Original article

Beyond fit: the missing link between leakage and peristomal skin health

ABSTRACT

Aim To examine how clinicians perceive peristomal skin health and define leakage, and to assess whether consideration of barrier formulation is associated with clinician confidence in leakage prevention and approaches to skin protection.

Methods A structured cross-sectional survey of 565 clinicians involved in ostomy care was conducted across multiple countries. The survey explored definitions of leakage, confidence in preventing leakage despite optimal fit and the role of barrier formulation in maintaining peristomal skin health. Data were analysed using descriptive statistics and exploratory cross-tabulation to identify patterns and associations.

Results Findings showed substantial variation in how clinicians define leakage. Overall, 51% defined leakage as any effluent under the barrier, 40% as effluent that compromises wear time or skin health, and 8% only when effluent escaped beyond the barrier. Despite optimal fit, 88% of clinicians reported they could not confidently say leakage would never occur. Although 56% reported always considering barrier formulation, 37% did so only sometimes. Clinicians who consistently considered formulation demonstrated greater confidence in leakage prevention, clearer definitions of leakage and a more proactive approach to peristomal skin health.

Conclusion Peristomal skin health cannot be defined by pouching system fit alone. Variation in leakage definitions and inconsistent integration of formulation into practice may hinder prevention-focused care. These findings support fit and formulation as complementary pillars of peristomal skin health and highlight the need for unified language, clinician education and evidence-based pathways to improve patient outcomes.

Keywords ostomy, leakage, skin health, fit, formulation.

For referencing Purnell P and Defante A. Beyond fit: the missing link between leakage and peristomal skin health. WCET™ Journal 2026;46(3):10-17.

DOI https://doi.org/10.33235/wcet.46.3.10-17

INTRODUCTION: THE CHALLENGES IN DEFINING PERISTOMAL SKIN HEALTH

Irrespective of ongoing advances in ostomy care, peristomal skin complications (PSCs) remain prevalent, affecting up to 73% of patients and leading to significant physical, emotional and financial burdens.[1,2,3,4] Leakage and skin irritation are persistent concerns, yet many patients and clinicians struggle to recognise or address early signs of skin compromise.[1,2,3,4]

Leakage plays a central role in driving peristomal skin complications, however, there remains little consensus in clinical practice on how leakage is also defined, recognised or managed.[5] Clinicians and researchers vary widely in what they consider a "leak," ranging from any effluent detected beneath the barrier to only overt or catastrophic failure.[5,6] This lack of definitional clarity has important implications for prevention and management strategies, clinician confidence and patient education. While secure pouching system fit has traditionally dominated leakage management, increasing attention is being directed toward barrier formulation and proactive skin protection strategies to address early or subclinical compromise. Understanding how clinicians conceptualise leakage - and whether formulation is consistently integrated into management decisions - is essential to advancing a more unified, prevention focused approach to peristomal skin health.

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WHY UNDERSTANDING PERCEPTIONS MATTERS

For clinicians

A deeper understanding of how skin health and leakage is perceived allows clinicians to better serve the needs of their patients, tailoring education and interventions to address real-world challenges and misconceptions.[1,2,3,4] Clarifying expectations around leakage and skin health may support

greater confidence and more proactive, prevention-oriented care.

For industry

By identifying gaps between clinician, end user, and expert perspectives, industry can act as connectors; bridging knowledge and practice to drive innovation, improve messaging and support evidence-based care.[1,2,3,4] Aligning education and communication with real-world clinical perceptions is critical to supporting consistent, outcome driven practice.

POTENTIAL BARRIERS TO THE CONCEPT OF PERISTOMAL SKIN HEALTH

While secure pouching system fit has traditionally been considered the cornerstone of peristomal skin health, emerging evidence and expert consensus highlight the critical role of formulation; specifically, the composition and technology of ostomy skin barriers and related products.[7,8] Formulation encompasses the materials, adhesives and protective ingredients designed to maintain skin integrity, prevent irritation and proactively address the risk of leakage.[7,8] Innovations in barrier technology, such as advanced hydrocolloid blends and moisture management systems,[9,10] have demonstrated measurable reductions in peristomal skin complications, even among patients with challenging stoma profiles.[7,8]

Despite these advances, many clinicians continue to emphasise fit more strongly than formulation, rather than weighing both equally, often due to ingrained prescribing habits or scepticism about the clinical significance of product differences.[7,8] This hesitation may be reinforced by limited targeted education, variable exposure to emerging technologies, or reliance on habitual prescribing practices.[11,12,13] However, studies show that proactive selection of appropriate formulations as an integral part of leakage management strategies can improve patient comfort, reduce the incidence of skin breakdown and enhance overall quality of life.[7,8]

To bridge this gap, it is essential to foster a mindset that values both fit and formulation as complementary elements of peristomal skin health.[7,8] Educational initiatives, transparent communication of evidence, and collaborative decision-making among clinicians, patients and industry partners can help overcome resistance and ensure that product selection is guided by clinical outcomes rather than habit or external influence.[7,8]

