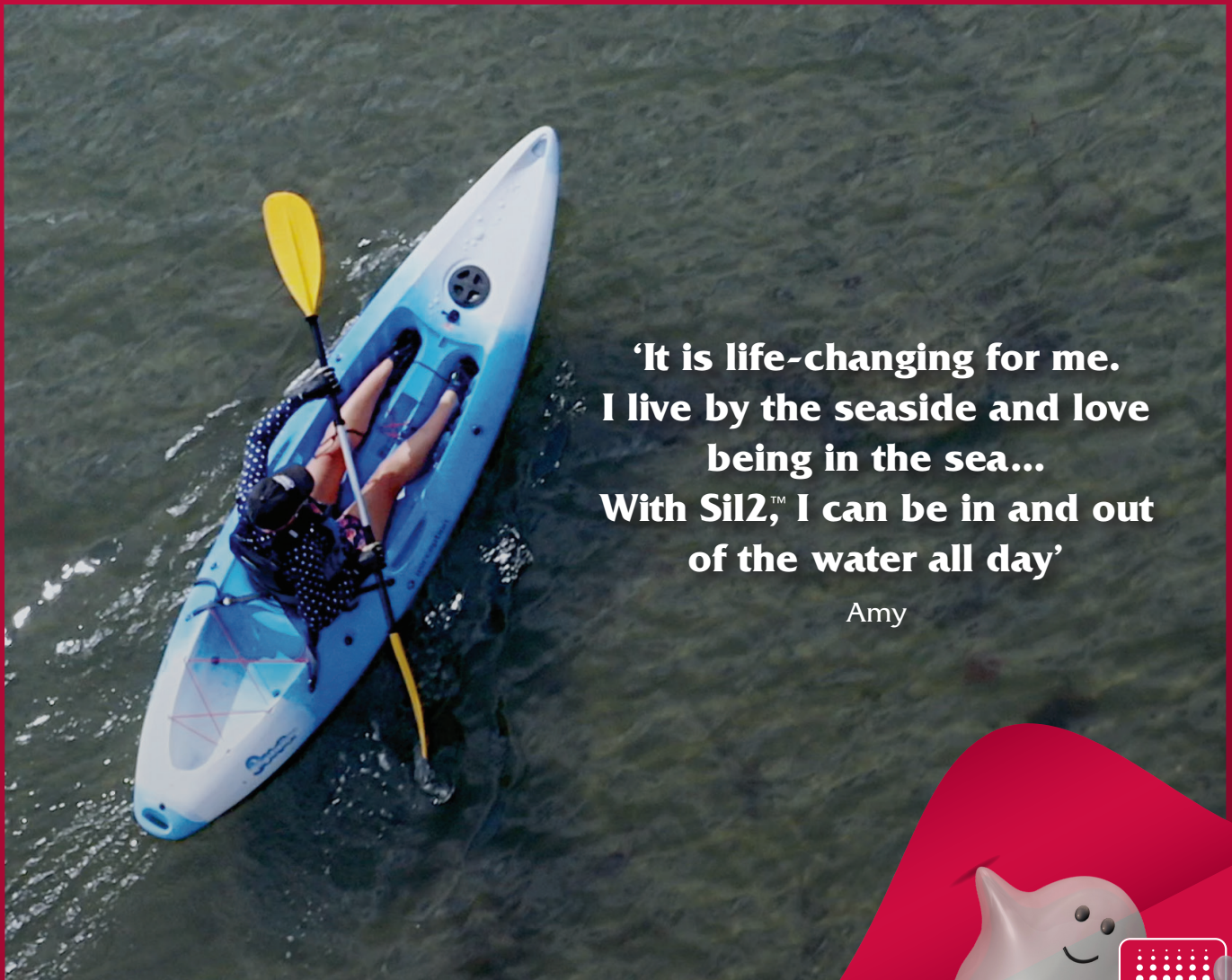


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Declaration of interest:

Thomas Swift and Gillian Westgate have been contracted by Trio Healthcare to work on Sil2 Breathable Silicone Technology; Stewart Lee has been an employee of Trio Healthcare; Amit Gefen, Fiona Le Ber and Julie Van Onselen have received an honorarium from MA Healthcare for their contributions to this supplement

Editor and Project Manager: Benjamin Wakefield

Lead Project Manager: Camila Fronzo

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Managing Director: Anthony Kerr

Published by: MA Healthcare Ltd, St Jude's Church, Dulwich Road, London, SE24 0PB, UK

Tel: +44 (0)20 7501 6726

Web: www.markallengroup.com

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Foreword: the prospects of new silicone-based biomaterial technologies in stoma care

Amit Gefen

Peristomal skin complications (PSCs) are a common occurrence. Evidence of this can be seen in a recent international study where 73% of ostomates reported experiencing a PSC in the previous 6 months (Voegeli et al, 2020). PSCs present with a variety of symptoms, from erythema to abrasion and up to full-thickness wounds, which make managing the stoma extremely difficult. These conditions may cause prolonged or chronic skin inflammation, leading to hyperplasia (buildup of epithelial tissue around the stoma), which complicates treatment further (Milne et al, 2011; Stelton, 2019). PSCs have a significant impact on the quality of life of people with a stoma. A US study indicated that ostomates with a PSC had approximately 1.5-times longer hospital admission periods, 1.4-times greater numbers of readmission episodes within 4 months following surgery and \$80 000 higher healthcare costs than those whose stoma surgery did not result in complications (Taneja et al, 2017). Moreover, treating these complications is costly, involving additional postsurgical nursing time and increased equipment expense.

The prevention and treatment of PSCs requires an understanding of what causes them. These potential causes are typically linked to failures in the protective, occlusive and adhesive functions of the ostomy appliance. An ostomy appliance is a disposable medical device that contains a flange (also called a baseplate, skin barrier or wafer), which adheres to the peristomal skin, both to protect it from the stomal output and to hold in place a pouch to collect the waste. In a two-piece appliance, the flange is separate from the pouch, whereas, in a one-piece system, the flange and pouch are combined. Both design variants of the ostomy appliance require continuous

contact between the flange and the peristomal skin. This need for unbroken contact is the source of many of the main risks of PSC development and can present particular challenges (Milne et al, 2011).

The majority of PSCs are caused by moisture-associated skin damage (MASD) and/or medical adhesive-related skin injury (MARS). MASD, also known as irritant dermatitis, results from exposure to excess moisture from perspiration or leakage of stomal output that accumulates between the flange and skin. The risk of MASD is often greater in people with an ileostomy, because they produce output that has not yet been processed by the large bowel and so typically contains high levels of proteolytic digestive enzymes and has high alkalinity, both factors being destructive to the peristomal skin. Meanwhile, MARS, results from sustained or traumatic mechanical forces, such as abrasion and skin stripping from removal of the adhesive flange. MARS has many parallels with medical device-related pressure ulcers (MDRPU), which account for more than 30% of all hospital-acquired pressure ulcers. The global incidence and prevalence of MDRPU have continued to climb since the breakout of the COVID-19 pandemic (Gefen et al, 2020; Martel and Orgill, 2020). Another common complication related to exposure of the peristomal skin to mechanical forces is folliculitis, which presents as pustules at the hair follicles and is caused by repeated pulling on the hairs surrounding the stoma when the appliance is removed—particularly in men who have more body hair. Loss of skin integrity due to any of the above factors may be exacerbated by microbial contamination, which adds to the loss of epidermal integrity. Likewise, fungal skin infections may occur under the appliance flange, where the dark, warm and moist skin environment is conducive to such infections (Milne et al, 2011; Stelton, 2019).

All of these causes are often exacerbated by an ill-fitting appliance, and this should be resolved with a more appropriate selection of products for the ostomate's needs.

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However, even with a good fit, conventional ostomy appliances often still leave patients vulnerable to PSCs. Stoma appliances have not fundamentally changed over decades, and the continued prevalence of PSCs suggests the engineering design of these devices requires a thorough revisit, including a critical review of the selection of the skin-contacting materials used in the flange.

Traditional flange designs are based on hydrocolloid materials, but these have been reported to cause inflammatory skin irritations (Omura et al, 2010). Moreover, the high absorption capacity of hydrocolloids causes these flanges to dilate, resulting in the development of swelling forces (Ferrari et al, 1994; 1995; Lanel et al, 1997). These forces gradually distort the peristomal skin under the flange, cause shearing of the skin and increase the level of mechanical stresses on the peristomal skin and underlying tissues. Once a hydrocolloid-based flange nears saturation, it loses its ability to manage additional moisture, resulting in maceration and favourable conditions for pathogen growth.

Compared with hydrocolloids, soft silicones have the potential to be better suited to the functions of an ostomy appliance. Soft silicones are impermeable to bacteria, incapable of being absorbed into the body tissues, hypo-allergenic, hygienic and non-odorous. A new silicone compound has been designed for contemporary ostomy appliances that has a stiffness that matches that of the native skin; a flexibility that allows conformation to the shape and contours of the stoma area; and a tacky quality and low surface energy that allow instant adhesion and easy removal. Most importantly for use in ostomy appliance flanges, this new silicone compound has been specifically designed to have a breathable material structure, which facilitates an evaporation-based mechanism of moisture management and passage of water vapour at a rate that is similar to native transepidermal water loss (TEWL). These important technological advancements have the potential to mitigate the disadvantages of established hydrocolloid-based solutions, particularly regarding saturation and its connection with MASD, MARSI and appliance wear time. Widespread implementation of such new technologies should ultimately reduce the incidence of PSCs; increase patient safety, satisfaction and quality of life; and decrease the massive healthcare costs of stoma care. The aforementioned novel skin barrier designs, the relevant biomaterial research outcomes and their clinical implications are comprehensively reviewed in this special supplement to the *British Journal of Nursing* and *Gastrointestinal Nursing*.

Clinicians who provide ostomy care (such as stoma care nurses; wound, ostomy and continence nurses; and enterostomal therapists) should be open to new developments in biomaterial and medical device technologies and to implementing new practices to improve patient care. The field of stoma care, particularly from the perspective of medical device design and technology, was becoming relatively stagnated. It deserves bio-engineering innovation and its adoption by clinicians and patients, leading to better quality of life for patients, as well as lowering costs for healthcare organisations.

However, achieving these goals requires out-of-the-box thinking from health professionals. In stoma care, clinicians have a professional duty to offer patients and their carers a range of device options, as well as to allow them to take advantage of progress and new advances in the field and not be constrained by old habits. Access to the best appliances and accessories, which incorporate the latest bio-engineering technology, can make a significant difference to the comfort and confidence of patients, improving their quality of life substantially, while also lowering the cost of stoma care. **BJN**

Declaration of interest: Amit Gefen has received an honorarium from MA Healthcare for writing this foreword

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Developments in silicone technology for use in stoma care

Thomas Swift, Gillian Westgate, Julie Van Onselen and Stewart Lee

Silicone describes any long-chain inert polymer that contains repeating chains of the element silicon, along with oxygen, carbon and hydrogen. There are a variety of silicone compounds used for various industrial purposes, but this article will focus on the type of soft silicone used in therapeutic medical devices. It charts the development of this technology and reviews the evidence for its efficacy compared with more traditional materials, beginning with silicone's established use in dermatology, wound care and stoma accessories. This is followed by an acknowledgement of the challenges presented by moisture management that have limited silicone's application in flanges for stoma appliances. The article then introduces new silicone compounds that are able to overcome these limitations with a novel method of moisture management, with considerable advantages over traditional hydrocolloid appliances.

Soft silicone polymers have a variety of advantages that make them particularly suitable for use. They are highly flexible, which allows them to conform well to the shapes and contours of the body. They have a tacky quality that allows them to adhere to dry surfaces and a low surface energy that provides instant adhesion. They are non-toxic, non-odorous and have a low allergy potential, as well as being impermeable to bacteria and incapable of being absorbed into the body, all of which makes them comfortable and hygienic to wear (Meuleneire and Rücknagel, 2013; Cronin, 2016).

SILICONE IN WOUND AND CONTINENCE CARE

Up to the beginning of the 21st century, wound dressings and similar devices designed to provide moisture and

ABSTRACT

Soft silicone's flexibility, adhesive capacity and non-toxic, non-odorous and hypoallergenic nature have made it an established material for adhesive and protective therapeutic devices. In wound care, silicone is a component of contact layer dressings for superficial wounds and silicone gel sheeting for reducing the risk of scarring, as well as of barriers for incontinence-associated dermatitis. Regarding stoma accessories, silicone is established in barrier films to prevent contact dermatitis, adhesive removers to prevent skin stripping and filler gels to prevent appliance leaks. Until recently, silicone has not been used in stoma appliances flanges, as its hydrophobic nature has not allowed for moisture management to permit transepidermal water loss and prevent maceration. Traditional hydrocolloid appliances manage moisture by absorbing water, but this can lead to saturation and moisture-associated skin damage (MASD), as well as increased adhesion and resultant skin tears on removal, known as medical adhesive-related skin injury (MARS). However, novel silicone compounds have been developed with a distinct evaporation-based mechanism of moisture management. This uses colloidal separation to allow the passage of water vapour at a rate equivalent to normal transepidermal water loss. It has been shown to minimise MASD, increase wear time and permit atraumatic removal without the use of adhesive solvents. Trio Healthcare has introduced this technology with a range of silicone-based flange extenders and is working with the University of Bradford Centre for Skin Sciences on prototype silicone-based stoma appliance flanges designed to significantly reduce the incidence of peristomal skin complications, such as MARS and MASD. It is hoped that this will also increase appliance wear time, reduce costs and improve patient quality of life.

Key words: Medical adhesive-related skin injury

- Moisture management ■ Moisture-associated skin damage
- Silicone ■ Transepidermal water loss

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protect the surrounding skin were primarily made from hydrocolloids and hydrogels, as well as alginates (Ghomi et al, 2019). The early 2000s saw the introduction of silicone-based wound dressings, which have successfully applied the advantages outlined above to protecting periwound

skin and minimising pain and trauma at dressing change (Meuleneire and Rücknagel, 2013).

