Gastrointestinal Nursing

An absorbent, enzyme-inhibiting seal reduces peristomal skin complications

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Background: Moisture-associated skin damage (MASD) to peristomal skin causes significant discomfort and is expensive to treat. It can be avoided by wicking moisture away from skin and controlling the source of excessive moisture with an absorbent seal. **Method**: In vitro testing determined the capacity for moisture absorption and combined faecal enzyme (elastase and lipase) inhibition of seven comparable leading UK ostomy seals. Ostomates using Eakin Cohesive® Seals were sent a postal questionnaire to rank the efficacy of this seal, while a different questionnaire was sent to stoma care nurses to rank the relative efficacy of different ostomy seals. **Results**: Eakin Cohesive Seals had the highest absorption capacity (4.0 g/g), while the range of absorption capacities for other seals was 1.0–2.9 g/g. The enzyme inhibition capacities of Coloplast Brava® Protective Seals and Eakin Cohesive Seals were 94.35% and 72.39% respectively, with other seals ranging from 39.45% to 59.96%. Users (n=2801) found Eakin Cohesive Seals helped prevent leakage (92.5%) and skin problems (73.3%), as well as treating sore skin (68.5%). Of nurses (n=194), 90.2% rated Eakin Cohesive Seal as good or excellent for treating denuded or excoriated skin. **Conclusion**: Eakin Cohesive Seals were highly absorptive, and this provided tangible clinical benefits.

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- Absorption
- Enzyme inhibition
- Moisture-associated skin damage (MASD)
- Peristomal skin
- User experience

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Many research studies have investigated the prevalence of complications in people who have undergone stoma-forming surgery. Bosio et al (2007) reported that prevalence of complications is affected by stoma type, with challenges faced by a third of colostomates and up to two-thirds of ileostomates and urostomates.

Despite the development by Meisner et al (2012) of the Ostomy Skin Tool (OST) to standardise the assessment of peristomal skin, there is still a high variance in literature regarding the prevalence of peristomal skin complications (PSCs). Meisner et al (2012) reported PSC rates ranging from 18–60%, with peristomal skin problems accounting for about 40% of all visits to stoma care nurses (SCNs). Meisner et al (2012) acknowledged that, although the incidence of such complications is highest in the first 5 years following stoma-creating surgery, the risk is lifelong.

These findings are backed up by Burch (2016), who discussed the importance of follow-up care by an SCN to not only facilitate adaptation and high quality of life but also to ensure cost efficiency and effectiveness of stoma care products used. The importance of follow-up care is also highlighted by Redmond et al (2009), who reported that, despite leakage being the most commonly reported complication for ostomates, it is also one that they are often unable to prevent, diagnose or treat without the support of an SCN.

Risk factors

Siting and formation

There are numerous risk factors that predispose patients to PSCs. In the case of emergency operations, pre-operative siting is rarely carried out by a specialist SCN, resulting in a high likelihood of a non-ideal stoma location and poor stoma visualisation. Rutledge et al (2003) also commented that often patients undergoing emergency surgery have a distended abdomen, which may mask potential problem areas, such as skin creases or folds, and therefore, if possible, it is ideal to consult with family members to understand the patient's normal body profile.

While the goal of a surgeon is to form a well-shaped and spouted stoma (Alvey and Beck,

2008), this can be challenging to achieve in the case of emergency surgery, which can result in the formation of irregularly shaped, flush, retracted or prolapsed stomas, which can require more complex management. It is, however, also the case with some planned surgeries that stoma siting can still be challenging, especially in patients who are obese, emaciated, immobilised or otherwise disabled (Kwiatt and Kawata, 2013).

The higher incidence of PSCs in ileostomates (compared with colostomates) could be a result of factors, including liquid output and, in the case of loop ileostomies, stoma mobility (telescoping). The associated challenges of liquid output are particularly relevant with high-output stomas. Carlson (2001) discussed how small-bowel stomas will normally begin to function within 24 hours, initially producing up to 2000 ml within 24 hours, with both volume and consistency improving over time, dependent on anatomy and underlying disease.

