, which leads to inflammation of the skin with or without erosion or secondary cutaneous infection.[8] Martins et al[9] identified peristomal MASD as the primary cause (34.5%) of PSCs.

Protective barrier rings can be worn to restrict contact between stomal effluent and the skin.[10] However, the absorbent nature of the hydrocolloid material used in most protective barrier rings means that the barrier material absorbs the ostomy output and swells, compromising structural integrity and subsequently disintegrating. It is likely that compromised protective hydrocolloid material, compounded by the absorption of corrosive stomal output, results in skin irritation and peristomal MASD.[11,12] Although standard barrier rings can delay peristomal MASD, they cannot prevent stomal output from contacting the skin over an extended period of time. The output from an ileostomy is more liquid and corrosive than a colostomy because it is more alkaline and has more proteolytic enzymes. As such, when a hydrocolloid barrier ring absorbs the output from an ileostomy, the risk to the end user is particularly acute.

Individuals using protective barriers are required to know the shape and size of their stoma and precisely form a hole in their ostomy pouch and/or barrier to achieve an accurate and secure seal.[13] Any errors in this process can result in leakage, which may subsequently lead to peristomal MASD. Limitations such as these present an opportunity to innovate and develop new

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medical accessories to ameliorate user error and peristomal MASD. Accordingly, a novel barrier ring (Ostoform Moldable Seal with FLOWASSIST Protection; Ostoform Limited, Mullingar, Ireland) has been developed (Figure).

This barrier ring has two essential components: (1) an open, moldable hydrocolloid ring that adheres to the user's skin and easily wraps around the stoma and (2) a nonabsorbent spout with flexible side arms that prevent the hydrocolloid ring from absorbing stomal effluent while facilitating flow into the ostomy pouch. The primary aims of this innovative barrier ring are (1) to prevent the hydrocolloid in the protective barrier ring from disintegrating by limiting the absorption of stomal effluent; (2) to improve the application process of the protective barrier with a split in the hydrocolloid ring, eliminating the requirement for definitive knowledge of the user's ileostomy shape and size; and (3) to simplify placement via use of the absorbent spout as a handling tab, which makes the barrier ring easier to handle and thus easier to accurately position.[12] The novel barrier ring has been evaluated in two previous studies[11,12] and demonstrated an average reduction in PSC levels in both studies, with positive scores reported for device comfort, security, and handling.

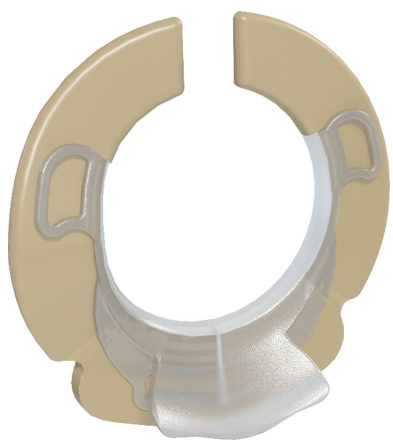
The purpose of this study was to evaluate the performance of the novel barrier ring by assessing changes in skin condition and user experiences through a single-arm, open-label, real-world study conducted among a cohort of individuals with ileostomies.

METHODS

The study was coordinated through Healthcare Innovation Hub Ireland, a public organization that facilitates the introduction of life science innovations into a clinical setting. Potential participants for this study were identified by stoma care nurses across three clinical sites: St James's Hospital, Tallaght University Hospital, and University Hospital Galway. Potential participants were approached by a research nurse or stoma nurse who explained the study; those willing to participate signed a consent form.

To be eligible for the study, participants had to meet certain inclusion criteria: aged 18 years and older, with an ileostomy of 3 months or longer duration, no evidence of open wounds near the stoma, and capable of changing their ostomy pouch and appliances independently or with a caregiver's assistance. Exclusion criteria were presence of a urostomy or colostomy; persons with an Ostomy Skin Tool (OST) score of 13 or higher; and those who were pregnant, breastfeeding, or undergoing radiotherapy.

Figure. OSTOMY BARRIER RING



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Procedure

Participants were asked to visit the clinic twice, for an initial visit (visit 1) and 4 weeks later (visit 2). At visit 1, participants were provided with the product and asked to wear the new barrier ring with their standard ostomy pouch for 4 weeks. Participants who already used an ostomy barrier ring were required to exchange their regular barrier ring with the study product for the study duration.

The new barrier ring is designed to be compatible with both one- and two-piece ostomy pouches. This allowed participants to continue using their standard ostomy pouches. Barrier ring sizing was dependent on the size of the ileostomy; two sizes of the novel barrier ring were used during the study, with inner diameters of 26 mm (for stomas 23–30 mm) and 34 mm (for stomas 30–40 mm). Ostomy pouch opening sizes were determined by the participant with the assistance of the nurse based on the size of the new barrier ring they needed.