Silicone wound contact layer dressings in superficial wounds

Silicone's atraumatic properties make it an ideal material for wound contact layer (WCL) dressings—dressings applied directly to a wound to protect it from direct contact with harmful substances and ensure an appropriately moist environment to promote healing. Because silicone adheres to the periwound skin but not to the wound bed, removing a WCL dressing made of silicone, compared with other materials, is less likely to result in skin tears, which can cause pain and further damage to the wound (White, 2014). This makes these dressings effective at protecting both the periwound skin and the wound bed, and they are especially appropriate in superficial wounds where skin is vulnerable, such as skin tears, burns, incontinence-associated dermatitis (IAD) and blistering diseases, where skin is vulnerable (Meuleneire and Rücknagel, 2013).

Silicone-based dressings have a number of clinical advantages over older, non-silicone products. For example, silicone adhesives do not deteriorate and become tacky over time. This is in contrast to hydrocolloid adhesives, which, as they absorb moisture, can become difficult to remove without potentially damaging fragile skin (Cronin, 2016; Chadwick 2018). Hydrocolloids also do not absorb wound exudate effectively, resulting in maceration and/or excoriation of the wound (Cronin, 2016; Chadwick, 2018).

A number of studies have shown that WCL dressings incorporating soft silicone technology result in improved outcomes for patients with exuding or non-exuding wounds compared with older product materials (Patton et al, 2013; Matsumura et al, 2014; Bateman, 2015; Suess-Burghart et al, 2015; David et al, 2018). A study by Klode et al (2011) evaluated the adhesive areas of 56 wound dressings (acrylate, n=23; silicone, n=9; hydrocolloid, n=17 and polyurethane, n=7) in healthy human volunteers by measuring the peel force required to remove the dressing from skin and the subjective pain intensity during removal using a visual analogue scale. The results showed statistically significant correlation between the adhesion and pain intensity, with the lowest pain intensity for silicone dressings. An observational study by Bateman (2015) examined 150 patients with acute or chronic exuding wounds treated using a foam dressing containing soft silicone. After 4 months, the data showed improvements in adherence, exudate management, maceration reduction and atraumatic application and removal.

There are a variety of silicone-based dressings—including bi-stretch soft silicone, soft silicone mesh,

soft silicone fixation tape, soft silicone foam and soft silicone foam with super-absorbers—that have been used successfully in the treatment of blistering diseases, such as epidermolysis bullosa (EB). EB is a group of rare, inherited skin disorders characterised by fragility and blistering of skin and mucous membranes, from even minimal friction or trauma. Patients with EB are vulnerable to a number of complex, chronic problems, including pain from blisters, skin erosion and skin scarring, which can involve the hands, feet, mouth, eyes and oesophagus. Children with EB can also experience secondary complications, including failure to thrive, nutritional deficiencies, cancer and anaemia (Danial et al, 2015). This makes wound care a particular challenge for the parents of these children. Recent clinical guidelines (Denyer et al, 2017) describe the underlying principle of lesion management in EB as the application of an atraumatic dressing to prevent blistering and damage to skin and wound bed, which can lead to pain and bleeding on removal. Dressings must be removed carefully to avoid further skin damage, and the use of a silicone medical adhesive remover can be helpful (Denyer et al, 2017). These principles also apply to other blistering conditions, such as bullous pemphigus, bullous pemphigoid and Hailey-Hailey disease.

Silicone gel sheeting in wounds at risk of scarring

Silicone has been used for some time in the treatment of healed wounds to reduce or prevent hypertrophic and keloid scarring (Meuleneire and Rücknagel, 2013). Hypertrophic scars are red and raised above the surface, but do not go beyond the boundaries of the original wound site; they can continue to thicken for up to 6 months and can be very itchy or painful (Van Onselen, 2019). Keloid scars, by contrast, grow beyond the boundary of the original wound site due to an overproduction of collagen; they can develop up to 1 year after injury and are painful, itchy and unsightly (Van Onselen, 2019).

Silicone gels and silicone gel sheeting (SGS) are both used to help reduce scarring, and there is no evidence to suggest that one is more effective than the other (Lin et al, 2018). Although the mechanism of action is not known, it is believed to relate to wound hydration. There is evidence that SGS affects the hydration status of the scar by decreasing the water vapour evaporation rate to almost half that of normal skin, causing a build-up of moisture on the skin surface under the SGS (Gilman, 2003). This increased hydration seems to be responsible for reduced capillary activity, hyperaemia and collagen deposition (Niessen et al, 1998), as well as causing electrostatic changes that influence collagen deposition and remodelling within the scar (Hirshowitz et al, 1993).

A reduced water evaporation rate that results in accumulation of water below the SGS can lead to skin maceration (Chan et al, 2005); other common side-effects associated with SGS include pruritus, skin breakdown and skin rash, and there are reported issues with poor durability of the sheet, failure of the sheet to improve the hydration of dry scars and poor patient compliance (Rabello et al, 2014).

A review by Hoeksema et al (2013) compared several types of semi-occlusive silicone products for scar reversal using transepidermal water loss (TEWL) and stratum corneum moisture levels as measured endpoints. The study suggested that products that reduce TEWL to near normal values help skin recover, and this could be of value when considering the relative occlusive properties of new silicone adhesive formulations in development.

A Cochrane review and an update of clinical guidelines regarding the prevention and treatment of scars (O'Brien and Jones, 2013; Meaume et al, 2014) both highlighted silicone-based products, including sheets and gels, as improving scar thickness and scar colour. Such products have been suggested by a European Working Group as first line prophylactic and non-invasive treatment options for all scars (Gold et al, 2014; Monstrey et al, 2014; Van Onselen, 2019).

Silicone barriers in incontinence-associated dermatitis

The complications of incontinence—whether of urine, faecal matter or both—include incontinence-associated dermatitis (IAD) (Langemo et al, 2011). IAD occurs when chronic or repeated exposure to urine or faecal matter leads to the breakdown and inflammation of the perineal skin, potentially involving maceration, blistering and/or

loss of the skin barrier function (Beeckman, 2017).

Management of IAD, according to a 2016 Cochrane review, should focus on skin cleansing to remove dirt, debris and microorganisms; skin moisturisation to repair or enhance the skin's barrier; and the application of skin protectants (Beeckman, et al, 2016). The Cochrane review states that, in practice, products and procedures are the same for both prevention and treatment, and the aim should be to protect the skin from further exposure to irritants.

Silicone-based barrier products, such as dimethicone, have been used in the prevention and treatment of IAD. These spread easily and are conformable to the periwound area or area of at-risk skin (Woo et al, 2017). In an alternative approach, Beeckman et al (2011) compared the effectiveness of a three-in-one, pre-moistened, perineal washcloth impregnated with 3% dimethicone vs standard of care in the prevention and treatment of IAD in 141 nursing home residents. After 4 months, there was a reduction in the prevalence of IAD in those treated with the 3% dimethicone washcloth (8.1% vs 27.1%) (Beeckman et al, 2011).

SILICONE IN STOMA ACCESSORIES

The skin surrounding a stoma, known as peristomal skin, is vulnerable to a number of complications that can cause considerable physical discomfort and emotional distress (Keeling, 2015) (*Figure 1*). Different studies have reported the incidence of peristomal skin complications to be between 35% and 74%, and those with an ileostomy are at the greatest risk (Herlufson et al, 2006; Richbourg, 2007; Williams et al, 2010; Salvadalena, 2013).

Although common, these complications can generally be prevented or resolved with correct use of the most appropriate stoma appliance (also known as a bag or pouch)



Figure 1. Complications caused by effluent contact with peristomal skin

and stoma care accessories for the patient's particular needs. A number of silicone-based stoma care accessories have been developed that have been shown to be effective at addressing these complications, including barrier films, adhesive removers and fillers (Cronin, 2016). Silicone is non-toxic and non-alcohol based, and thus non-irritant, as well as able to repel water and chemical attack, all of which help these accessories maintain skin integrity, appliance adherence and patient comfort (White, 2014).

Silicone barrier films to prevent contact dermatitis

The most common peristomal skin complication is contact dermatitis. Contact dermatitis manifests as irritation and redness, and it occurs when the skin is exposed to the stoma's corrosive effluent (faeces or urine), typically after a gap forms in the seal between skin and appliance flange (also known as a wafer, faceplate or baseplate) (Burch, 2011).

Barrier films are accessories that provide a temporary layer of protection against contact with harmful substances, as well as improving appliance adhesion (*Figure 2*). Available

as wipes or sprays, barrier films are applied directly to the peristomal skin before the appliance is fitted. Silicone-based barrier films are long-lasting and pain-free, and patented formulations have been developed that serve to protect the stratum corneum from chemical irritants and soothe reddened and sore skin. Newer barrier films contain cyanoacrylate, as well as silicone.

Barrier films are used wherever there is likely to be contact with an irritant, and they are an established treatment for extant contact dermatitis. There is debate as to whether they should also be used as a preventive measure in healthy peristomal skin. This is an extra cost burden, but some stoma care nurses do encourage their use after hospital discharge (Rudoni and Dennis, 2009). Prevention is often better than cure, because, once peristomal skin becomes damaged, it is harder to control leakage and prevent further harm, and, once use is stopped, the skin may again be exposed to damage.

Silicone adhesive removers to prevent skin stripping

As with wound dressings, the adhesive flange, which keeps the appliance on the skin and forms a seal around the stoma, needs to be removed. Repeated and/or traumatic removal can lead to painful skin stripping. As a conservative measure, patients can be encouraged to be gentler in how they remove their appliances. Likewise, although stoma appliances need to be changed on a regular basis, ostomates should be encouraged to minimise removals by maximising the wear time of their flange, perhaps by switching to a two-piece appliance.

This advice may not be sufficient for all ostomates, especially those with delicate skin. These patients may benefit from using adhesive removers, available as sprays and wipes, which loosen the adhesive bond to make removal easier and less likely to damage the skin. These were traditionally based on either alcohol or oil. However, these have been superseded by silicone-based adhesive removers (*Figure 3*), which have the advantages of evaporating quickly and avoiding skin dryness, stinging sensation and persistent sticky residue associated with traditional alcohol- and oil-based solvents (Burch, 2011). Any adhesive residue left by an appliance change should be removed to prevent the skin from drying, which leaves it susceptible to breakdown. More recent silicone formulations have been improved to eliminate environmentally harmful cyclic siloxanes.

Silicone fillers to prevent stoma appliance leaks

As well as causing contact dermatitis, gaps in the seal between appliance and peristomal skin can further weaken

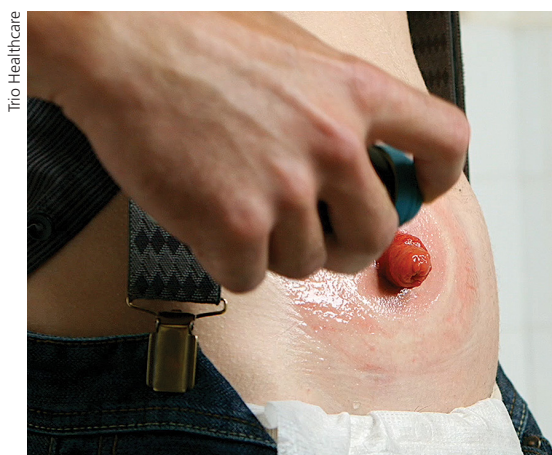


Figure 2. Silicone-based barrier film (Trio Elisse)



Figure 3. Silicone adhesive remover (Trio Elite)

the appliance adhesion, often resulting in leakage of effluent that causes odour, soiling and serious negative psychosocial consequences. Although leaks are a common problem for many ostomates, they can usually be significantly minimised with appropriate accessories (White, 2014).

Flanges adhere best to flat peristomal skin around a spouted stoma. Leaks are made more likely by issues with the stoma itself, whether it is retracted, prolapsed or poorly sited, as well as by an uneven skin surface. Many people's abdomen contains dips, creases and folds, and these can develop with age, changes in weight and other complications, such as a parastomal hernia. A number of silicone-based stoma accessories have been developed to compensate for these issues.

Fillers, available as pastes and gels (Figure 4), are squeezed from a tube or syringe into recesses in the skin, where they are sculpted into a flat surface for the flange to adhere to. Older filler pastes took some time to set before the flange could be applied. However, silicone-based filler gels set in just 20 minutes from application via a process known as room-temperature vulcanisation, triggered by the moisture and humidity that emanates from the skin surface (White et al, 2014; Cronin, 2016). Silicone gels are also waterproof, transparent and tacky to the touch.

CHALLENGES OF MOISTURE MANAGEMENT

Until recently, despite silicone's established success in many stoma accessories, it has not been applicable to the most important piece of ostomy equipment, the appliance flange itself. This is because the same hydrophobic and occlusive properties that make silicone so effective as a protective material also traditionally present challenges for devices that require an effective system of moisture management. An understanding of these limitations, and how they can be overcome, requires an explanation of how silicone interacts with the outermost layer of the skin, the stratum corneum.



Figure 4. Silicone-based filler gel (Trio Silken)

The stratum corneum and transepidermal water loss

The stratum corneum (Figure 5) is around 10–20 µm thick and is composed of enucleated and flattened corneocytes, formed from terminal differentiation of epidermal keratinocytes. Corneocytes are interleaved with many lamellae sheets enriched with cell-bound free fatty acids and ceramides (Matsui et al, 2015). Among the most crucial of the stratum corneum's many protective functions is as a permeability barrier that ensures the body remains watertight and permits survival in very dry environments. There is a steady flux of water through the skin, as it diffuses from the extremely hydrated lower layers of the epidermis and dermis to the stratum corneum, before exiting the skin via either the sweat glands or TEWL (Machado et al, 2010).

The rate of flux varies, with higher TEWL associated with smaller corneocytes, warmer tissue temperature and lower air humidity (boundary layer water vapour pressure), as well as thinner parts of the stratum corneum and bodily extremities, such as the feet and palms. Higher TEWL is also linked to disrupted (irritated or mechanically damaged) skin, and a slower rate of diffusion is usually linked to a healthier permeability barrier (Taylor et al, 2013). TEWL can be tested with simple and inexpensive equipment, such as a handheld vapour meter, which gives results in g-2hr-1. This test should ideally occur under standardised environmental temperature and humidity, and after a period of acclimatisation following removal of clothing or any other covering that may affect boundary-layer water vapour pressure.