Baker and Greening (2009) highlighted another challenge associated with high-output stomas (jejunostomy), which, because of the production of a higher concentration of digestive enzymes, can lead to corrosion of the skin and breakdown of the hydrocolloid, resulting in appliance leakage.

Fitting the appliance

Appliance selection, cutting to size and fitting are all essential in ensuring peristomal skin health is maintained. Erwin-Toth (2003) discussed the importance of considering the size, type and location of a stoma, alongside the amount of effluent and individual patient characteristics, including visual acuity and manual dexterity. With many patients relying on pre-cut pouches or personal hand-cutting of ostomy pouches, it is often difficult to achieve the correct fit. Hess (2012) defined the correct fit as 1/8–1/4 in bigger than the stoma, to protect the peristomal skin while providing enough tolerance for expansion during stoma functioning without causing trauma to the stoma mucosa.

When managing a stoma, it is also considered good practice to ensure that peristomal skin is clean and dry prior to application of stoma appliances. However, skin preparations can often impact on peristomal skin integrity and inhibit the level of adhesion of subsequent appliances.

Arumugam et al (2003) and Colwell et al (2004) list wound complications in or adjacent to the peristomal field, recurrent disease and hernia as additional risk factors for PSCs.

Accessory products

While literature on the effect of various medications on peristomal skin is somewhat limited, Rolstad et al (2011) listed corticosteroids, anti-cancer drugs, diuretics, analgesics, antidepressants, antibiotics and hormone treatments as all having a pathological impact on skin, with the potential to result in specific challenges for ostomates.

It is also the case that various medications can cause a change in the volume and consistency of stomal output. Research into the effect of medications on stoma effluent is limited, but general side effects relating to bowel function are widely documented, specifically for chemotherapy—including diarrhoea (Wallace and Taylor, 2011)—and for steroids. With high usage of steroids in the treatment of IBD and a considerable number of ostomates undergoing chemotherapy for treatment of bowel cancer and/or secondary cancers, it is not unreasonable to assume a proportion of stoma patients will see changes in the volume or consistency of their stoma output because of such treatments.

Financial impact

Despite training and education being provided in the UK and many other countries to encourage successful self-management of a stoma, the prevalence of PSCs remains high (Meisner et al, 2012). The lack of standardisation regarding education, continuity of care and follow-up, both in the UK and internationally, presents a risk of patients developing PSCs. Although the Association of Stoma Care Nurses (ASCN) UK has started to address the lack of agreed evidence-based guidelines on follow-up for ostomates, there are still no UK national guidelines on this topic.

The cost of treating PSCs has been the topic of many papers, but the cost model developed by Meisner et al (2012) is particularly interesting. In this model, costings are calculated for the treatment of irritant contact dermatitis, allergic dermatitis, mechanical trauma, disease-related PSCs or infection-related PSCs, according to three levels of severity: mild, moderate and severe. Costings are based on 7-week treatment plans, as Martins et al (2008) reported clinically significant improvement in PSCs over a 6–8-week treatment period.

Meisner et al (2012) do not discuss the prevalence of each PSC. However, as an example, assumptions made in costing moderate irritant contact dermatitis include:

- All patients require an SCN consultation
- 51% of patients require a second consultation
- 15% of patients require a third consultation
- 6% of patients require corticosteroid therapy.

Cottam and Richards (2013) commented that up to one-in-three ostomates had problems with their stoma that necessitated the use of one or more accessories to aid in its management. Cottam and Richards (2013) also noted that barrier rings were one of the most commonly used accessories when dealing with stoma-related problems. However, with the rising costs of stoma care and tightening health-care budgets, the decision to introduce any accessory product should be made by a qualified health professional—ideally an SCN—based on clinical need and product efficacy. Equally vital is patient education regarding the safe and effective use of any accessories introduced.