THE PARADOX OF PATIENT CHOICE IN PRODUCT SELECTION

The paradox of choice is especially pronounced in ostomy care, where new patients are often presented with a range of product options despite having little to no prior experience or understanding of their implications.[11,14,15,16] While patient empowerment and autonomy are important, offering extensive choice without adequate education can lead to confusion, anxiety and suboptimal decision-making.[11,14,15,16]. Without structured guidance, product selection may be driven by preference rather than evidence or individualised assessment.[11,14,15,16] This may result in an increased risk of peristomal skin complications, dissatisfaction, and a cycle of trial and error that undermines both patient outcomes and confidence.[11,14,15,16]

For clinicians, the flipside of this choice is complex. When product selection is driven by patient preference or manufacturer relationships rather than clinical judgment, the clinician's expertise may be undervalued.[13] This shift risks diminishing the clinician's role as an expert guide in evidence based decisionmaking.[13] This shift can also erode the clinician-patient relationship and diminish the perceived value of clinical assessment and evidence-based recommendations.[13] Ultimately, the risk is that both parties lose: patients may not receive the optimal care they need, and clinicians may find their professional contributions marginalised.[13]

To address this, it is essential to balance patient autonomy with structured education and clear clinical pathways.[12] Clinicians should be empowered to guide product selection based on evidence and individual patient needs, while patients should be supported to make informed choices.[12] This approach not only improves outcomes but also reinforces the value of clinical expertise in the management of peristomal skin health.[12]

This paradox reflects a broader lack of shared definitions around leakage and peristomal skin health, which may undermine confident, evidence-based decision-making. To explore how clinicians define leakage, assess preventability, and incorporate formulation into practice, a structured survey was conducted across a broad clinical population to capture these points.

SURVEY DESIGN AND METHODOLOGY

To better understand how clinicians perceive peristomal skin health and leakage in practice, a structured cross-sectional survey was developed for clinicians involved in ostomy care. Survey questions were developed in collaboration with biostatisticians from the Global Marketing & Analytic Insights department of Hollister Incorporated to support the integrity, reliability, and validity of the instrument.[17] The survey explored how clinicians define leakage, their confidence in preventing leakage despite optimal pouching system fit, and the role of barrier formulation in maintaining peristomal skin health. It was administered predominantly in English to acute care, rehabilitation and community care clinicians performing stoma care; however, local translations were provided in some countries to improve clarity and support participation. Available translations included Japanese, French, German and Portuguese. The anonymous survey was delivered via SurveyMonkey, with data housed in Qualtrics. Distribution occurred by email using local internal databases, except in the United States, where the survey was distributed through the Wound, Ostomy and Continence Nurses Society (WOCN).

In the United States, Hollister Incorporated provided funding to support WOCN distribution to its membership list; no funding was provided for survey distribution in other countries. Response rates varied by country from 5.98% to 65%, with an overall average response rate of 42.2% across the aggregated dataset. A total of 631 responses were initially received; however, incomplete survey responses were discarded, resulting in a final analytic sample of 565 responses.

The survey included demographic questions to characterise respondents by role, years of experience, practice setting and geography, followed by targeted questions focused on leakage definition, prevention and skin health management strategies. Emphasis was placed on distinguishing between fit based and formulation-based approaches to skin protection, reflecting emerging discussions within ostomy care regarding the multifactorial nature of peristomal skin health.

More than 550 clinicians participated, representing a broad range of experience levels, practice settings and countries. While responses were predominantly from the US, international participation provided valuable comparative insights into how leakage and formulation are conceptualised across regions.

Survey data were analysed using descriptive statistics and exploratory cross tabulation to identify patterns across leakage definitions, clinician confidence and consideration of barrier formulation. As a cross-sectional, self-reported survey, findings describe associations rather than causality and are subject to response bias. Although the sample was large (n=565), the predominance of US respondents may limit generalisability. Percentage differences represent absolute differences between groups based on descriptive cross tabulation and were not subjected to inferential statistical testing. Results are, therefore, intended to be hypothesis generating and to inform education and future research.

RESPONDENT CHARACTERISTICS

Survey respondents represented a highly experienced and clinically engaged population, lending credibility to the findings. Over two thirds of participants reported more than 10 years of clinical experience, and respondents practiced across acute, community, rehabilitation, and mixed care settings (see Figure 1)[17].

Geographically, most respondents were based in the US, with additional representation from Japan, the United Kingdom, Australia and multiple European countries (see Figure 1). Although US responses dominate the dataset, the breadth of experience and practice environments supports the relevance of the findings across diverse clinical contexts.[17]

CORE SURVEY FINDINGS

Confidence in preventing leakage

Despite advances in pouching system design and fitting techniques, 88% of clinicians reported that they could not confidently say their patients would never experience leakage under the barrier, even with optimal fit.[17] Only 12% responded affirmatively. When examined by experience level, responses were similar across groups, suggesting that years of experience do not substantially influence clinician confidence in preventing leakage with optimal fit (see Figures 2 & 3). By practice setting, clinicians in acute and rehabilitation settings appeared more confident about preventing leakage than those in community settings. However, there did not appear to be a clear relationship between respondents' definitions of leakage and their confidence in preventing it across care settings (see Figures 4 and 5).

