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Changes in Peristomal Skin Condition and User Experience of a Novel Ostomy Barrier Ring With Assisted Flow

A 6-Week Feasibility Study

Rhona Hunt ◆ Kevin Kelleher ◆ J. Calvin Coffey ◆ Mary Clarke Moloney ◆ Mary Ahern ◆ Elaine Conway ◆ Ailish Hannigan ◆ Paula Erwin-Toth ◆ Leonard W. O'Sullivan

ABSTRACT

PURPOSE: This purpose of this study was to evaluate a novel barrier ring with an assisted flow mechanism by assessing changes in peristomal moisture-associated skin damage (MASD) and perceptions of comfort, security, handling, and discretion in persons with an ileostomy for 6 months or longer.

DESIGN: Single-arm, open-labeled feasibility study.

SUBJECTS AND SETTINGS: Twenty participants (aged ≥18 years) with an ileostomy for 6 months or more participated in the study and 12 completed data collection. The primary reason for dropouts concerned compatibility issues with the barrier ring when used with certain convex pouching systems.

METHODS: Participants used the barrier ring along with their normal ostomy pouching system for a period of 6 weeks. Changes in skin condition were assessed using the Ostomy Skin Tool (OST). Participants' perception of the barrier rings' comfort, security, handling, and discretion were also recorded on a 10-point scale, where participants would offer a low score if their experience was negative and a higher score if their experience was positive. Participants changed pouches and barrier rings at their own discretion. For participants who completed the study, the average skin condition and median ratings of comfort, security, handling, and discretion at 6 weeks were compared to baseline values.

RESULTS: Twelve of the 20 participants (60%) completed the study. For those who completed, the mean score on the OST decreased from 6.2 ± 1.90 (mean ± SD) at baseline to 3.4 ±1.73 at 6 weeks, indicating a mean reduction of 2.8 (95% CI, −1.6 to −3.9; $P < .001$). The peristomal skin condition of 9 participants improved, whereas 3 experienced no change. All participants who completed the study rated comfort, handling, security, and discretion highly (median score 10 at baseline and at 6 weeks).

CONCLUSIONS: Study findings indicate the novel ostomy barrier ring may reduce levels of peristomal MASD in persons living with an ileostomy, though a more extensive trial with a control group is recommended.

KEY WORDS: Peristomal Skin Complications, Ostomy Care, Barrier Ring.

INTRODUCTION

Peristomal skin complications are prevalent, particularly for people with ileostomies, with prevalence rates of 66% reported in literature.[1] Peristomal skin complications account for more than 1 in 3 visits to ostomy nurses.[2] Peristomal moisture-associated skin damage (MASD) is the most common form of peristomal skin damage[3]; it occurs when exposure to fecal or urinary effluent leads to inflammation of the skin, with or without erosion or secondary cutaneous infection.[4] Jemec and colleagues[1] reported that peristomal MASD accounted for 35% of skin complications in their study. Hydrocolloid ostomy barrier rings prevent peristomal MASD in some; we hypothesize that the incomplete barrier offered by current ostomy barrier rings may be due to the absorbency of the hydrocolloid material used in these products.

Rhona Hunt, *MSc, School of Design, University of Limerick, Limerick, Ireland.*

Kevin Kelleher, PhD, *School of Design, University of Limerick, Limerick, Ireland.*

J. Calvin Coffey, PhD, MB, BCh, BAO, BMedSci, FRCS, *Graduate Entry Medical School, University of Limerick and University Hospitals Limerick, Limerick, Ireland; and Health Research Institute, University of Limerick, Limerick, Ireland.*

Mary Clarke Moloney, PhD, *Health Research Institute, University of Limerick, Limerick, Ireland.*

Mary Ahern, BBs, *Department of Colorectal Surgery, University Hospital Limerick, Limerick, Ireland.*

Elaine Conway, BBs, *Health Research Institute, University of Limerick, Limerick, Ireland.*

Ailish Hannigan, PhD, *Graduate Entry Medical School, University of Limerick and University Hospitals Limerick, Limerick, Ireland; and Health Research Institute, University of Limerick, Limerick, Ireland.*

Paula Erwin-Toth, MSN, RN, CWOCN, CNS, FAAN, *PETprojects, Deerfield, Ohio.*

Leonard W. O'Sullivan, PhD, *School of Design, University of Limerick, Limerick, Ireland; and Health Research Institute, University of Limerick, Limerick, Ireland.*

Authors R. Hunt, K. Kelleher, and L. O'Sullivan declare a financial interest by way of shareholding in a company that is commercializing the device.