Moisture-associated skin damage

Reviews have shown that the majority of peristomal skin problems are a direct result of contact with faeces. In recent years, the category of moisture-associated skin damage (MASD) has been introduced to cover all cases of skin damage in which prolonged exposure to various sources of moisture is the predominant factor. The four most common forms are incontinence-associated dermatitis, intertriginous dermatitis, peristomal moisture-associated dermatitis and peri-wound moisture-associated dermatitis (Gray et al, 2011; Voegeli, 2012; 2013).Gray et al (2011) discussed the clinical consensus recommending the required steps for the management of MASD, namely:

- Adopting a structured skincare regime
- Using products that wick moisture away from at-risk skin
- Controlling the cause of excessive moisture
- Treating secondary infection.

The use of an absorptive ostomy seal covers the first two factors. Using an absorptive ostomy seal should prevent peristomal skin breakdown, eliminating the risk of secondary infection. As, in stoma care, it is not possible to control the source of excessive moisture, the use of an absorptive ostomy seal from the first instance should prevent MASD. Boyles (2010) stated:

'The prevention of repeated stoma problems through the judicious use of accessories can help prevent the physical, psychological and financial ramifications of persistent stoma complications.'

Should skin integrity become impaired, an SCN will undertake a staged problem-solving approach, often introducing an ostomy seal to prevent leakage and protect the peristomal skin.

Objectives

As it is the expressed opinion of the authors that having a highly absorptive ostomy seal is vital to ensure protection of the peristomal skin against leakage, it was decided to investigate the relative absorption capacity of various available ostomy seals, including Eakin Cohesive® Seals.

Furthermore, considering the detrimental effect of faecal enzymes on skin (Andersen et al, 1994) and the high prevalence of leakage-related PSCs, it was deemed necessary to also assess the ability of these seals to inhibit faecal enzymes, namely elastase and lipase.

To gain a more holistic understanding of the effectiveness of Eakin Cohesive Seals in particular, it was decided to complement the data on their comparative physical properties with user-experience data. Thus feedback on product performance would be collected from both SCNs and ostomates in the UK.

Methods

Absorption testing

Absorption capacity was tested in vitro. All seals tested were dimensionally comparable, with an outer diameter of approximately 48 mm. The leading brands of ostomy seal included in the study were:

- Eakin Cohesive Seals
- Coloplast Brava® Mouldable Rings and Brava® Protective Seals
- Dansac TRE Seals
- Hollister Adapt Barrier Ring and Adapt CeraRing™ Barrier Rings
- Salts Aloe Ring

Absorption capacity was measured on a weight-gain basis over a 72-hour period. Each ostomy seal was applied to a semi-permeable pouch filled with 100 ml of distilled water and incubated in an oven at body temperature (37±1 °C). The experiments were carried out in triplicate.

Enzyme-inhibition testing

The faecal elastase and lipase inhibition of the seals were also tested in vitro. The School of Pharmacy at Queens University Belfast was deemed to have the required expertise and was therefore commissioned to complete this aspect of the study. To emulate stomal output as closely as possible in a laboratory setting, the typical physiological concentrations of elastase and lipase from an ostomy were ascertained from a literature search (Andersen et al, 1994). The relevant physiological concentrations were used for both enzymes.

Each chosen seal was placed in separate sterile containers with elastase and then with lipase with their specific buffer, and then the vial was incubated at 37±1 °C. At chosen time points, 1 ml of the solution was pipetted off and enzymatic activity measured using a spectrophotometer. The enzymatic activity of a control, which contained only the enzyme-buffer solution (and no seal), was also measured at each time point and used to standardise the results. Four replicates of each setup were carried out to eliminate experimental error. The activity of each seal–enzyme combination was measured and reported as a percentage of the control activity, thus allowing assessment of each seal's ability to inhibit faecal enzymes.