This finding underscores a critical disconnect between the traditional emphasis on fit and the lived reality of leakage in clinical practice. It suggests that optimal fit alone is not perceived as sufficient to guarantee leakage prevention,

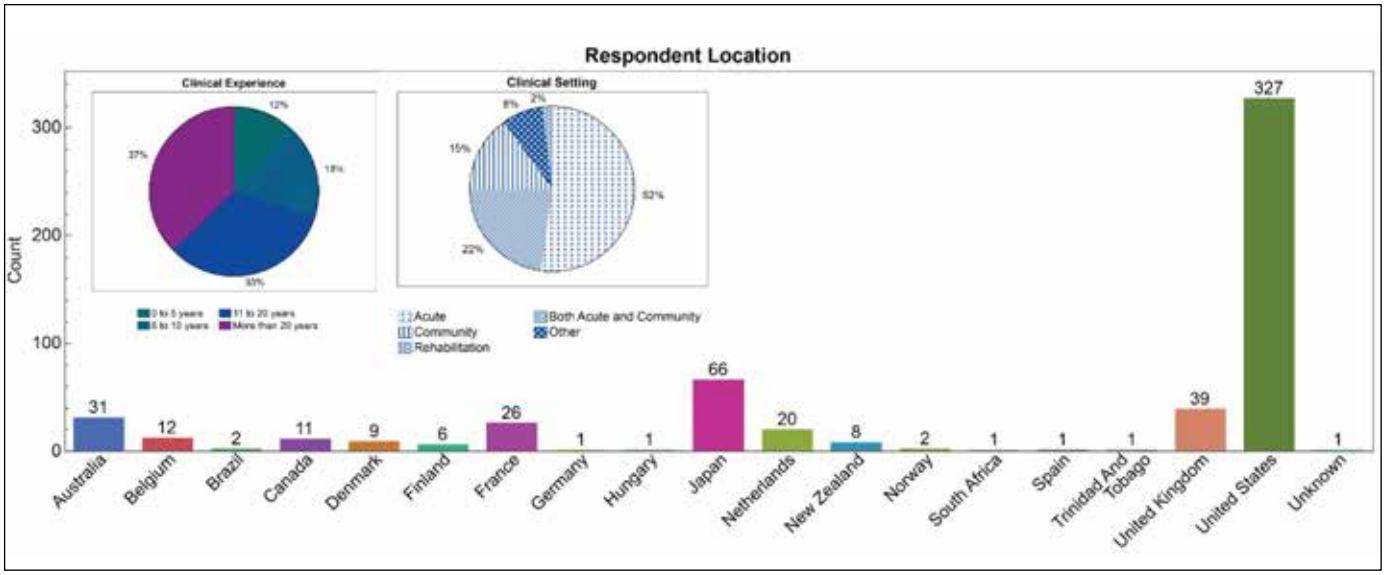


Figure 1. Response characteristics of survey participants

reinforcing the need for broader strategies to support peristomal skin health.

Definitions of leakage vary widely

When asked when they consider a leak to have occurred, clinicians demonstrated significant variability in definitions. The data suggests that after 5 years of experience, respondents answered similarly about their definitions of leakage. These results, in context with the response about preventing leakage, show that - despite differences in definitions of leaks and different levels of experience - the respondents feel the same about leakage prevention (see Figure 5).

- 51% defined leakage as *any* effluent present under the barrier, even a minor amount
- 40% defined leakage as effluent under the barrier that compromises wear time or skin health
- >8% defined leakage only when effluent escapes beyond the edges of the barrier

The role of barrier formulation in skin health

Most clinicians reported that barrier formulation plays a role in maintaining peristomal skin health:

- 56% reported they *always* consider formulation
- 37% reported they *sometimes* consider formulation
- <8% reported they *rarely* or *never* consider formulation

While it is encouraging that formulation is top of mind for more than half of respondents, the sizeable "sometimes" group suggests inconsistency in how formulation is integrated into routine clinical decision-making.

Importantly, clinicians who only *sometimes* consider formulation were more likely to report lower confidence in preventing leakage (>11%), suggesting a potential disconnect between recognising formulation as a tool and fully leveraging it as part of a proactive skin health strategy.

These findings highlight the absence of a shared, standardised definition of leakage. More nuanced definitions appear to capture early or subclinical compromise, whereas narrower definitions focus on overt or "catastrophic" failure.

Of interest, clinicians appear more likely to prioritise leakage management strategies that relate to fit, such the use of differing convexities, patient education and the use of barrier rings/seals rather than considering a change in skin barrier formulation (Figure 6).

