

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; Salvadlena, 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

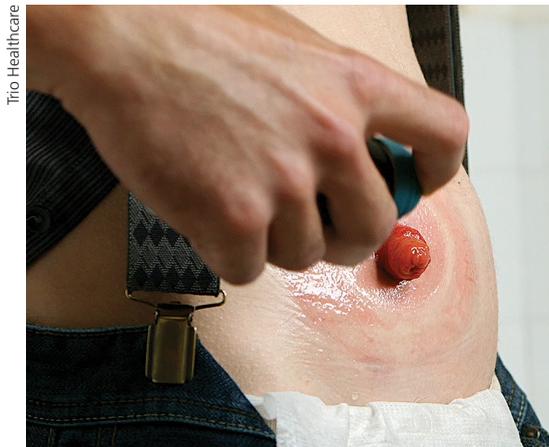


Figure 2. Silicone-based barrier film (Trio Elisse)



Figure 3. Silicone adhesive remover (Trio Elite)

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

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.

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 4. Silicone-based filler gel (Trio Silken)

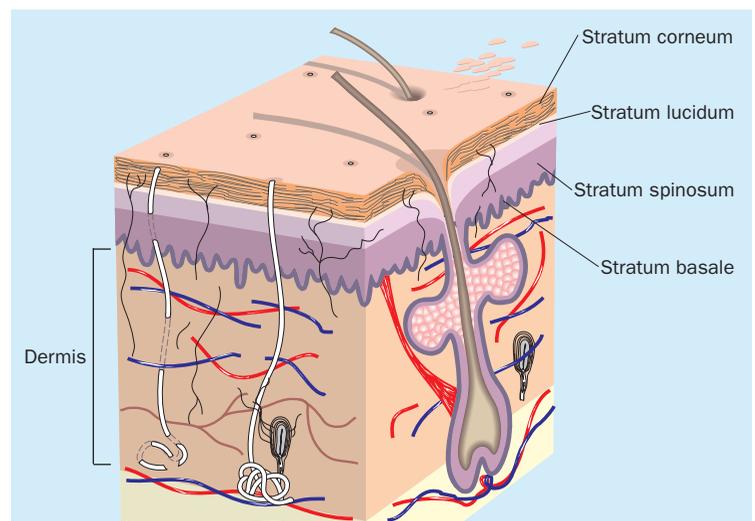


Figure 5. Structure of skin

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.