Feedback questionnaires

A review using two questionnaires was designed and undertaken by TG Eakin to obtain user and nurse feedback related to the product performance of Eakin Cohesive Seals. Recruitment was carried out over a period of 3 months, and consent to participate was confirmed by return of a completed questionnaire. Limited access to product-specific clinical data on other ostomy seals (apart from Eakin Cohesive Seals) prevented a comprehensive review being carried out.

One questionnaire was designed specifically for ostomy patients who used these seals. The user-specific questionnaire, with a pre-paid return envelope, was placed inside each stock box of Eakin Cohesive Seals delivered to all UK users. Its key questions characterised users' stoma type, assessed users' rationale for using these seals and asked whether they were essential to users' stoma care regime. It also assessed how far users felt Eakin Cohesive Seals helped:

- Treat sore skin
- Increase security and confidence
- Extend pouch wear time
- Prevent leakage
- Prevent skin problems.

The other questionnaire was designed specifically to assess the professional perspectives of SCNs on the functionality of Eakin Cohesive Seals. The nurse-specific questionnaire was posted with a pre-paid return envelope to all hospital-based SCNs in the UK, on the assumption that they would have professional knowledge of ostomy seals. Several key questions asked nurses to rate the efficacy of Eakin Cohesive Seals—as poor, average, above average, good or excellent—with respect to:

- Extending pouch wear time
- Moulding around the stoma to provide skin protection
- Preventing skin irritation
- Treating denuded or excoriated skin.

Nurses were also asked to grade the overall performance of a variety of UK-marketed ostomy seals and select the seal that they considered best for stoma care.

Results

Absorption testing

The results of in-vitro absorption testing of various ostomy seals is summarised in *Figure 1*. Significant variation was observed in the measured absorption capacity of these seals. Eakin Cohesive Seal had the highest absorption capacity (4.0 g/g), with the next most absorptive seals being Hollister Adapt Barrier Ring (2.9 g/g) and Adapt CeraRing (2.4 g/g). Salts Aloe Ring, Coloplast Brava Mouldable Ring and Dansac TRE Seal recorded absorption capacities of 2.2 g/g, 2.1 g/g and 1.8 g/g, respectively. The