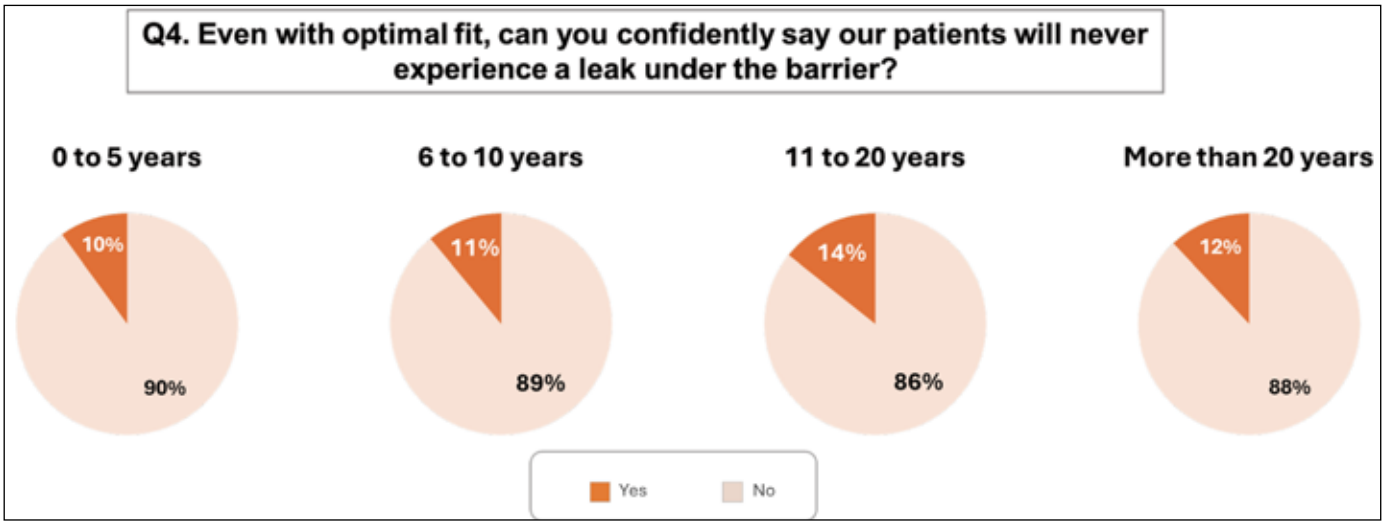


Figure 2. Aggregate of clinicians' levels of experience and relation to leakage with optimal fit

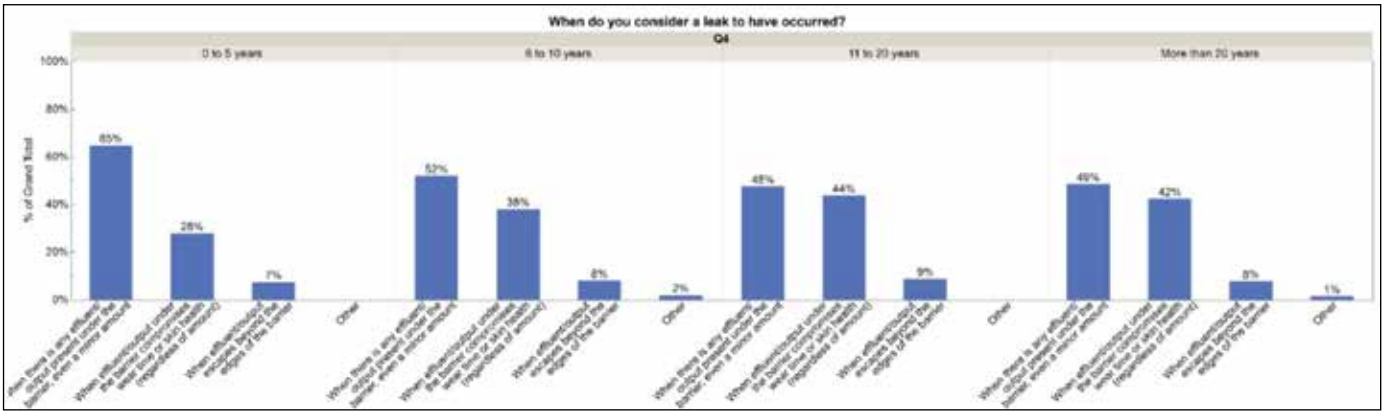


Figure 3. Details of clinicians' levels of experience in relation to leakage with optimal fit

CROSS ANALYSIS AND KEY INSIGHTS

Leakage definition influences confidence and strategy

Clinicians who defined leakage narrowly (only when effluent escapes beyond the barrier) were more likely to believe leakage could be prevented (>19%) and more likely to report *always* considering formulation (>12%) (Figure 7). In contrast, clinicians who used broader, more nuanced definitions of leakage were less confident in their ability to prevent leaks and more likely to report only *sometimes* considering formulation.[17]

This pattern suggests that when leakage is conceptualised as a binary or catastrophic event, prevention feels more achievable. Conversely, when leakage is understood as a spectrum - including early or minor compromise - prevention may appear less attainable without more sophisticated tools and strategies.