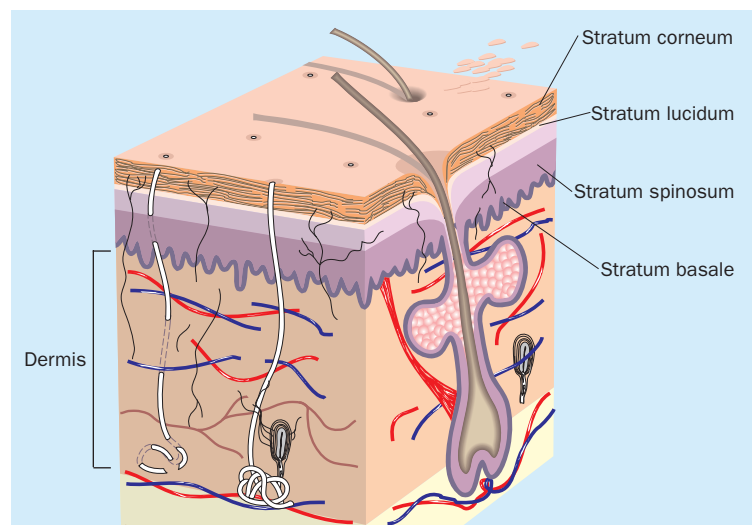


Figure 5. Structure of skin

Moisture-associated skin damage

Many protective devices are designed to cover the skin or wound bed to protect it from harmful contact with external substances. However, an occlusive device with low water permeability can also obstruct the normal evaporation of water from the skin, leaving it to build up in the stratum corneum, which has a significant absorptive capacity (300–400% of its dry weight) (Gray et al, 2011). In healthy skin, when occlusion is removed, the accumulated water will evaporate at a higher rate than normal until a healthy equilibrium is restored, meaning that even repeated short-term occlusion should not have adverse effects (Gioia et al, 2002). However, prolonged occlusion can lead to maceration, along with mild skin irritation, which can adversely affect barrier function and lead to moisture-associated skin damage (MASD) (Bouwstra et al, 2003; Warner et al, 2003; Jungersted et al, 2010; Whitehead et al, 2017). Even short-term occlusion can be problematic in scar tissue, which has a raised TEWL, and in stretch

marks at the affected site, which can have altered barrier properties (Dabboue et al, 2015).

Therefore, protective devices that need to be worn for long periods, or on skin with altered barrier function, require an effective system of moisture management to prevent maceration. The hydrophobic nature of silicone has traditionally made it unsuitable as a material for managing moisture. Instead, this has traditionally been achieved by using devices made of hydrocolloid, a highly absorptive material that draws moisture away from the skin. However, as moisture is absorbed, the device swells in volume, becomes deformed and increases in adhesive strength (Figure 6) (Ferrari et al, 1994; 1995). Eventually, the hydrocolloid becomes saturated, losing its ability to manage moisture and, instead, contributing to maceration and resulting in warm and humid conditions ideal for pathological micro-organism proliferation (Lyon, 1999). This degradation of function limits the effective wear time of hydrocolloid devices (Figure 7).

‘silicone devices do not undergo the marked swelling, increased adhesion, saturation and degradation of function associated with hydrocolloids’

Medical adhesive-related skin injury

Many medical devices are held in place with an adhesive component that is attached to the patient’s skin. This needs to be adhesive enough to stay in place, but not so adhesive that it cannot be removed without causing excoriation.

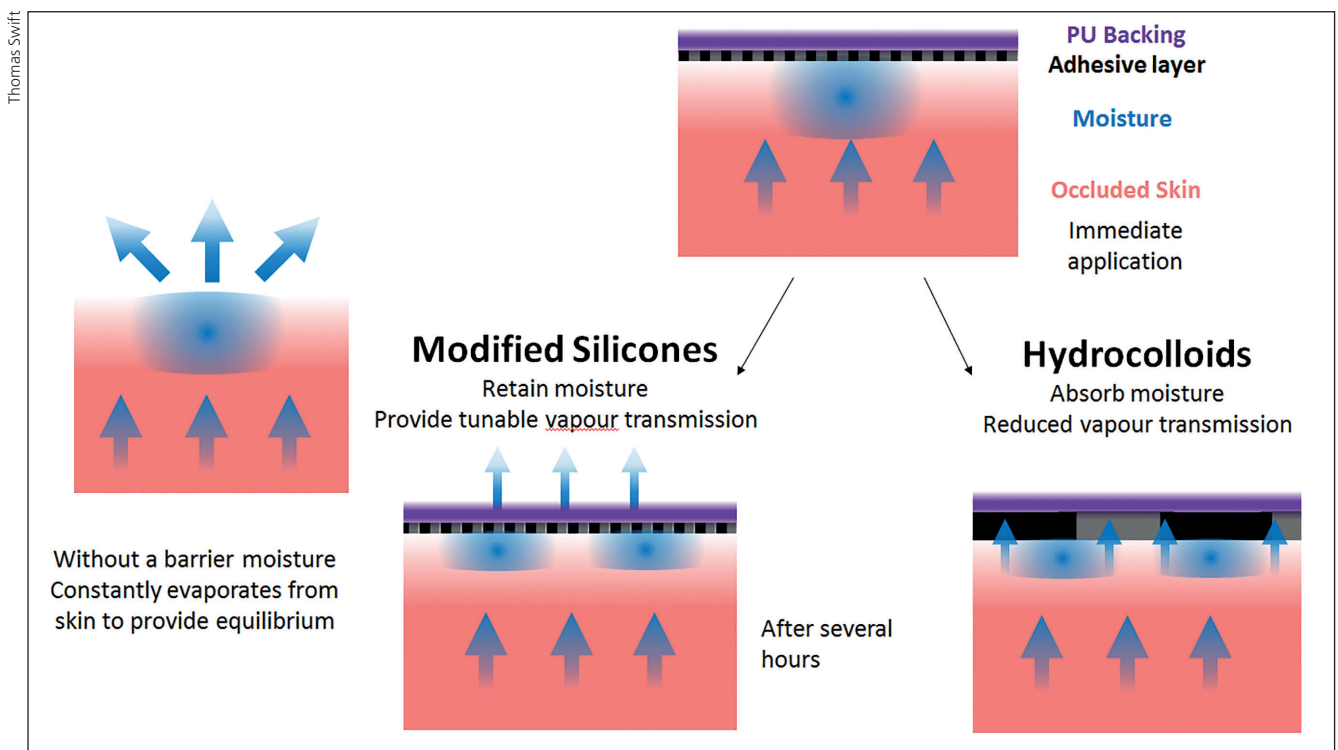


Figure 6. Proposed moisture management technique of silicone versus hydrocolloid flange extenders on occluded skin

Excoriation occurs when the bond between the device and the skin is stronger than the bond between the cells within the stratum corneum, so that, when the device is removed, skin cells in the topmost layer, including corneocytes, are pulled with it. This excoriation makes the process of removal painful for the patient and the skin more vulnerable to infection and disease. The more frequently adhesive devices are removed from a patch of skin, the greater the risk or severity of skin tearing, known as medical-adhesive related skin injury (MARSi) (Farris et al, 2015).

This is a problem for adhesive devices made from hydrocolloids. As hydrocolloid absorbs moisture, it becomes tacky and more adhesive, requiring a greater peel force to remove (Figure 8). Thus, the longer a hydrocolloid device is worn, the more likely it is to be difficult to remove and result in discomfort, pain and/or MARSi. These issues may be blamed on poor application technique or pre-existing conditions, when they result from chemical deficiencies inherent to the hydrocolloid material (Williams et al, 2010).

MOISTURE MANAGEMENT IN NOVEL SILICONE STOMA FLANGES

This risks of MARSi and MASD, and associated limited wear time, are significant drawbacks for hydrocolloid as a material for stoma appliance flanges. This has led to the development of novel silicone compounds that overcome the limitations of traditional silicone technologies to provide a novel method of moisture management that has significant clinical advantages over traditional hydrocolloid flanges.

Mechanism of action

Rather than absorbing water, silicone is water-repellent (hydrophobic), composed of fully crosslinked inorganic polymer chains (Owen, 2014). However, a compound of silicone and water-attracting (hydrophilic) additives has a natural microporosity that, when cast in sheets or wafers, allows water to pass through it as vapour, while still repelling aqueous liquids. As this moisture is not permanently retained, silicone devices do not undergo the marked swelling, increased adhesion, saturation and degradation of function associated with hydrocolloids.

This works via colloidal separation, in which water molecules can osmose through a sea of hydrophobic silicone particles (the oily phase) by diffusing between microscopic islands of hydrophilic polymers (the aqueous phase). This is a key advantage, as traditional unmodified silicone dressings were either restricted to net materials with plenty of room for moisture penetration (Platt et al, 1996) or risked a reservoir of water building up beneath



Figure 7. Breakdown of hydrocolloid flange due to saturation



Figure 8. Peel force on peristomal skin during removal of an adhesive flange

the dressing that could lead to patient complications (Nikkonen et al, 2001).

If formulated correctly, the silicone compound contains internal pores large enough for moisture vapour to diffuse (Figure 9). Hydrophilic additives play a crucial role in driving this phase separation. Materials using too strongly water-binding additives in too large a volume will result in the device retaining moisture and reduce TEWL at increased humidity (Lei et al, 2011). Absence of additive results in a completely water-repellent material with almost no TEWL capacity at all. Composite materials can be designed with the most appropriate ratio of additives, as well as material thickness, to suit applications specific to temperature and humidity (Wang et al, 2017).

These novel silicone compounds are not only effective at reducing MASD, their non-absorptive method of moisture management also avoids the increased adhesion and risk of MARSi associated with hydrocolloids. The number of

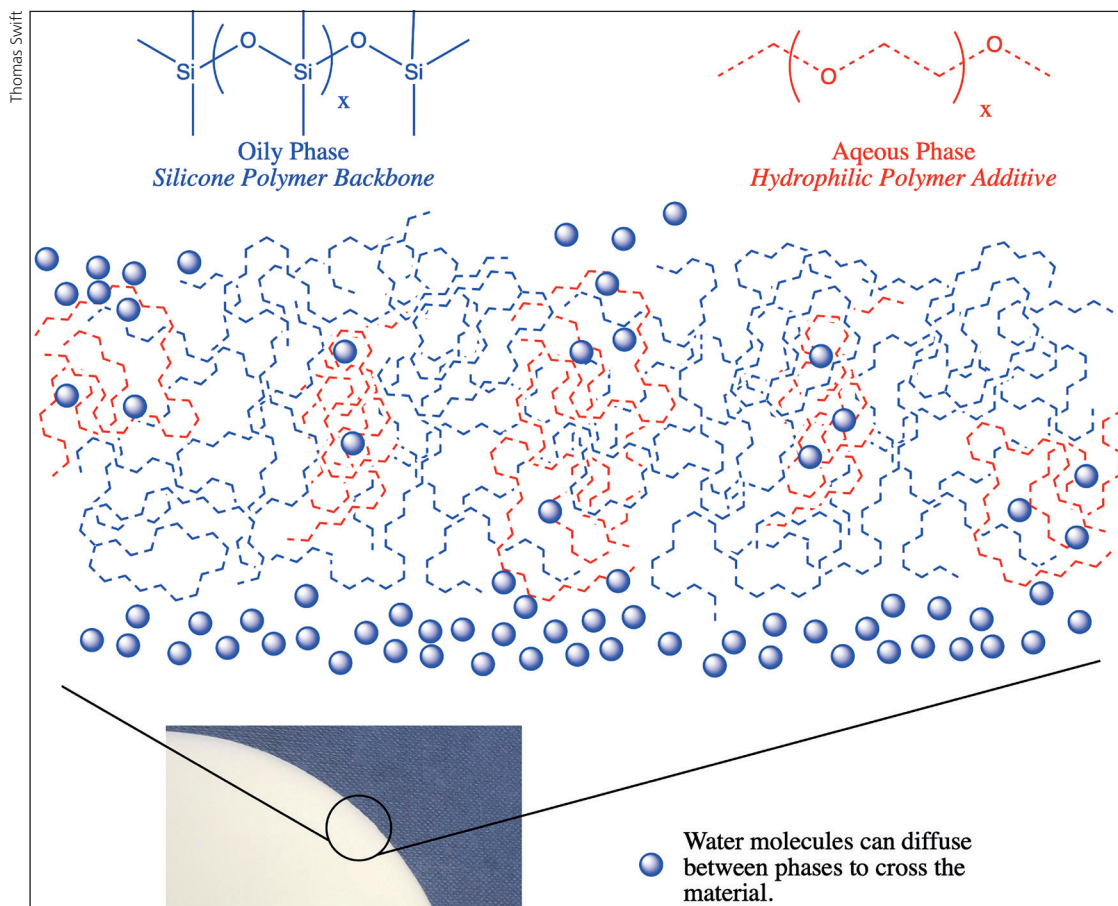


Figure 9. Gradual diffusion of water molecules through a novel silicone compound

cells that remain stuck to the adhesive film can be used to measure the extent of skin damage (Gao et al, 2013), and MARSII has been shown to occur when adhesives have a peel force above 2N (Omura, 2010). The University of Bradford Centre for Skin Sciences ran an ex vivo study on behalf of Trio Healthcare to compare the peel force required to remove two otherwise equivalent prototype adhesive

wafers, one made of silicone and the other of hydrocolloid. The wafers were attached to porcine skin, incubated in protein stain Ponceau S and then rinsed in deionised water. The silicone wafers showed no protein removal (although there was background staining of the material, from white to a slight pink), while the hydrocolloids showed clear indications of protein stripping (evident from deep red particulate stains on the stripped adhesive material) (Figure 10). The peel force of the prototype silicone wafer was concluded to be sufficient to ensure adhesive stability but lower than that of hydrocolloid equivalents, with less potential for MASD. This appeared to result from increased TEWL and reduced osmotic swelling.