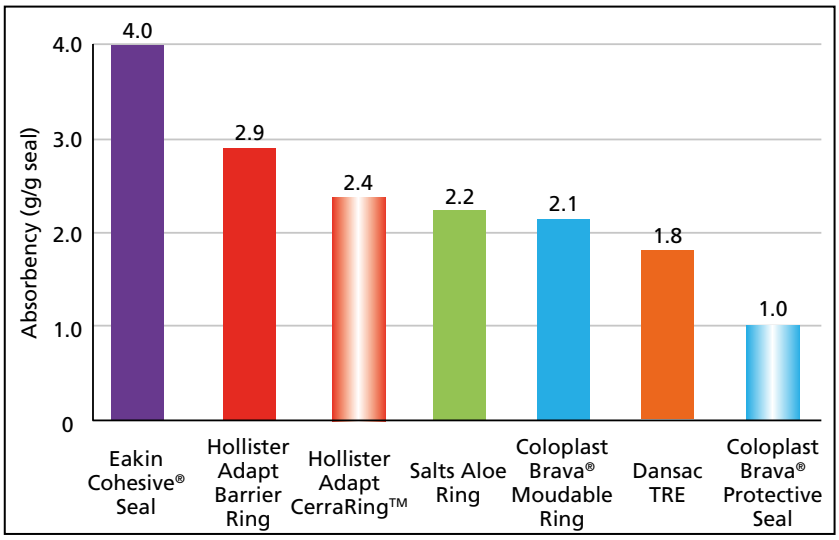

Figure 1. Moisture absorption capacity of seven different ostomy seals

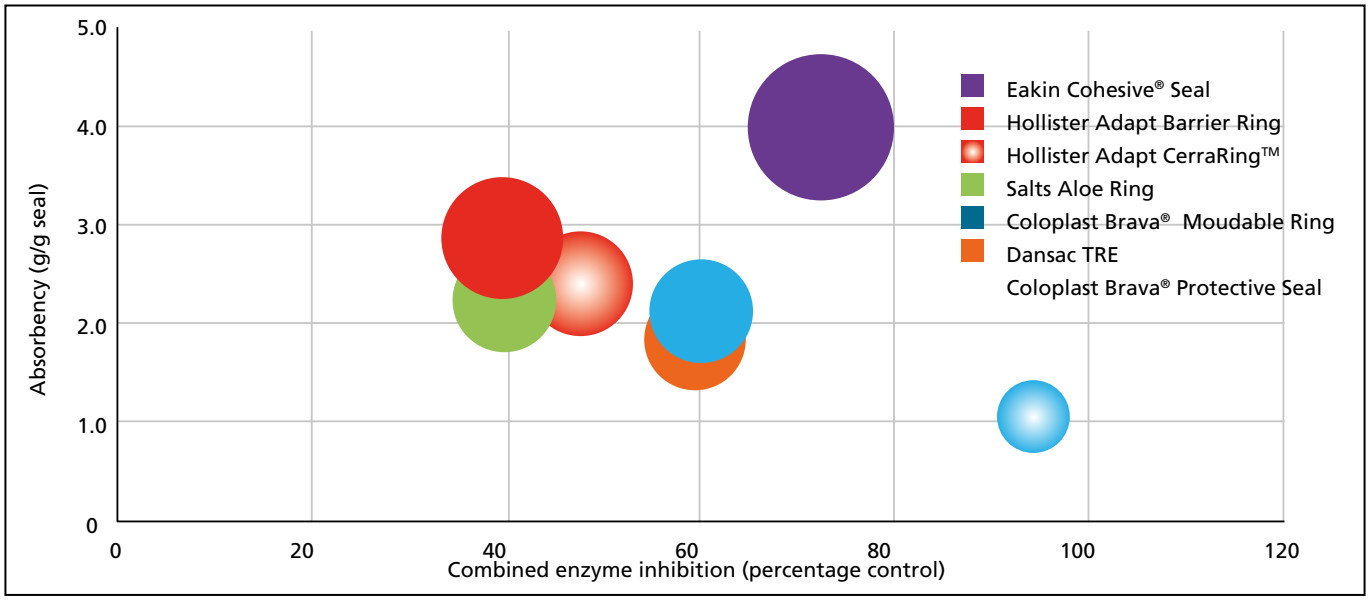

Figure 2. Combined faecal enzyme (elastase and lipase) inhibition of ostomy seals