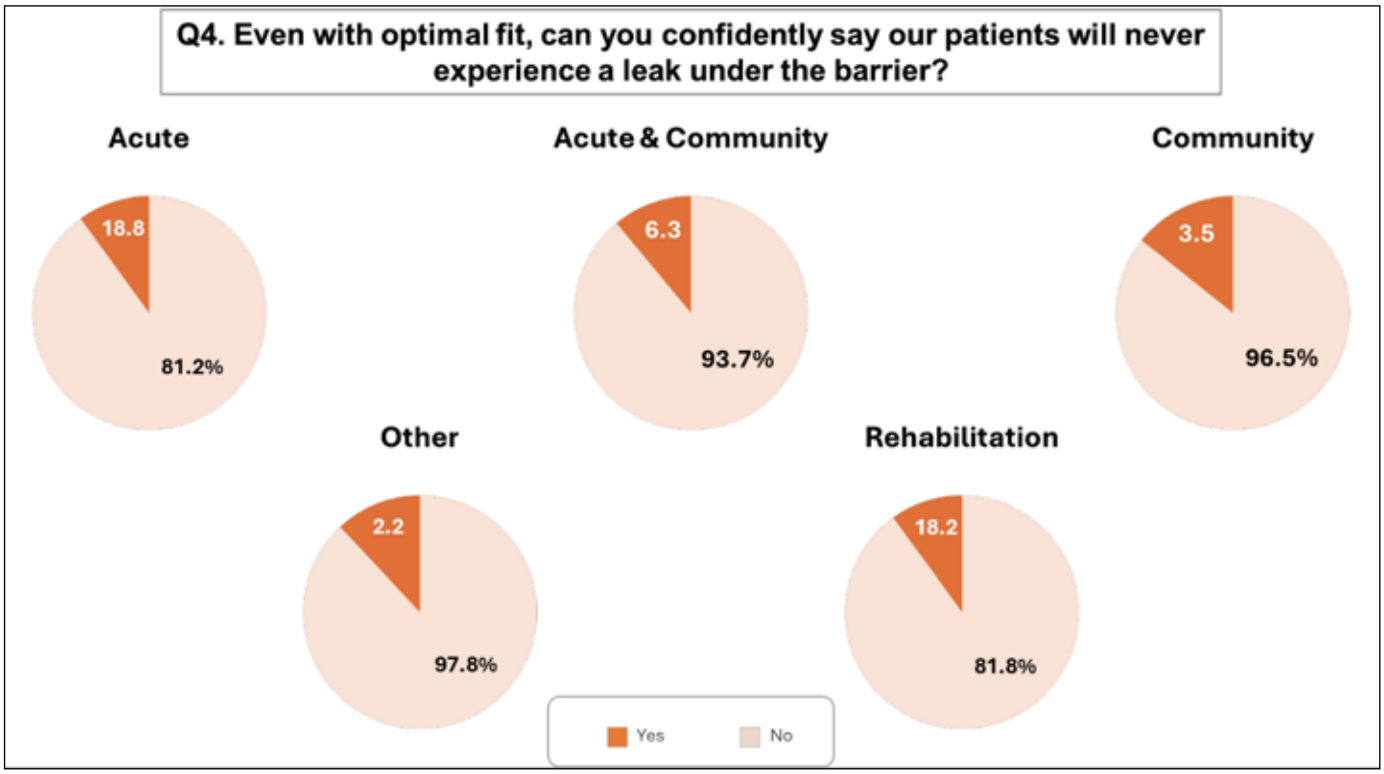


Figure 4. Aggregate of clinicians' practice settings in relation to leakage with optimal fit