At visit 1, participants were instructed on how to use the new barrier ring in conjunction with their standard ostomy pouch. Participants' skin condition was assessed at visit 1 (baseline score) and again at visit 2 using the OST.[14] The OST is a validated, standardized instrument that uses discoloration (D), erosion (E), and tissue overgrowth (T) to evaluate peristomal skin condition (resulting in a "DET" score). A score between 0 and 3 is assigned to the area affected, and the severity is scored between 0 and 2. As such, the three domains each have a cumulative score between 0 and 5, and the DET score is the sum of the three domains, giving an overall number between 0 and 15 (<4, mild; 4–6, moderate; ≥7, severe).[15] Nurses who were previously trained in the use of the OST collected the DET scores for the study.

To gain further insight into user perceptions of the novel barrier ring, participants were asked to rate various metrics on a scale from 1 to 5 (1, the most negative

Table 1. PARTICIPANT CHARACTERISTICS (N = 25)

Characteristics	n (%) or Median (Range)
Median age, y (minimum, maximum)	55 (25, 73)
Sex	
Female	16 (64)
Male	9 (36)
Reason for stoma	
Ulcerative colitis	9 (36)
Crohn disease	6 (24)
Cancer	6 (24)
Trauma	3 (12)
Other	1 (4)
Ileostomy type	
End	23 (92)
Loop	2 (8)
Stoma type	
Protruding	16 (64)
Retracted	3 (12)
Flush/retracted	1 (4)
Missing data	5 (20)

experience; 5, the most positive). Researchers developed a brief questionnaire of these metrics including:

- Is the product easy to put on?
- Is the product easy to remove?
- Is the product comfortable?
- Is the product effective in protecting skin?

In addition, participants were asked six yes or no questions:

- Did you experience problems using the pouch?
- Does the product easily adhere to moist skin?
- Are the instructions easy to follow?
- Did you experience pain on product removal?
- Does the product last longer than the current seal you use?
- Can you wear your ostomy pouch for a longer period with the study product than your regular barrier ring?

Data Collection and Analysis

Nurses collected the data using paper questionnaires. On study completion, data were coded: each participant was assigned a number, keeping participant names confidential (stored in a locked filing cabinet). Unblinded data were transferred by the Health Innovation Hub to a digital spreadsheet for analysis. All paper records were stored in the locked filing cabinet.

Ethical Considerations

Ethical approval for this study was granted through the local hospital ethics committees connected to each clinical site, and appliances used in the study received regulatory approval (CE marked). All participants provided written, informed consent prior to study enrollment.

RESULTS

Twenty-six people with ileostomies consented to participate in the study. One withdrew prior to commencing product use. Table 1 lists characteristics of the 25 participants. Of those who took part in this study, 20 (80%) completed it. The reasons for not completing the study include loss to follow-up (n = 2), participant did not like the product (n = 2), and adverse effects (nausea, vomiting, and swelling at stoma site), although these were not attributed to the novel barrier ring (n = 1). The baseline DET score for those who dropped out of the study was 0 for three participants, 1 for one participant, and 4 for the remaining participant.

Table 2 shows that the median DET score at baseline was 0 (range, 0 to 8). Median DET score at visit 2 was also 0 (range, 0 to 6). The change in DET score (visit 2 minus visit 1) is summarized in Table 3. The median change in DET score was 0 (range, –6 to 3). There was no statistically significant change in DET score over time (P = .25).

Of the 20 completers, 14 had used a variety of barrier rings prior to the study (five different brands). Six of the 14 participants who used a barrier ring experienced an improvement in skin condition, 7 stayed the same, and 1 got worse. User experience ratings at visit 2 are summarized in Table 4; all scored a median of 5. Other user perceptions of the novel barrier ring are also summarized in Table 5. At visit 2, the majority of participants (71%) who had used a barrier ring previously perceived the novel barrier ring to last longer than their usual barrier ring. The majority (55%) felt that pouch wear time was also longer, had no pain on removal (95%), and found the instructions easy to follow (95%).

DISCUSSION

Martins et al[9] reported PSC rates of 66% for people with an ileostomy. Similarly, NybæK et al[16] reported PSC rates at 46% for people with an ileostomy, whereas Herlufsen et al[1] report the rate at 57%. In the current study, 44% of participants scored 0 on the DET scoring

Table 2. DISCOLORATION, EROSION, AND TISSUE OVERGROWTH SCORE AT FIRST VISIT (N = 25)

Baseline Score	n (%)
0	14 (56)
1	2 (8)
2	5 (20)
3	2 (8)
4	1 (4)
8	1 (4)

Table 3. CHANGE IN DISCOLORATION, EROSION, AND TISSUE OVERGROWTH SCORE FROM FIRST TO SECOND VISIT (N = 20)

Change in Score	n (%)
–6	1 (5)
–2	4 (20)
–1	2 (10)
None	11 (55)
2	1 (5)
3	1 (5)

system, and 92% of participants had a mild skin complication (DET score of <4). It may therefore be stated that the incidence of clinically significant baseline skin complications was exceptionally low (8%). In previous studies conducted using the study product, participants with ileostomies had an average baseline DET score of 5.4 (n = 5)[11] or 6.2 (n = 12).[12] The lower DET scores upon enrollment in the current study likely meant that demonstrating improvements in skin condition was not possible or necessary.