Silicone flange extenders and ostomy seals

For the past two decades, the adhesive flanges of stoma appliances have almost all been made from hydrocolloid, often with a polyurethane backing (Berry et al, 2007). Hydrocolloid superseded acrylate as the principal material for flanges, as hydrocolloid's absorptive mechanism of



Figure 10. Peel test on porcine skin comparing degree of skin tearing in silicone (a) and hydrocolloid (b) prototype flanges

moisture management comparatively reduced the degree of maceration (Black, 2013), as well as reducing the potential for allergic reactions and providing potential cost savings (Smith et al, 2007). It is hoped that the material properties of the novel silicone compounds will again transform how stoma appliances manage moisture.

‘moisture management based on evaporation rather than absorption [may] reduce the incidence of peristomal MASD and MARSI’

To explore the potential of these prototype silicone compounds, Trio Healthcare launched a range of silicone accessories, including flange extenders (*Figure 11*) and ostomy seals (*Figure 12*). Flange extenders are accessories in the shape of strips and rings that extend the adhesive area of the stoma appliance flange, allowing for greater adhesion to uneven or otherwise problematic peristomal skin. An ostomy seal is a small ring that is moulded around the stoma to help prevent effluent from making contact with the peristomal skin in patients who have difficulty creating a perfect seal with an appliance flange alone. These accessories have similar material requirements for adhesion and protection to the flange itself, but are a more temporary, supportive measure. Compared with traditional hydrocolloid accessories, these silicone versions benefit from the novel compound’s non-absorptive mechanism of moisture management, which prevents maceration and excoriation, improves comfort and extends wear time. The silicone seal naturally settles back to its original shape and therefore provides a close fit around the contours of the stoma, moving with peristaltic motion of the bowel and ensuring a close contact at all times. This was a bridging step intended to provide the user experience necessary to develop the first appliances with flanges made from a silicone compound.

Prototype silicone flanges for stoma appliances

All this has led to the development of the first prototype stoma appliances with silicone-based flanges. The intention has been to create an appliance that is ideal for all types of peristomal skin—able to protect healthy skin, soothe irritated skin and encourage repair of damaged skin. This contrasts with hydrocolloid devices, which are not appropriate for use on excoriated skin (Berry et al, 2007). The challenge has been to engineer a reformulated silicone compound that is sufficiently microporous to permit



Figure 11. Silicone-based flange extender (Trio Silex)



Figure 12. Silicone-based seal (Trio Siltac)

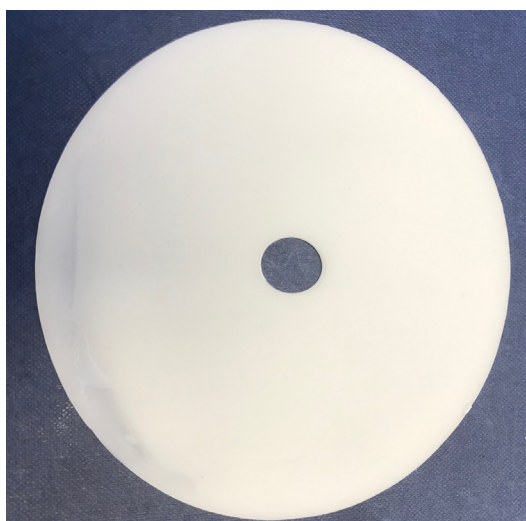


Figure 13. Prototype silicone flange for a stoma appliance

optimal evaporation, while retaining silicone’s protective properties and ensuring surface adhesion and long-term stability in use (*Figure 13*). Likewise, the chemical properties of the flange need to match the requirements of different

kinds of skin, protecting and preserving its health and being gentle on inflamed skin during removal, and these chemical properties need to remain constant during use.

Prototype formulations from Trio Healthcare have been tested for TEWL at elevated humidity and temperature, as well as for peel force on removal from the stratum corneum, and these have so far shown promising results. Some choice in selection of a product with particular properties, depending on the status of the patient's skin, could be vital to ensure optimal healing and maintenance of skin health.

With a system of moisture management based on evaporation rather than absorption, silicone flanges appear to avoid maceration and excoriation of the stratum corneum, thus having the potential to significantly reduce the incidence of peristomal MASD and MARS. This should improve not only peristomal skin health, but also ostomates' overall comfort, confidence and quality of life. These flanges should also extend the wear time of appliances and reduce the necessity of adhesive removers, reducing the major financial burden associated with stoma care.

CONCLUSION

In stoma care (as in dermatology, wounds and continence), promoting skin health is a high clinical priority, essential to the patient's physical and psychological wellbeing. Protective and adhesive technologies provide a number of indispensable tools for achieving healthy skin, but suboptimal application of these materials can have significant dermatological drawbacks. Therefore, understanding the considerable variation in available devices, including their indications and mechanism of action, is vital to make a sound evidence-based decision as to which is the most appropriate for a particular patient's needs (Meuleneire and Rücknagel, 2013).

The value of silicone in wound and continence care and certain stoma accessories has been well established. However, the challenge of moisture management had previously held back silicone's full therapeutic potential from being applied to stoma appliance flanges and related accessories. This challenge has been met with the development of new silicone compounds that have a breathable matrix, which provides a more natural environment and allows the skin to stay healthy. This new material has a proven ability to effectively both adhere to and protect peristomal skin, without causing damage from maceration or excoriation. Compared with equivalent materials, its non-absorbent mechanism of moisture management prevents degradation and the increase of adhesion over time, thus maximising wear time and minimising traumatic removal (Cronin, 2016). **BJN**

Declaration of interest: Thomas Swift and Gillian Westgate have been contracted by Trio Healthcare to work on Sil2 Breathable Silicone Technology; Stewart Lee has been an employee of Trio Healthcare; Julie Van Onselen has received an honorarium from MA Healthcare for her contribution to this article

Note: This article was first published in the *British Journal of Nursing*, volume 29, number 16

Acknowledgement: The authors would like to thank Dr Stephen Sikkink (University of Bradford, Centre for Skin Sciences) for carrying out Ponceau S total protein staining

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Using a novel breathable silicone adhesive (Sil2 technology) in stoma appliances to improve peristomal skin health: answering the key questions

Fiona Le Ber

Following the introduction of a range of silicone-based stoma care accessories, Trio Healthcare is further developing its range of novel silicone-based adhesive stoma products. This includes stoma appliances made from a unique patented formulation, known as Sil2 technology, that has been designed to maintain skin health by allowing the skin to breathe. As the use of silicone technology in stoma care is new, it has raised a number of questions among stoma care nurses. This Q&A draws on clinical evidence and the author's experience as a specialist stoma care nurse to answer these questions and help nurses select and use the most appropriate appliance for their patients.

What makes silicone an appropriate material for use in stoma appliances?

Silicone is widely used in wound care, continence and stoma care accessories, due to its inert, waterproof, non-toxic, non-odorous and hypoallergenic qualities. These properties also make it a safe and effective material for stoma appliances.

Many ostomates have an abdomen with an uneven surface for the flange to adhere to, which can cause problems with leaks and subsequent sore skin. Silicone polymers are extremely malleable and so can be easily moulded into creases and crevices around the stoma. This

ABSTRACT

Fiona Le Ber answers some of the questions that stoma care nurses may have regarding this novel silicone adhesive based technology, which helps to avoid medical adhesive related skin injury (MARS) and moisture-associated skin damage (MASD). Whereas hydrocolloid stoma appliances absorb moisture, this has a non-absorptive method of moisture management that prevents peristomal skin becoming damp and excoriated.

flexibility provides an excellent fit to the contours of the body and an effective seal against urine or faecal output (Meuleneire and Rücknagel, 2013).

Some silicones have been developed with adhesive properties, which allow a device to attach securely to the skin, preventing peeling or separation. Unlike other adhesive materials, soft silicones are less likely to deteriorate, and they do not leave a sticky residue (Burch, 2011). Sil2 has been especially modified to allow it to sustain a persistent level of adherence over time, as well as making it softer and gentler on the skin (Fumarola et al, 2020). These properties make silicone an effective material for products designed to meet the needs of ostomates and stoma care nurses.

Why should nurses consider changing from a familiar material that they already know to be effective?

Experienced stoma care nurses will understand that no two patients are the same. An appliance that has had fantastic results on one patient may not be as effective on another, and so stoma care nurses and ostomates may

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need to try products from several companies before finding the right one (Sica, 2018). Stoma care nurses need to be aware of the full variety of stoma appliances available, including one-piece and two-piece systems, each designed to accommodate different body shapes and types of stomal output. Finding the correct appliance can make a significant difference to a patient's quality of life.

To achieve this, the manufacturers of stoma appliances need to be innovative, creating new technologies to develop more effective products for ostomates and stoma care nurses to use. Furthermore, innovation also requires practitioners and users to be open-minded and willing to compare all available options. Part of this is the recognition that established technologies may not be perfect and often have drawbacks that can be improved on.

'the prevalence of MARSI among ostomates could be as high as 54%'

One such example is moisture management in stoma appliances. Normally, moisture on the skin is lost via evaporation, and this is known as transepidermal water loss (TEWL). This presents a challenge for occlusive devices that cover the skin for prolonged periods, because this will prevent TEWL and trap moisture in the skin, unless the technology has an effective method of moisture management. This is vital in stoma care, because peristomal skin, the area of skin around the stoma that is covered by the flange, is exposed to biochemical and mechanical stresses on a daily basis, and these can damage the skin's defensive, sensory and regulatory functions (Nichols, 2018). Peristomal skin damage is a common, painful and debilitating issue that significantly impacts 70% of ostomates (Gray et al, 2013).

What specific drawbacks are there to established hydrocolloid stoma appliances that could be improved on?

Traditional hydrocolloid stoma appliances manage the issue of TEWL by absorbing moisture from the peristomal skin directly into the flange (also known as the baseplate). However, the hydrocolloid flange retains this moisture against the skin, where, over time, it has the potential to cause moisture-associated skin damage (MASD). MASD refers to skin damage caused by excessive or prolonged contact with moisture. This may be secondary to contact with stomal output, wound exudate, faeces, urine, sweat, mucus or saliva. MASD can be divided into four categories (Box 1). Some degree of peristomal skin damage has been reported by 62% of all ostomates (Nichols, 2018), and peristomal MASD was three times more common in ileostomates than in colostomates (Nagano, 2019).

Additionally, this absorption of moisture into the hydrocolloid increases its adhesive strength. This makes the flange harder to remove, which, over time, may cause peristomal medical adhesive-related skin injury (MARSI) (Figure 1). MARSI is characterised by erythema, blisters, erosion and/or skin tears that continue for 30 minutes or more following removal of an adhesive device (Le Blanc et al, 2019). Peristomal MARSI is caused by excessively frequent or traumatic removal of a stoma appliance flange. Therefore, the more often an ostomate removes their appliance, and the stronger its adhesive properties at the time of change, the more likely they are to develop a peristomal MARSI. Studies have suggested that the prevalence of MARSI among ostomates could be as high as 54% (Fumarola et al, 2020).

These issues present the need for a more effective stoma appliance that can prevent the build-up of moisture on the peristomal skin, increase wear time and decrease the incidence of peristomal complications, including MASD and MARSI.

Box 1. Classification of moisture-associated skin damage (MASD)

Category I Erythema with no loss to skin integrity
Category IA Mild-to-moderate erythema (pink)
Category IB Severe erythema (dark pink or red)
Category II Erythema with loss to skin integrity

Source: Haesler, 2018



Figure 1. Peristomal medical adhesive-related skin injury (MARSI)

Caroline Rudoni

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If silicone does not absorb water, how can a silicone stoma appliance prevent the skin becoming damp and excoriated?

The appliances developed by Trio Healthcare and the University of Bradford Centre for Skin Sciences have a distinct evaporation-based mechanism of moisture management. They are made from a unique silicone compound, Sil2, which is different to the silicone used in other silicone devices (for example, in wound dressings). This novel formulation has been modified with the introduction of compounds that aid colloidal separation, which allows water vapour to find a path through the material (*Figure 2*). This has been used to create breathable stoma appliances that allow moisture to escape from the surface of the skin, through the flange and into the air. Because the water vapour passes through the silicone and into the air, the moisture is not held in the device, and, therefore, there is none of the permeation, engorgement or increased adhesion typical of hydrocolloids. Unlike the absorption process in a hydrocolloid flange, Sil2 also adapts to differences in moisture levels, allowing moisture vapour through, thus maintaining the skin under the flange at a normal healthy moisture level (Swift et al, 2020).

What unique benefits does a silicone appliance have for the patient that give it an advantage over existing options?

The effective and novel moisture management system of silicone appliances can provide a more natural moisture level for the peristomal skin, reducing the risk of MASD. The naturally hydrophobic material means that the appliance keeps a constant shape and does not swell, deform or break down. Likewise, its adhesive properties remain stable over time, providing an appliance that can be removed safely with no increased risk of MARSI (*Figure 3*). All of these properties can provide an extended wear time, adding up to an appliance that is comfortable and dependable for the patient, as well as cost-effective for the health service. The Sil2 products would be an especially appropriate choice for ostomates who are experiencing sore skin due to contact dermatitis resulting from effluent that has been absorbed in the hydrocolloid flange, as they would provide protection and respite for the skin. They have been developed to not absorb moisture, such as sweat and stomal output, throughout the day, which helps maintain skin integrity and prevent peristomal skin damage.

Because silicone is more flexible than hydrocolloid, a Sil2 appliance is better able to mould into the dips and creases of an uneven skin surface. This increases the overall contact area between the adhesive appliance and peristomal

skin, distributing the necessary adhesion across a greater number of skin cells and thus reducing the likelihood of traumatic removal and MARSI (*Figure 4*).

Which patients are suitable for silicone appliances, and do they have any specific limitations?

Silicone appliances are suitable for most ostomates, including those with challenging stomas. This includes people whose stomas have sunk deeper into the skin, as the softness and flexibility of the flange allows it to be moulded around the recessed stomas, which provides a snugly fitting barrier that offers added security and confidence. In older patients, the gentleness of silicone, compared with hydrocolloid, makes it an effective covering for thin and fragile skin, which is at high risk of skin tears (Hadfield, 2019).