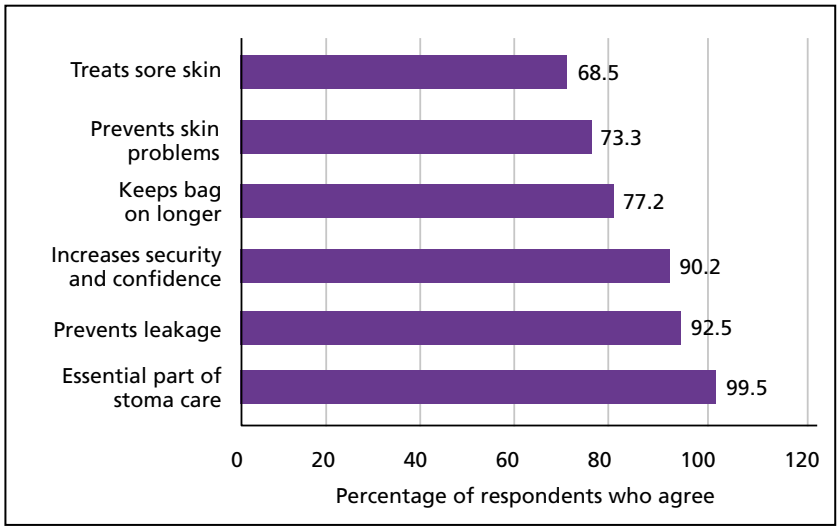

Figure 3. Key results of the user questionnaire

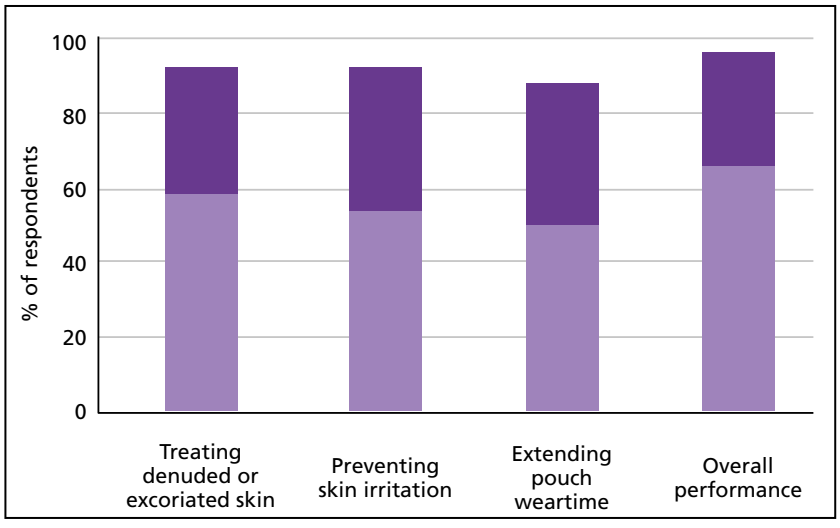

Figure 4. Key results of the stoma care nurse questionnaire

Coloplast Brava Protective Seal had the lowest absorption capacity (1.0 g/g).

Enzyme-inhibition testing

As the authors consider absorbency to be the foundation of an effective ostomy seal, enzymatic inhibition data was not analysed in isolation. Instead, the combined enzyme inhibition data is presented alongside the absorption capacity data in a bubble chart (*Figure 2*). The size of the bubble automatically corresponds to the metric deemed to be of primary importance, which in this case is the y-axis, representing absorption capacity.

There was a significant difference in the combined enzyme inhibition capabilities of each of the various seals. The highest combined enzyme-inhibiting seals were the Coloplast Brava Protective Seals, with 94.35% inhibition. The combined enzyme-inhibition capacity of Eakin Cohesive Seals was 72.39%, followed by Coloplast Brava Mouldable Rings and Dansac TRE Seals at 59.96% and 59.24%, respectively. Hollister Adapt CeraRings, Salts Aloe Rings and Hollister Adapt Barrier Rings had inhibition rates of 47.01%, 39.89% and 39.45%, respectively.

Feedback questionnaires

Of the surveys sent to users of Eakin Cohesive Seals in the UK, 2801 questionnaires were returned, and the results are presented in *Figure 3*. Of the nurse-specific surveys sent to all UK-based SCNs, 194 questionnaires were returned, and the results are depicted in *Figure 4*.

Discussion

In-vitro testing showed Eakin Cohesive Seals to be the most absorptive ostomy seal of those tested. Eakin Cohesive Seals absorbed 37.8% more than Hollister Adapt Barrier Rings, 66.7% more than Hollister Adapt CeraRings, 81.8% more than Salts Aloe Rings, 90.5% more than Coloplast Brava Mouldable Rings, 122.2% more than Dansac TRE and 300% more than Coloplast Brava Protective Seals. The newer seals on the market—namely Coloplast Brava Protective Seals and Hollister Adapt CeraRings—have significantly reduced absorption capacities, compared with older versions—Brava Mouldable Rings and Adapt Barrier Rings. Page (2009) described the function of ostomy seals as:

'Providing absorption of perspiration and secretions, meaning they can increase the wear time of a pouch by maintaining adhesion and a healthy skin balance against fungal and bacterial attack.'