Table 4. RATINGS AND PRODUCT PERCEPTIONS AT SECOND VISIT (N = 20)

Metric/Perception	Median Rating (Range) or n (%)
Easy to put on	5 (1–5)
Easy to take off	5 (4–5)
Seal comfortable	5 (2–5)
Seal effective in protecting skin	5 (2–5)
Problems using pouch	
No	12 (60)
Yes	8 (40)
Easy to adhere to moist skin	
No	1 (5)
Yes	17 (85)
Missing data	2 (10)
Instructions easy to follow	
No	1 (5)
Yes	19 (95)
Pain on removal	
No	19 (95)
Yes	1 (5)
Product lasts longer than current seal	
No	4 (29)
Yes	10 (71)
Longer wear time with product	
No	7 (35)
Yes	11 (55)
Missing data	2 (10)

Table 5. PRODUCT PERCEPTIONS AT SECOND VISIT (N = 20)

Perception	Visit 2 n (%)
Problems using pouch	
No	12 (60)
Yes	8 (40)
Unsure	—
Easy to adhere to moist skin	
No	1 (5)
Yes	17 (85)
Unsure	—
Missing	2 (10)
Instructions easy to follow	
No	1 (5)
Yes	19 (95)
Pain on removal	
No	19 (95)
Yes	1 (5)
Ostoform lasts longer than current seal	
No	4 (29)
Yes	10 (71)
Longer bag wear time with Ostoform Seal	
No	7 (35)
Yes	11 (55)
Missing	2 (10)

Ten of the 20 completers commenced the study with a DET score of 0 and remained at 0 at visit 2. Seven of the 20 completers improved, and 2 got worse. The most notable change in DET score was from a baseline score of 8 to 2 in 4 weeks. Future studies aiming to assess the novel barrier ring should recruit participants with a baseline DET score of 4 or higher to enable greater potential for improvements in skin condition.

For the 14 participants who used a barrier ring prior to commencing the study, median DET score was reduced from 1 to 0 (average change of 0.93 points [62%]). Although the analysis is limited and this change may not be clinically relevant, there was a trend toward improvements in skin condition, even among participants who already used a barrier ring. Although there is insufficient evidence to definitively state that the novel barrier ring acts to protect the skin from effluent, these results are encouraging.

User Experience

User perceptions offer another important method of evaluating the performance and usability of the novel barrier ring. For handling metrics (easy to put on and take off), participants scored a median of 5 out of 5, suggesting that the novel barrier ring's handling tab was positively received by users because they could avoid handling the

sticky hydrocolloid material upon application. The split hydrocolloid ring may also have proved helpful, because each participant could accurately wrap and seal each arm of the device around their stomas. These features may enhance user ability to correctly position the barrier ring.

A median score of 5 out of 5 for comfort suggests that the novel ring conforms adequately to the contours and movements of the user's abdomen. Participants generally perceived the barrier ring as effective in protecting their skin, scoring a median of 5 out of 5, which would be consistent with 90% of completers having either an improvement in skin condition or no change from a starting DET score of 0. Both participants whose DET score increased at visit 2 gave high user experience scores, and the lowest score was 4 for handling, comfort, or effectiveness in protecting the skin. This suggests that participant perception of skin condition and clinical assessment may not always align, although a sample size of two is too small to draw any definitive conclusions.

Barrier Ring Longevity

Investigators did not prescribe appliance changes, and participants did so at their discretion. As such, it was not feasible to measure or compare the number of pouch changes relative to their standard practice. However, 71% of participants stated that the novel barrier ring lasted longer than their current barrier ring, suggesting that fewer pouch changes may be required with the study product, resulting in potential savings for the end user, the healthcare system, and/or insurance providers. By protecting the hydrocolloid from excessive effluent absorption using a flexible, nonabsorbent component, material breakdown is limited, and the barrier ring can last for longer periods.

Dropouts

Trying new products requires users to stop using those that they may become accustomed to, and changes in habit can prove challenging. Two of the participants who did not complete the study did not like the novel barrier ring. Considering many users will have become accustomed to the use of their current system and switching products may cause some users unwanted stress, an element of resistance to new appliances is to be expected.

Limitations

Although a sample size of 20 completers provides a good indication of user experience, those recruited had DET scores that were too low to demonstrate whether the novel barrier ring is effective in reducing skin complications. Further, the study was conducted without a control or comparison group. Identifying a control group that is directly comparable among patients with ostomies is challenging because of the array of stoma types and product options. As such, researchers decided to use baseline skin condition as the comparison. Finally, output data for the study may have been impacted by the fact that investigators did not control the frequency and variability of appliance changes. If users changed their habits, it may have changed their perception of the product.

CONCLUSIONS

The purpose of this practical application study was to evaluate the effectiveness of a novel barrier ring in protecting the skin of individuals with ileostomies, as well as to gather feedback on user experience. Although not statistically significant, there was a clear trend toward improvement in peristomal skin condition with the novel barrier ring, even for participants who had used a barrier ring previously. User feedback was positive and most participants who had used a barrier ring previously indicated that the product would result in a longer wear time, potentially resulting in savings for individuals, healthcare systems, and insurance companies. ●

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