‘these properties can provide an extended wear time, adding up to an appliance that is comfortable and dependable for the patient, as well as cost-effective’

Sil2 should not be used in the rare cases of patients who have an allergic reaction to the silicone or any of its other ingredients. A patch test can be carried out for patients who are known to have sensitive skin. Silicone is hypoallergenic by nature, and allergy is very rare, making it a comprehensively suitable material for adhesive and protective therapeutic devices. However, as will be familiar to experienced stoma care nurses, there will be some challenges where finding the most effective solution requires trial and error.

Can silicone appliances be used on moist and/or excoriated peristomal skin?

As with all existing appliances, getting it right can be particularly challenging if the peristomal skin is excessively moist. A flange of any material (silicone or hydrocolloid) will not effectively adhere to moist skin without the skin being dried first.

Before using any kind of appliance, stoma care nurses and ostomates must be able to identify wet and sore peristomal skin, which may show signs of redness, inflammation and swelling, as well as, in severe cases, development of blisters (Voegeli, 2019).

There are several comprehensive assessment tools that stoma care nurses can use at each assessment to monitor deterioration or improvement in peristomal skin health and objectively evaluate the efficacy of interventions

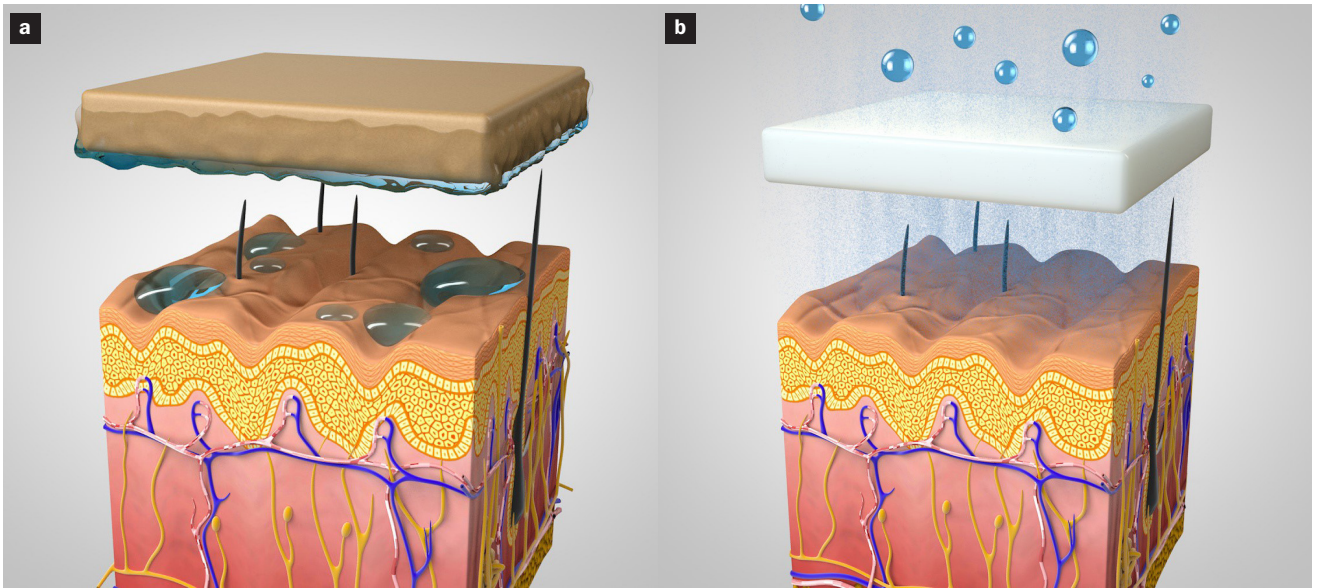


Figure 2. Moisture management in stoma appliances made from (a) hydrocolloid, where water is absorbed into the material and retained against the skin, and (b) Sil2 technology, where water vapour passes through the material into the air

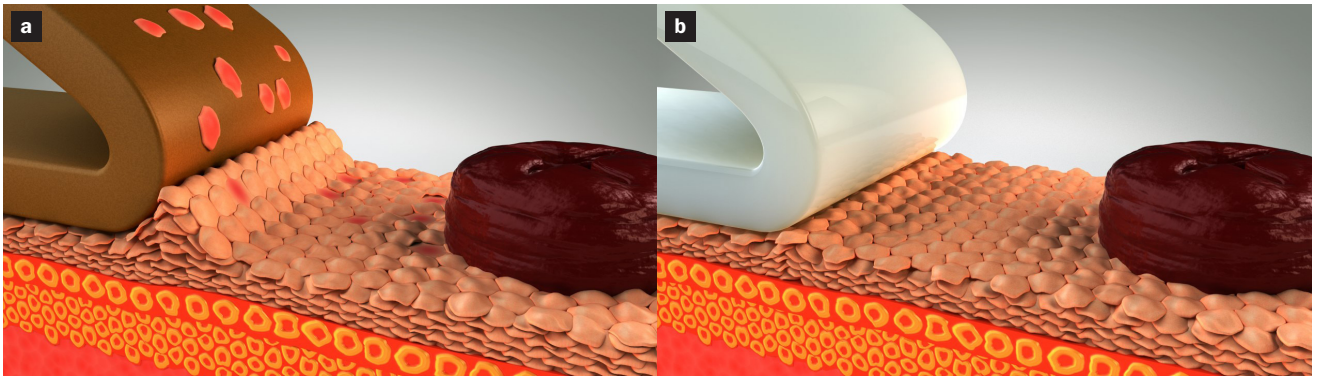


Figure 3. Removal of adhesive from peristomal skin in stoma appliances made from (a) hydrocolloid, with increasing adhesive strength that risks skin injury, and (b) Sil2 technology, with consistent adhesive strength that allows atraumatic removal

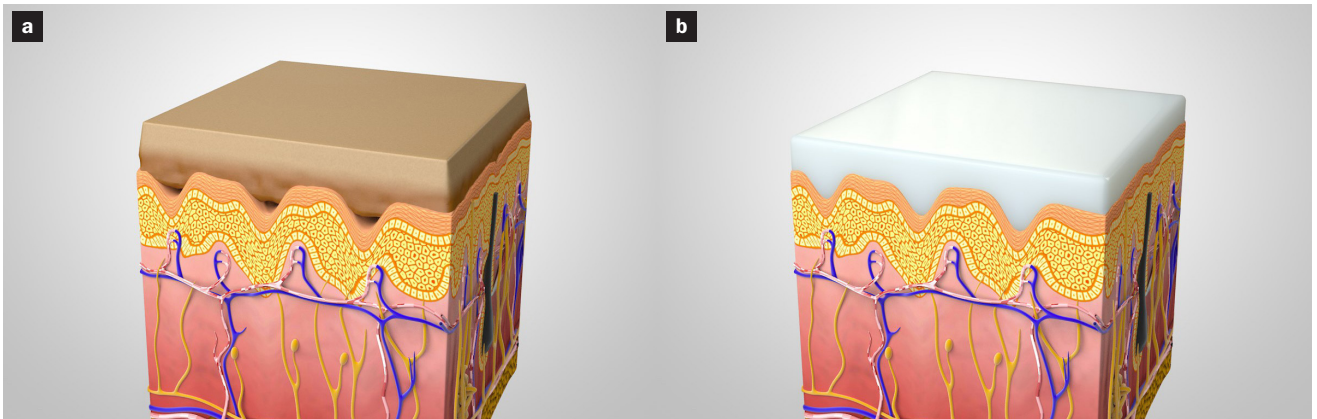


Figure 4. Peristomal skin surface contact with stoma appliances made from (a) hydrocolloid, with limited mouldability that limits contact area, and (b) Sil2 technology, with greater mouldability that maximises contact area

(Table 1). It is also worth assessing the social and emotional impact of peristomal complications. Stoma care nurses often hear patients saying that they are scared to go out, as they are frightened that their appliance will leak. This often seems to concern ostomates more than the peristomal skin soreness, although these issues usually go hand-in-hand. Ostomates can also be encouraged to monitor their own peristomal skin health, using a variety of online resources and visual aids available for self-assessment (Coloplast, 2020).

In order to optimise adhesion on sore, wet, macerated peristomal skin, the surface must be gently cleaned with plain water and then dried, bearing in mind that this may be very painful for the ostomate. A common treatment for MASD involves applying calamine lotion or a hydrocolloid powder (Metcalf, 2018). The hydrocolloid powder adheres to the broken skin, forming a tacky layer that soaks up moisture and creates a dry surface for adhesion (Evans and Burch, 2017). However, ostomates should be made aware that overenthusiastic application of this powder could have the opposite effect, weakening rather than improving adhesion on the skin. Appliance adhesion can also be increased by using one of an array of barrier sprays and wipes to create a protective film over the skin. There are silicone-based skin barrier films available, which have the advantages of not stinging on application and drying quickly. When peristomal skin is too sore to touch, the use of a barrier spray rather than a wipe avoids adding to the pain levels, as there is no need to touch the skin during application (Bibi, 2019). These interventions should suffice to apply a flange to excoriated peristomal skin; however, in extreme cases of highly excoriated, wound-like skin, another approach may be required. It is worth noting that application of silicone skin barrier films can increase the adhesion of the appliances, and, therefore, adhesive remover may be required to avoid further injury.

How can stoma nurses know whether silicone appliances are a safe, appropriate and effective choice?

Any new product must be based on robust evidence that is fully transparent to users. Moreover, companies must afford proof of the efficacy of a new product, be able to define the difference between products and offer samples so that stoma care nurses are able to assess the product independently (Bibi, 2019). Ostomy products are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Drug Tariff, and so their safety and efficacy must be demonstrated before they are approved and brought to market. Manufacturers are also legally obliged to undertake post-marketing

Table 1. Stoma care assessment tools

Tool	Areas of assessment	Source
Ostomy Skin Tool	Clinical observation of discoloration, erosion/ulceration and tissue overgrowth (0–15)	Martins (2010)
Peristomal Skin Soreness Tool	Severity and contributing factors of moisture-associated skin damage	Association of Stoma Care Nurses UK (2017)
Stoma Care Ostomy Research Tool	Stoma size, shape and output and changes in body weight, skin elasticity and muscle tone	Williams (2010)
Ostomy Leak Impact Tool	Burden of leakage (emotional impact; usual and social activities; coping and control)	Nafees et al (2018)

surveillance to ensure their products are being used safely and effectively. Engaging with the emerging evidence on new technologies is a key part of the duty of care that stoma care nurses have to their patients, as it is essential for finding the most appropriate appliance for each individual.

The safety, efficacy and relevance of silicone are indicated by transferable evidence from wound care, continence and stoma accessories. In wound care, silicone's adhesive properties have made it a popular material for dressings, compared with other substances that can cause pain and further damage to the wound (Meuleneire and Rücknagel, 2013). Silicone wound dressings are used extensively by a variety of manufacturers, including Molnlycke (2020), which reports that 4 billion silicone dressings have been used on over 100 million patients over the past 30 years. In continence care, the biocompatibility of silicone catheters has proven to be gentle on the urethral mucosa (Nazarko, 2019).

In stoma care, there are many effective silicone-based accessories available, including stoma paste, adhesive removers, barrier films and barrier rings/seals. In my own experience, I have had excellent results using silicone-based adhesive removers and barrier films to treat painful, excoriated peristomal skin. Patients reported healed skin and no pain after just two or three applications of a sting-free skin barrier (Elisse, Trio Healthcare). I have also found silicone-based barrier rings (Siltac and Silvex, Trio Healthcare) to be effective on sore peristomal skin, providing a non-absorbent barrier for stomal effluent.

This transferable evidence and user experience have gone into devising innovative silicone-based stoma appliances, which will provide nurses and ostomates a more comprehensive choice to suit their needs. All this suggests that it will increase appliance wear time, reduce costs

and improve patient quality of life and, most importantly, considerably reduce the occurrence of peristomal MARSI and MASD (Swift et al, 2020).

How can nurses determine which patients are most suitable for trying silicone?

At present, there is limited understanding of the application of silicone in stoma care practice. Therefore, in order to familiarise themselves with this new technology, nurses should try silicone appliances on ostomates with peristomal skin problems of mild-to-medium severity. Familiarisation, proficiency and confidence with silicone appliances will result in better patient outcomes.

Not only is it important for stoma care nurses to be informed of innovations in stoma appliances, it is also important for ostomates themselves to be kept updated on developments that could have a significant impact on their quality of life. In the author's own experience as the community stoma care nurse on an island off mainland UK, ostomates on the island find it difficult to attend stoma open days and participate in national stoma-specific support groups. However, there is a local support group, and together we hold a biennial stoma exhibition to give everyone on the island the opportunity to see, feel and try samples of new appliances and accessories. The hypoallergenic qualities of silicone make these products a suitable option for all ostomates to try, to see if they result in better outcomes and are preferable to established alternatives. We find that some ostomates are keen to try new things, while others are more reluctant and feel safer sticking with what they know, even if they are having problems. However, encouraging these patients to step outside their comfort zone and try new things can often resolve long-term challenges and improve their quality of life, particularly if they are experiencing problems with leaks and sore skin. Local ostomates have responded positively to silicone-based accessories in the past, and a similar response can be anticipated to silicone-based appliances. The best way to determine the suitability and efficacy of a device is to allow a patient to try it. **BJN**

Declaration of interest: Fiona Le Ber has received an honorarium from MA Healthcare for writing this article

Note: This article was first published in the *British Journal of Nursing*, volume 29, number 16

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Use of breathable silicone technology in an ostomy appliance flange

Peta Lager and Lisa Loxdale

A stoma (or ostomy) is a piece of bowel surgically diverted to the surface of the abdomen. This creates an opening for the expulsion of faeces or urine (output or effluent), depending on whether the stoma diverts from the ileum (ileostomy), colon (colostomy) or urinary tract (urostomy). Stomas are formed on a temporary or permanent basis, often as a result of colorectal cancer or severe inflammatory bowel disease (Burch and Black, 2017).

For people with a stoma (ostomates), the products that they use in their stoma care routine have a major impact on their quality of life (Nichols, 2018). An effective product is often the difference between a secure pouching system and recurrent leaks, as well as between healthy peristomal skin and painful complications. Many ostomates come to accept these, as demonstrated in a study of ostomates diagnosed with a complication, where only 38% accepted they had a PSC and only 20% sought professional care (Herlufsen et al, 2006). Even with the most advanced existing ostomy products, the risk of leaks and skin damage remains a fact of life for many ostomates, suggesting that there is room for improvement in technological solutions.