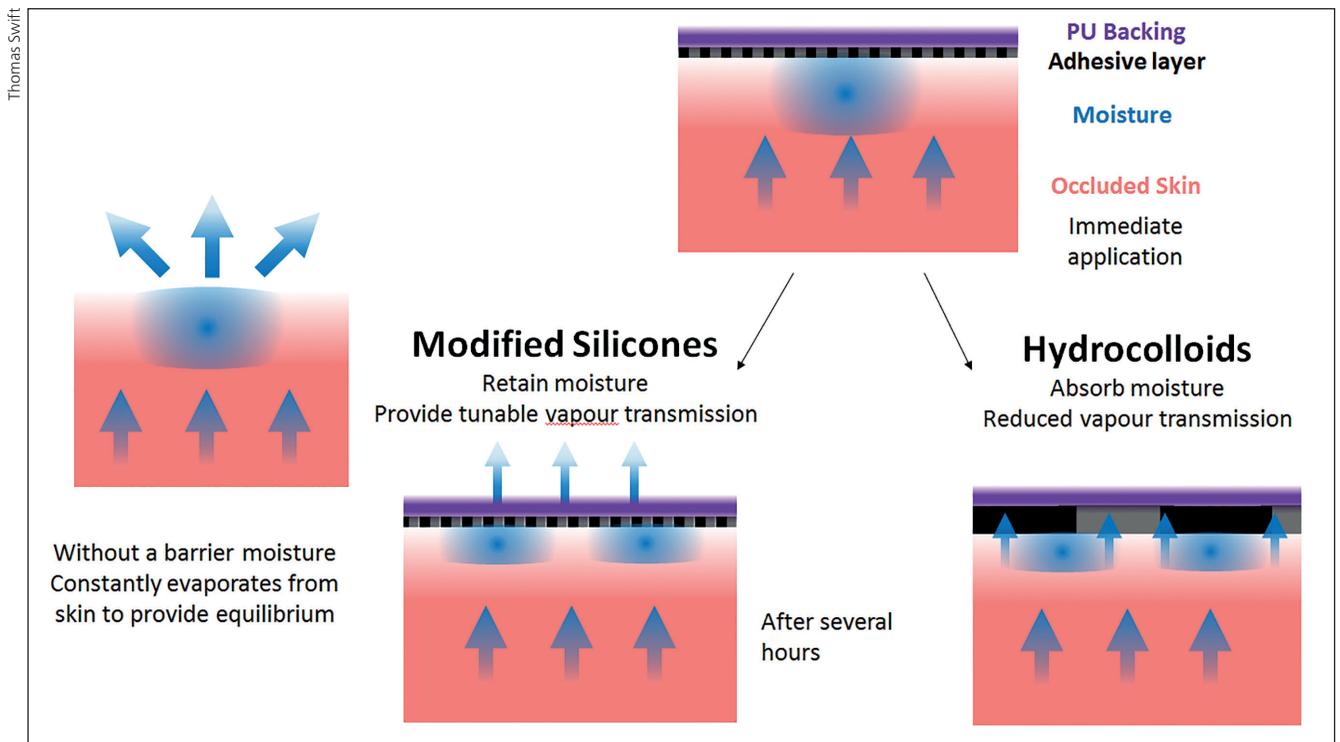


Figure 6. Proposed moisture management technique of silicone versus hydrocolloid flange extenders on occluded skin

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 (MARS) (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 MARS. 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 MARS 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 MARS associated with hydrocolloids. The number of

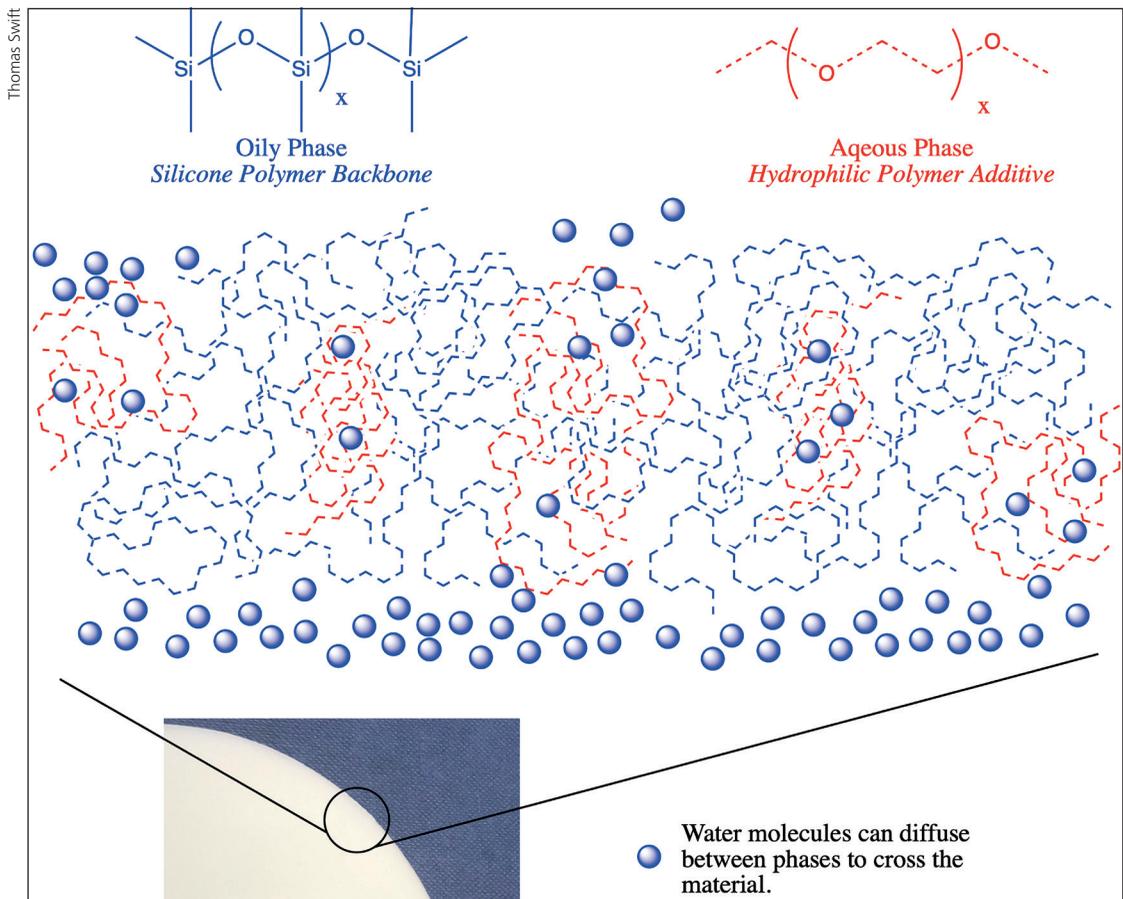


Figure 9. Gradual diffusion of water molecules through a novel silicone compound

cells that remain stuck to the adhesive film can be used to measure the extent of skin damage (Gao et al, 2013), and MARSIS 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**

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