Correspondence: *Leonard W. O'Sullivan, PhD, School of Design, University of Limerick, Castletroy, Limerick V94 T9PX, Ireland (Leonard.osullivan@ul.ie).*

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We sought to establish the feasibility of a novel ostomy barrier ring design through a 6-week single-arm, open-labeled study. Participants' skin condition was recorded at the beginning of the study and again at 6 weeks. In addition, participants' perception of the experimental device was rated based on comfort, security, handling, and discretion based on a scale of 1 to 10. These metrics were anticipated to offer researchers an indication of whether the device would be adopted by persons with ostomies outside the research setting.

METHODS

Potential study participants were recruited from the stoma care nurse's outpatient list at the University Hospital Limerick. Inclusion criteria were adults aged 18 years and older with an end or loop ileostomy created more than 6 months prior to study participation, intact peristomal skin, and capable of changing their pouching system independently or with a caregiver's assistance. Participants currently using a commercially available ostomy barrier ring were eligible for inclusion but were required to stop using their regular barrier ring for the duration of the study. Exclusion criteria were participants who had a DET (Discoloration [D], Erosion [E], and Tissue Overgrowth [T]) score of 10 or more or persons with an enterocutaneous fistula.[1]

Two sizes of the novel barrier ring were used during the study; their inner diameters were 26 or 34 mm. These sizes were selected based on prior fit-testing research, whereby various prototype sizes were manufactured and tested on prosthetic stomas. It was ultimately determined that, because of the flexibility of the device, a 26-mm size could fit stomas from 18 to 28 mm in diameter and a 34-mm size could fit stomas from 29 to 42 mm in diameter.

The study was conducted at the University Hospital Limerick in collaboration with the School of Design in the University of Limerick, Limerick, Ireland. Ethical approval was granted through the Health Products Regulatory Authority and the University Hospital Limerick.

Participants wore a novel ostomy barrier ring (OSTOFORM Mouldable Seal with FLOWASSIST Protection) developed by the Ostoform Research Group in the University of Limerick. The ring comprises a hydrocolloid ring with a flexible, nonabsorbent component, designed to prevent effluent coming into contact with the skin (Figure 1). Commercially available barrier rings are primarily circular, but the novel device comprises a broken circle so that the users can wrap it around their stoma shape for a complete fit and seal. The nonabsorbent spout is proximal to the stoma; it was designed to enable effluent to flow more efficiently into the bag, protecting the skin inferior to the stoma. An added feature of the device is that its nonabsorbent component acts as a handling tab, enabling the user to hold the barrier ring while positioning it with little effort. Feedback from initial evaluations suggests this feature makes it easier for the users to accurately position the barrier ring around their ileostomy.

Instruments

The Ostomy Skin Tool (OST) is a validated instrument that employs a DET scoring system to evaluate the peristomal skin in 3 domains: Discoloration (D), Erosion (E), and Tissue Overgrowth (T).[1] Scoring is based on the area of peristomal skin affected and the severity of the skin changes. The area affected is assigned a score between 0 and 3, and the severity is scored between 0 and 2. Therefore, each of the 3 domains has a cumulative score between 0 and 5, and their scores are summed to give a total DET score of 0 to 15.[5] A cumulative DET score less than 4 is classified as mild skin complications, scores ranging from 4 to 6 are classified as moderate, and scores 7 or more as severe. The DET scores were collected by a research nurse who was trained in the use of the OST and in ostomy pouch changing techniques. The trainer was a clinical nurse specialist in ostomy care in the University Hospital Limerick.