Stoma care nurses (SCNs) are in a positive position to work constructively with ostomy manufacturers to develop increasingly effective stoma products. This professional collaboration is in keeping with guidelines from the Nursing and Midwifery Council (2018) and the Association of Stoma Care Nurses UK (2016). Such involvement has the potential to improve patients' clinical outcomes, including their physical health and psychological wellbeing.

ABSTRACT

Leaks and peristomal skin complications are highly prevalent among people with a stoma, reported by over 80% of ostomates within 2 years of surgery. This suggests that there is room for improvement in ostomy appliances, particularly in their hydrocolloid-based adhesive flanges. Hydrocolloid has an absorptive method of moisture management that, over time, risks maceration and skin stripping, potentially leading to moisture-associated skin damage (MASD) and medical adhesive-related skin injury (MARS). The newly developed Genii ostomy appliances (Trio Healthcare) use novel Sil2 Breathable Silicone Technology to provide secure, effective adhesion and manage moisture levels by replicating natural transepidermal water loss (TEWL). This has the potential to increase appliance wear time, reduce incidence of MASD and permit atraumatic removal without adhesive remover, reducing the risks of MARS, as well as time burdens on the user and economic burdens on the healthcare system. Meanwhile, the silicone flanges and water-resistant sports fabric pouches are lightweight, flexible and unobtrusive, and they are the first appliances to be available in colours to match different skin tones, all of which provides security, comfort, confidence and discretion. This article explores the features of Sil2 and Genii ostomy appliances, with reference to preliminary data from a user evaluation.

Key words: Medical adhesive-related skin injury ■ Moisture management ■ Moisture-associated skin damage ■ Peristomal skin complications ■ Stoma care

ROOM FOR IMPROVEMENT

Ostomates need to continually wear a disposable ostomy appliance. This appliance consists of a pouch and an adhesive flange (also known as a baseplate or skin barrier), which can be combined (one-piece) or separable (two-piece). The pouch collects the stomal output (also known as effluent). Meanwhile, the flange serves the dual purposes of holding the pouch in place over the stoma and protecting the peristomal skin from contact with the

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corrosive output. The flange must also maintain normal moisture levels on the skin, as well as allow for atraumatic removal (*Box 1*) (LeBlanc et al, 2019; Voegeli et al, 2020).

The efficacy of the appliance flange is of the utmost importance. Poor performance leads to leakage and the development of peristomal skin complications (PSCs). PSCs typically manifest as redness, discomfort and/or pain, and they often impede flange adhesion (Burch et al, 2021). Repeated leaks and PSCs can make adhesion of the flange harder to achieve, which can result in a viscous cycle of issues for ostomates. This is likely to harm body image and confidence, which can cause long-term anxiety, depression and self-imposed social isolation (Brown, 2017). All of this means that the efficacy of a flange has a direct and significant impact on patient outcomes and quality of life.

The occurrence of leaks and PSCs among people with a stoma remains common (Gray et al, 2013). This has resulted in ostomy appliance manufacturers evolving the technology used in an attempt to improve user experience. Prevalence statistics vary, but are typically high, with 80% of ostomates reporting a PSC within 2 years of surgery (LeBlanc et al, 2019) and 73% reporting a PSC in the previous 6 months (Voegeli et al, 2020). Patients with PSCs have been shown to have higher care costs and a significantly greater likelihood of being readmitted to hospital (Taneja et al, 2019).

SIL2 BREATHABLE SILICONE TECHNOLOGY

Improvements in material technology could allow for more effective appliances that are better able to hold the pouch in place, protect the skin and manage moisture, while allowing for a longer wear time and atraumatic removal at any time. At present, ostomy flanges are largely manufactured from hydrocolloid, an occlusive, moisture-retentive substance with flexible, protective and adhesive qualities (ScienceDirect, 2021). In recent decades, a number of occlusive and adhesive devices in wound and continence care, as well as some stoma care accessories, have made use of silicone technology (Swift et al, 2020). Established soft silicone polymers are suited to these uses because they are flexible enough to conform to the shapes and contours of the body, and they have a naturally tacky quality and a low surface energy that allow instant adhesion to dry surfaces. These silicones are comfortable, hygienic, non-odorous

Box 1. Key functions of an appliance flange

- Holds the pouch in place over the stoma
- Protects the skin from contact with stomal output
- Maintains normal moisture levels on the skin
- Allows for atraumatic appliance removal

and hypo-allergenic (Meuleneire and Rücknagel, 2013). They are also non-toxic, impermeable to bacteria and incapable of being absorbed into the body (Meuleneire and Rücknagel, 2013). All of these advantages could make silicone an ideal material for an ostomy appliance flange. However, established silicone formulations, such as those used in wound care, have not provided the effective adhesion and moisture management necessary for this use.

Therefore, Trio Healthcare has developed Sil2 Breathable Silicone Technology, a patented silicone polymer specifically engineered to provide effective adhesion and moisture management, properties that are essential to meet the needs of an ostomy appliance flange (Swift et al, 2020). In late 2020, Trio Healthcare undertook a user evaluation of prototype Sil2 flanges, involving 30 established ileostomates and colostomates who met the inclusion criteria, 29 of whom returned completed evaluations. The study was limited to those with healthy peristomal skin or mild skin irritation. Preliminary results from evaluation are referenced in this article (*Figures 1* and *2*), and the full results will be published at a later date.

The success of this evaluation supported the development of a complete ostomy appliance system under the brand name Genii (Trio Healthcare). Genii appliances are available in closed and drainable one-piece systems (*Figure 3*), and two-piece systems have been developed for launch in the near future (*Box 2*). This article details the features of the Genii system and the results of this preliminary user evaluation.

NATURAL MOISTURE MANAGEMENT

Sustained contact between output and skin will often result in moisture-associated skin damage (MASD), which is defined as any PSC that is primarily caused by chemical irritation from corrosive output (contact dermatitis) and/or maceration from increased moisture levels (Voegeli, 2019). MASD can be exacerbated if the flange does not adequately manage moisture levels and instead allows moisture to build up on the skin.

Despite many positive developments, the traditional hydrocolloid technology used in stoma appliance flanges has a number of drawbacks. Perhaps the most notable of these is hydrocolloid's method of moisture management. Hydrocolloid is hydrophilic, which means that it absorbs moisture from its surroundings. This allows flanges made from this material to temporarily maintain normal moisture levels on the skin and avoid maceration. However, hydrocolloid has a saturation point beyond which it cannot absorb more moisture, especially at the hydrocolloid-skin interface. Once this point is reached, the material breaks down and becomes gelatinous, and the skin is left

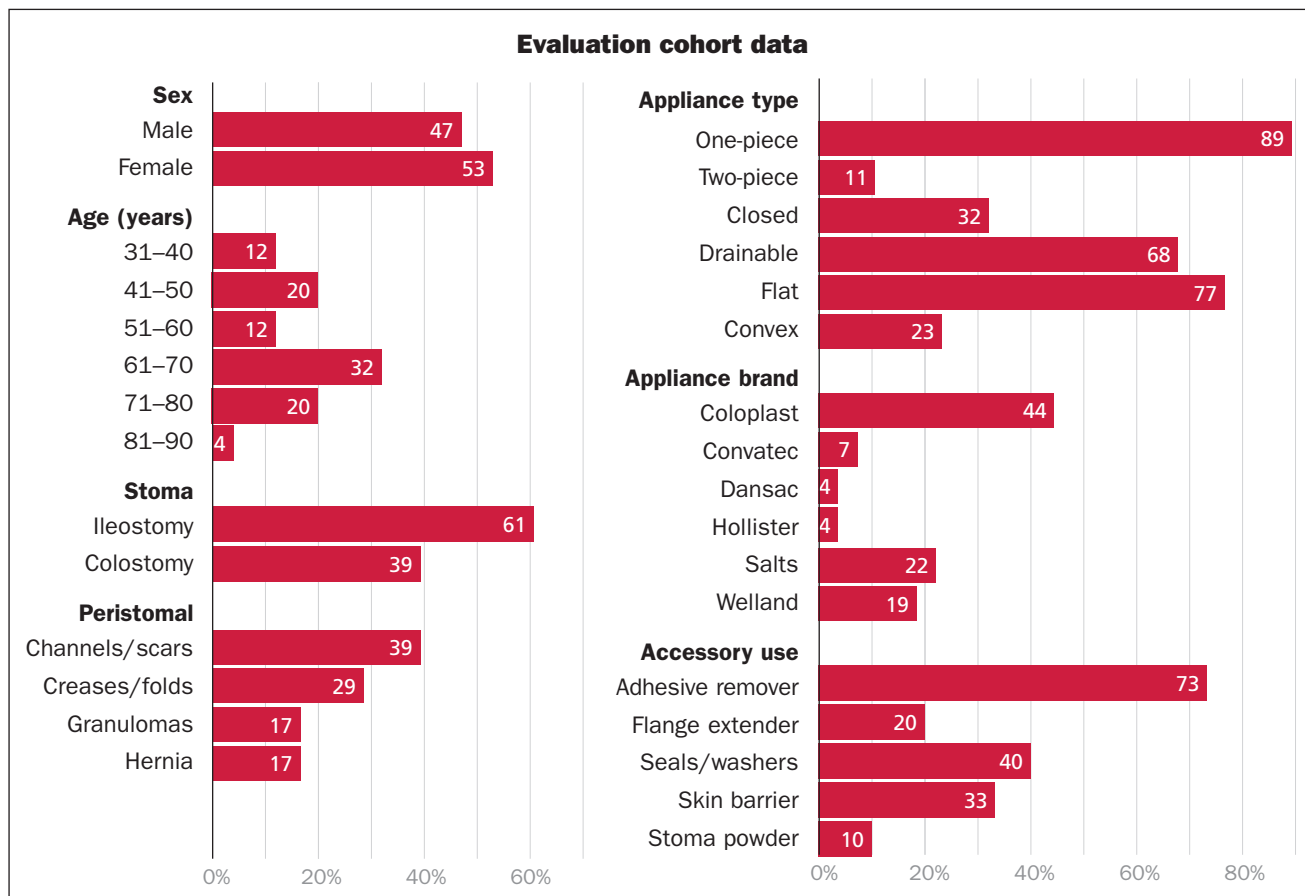


Figure 1. Preliminary data on participant profiles in clinical user evaluation, % (n=30)

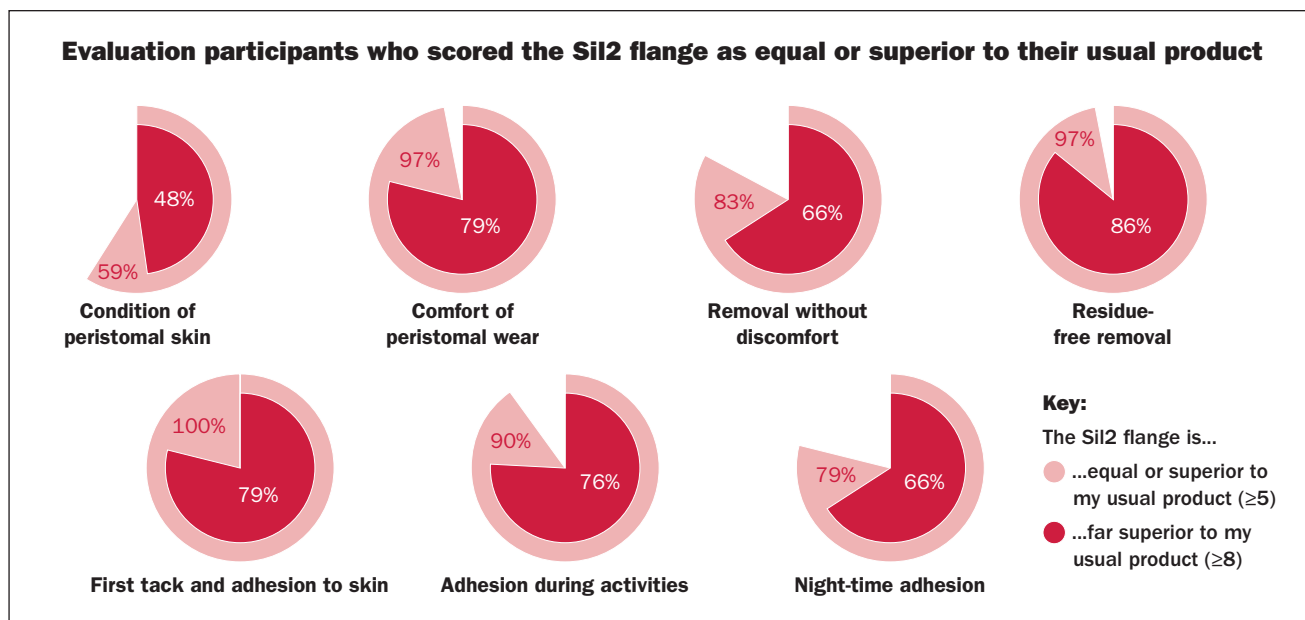


Figure 2. Preliminary results of participant responses at end of trial, comparing Sil2 flanges with their usual product (n=29)



Figure 3. Closed (left) and drainable (right) options for Trio Genii ostomy appliances, in colours that match different skin tones

Box 2. One-piece and two-piece appliances

Closed ostomy appliances are available as one-piece systems, which are single-use, or two-piece systems, which have a removable pouch that can be detached from the flange and renewed a number of times before replacing the entire system. One-piece systems can be more convenient and physically flexible, whereas two-piece systems can provide a longer wear time, which can be more economical and kinder to the peristomal skin. The choice should be guided by the individual needs and preferences of the user, with regard to the consistency of their stomal output (Black, 2013). These appliances have a cut-to-fit flange of 15–60 mm and come with three sizes of pouch (mini, midi and maxi).