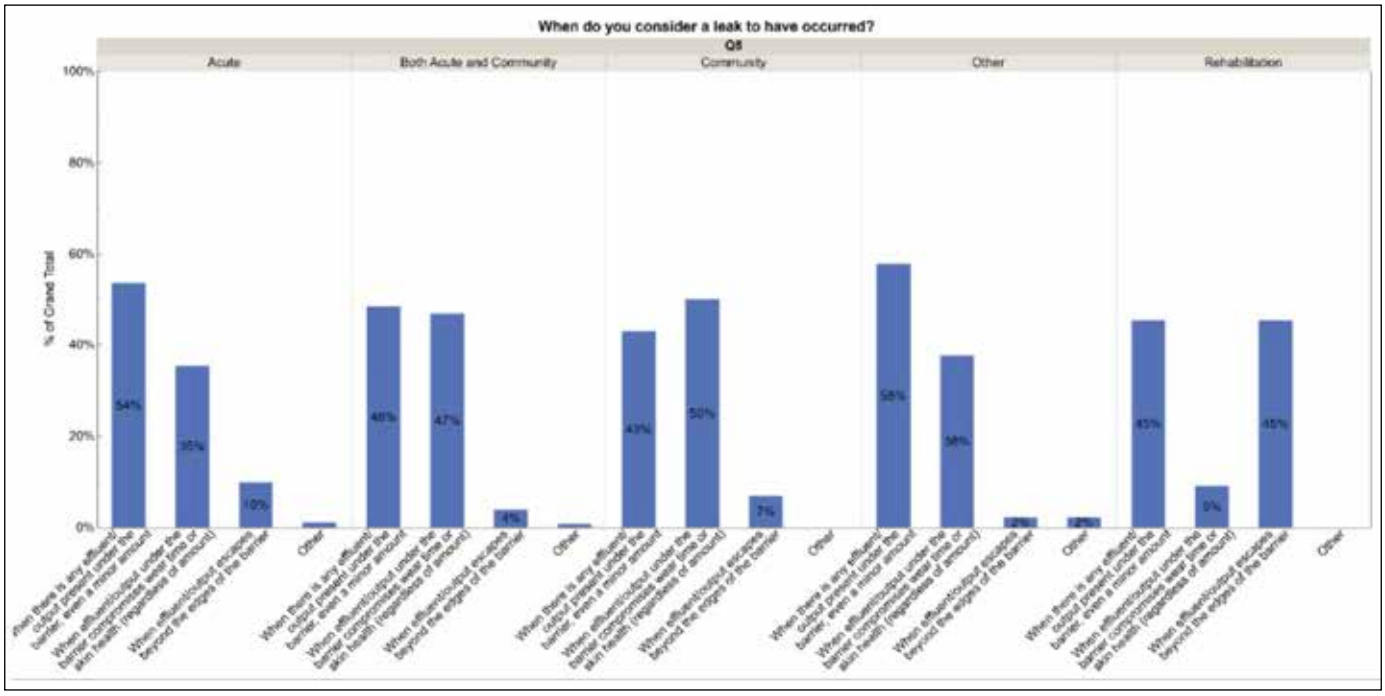


Figure 5. Details of definitions of leakage responses by practice setting

Formulation focused clinicians show greater confidence

Clinicians who identified formulation-based strategies (such as changing barrier formulation rather than shape alone) were:

- More likely to believe leakage can be prevented (>19%)
- More likely to *always* consider formulation (>19%)
- More likely to hold a clearer, more consistent definition of leakage (>8%) (see Figure 6d)

These findings support the hypothesis that formulation focused thinking aligns with a more proactive, prevention-oriented approach to peristomal skin health.

Regional differences suggest opportunity for education

Non-US respondents were more likely to:

- Define leakage more precisely (>5%)
- Consider formulation as top of mind (>9%)
- Report greater confidence in leakage prevention (>10%)

a.)

When a leak occurs, how do you typically address peristomal skin health? (Please choose your top three strategies)	% Response	Focus
Barrier rings/seal	79%	Fit
Change to a different barrier formulation (e.g., switch from standard wear to extended wear)	25%	Formulation

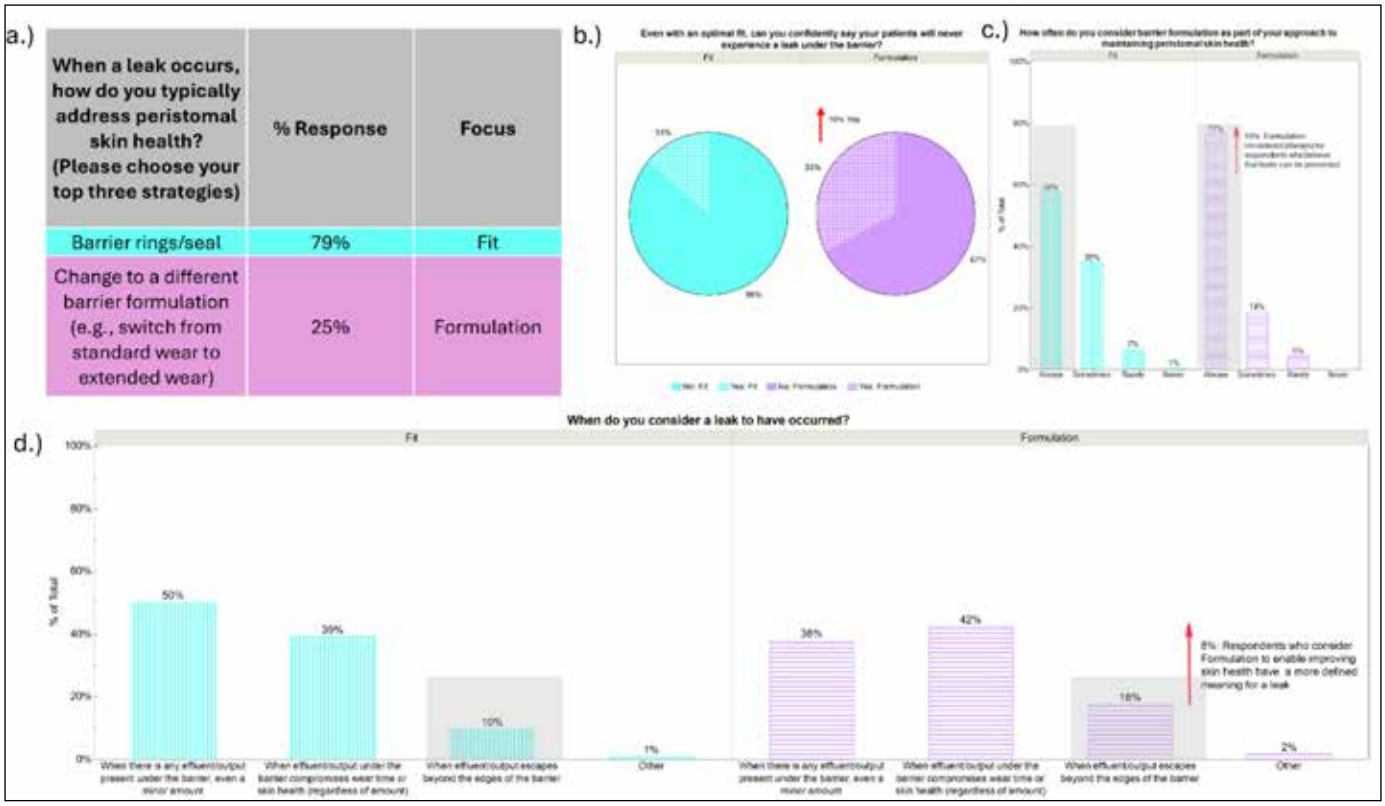


Figure 6. a) to d) Cross sectional analysis comparing fit versus formulation strategy