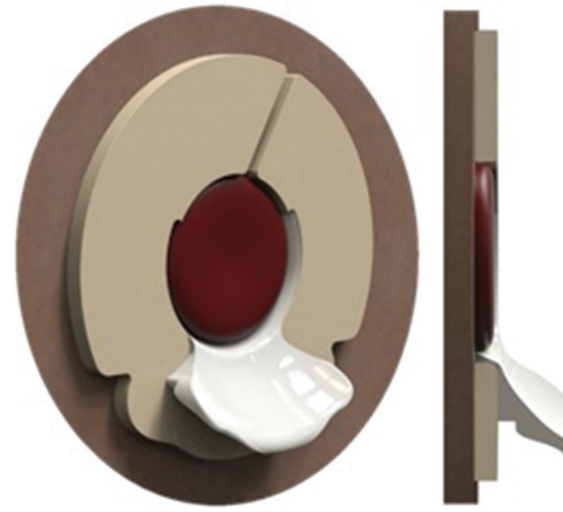

Figure 1. The OSTOFORM Mouldable Seal with FLOWASSIST Protection.

Secondary outcome measures of comfort, security, handling, and discretion were gathered on nonvalidated 10-point scales, whereby the participants were asked, by the same research nurse, to rate their perception of each. A score of 1 was considered to be the most negative result (eg, very uncomfortable) and a score of 10 was considered to be the most positive result (very comfortable).

Study Procedures

Participants were evaluated at 3 time intervals: baseline ($T = 0$), after 2 weeks ($T = 2$), and at 6 weeks ($T = 6$). Participants wore the novel barrier ring for the 6-week period, along with their own ostomy bags, and returned to their standard practice upon completion of the 6-week study.

Additional measurements recorded by the research nurse at baseline included stoma height and diameter, and waist circumference measured while the participant stood. These measurements were collected to help understand any potential challenges of certain stoma types with the new device design. For example, it would prove useful to know if the device worked with flush or retracted stomas. In the case of a loop ileostomy, the mucus stoma height diameter was recorded. Study measurements and time points are summarized in Figure 2. The novel barrier ring was developed with potential risks or serious adverse events considered, and risk analyses were regularly performed with procedures in place for reporting any serious adverse events.

Data Analysis

Categorical variables were summarized using counts and percentages. Numeric variables were tested for normality