Notably, all prototype Sil2 appliances used in the evaluation were one-piece, which added a level of unfamiliarity for those used to two-piece systems

vulnerable to maceration and MASD. Moreover, should the absorbed moisture include any stomal output, the hydrocolloid holds the corrosive chemicals, enzymes and moisture contained in the output against the skin, where it can further exacerbate MASD.

Sil2 Breathable Silicone Technology is distinct from established silicone compounds in that it has a novel mechanism of moisture management capable of maintaining normal moisture levels on covered and protected peristomal skin (Swift et al, 2020). Sil2's mechanism is designed to replicate the skin's natural ability to regulate moisture and body temperature via transepidermal water loss (TEWL) (Gioia and Celleno, 2002). The presence of an occlusive device, such as an ostomy flange, usually prevents TEWL, because it traps the moisture accruing on the epidermis and stops it from evaporating into the air (Machado et al, 2010). Where a hydrocolloid flange would absorb this trapped

moisture, silicone is hydrophobic and so does not absorb moisture. Instead, Sil2 uses a compound of hydrophobic silicone and hydrophilic additives to form a matrix that allows water molecules to pass through from the skin into the air as vapour, while still repelling entry of water from the outside (Figure 4). The Sil2's breathable matrix has also been designed to react and adapt to changes in skin moisture levels resulting from activity or warmer weather, which helps prevent circumstantial build-up of moisture under the flange (Swift et al, 2020).

Because the water vapour is not retained in the matrix, Sil2 manages moisture levels in a way that avoids the risks of saturation, deformation, maceration and increased adhesion that are associated with hydrocolloid's absorptive method of moisture management. This means that water and stomal output are not held against the skin, where they could contribute to MASD (Swift et al, 2020).

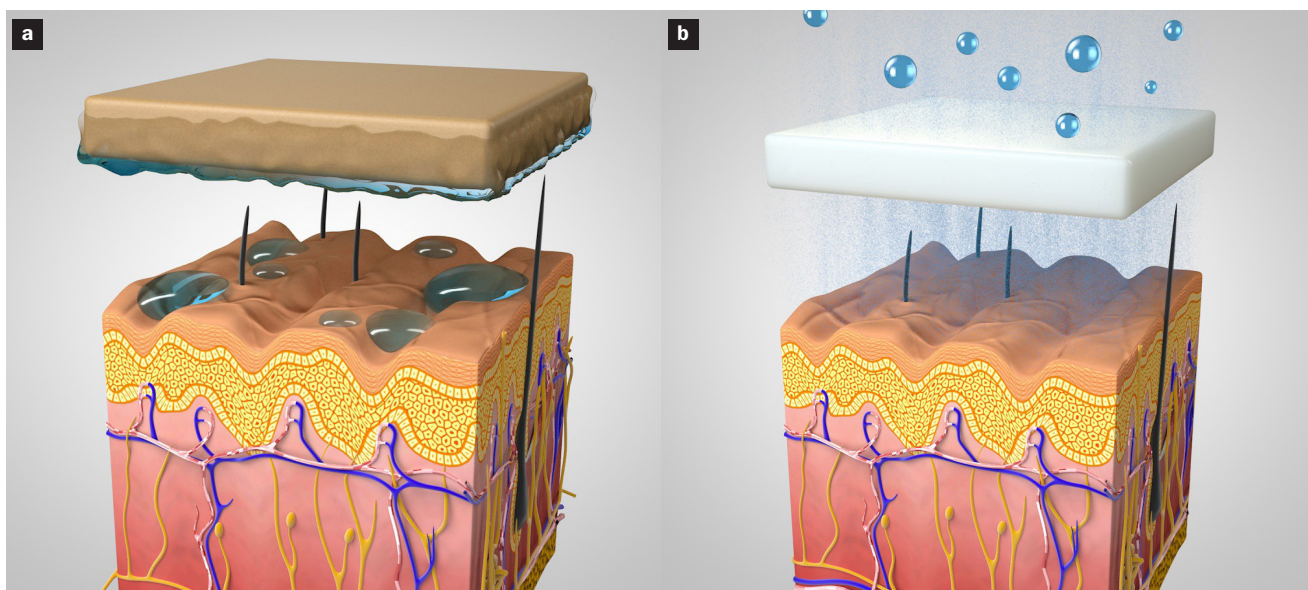
The ability of Sil2's method of moisture management to minimise the causes of MASD could have contributed to reported improvements in the condition and appearance of peristomal skin following use of this product (Figure 5). Visible improvement over a 7-day evaluation would be particularly notable, because the skin typically renews over a 28-day cycle (Galderma, 2021). When participants compared the condition of their peristomal skin before and after the evaluation, nearly two-thirds found it was least as good and around half that it was considerably better after using the Sil2 flange. Five evaluation participants opted into providing further information on their experiences and formed a focus group. After switching to the Sil2 flange, members of group noted that:

'My skin can be quite sensitive, but there was no redness or any soreness using the Trio flange. This is a huge bonus, as I know my stoma is with me for life, so whatever I use needs to be skin-friendly. The skin around my stoma looked the same as the rest of my tummy, rather than red and itchy.' Amy

'My skin was slightly rashy before, but, after trialling Sil2, my skin was most definitely better and cleared up completely ... I cannot wait to use it full time. I am back to my original pouch, and my skin is slightly irritated again.' Sally

EFFECTIVE ADHESION

Adhesion to the peristomal skin is essential. If a flange fails to adhere, the stomal output will leak out of the pouch,



TANK2Create

Figure 4. Moisture management in stoma appliances made from (a) hydrocolloid, where water is absorbed into the material and retained against the skin, and (b) Sil2 technology, where water vapour passes through the material into the air

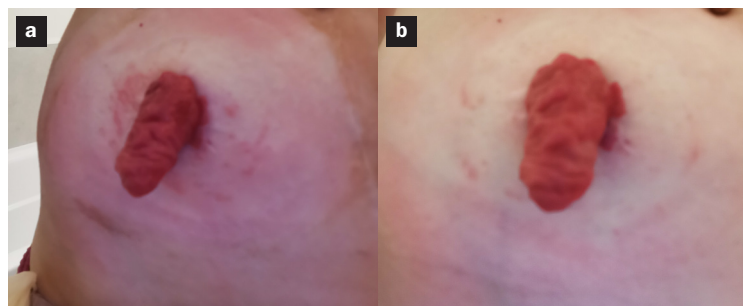
resulting in soiled clothes, unpleasant odour and intense psychological distress (Brown, 2017).

Genii's Sil2 flange is designed to adhere to and create an effective seal with the peristomal skin (Swift et al, 2020). This is supported by the preliminary results from the user evaluation, in which 100% of the participants reported that the Sil2 flange successfully adhered to their skin.

Three further questions asked participants to rate—out of 10, where 1 was poor and 10 excellent—the adhesion of Sil2 in different circumstances. Nearly 80% of participants scored 8 or more for first tack and adhesion to skin, for adhesion during activities and for adhesion at night. These last two situations are of particular importance. Physical activity can put extra strain on a flange, which increases the risk of leaks, the fear associated with that risk and the consequent avoidance of activities. At night, the occurrence, risk and fear of leaks can be highly disruptive, leading to broken sleep and waking up multiple times. Therefore, these results suggest that users might have found Genii flanges to be beneficial in these key aspects of ostomates' quality of life.

The focus group compared the adhesion and tack of Sil2 favourably with that of hydrocolloids:

'There was instant tack, unlike hydrocolloids, where you need to let the adhesive warm before the adhesive gains its full tack.' **Hannah**



Used with consent of participant

Figure 5. Peristomal skin at days 5 (a) and 9 (b) of using a Sil2 flange, showing pre-existing skin irritation that significantly improved throughout the evaluation (very active female ileostomate in her 30s)

The absence of leaks was remarked upon:

'I had no leaks or even "near misses" when using the new product.' **Kieran**

One member of this group also noted how this adhesion remained consistent, even after the appliance was repositioned:

'This new development is incredible, a real game changer as far as I'm concerned, no crinkles in my skin (apart from age wrinkles), adhesive that not only sticks like a second skin but, if I've put it on the wrong place, I can adjust it without compromising the adhesive quality, and it doesn't leave a mark.' **Amy**

Members detailed how switching to a Sil2 flange had improved their confidence and/or sense of security. They noted a positive impact on their lifestyle, both during physical activity and at rest:

‘Without a doubt, as a gym goer, I had a lot more confidence. The comfort while stretching and exercising was so much better; it almost didn’t even feel like I had a pouch.’ Sally

‘81% of participants gave a rating of 5 or more, indicating that Sil2 was as comfortable as or more comfortable to remove, with equal or less pain’ [without using adhesive remover]

‘The Sil2 flange was very good, comfortable, very confident while it was on, day and night’ Ken

ATRAUMATIC AND UNAIDED REMOVAL

A flange not only needs to stay adhered to the skin; it also needs to be easy to remove. If the adhesive bond is too strong, removing the flange will pull away the outer layer of skin cells (skin stripping) (Williams et al, 2010). Repeated traumatic removal can result in medical adhesive-related skin injury (MARS), defined as any PSC primarily caused by traumatic and/or excessively frequent appliance removal (Fumarola et al, 2020). MARS is implicated in increased morbidity, readmission and care costs, as well as reduced, psychosocial status and quality of life (LeBlanc et al, 2019). Evidence on the prevalence of MARS suggests that it is present in anywhere from 3.4% to 25% of ostomates (Farris et al, 2015).

One of the drawbacks of hydrocolloid stoma flanges is that, as they become more saturated, they swell, changing in shape, increasing in size and breaking down on a chemical level. This presents a number of issues, the most significant of which is a considerable increase in adhesive strength. The more moisture a hydrocolloid flange has absorbed, the more difficult it is to remove and the greater the risk of skin stripping and MARS (Swift et al, 2020).

In contrast, Sil2 was designed to permit atraumatic removal and reduction of MARS without use of an adhesive remover. The absence of swelling and increased adhesion also means that the adhesive strength of a Sil2 flange remains consistent over time, distributing peel force evenly and allowing for comfortable, safe and easy appliance removal. This makes removal more comfortable and reduces the risk of MARS (*Figure 6*) (Swift et al, 2020).

In the preliminary results of the evaluation, participants rated the level of discomfort or pain that they experienced during removal (without using an adhesive remover) of the Sil2 flange compared with their usual hydrocolloid appliance. On a scale of 1–10, where 1 was more and 10 less discomfort/pain, 79% of participants gave a rating of 5 or more, indicating that Sil2 was as comfortable as or more comfortable to remove, with equal or less pain. This includes the participants whose previous product was already providing comfortable and painless removal, for whom parity represents a successful result.

REDUCED PRODUCT USAGE

Leaks and PSCs often result in more frequent appliance changes and increased use of stoma care accessories, which are time-consuming for the patient and place a major financial burden on healthcare resources (Bird, 2017). In addition, the tendency of hydrocolloid

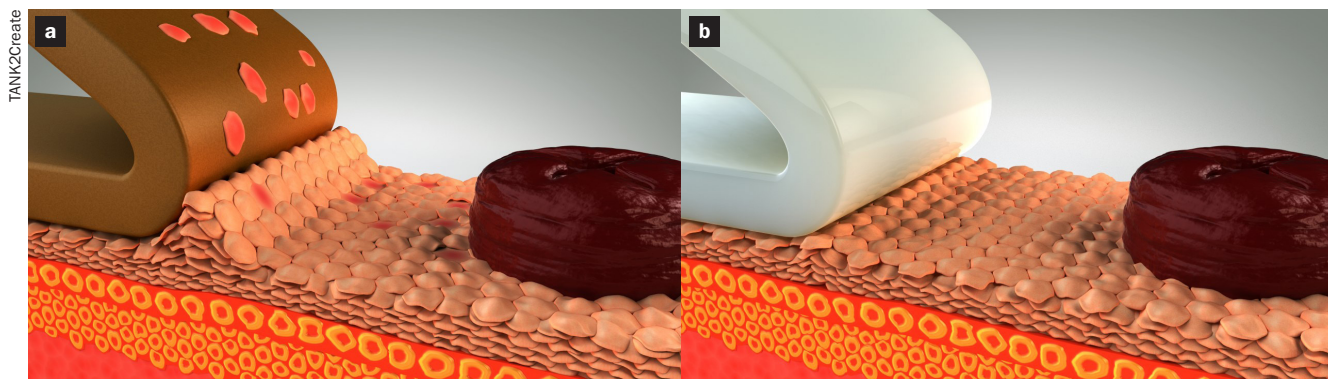


Figure 6. Removal of adhesive from peristomal skin in stoma appliances made from (a) hydrocolloid, with increasing adhesive strength that risks skin injury, and (b) Sil2 technology, with consistent adhesive strength that allows atraumatic removal

flanges to increase in adhesive strength over time can limit appliance wear time (Swift et al, 2020). This both increases the frequency of removals, which is time-consuming and compounds the risk of MARSI, and increases the rate of ostomy appliance use, which is uneconomical. This increase in adhesive strength can also necessitate the use of an adhesive remover wipe or spray to avoid uncomfortable removal and/or MARSI. All of this presents consequent burdens on patient time and healthcare resources (White, 2014).

The non-absorptive nature of Sil2 provides Genii appliances with a greater potential wear time than hydrocolloid appliances (Swift et al, 2020). These longer wear times can be convenient for the user and help reduce risk of MARSI, as well as appliance usage and costs. In the evaluation, participants were asked to describe how switching to the Sil2 flange affected their accessory use. Some reported that it removed the need for accessories entirely:

‘I was able to go out without all the products to replace a pouch (spray and remover). It took less than 5 minutes to change against 20 minutes with my old pouches.’

‘I did not use any accessories, only the flange and warm water.’

‘I didn’t use or need to use any extra accessories.’

More specifically, others singled out that the Sil2 flange reduced or eliminated their need for adhesive removers, which are expensive for the health system and time-consuming for the user (Bird, 2020). Backing up the result that 83% of users experienced the same or less discomfort and pain, participants stated:

‘I used less barrier spray and only a little adhesive remover.’

‘I’ve always used adhesive remover with all my previous products, but not with the silicone flange.’

‘I removed [it] without adhesive remover.’

‘I had no need for either the adhesive remover or skin protector.’