The importance of absorption in an ostomy seal is also supported by Voegeli (2012), who discussed the necessity of a product to 'wick moisture away from at-risk skin' to prevent MASD. In conjunction with these theoretical assumptions, it is important to consider whether this is supported by clinical evidence. Consumer (n=2801) and nurse (n=194) survey results indicated that use of a highly absorptive ostomy seal (Eakin Cohesive Seals) provided tangible, observable clinical benefits. With users (n=2801), 92.5% of respondents agreed that the Eakin Cohesive Seals helped prevent leakage, with 73.3% agreeing that these seals prevented skin problems and 68.5% agreeing they treat sore skin. These results were further supported by the results of the SCN survey (n=194), where 90.2% of nurses rated Eakin Cohesive Seals as good or excellent for treating denuded or excoriated skin, and with 88% of nurses agreeing that Eakin Cohesive Seals prevented skin irritation.

As shown in *Figure 2*, the newer versions of seals from Hollister and Coloplast (Adapt CeraRings and Brava Protective Seals)—while recording a reduced absorption capacity—did show significant improvement in their ability to inhibit a combination of elastase and lipase. In particular, Coloplast Brava Protective Seals achieved a high degree of combined enzyme inhibition.

Limitations

The authors acknowledge the limitation of using non-standardised test methods for measuring absorption. Consideration was given to using the International Organization for Standardization (ISO) standard test method, namely ISO EN 12505-1:2014 (ISO, 2014). Critical analysis of the ISO test methodology deemed it to be unsuitable, due to the final timepoint of 6 hours not being reflective of ostomy seal wear times. User feedback collated from post-market surveillance by TG Eakin revealed that wear times of 1–7 days were more representative of ostomy seal usage. This feedback informed the development of the in-house test method, in which a timepoint of 72 hours was chosen to emulate average ostomy seal wear time.

It should also be noted that properties other than absorption and enzyme inhibition may also be advantageous for an ostomy seal. Hence this study is somewhat limited as an overall evaluation of seal effectiveness, because it exclusively focuses on these two features.

A comprehensive review of the literature relating to risk factors of PSCs was beyond the scope of this study. As a result, the authors accept that there may be additional factors that influence the prevalence of PSCs. One of the limitations of the user-based questionnaire was not having access to full medical history, which could have provided additional context. On reflection, both the user- and nurse-specific questionnaires could have benefited from open questions to obtain information relating to the respondents' experience and knowledge of alternative ostomy accessories.

Conclusion

In-vitro absorption testing showed that, of the ostomy seals tested, Eakin Cohesive Seals were the most absorbent ostomy seal and provided a high level of combined enzyme inhibition. This conclusion was supported by clinical data from ostomates and SCNs regarding treatment and prevention of skin irritation. Additional clinical data in relation to the prevention of leakage, the extension of pouch wear time and increased security and confidence supported the hypothesis that in-vitro absorption testing can be used as a predictor of product functionality and efficacy of an ostomy seal.

The primary importance of a seal's absorption capacity was supported by Berg et al (1994), who

CPD reflective questions

- What are the main risk factors for peristomal skin complications, and moisture-associated skin damage in particular?
- Consider how moisture affecting peristomal skin can be reduced
- Reflect on how you would evaluate the relative efficacy of an ostomy seal

in a study of 1601 patients reported that skin wetness caused more significant dermatitis than variation in skin pH. There has been, however, limited evidence to support claims made in some marketing literature regarding any associated clinical benefits of using a durable ostomy seal or a seal that provides pH buffering.

The potential improvement in quality of life associated with achieving a secure and reliable stoma care routine should not be underestimated. Boyles (2010) acknowledged the importance of accessory usage by stating that 'for many patients, accessories can mean the difference between managing and not managing their stoma'. **GN**

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