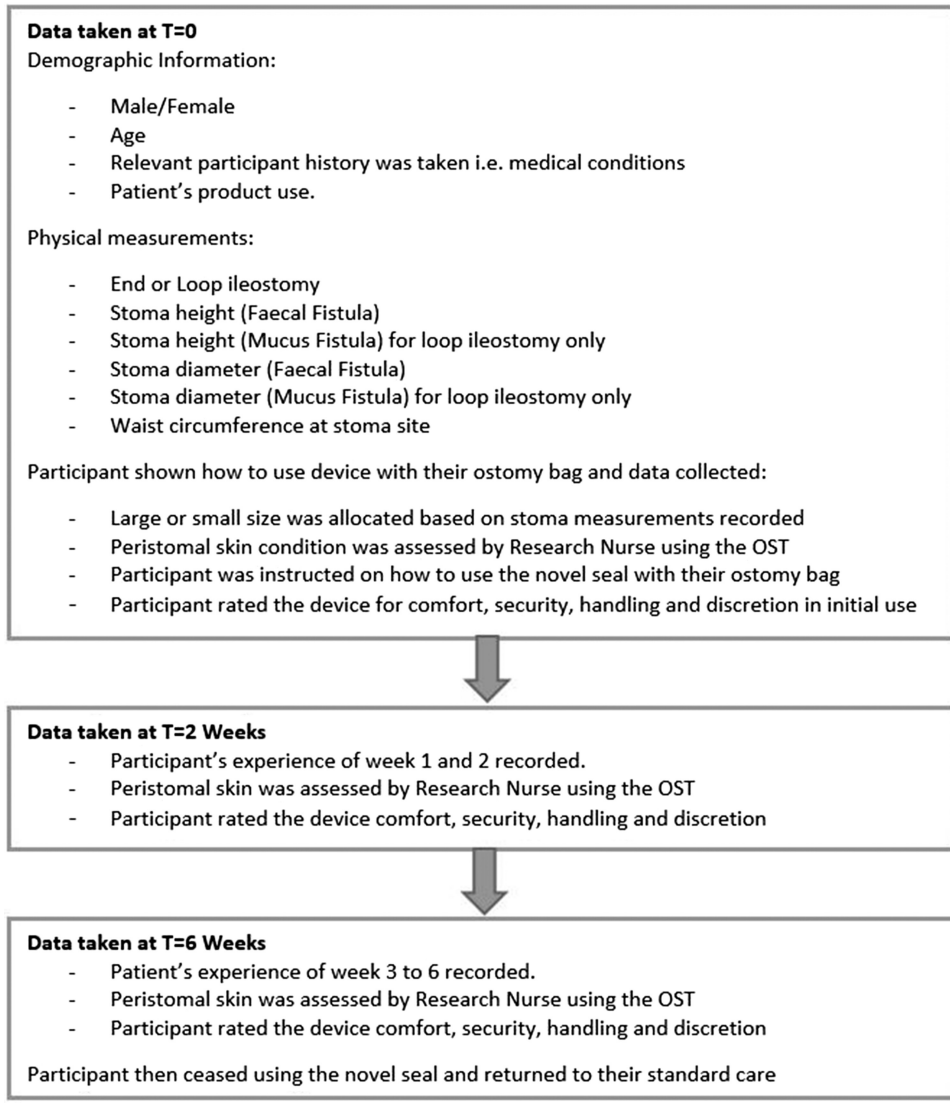

Figure 2. Overview of study measurements at each time point.

and summarized using mean (SD) for normally distributed variables or median (minimum, maximum) for skewed data. Changes in total DET scores and domain scores from baseline to 6 weeks were tested for normality, and a paired *t* test was used to test for a statistically significant mean change over time. A 95% confidence interval for the mean change was calculated. Pearson's correlation coefficient was used to measure the strength of the association between change in DET score and baseline DET score. Characteristics of completers and noncompleters were compared using a Mann-Whitney test for skewed distributions, independent-samples *t* test for normally distributed distributions, and χ^2 test for categorical variables. A 5% level of significance was used for all tests. SPSS for Windows version 22 was used for all analyses.

RESULTS

Twelve of the 20 participants (60%) who provided informed consent for participation completed data collection. Eight participants dropped out before week 12, 6 left before week 2, and 2 between weeks 2 and 6. Reasons for dropping out are summarized in Table 1. Noncompleters were more likely to be male, older, with larger waist circumferences and higher baseline DET scores than those who completed the study (Table 2).

The mean age of the completers was 49 years (SD = 11.7; range, 30-65 years). Seven (58%) were female. Eight (66%) had an end ileostomy, and 4 (33%) had a loop ileostomy. Four completers (33%) were using commercially available

TABLE 1.
Reasons for Noncompletion

Leakage due to a scissor puncture in the convex bag.
Too much pressure with the use of a hernia belt.
Inconclusive. Sore peristomal skin with no leaks experienced.
Convex bag opening size restriction was too small for correct use of the product.
Difficult mucus stoma position. Mucus emptying at 1 o'clock position.
Participant not using the correct indicated opening size.
Noncompliant patient with incorrect use of paste with the product and unwell due to Crohn disease flare-up.

TABLE 2.
Physical Characteristics of Noncompleters Compared to Completers

Characteristics	Noncompleters (n = 8)	Completers (n = 12)	*P*
Mean age in years (range)	59 (41-77)	49 (30-65)	.09
Male, n (%)	6 (75)	5 (42)	.20
End ileostomy, n (%)	6 (75)	8 (67)	1.00
Median stoma height (fecal fistula) (range)	21.5 (4-29)	19.5 (11-40)	.65
Median stoma height (mucus fistula) (range)[a]	18 (16-20)	6.5 (1-37)	…[b]
Median waist circumference (range)	1080 (690-1430)	900 (730-1160)	.07
Median baseline DET score (range)	8 (4-9)	6 (2-9)	.38

Abbreviation: DET, Discoloration, Erosion, and Tissue Overgrowth.
[a]n = 2 for dropouts and n = 4 for completers. [b]Number too small to assess.

hydrocolloid barrier rings before study participation. Physical characteristics of noncompleters and for the 12 completers are summarized in Table 2.