The Sil2 flange used in Genii appliances was designed to allow atraumatic removal without the need to use

adhesive remover (Swift et al, 2020). Members of the focus group noted this as a major benefit:

‘The product was easy to apply with good adhesion, yet was easy to remove without an adhesive remover, which I have always used with my normal stoma pouch.’ Kieran

‘...easy to remove; very confident with the product; it also saves time on changing, with no messing with adhesive removal sprays and wipes.’ Ken

Hydrocolloid can leave a residue on the peristomal skin following removal, the cleaning up of which can take time and resources and, in some circumstances, contribute to skin damage (Hess, 2003). By contrast, when evaluation participants rated the level of residue left out of 10, where 1 was a lot and 10 was none, Sil2 flanges received an average rating of 8.8, with 86% giving a score of 8 or above. This was reflected in user comments, comparing Sil2 with their usual hydrocolloid flange:

‘Not needing to use my fingernails or adhesive remover was a huge plus.’

Adhesive remover was not the only accessory to be specified by participants as no longer necessary after switching to a Sil2 flange:

‘My current skin barrier ripples around the edge, as it’s trying to mould over a rounded area of my abdomen, and I use tape to hold it flat. I didn’t need to do this with the Trio skin barrier.’ Hannah

‘I still needed to use my seal but had no use for the tape, which I used to add extra adhesion to the side that lifted at night.’

It should be noted that accessory seals may require adhesive remover, even when the flange itself does not.

FLEXIBILITY AND COMFORT

People with a stoma need to wear an ostomy appliance against their skin at all times, and therefore the comfort of that appliance is a major priority (Burch and Black, 2017).

Both of the distinct materials used in Genii appliances are designed to help provide greater, longer-lasting comfort than established ostomy appliances. Both the silicone compound used in the flange and the sports fabric used in the pouch are designed to be lightweight, flexible and soft against the skin. This is reflected in the evaluation, where participants were asked to rate the comfort of wearing a

Sil2 flange against their skin, compared with their usual product. They gave an average comfort score of 8.5 out of 10, with 79% giving a relative comfort score of 8 or above.

**‘with 79% giving a relative comfort score of 8 or above’
[compared with their usual product]**

The focus group described the feeling of wearing the silicone flange against their skin, comparing it with how they felt when wearing a traditional hydrocolloid flange. Some noted the absence of hard plastic edges as a major benefit:

**‘Very comfortable, no hard plastic edges’
Ken**

‘The silicone barrier feels more comfortable; there’s no pulling as the pouch fills, and it’s a lot more comfortable around the stoma itself. There’s no stiffness or hard edges... The comfort of Sil2 is on a whole other level and most definitely a game-changer for the ostomy world.’ Sally

It was also noted that the flange did not crease or fold, which can provide channels for output escape and leakage:

**‘There was no folding or bunching up of the flange, unlike what happens when underwear rubs against my usual product.’
Amy**

‘Easy to fit, movement very good, no creases in the flanges.’ Ken

Sil2 is an extremely flexible material, allowing for flanges that can be moulded to conform completely to the uneven surface of the peristomal skin (*Figure 7*). This creates a larger contact area, which improves adhesion, reduces the risk of leaks and allows complete freedom of movement (Swift et al, 2020). Silicone also allows for a widespread and consistent contact with the skin that give the material a low surface tension (Swift et al, 2020). Members of the focus group emphasised Sil2’s flexibility and consequent ability to conform to the skin, including to uneven body profiles:

‘It seems to conform to the body shape more readily, especially as I have a hernia around the stoma.’ Kieran

‘I found the silicone barrier incredibly conformable to the skin ... It was incredibly flexible, a little larger than my current skin barrier, but this greater coverage made me feel more secure.’ Hannah

DISCRETION

The low surface tension of Sil2 minimises the noticeable sensation of wearing the Genii appliance on the skin (Le Ber, 2020). One user comment suggested that the comfort of the silicone flange was such that it felt invisible:

‘I couldn’t feel it!’ Amy

This sense of invisibility encapsulates how discretion is often a major priority for many people with a stoma (Brown, 2017). To meet this underserved need, Genii appliances have been designed to be unobtrusive (*Box 3*). This means both that the ostomate should not be continually reminded of its presence and that they should be able to keep their ostomy discreet from people they come into contact with.

The lightweight fabric of the Genii pouch is not only discreet to the touch, it is also designed to minimise audible rustling. These pouches are also equipped with a high-performance carbon filter, designed to minimise the unwelcome sound and smell of flatus, as well as to manage airflow and reduce ballooning and pancaking.

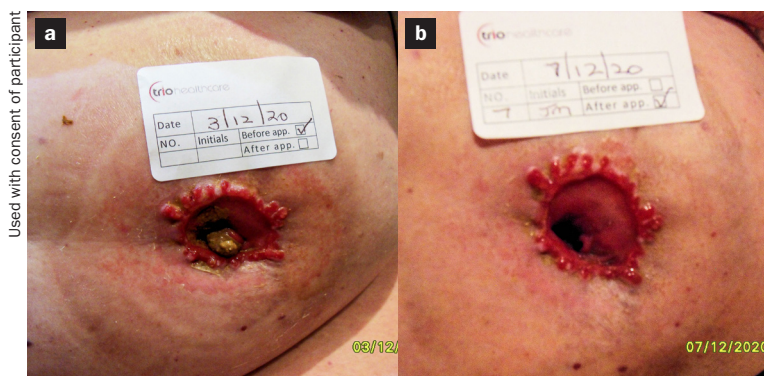


Figure 7. Peristomal skin at days 1 (a) and 5 (b) of using a Sil2 flange, showing improvement around where the skin was initially raised due to irritation, as well as effective management of irregular contours around the stoma (female colostomate)

Box 3. Multisensory discretion

Genii ostomy appliances are designed with a variety of features to maintain a discreet profile:

- Sight** Colours that match different skin tones
- Smell** Carbon filter that reduces flatus odour
- Sound** Fabric pouch that reduces rustling
- Touch** Flexible silicone flange and soft, lightweight fabric

Genii is the only range of ostomy appliances on the market that is available in a variety of colours to match different skin tones (Stoma Care Handbook, 2020). Other appliances are often available in colours, such as white or beige, that visually stand out from human skin, when users would rather that they blend in. Those that do attempt to blend in with the skin have previously only matched certain pale skin tones, which has been a disservice to people with a stoma who have darker skin. Genii goes some way to addressing this health inequality by being available in three different colours (light, medium and dark), providing camouflage and discretion for people of various complexions. A clear drainable option is under development (Box 4).

Genii drainable appliances are designed to allow for discrete emptying, which can be particularly useful in shared and/or public toilet facilities. The outlet has a pull tab that is easy to clean and makes draining quick and simple.

SUITABILITY FOR ACTIVE LIFESTYLES

In the user evaluation, participants were asked how well the Sil2 flanges stayed adhered during physical activity, and 90% found it to be at least as good and 76% significantly better than their usual product.

Genii appliances have a cover made of fabric, as opposed to the non-woven comfort backing used in most older appliances. This lightweight sports fabric is soft, water-resistant and designed for active wear, which makes it more comfortable during increased perspiration, such as during physical exercise (Figure 8). Like the breathable silicone flange, the fabric pouch has a breathable design that allows moisture to escape and is dry to the touch after showering.

In the user evaluation, different members of the focus group emphasised how the Sil2 flange was better suited to use in water than hydrocolloid products:

‘The silicone flange doesn’t go gooey when subjected to water, so this will enable me to enjoy longer periods swimming on holiday—or, if I enjoy a spa day, I’ll feel more confident and not have the need to change the pouch straight after getting out the pool and jacuzzi. The ability to not necessarily *have* to change the pouch after the adhesive gets wet is a bonus. Currently, all pouch changes are coordinated with baths and showers, so this could be a big thing for me ... I feel that it ticks the boxes for everything that I would be looking for.’ Hannah

Box 4. Postoperative option

In the near future, the opaque Genii appliances are set to be joined by a drainable option with a clear cover. Clear appliances are designed for postoperative hospital use, as they allow stoma care nurses and other health professionals to view the stoma and output without having to remove the appliance. Peristomal skin can be particularly sensitive in the postoperative period, and frequent removal can disrupt the surgical site, damage the skin and cause emotional trauma for the patient. Sil2’s protective, atraumatic properties could give it particular advantages over hydrocolloid in this setting, and there is evidence from wound care linking silicone dressings with improved healing (Matsumura et al, 2014).

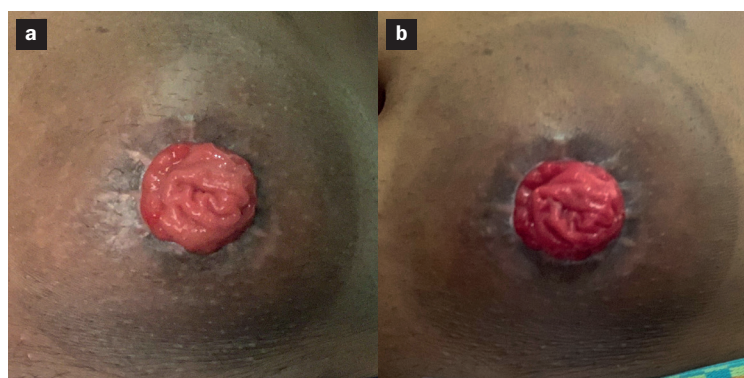


Figure 8. Peristomal skin at days 1 (a) and 7 (b) of using a Sil2 flange, showing healthy skin and effective management of skin ridges (very physically active male ileostomate in his 40s)

Used with consent of participant

This represents an additional benefit for Genii’s non-absorptive method of moisture management (Swift et al, 2020), which could be particularly significant for certain patients, depending on their lifestyle. One user emphasised how its water resistance also saved on product use—and consequently on time and healthcare resources:

‘It is life-changing for me. I live by the seaside and love being in the sea. With other products, every time they get wet the adhesive becomes “gooey”, and taking that off is no fun. With the silicone flange, I can be in and out of the water all day with my grandchildren without any worries about having to use my nails or a chemical product to get rid of the adhesive left on my skin. I can shower with the flange, which extends the wear time of my appliance.’ Amy

NURSE EVALUATION

On launch of the Genii ostomy appliances, a sample was sent to two clinical nurse specialists in stoma care working

at Basildon Hospital. Both having been in post for over 20 years and having seen many changes in stoma appliances and accessories, they were interested in an early trial of the first silicone-based appliances.

The nurses' first impression of the silicone adhesive was that it was very soft, supple and flexible, and they found the fabric to be quiet and very soft. They also noted that the available range of colours was a better match with true skin tones than other products on the market.

The nurses had a brief opportunity to trial the appliances on three of their patients. All were male colostomates with intact healthy skin at the time of trying the product. Two of the colostomates were long-established with their stoma and the other had only had their stoma formed in the past 6 weeks.

In terms of security, the two established ostomates found the silicone adhesive to be very secure, even during showering. However, the newer colostomate reported finding it difficult to adhere securely, which may have been a consequence of limited experience, confidence and instruction from a nurse in the correct use of the product. The established ostomates were both particularly impressed that no adhesive remover was required when replacing the appliance. One ostomate noted an odour at night, despite no signs of leakage, and so questioned the efficacy of the filter. Both established ostomates felt that the pouch was aesthetically very pleasing, and one reported that:

'The material is nice and feels fine on the skin. The silicone adhesive seal is so much smoother and comfortable. It secures snug and collects waste fine, and it is surprisingly easy to remove without spray.'

CONCLUSION

Overall, the qualitative responses given by evaluation participants were positive about the experience of changing a Sil2 flange, describing it as 'Excellent ... seriously impressed', 'Very good' and 'Much better, a lot easier to change' and saying that it went 'Very well—I had no issues'.

Genii ostomy appliances are the first to use Sil2 Breathable Silicone Technology, giving them a unique ability to manage moisture by facilitating natural TEWL, as well as to avoid skin stripping and MARS on removal. Coupled with a comfortable and discreet pouch design, the Genii range has the potential to improve ostomates' quality of life, as well as reduce PSC occurrence and associated burdens on healthcare resources. **BJN**

Declaration of interest: Peta Lager and Lise Loxdale have not received any financial incentives for their contributions to this article

Note: This article has been written with the assistance of a medical writer. All preliminary data related to this trial, including all quotes and statistics used in this article, are on file and accessible from Trio Healthcare (careline@triohealthcare.co.uk)

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Genii ostomy appliances: product information

Light

Pip Codes	Code	Size	Flange	Bag size	Filter	Pack Size
Closed bags						
416-5304	TR321N	15-60mm	cut to fit	Mini	✓	30
416-5270	TR322N	15-60mm	cut to fit	Midi	✓	30
416-5247	TR323N	15-60mm	cut to fit	Maxi	✓	30
Drainable bags						
416-5395	TR324N	15-60mm	cut to fit	Mini	✓	30
416-5361	TR325N	15-60mm	cut to fit	Midi	✓	30
416-5338	TR336N	15-60mm	cut to fit	Maxi	✓	30

Medium

Pip Codes	Code	Size	Flange	Bag size	Filter	Pack Size
Closed bags						
416-5296	TR321T	15-60mm	cut to fit	Mini	✓	30
416-5262	TR322T	15-60mm	cut to fit	Midi	✓	30
416-5239	TR323T	15-60mm	cut to fit	Maxi	✓	30
Drainable bags						
416-5387	TR324T	15-60mm	cut to fit	Mini	✓	30
416-5353	TR325T	15-60mm	cut to fit	Midi	✓	30
416-5320	TR336T	15-60mm	cut to fit	Maxi	✓	30

Dark

Pip Codes	Code	Size	Flange	Bag size	Filter	Pack Size
Closed bags						
416-5288	TR321C	15-60mm	cut to fit	Mini	✓	30
416-5254	TR322C	15-60mm	cut to fit	Midi	✓	30
416-5221	TR323C	15-60mm	cut to fit	Maxi	✓	30
Drainable bags						
416-5379	TR324C	15-60mm	cut to fit	Mini	✓	30
416-5346	TR325C	15-60mm	cut to fit	Midi	✓	30
416-5312	TR336C	15-60mm	cut to fit	Maxi	✓	30