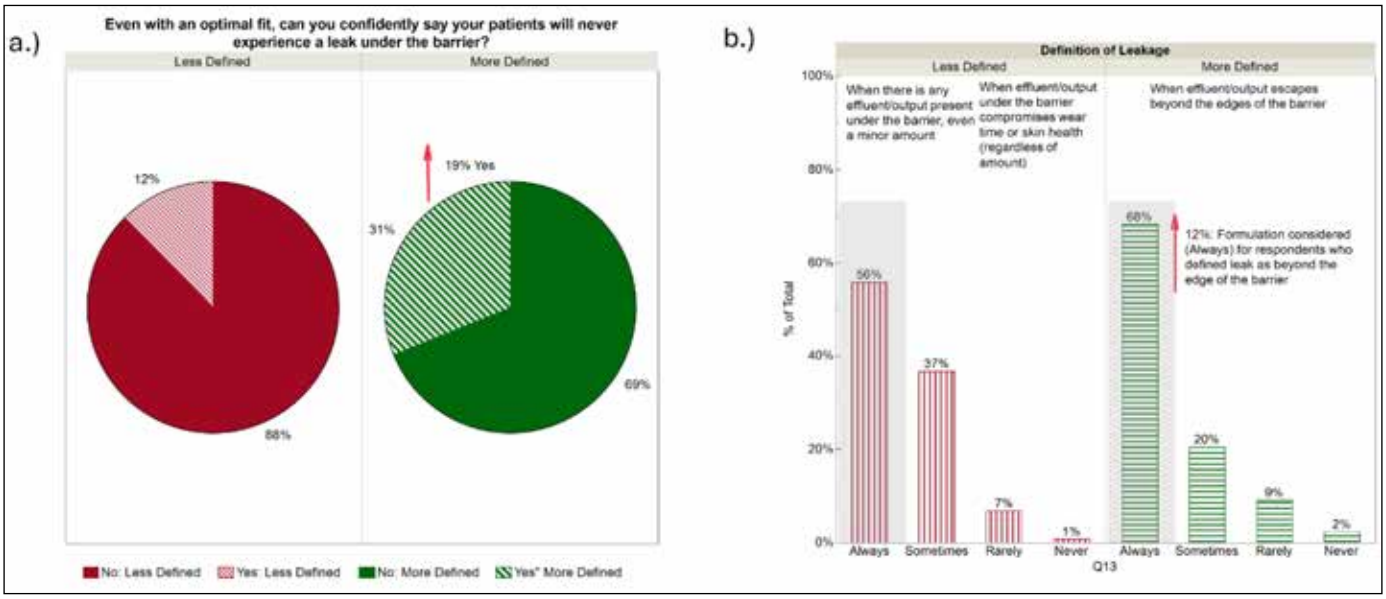


Figure 7. a) and b) Cross sectional analysis connecting leakage definition and leakage prevention

This may reflect differences in education, prescribing practices or exposure to formulation-focused discussions internationally. While US responses dominate the dataset, these regional differences highlight opportunities to strengthen education and messaging around formulation in markets where fit has traditionally been emphasised (Figure 8).

KEY TAKEAWAYS FOR CLINICAL PRACTICE

Leakage remains expected, even with optimal fit, reinforcing that fit alone is insufficient to define or ensure peristomal skin health.