Among those who completed the study, we found a 45% reduction in the average DET score from baseline to week 6. The mean DET score at baseline for the 12 completers was 6.2 ±1.90. Skin condition of 1 participant was rated mild (DET <4), of 6 as moderate (DET = 4-6 category), and of 5 as severe (DET ≥7). After 6 weeks, the mean DET score for the 12 completers was 3.4 ± 1.73. Figure 3 illustrates the distribution of changes in DET score from baseline to 6 weeks, with 9 (75%) of the 12 completers having a decrease in DET scores over time, ranging from a decrease of 2 to 5, and 3 (25%) experiencing no change in DET score. At 6 weeks, the skin condition of 8 completers were rated mild (DET <4), of 3 as moderate (DET = 4-6 category), and of 1 as severe (DET ≥7).

The mean change over time represents a decrease of 2.75 in the DET score (95% CI, −1.6 to −3.9; $P < .001$). The change in DET score was strongly correlated with baseline DET score ($r = -0.57$; $P = .06$), with higher baseline scores associated with greater reductions. The mean reduction in DET score over time for those with loop ileostomies (n = 4) was comparable to the mean reduction in those with end ileostomies (n = 8) (2.5 ±1.92 vs 2.9 ± 1.89; 95% CI, −2.19 to −2.99; Figure 3). All 4 participants who previously used a barrier ring had a reduction in baseline DET score over time, with a mean reduction of 4.25 (95% CI, 3.45-5.04).

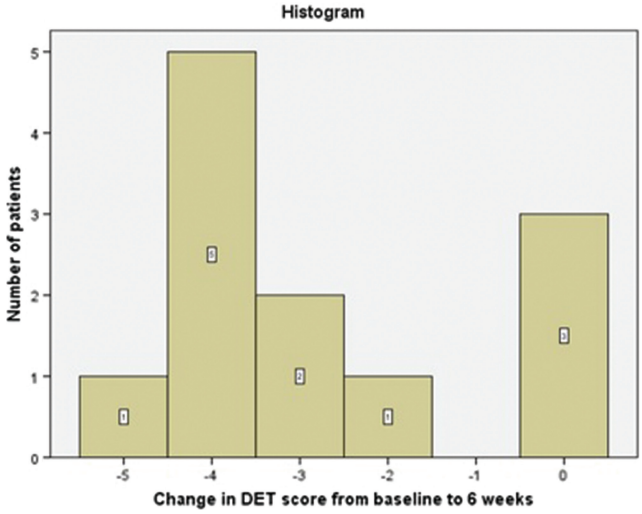

Figure 3. Distribution of changes in DET score from baseline to 6 weeks.

Tissue overgrowth was scored zero for both area and severity for all 12 completers at all 3 time points. As a result, changes in DET reflected the domains of discoloration and erosion. Discoloration area reduced from a baseline mean of 2.25 ± 0.75 to 1.75 ± 0.75 (95% CI, −1.20 to 0.19; $P = .14$), indicating a mean reduction of −0.50. Discoloration severity declined from a baseline mean of 1.33 ± 0.49 to 1.08 ± 0.29 (95% CI, −0.54 to 0.04; $P = .08$), reflecting a mean reduction of −0.25 (Table 3).

Erosion area declined from a baseline mean of 1.5 ± 0.15 to 0.30 ± 0.65. Erosion severity declined from a baseline mean of 1.08 ± 0.51 to a mean of 0.25 ± 0.45 (Table 3). There was a statistically significant ($P < .001$) reduction in total erosion score (area + severity) from baseline to 6 weeks, with 8 participants eradicating erosion.

Secondary Outcomes

For the 12 completers, their ratings of security, handling, comfort, and discretion are summarized in Table 4. The median scores were high (≥9.5) at each time point. Four of the 12 completers reported leakage prior to using the device. At 6 weeks, one of these no longer reported leakage.

There were 2 records of adverse events. One patient with ulcerative colitis was diagnosed with pouchitis after presenting to hospital with lower abdominal pain, rectal bleeding, and bleeding through the stoma. The principal investigator (J.C.C.) deemed the patient's adverse event was not product related. A second participant was admitted to the hospital presenting with right-sided abdominal pain, which was diagnosed with cholecystitis. The event was deemed not to be product related by the research nurse (E.C.) and the principal investigator (J.C.C.). In both instances, the principal investigator deemed there was no safety risk to the patients, so they remained in the study.