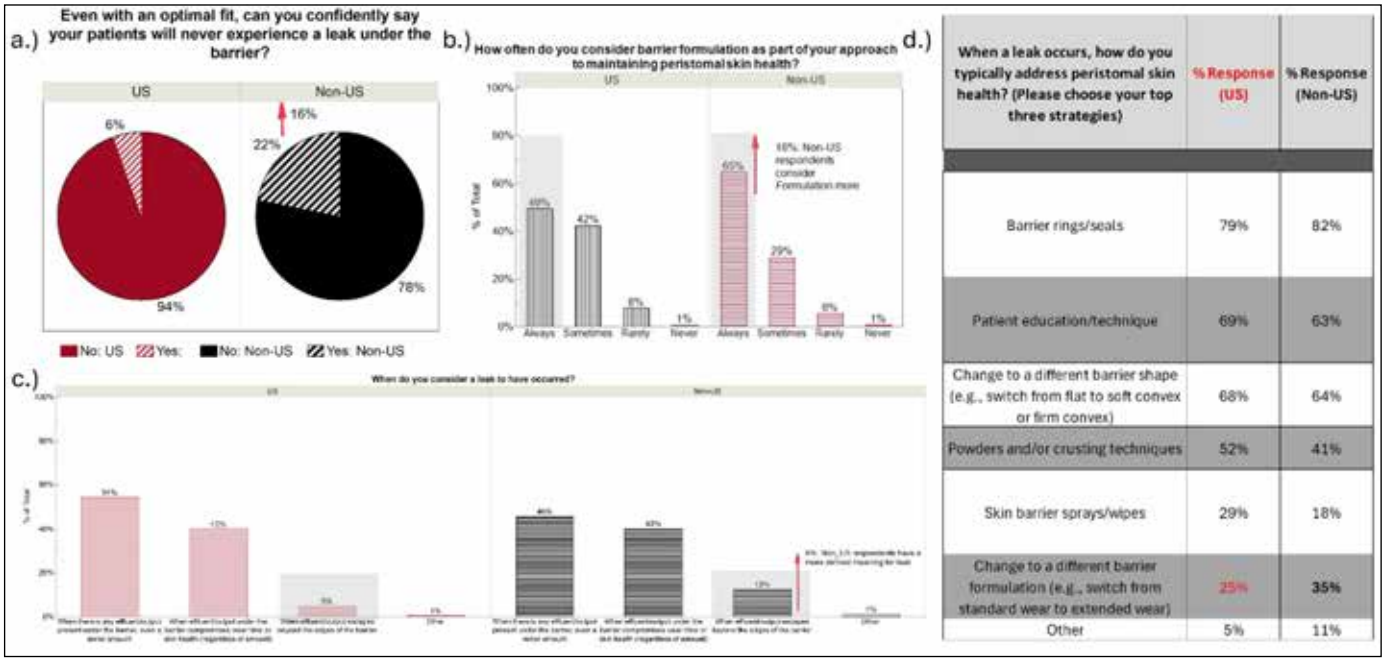
1. Definitions of leakage vary substantially, creating challenges for consistent education, communication and outcome measurement.
2. Barrier formulation is widely recognised, but not yet universally or consistently applied as a core preventive strategy.
3. Clinicians who consistently consider formulation demonstrate greater confidence, clearer leakage definitions, and a more proactive approach to skin health.
4. There is a clear opportunity to unify language, education and clinical pathways that integrate both fit and formulation as complementary pillars of peristomal skin health.

DISCUSSION

Preliminary discussions suggest that while clinicians recognise the importance of secure pouching system fit, there is growing awareness that formulation and proactive skin care are equally vital.[7,8] Persistent leakage, even with optimal fit, challenges the assumption that fit alone ensures skin health.[7,8] This underscores the need for a broader, more nuanced definition of skin health - one that incorporates prevention, early intervention and patient education.[7,8] To advance peristomal skin health, clinicians should give equal weight to fit and formulation throughout product selection and ongoing management.[7,8] Critical analysis should not end at achieving a secure fit; clinicians must rigorously evaluate the composition, technology, and protective properties of skin barriers and related products.[7,8] Evidence demonstrates that innovations in formulation, such as advanced hydrocolloid blends, moisture management systems and tailored adhesives, can significantly reduce peristomal skin complications and improve patient comfort, even in cases where fit is optimal.[7,8] By integrating both fit and formulation into clinical decision-making, and grounding choices in the latest research, clinicians can move beyond habit or external influence and deliver care that is truly individualised, and outcome driven.[7,8] This dual approach is essential for preventing persistent leakage, promoting skin integrity and achieving the highest standards of patient well-being.[7,8]

IMPLICATIONS FOR CLINICAL PRACTICE AND EDUCATION

Wide variation in how clinicians define leakage, combined with limited confidence in preventing leakage even with optimal fit, underscores the importance of clearer, shared language and more proactive management strategies. While many clinicians recognise the relevance of barrier formulation, inconsistent integration into routine decision-making suggests an opportunity to strengthen education around formulation as a preventive, not reactive, tool. Aligning clinical pathways to explicitly integrate both fit and formulation - supported by unified definitions of leakage - may improve clinician confidence, reduce reliance on trial-and-error approaches and promote earlier intervention to protect skin integrity.



When a leak occurs, how do you typically address peristomal skin health? (Please choose your top three strategies)	% Response (US)	% Response (Non-US)
Barrier rings/seals	79%	82%
Patient education/technique	69%	63%
Change to a different barrier shape (e.g., switch from flat to soft convex or firm convex)	68%	64%
Powders and/or crusting techniques	52%	41%
Skin barrier sprays/wipes	29%	18%
Change to a different barrier formulation (e.g., switch from standard wear to extended wear)	25%	35%
Other	5%	11%

Figure 8. a) to d) Cross sectional analysis comparing US and Non-US responses

Educational initiatives that reinforce formulation-focused thinking alongside traditional fitting principles have the potential to advance more consistent, prevention oriented peristomal skin health practices.

CONCLUSION

Peristomal skin health cannot be defined by pouching system fit alone. Recent survey findings confirm that leakage is widely expected despite optimal fit, reflecting inconsistent definitions of leakage and skin health that hinder prevention, education, and outcomes.[17] These survey findings also indicate that clinicians who consistently consider barrier formulation demonstrate greater confidence, clearer leakage definitions and a more proactive approach to skin protection, reinforcing formulation and fit as complementary pillars of care that should be given equal consideration in clinical practice. Addressing regional variation and the paradox of patient choice through unified definitions, evidence-based education and clinician-led guidance is essential to advancing peristomal skin health and improving patient outcomes.[17]

CONFLICT OF INTEREST

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FUNDING

The authors are salaried employees of Hollister Inc.

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