DISCUSSION

We designed and tested a novel ostomy device with a nonabsorbent component to prevent the skin from exposure to prolonged contact with fecal effluent. We assert that this feature of the design is one important reason why participants who had been wearing a barrier ring before commencing the study experienced an improvement in skin condition. Of the 12 participants who completed the study, 4 had loop ileostomies.

TABLE 3.
Changes in Discoloration and Erosion Over Time (n = 12)

	Discoloration		Erosion	
	Area	Severity	Area	Severity
Mean (SD) at baseline	2.25 (0.75)	1.33 (0.49)	1.50 (0.80)	1.08 (0.51)
Mean (SD) at 6 wk	1.75 (0.75)	1.08 (0.29)	0.33 (0.65)	0.25 (0.45)
Mean difference over time (95% CI)	−0.50 (−1.20 to 0.19)	−0.25 (−0.54 to 0.04)	−1.2 (−1.62 to −0.71)	−0.83 (−1.20 to −0.47)
P	.14	.08	<.001	<.001

The change in skin condition for these 4 participants was comparable to those with end ileostomies, indicating that the novel barrier ring may be useful for both types of stoma.

Participants rated the handling of the product highly (median score of 10 at all time points). An added feature of the spout design was that it could be used as a handling tab, enabling users to position the barrier ring underneath the stoma during use without touching the hydrocolloid ring. The research nurse observed that participants were inclined to use the device in this manner. It seems plausible that the ability to avoid toughing the ring's hydrocolloid may improve positioning accuracy and the quality of seal around the stoma. A potential concern for the protruding spout is whether it would be visible underneath the user's clothes, but ratings of discretion were also high (median score of 10 at all time points), suggesting that the spout protrusion and overall design were sufficiently discreet.

Eight of the 20 participants did not complete the study; completers were older, had higher baseline DET scores, and were of larger waist circumference. Trying a new accessory can require some changes in practice for the user, which may prove more challenging for older users who have become accustomed to using their current pouching system. For 3 participants who opted out, the use of their convex bag in combination with the novel barrier ring proved challenging. Because the hydrocolloid in the novel barrier ring is thick (3 mm), combining a convex bag with a thick protective ring can result in accumulated peristomal pressure. Pouching systems with convexity create some pressure against the peristomal skin, and the introduction of additional material to the peristomal area may further increase pressure to this area, potentially causing discomfort. In one case, the participant used an ostomy belt, which, again, was suspected to have contributed to increased pressure. Further product development could include a thinner version of the novel barrier ring for use with convex bags.

Limitations

The study included no control or comparison group and a completer analysis was undertaken after 8 patients (60%) withdrew from participation before completing data collection. We recommend additional studies with a larger sample size and control or comparison groups to provide more definitive evidence of the efficacy of the novel barrier ring tested in this study.

We used the OST to measure changes in peristomal skin condition. The OST is a validated instrument[1] that measures the overall skin condition rather than peristomal MASD. Therefore, other factors such as mechanical dermatitis and allergies may also affect the DET score. To the researchers' knowledge, at the time of data collection, no validated measurement tool specifically for peristomal MASD is available.

TABLE 4.
Median (Min, Max) Participant Rating for Security, Handling, Comfort, and Discretion (n = 12)

	Baseline	Week 2	Week 6
Security	10 (5, 10)	9.5 (5, 10)	10 (6, 10)
Handling	10 (5, 10)	10 (8, 10)	10 (7, 10)
Comfort	10 (6, 10)	10 (8, 10)	10 (7, 10)
Discretion	10 (7, 10)	10 (7, 10)	10 (6, 10)

CONCLUSIONS

We conducted a feasibility study of a novel ostomy barrier ring designed to prevent peristomal MASD. The barrier ring's nonabsorbent spout component for assisted flow was designed to minimize the amount of effluent contacting the peristomal skin, and initial participant data from this 6-week feasibility study suggest that the device may be effective for prevention of peristomal MASD. In addition, participant ratings relating to the usability of the novel barrier were high. A trial with a larger participant sample size is recommended to provide more definitive evidence of device efficacy.

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