Novel stoma appliances to minimise complications and improve patient outcomes

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ABSTRACT

Stomas are created for a number of reasons and, if they are formed without the opportunity for preoperative care and consideration, such as siting, stoma care needs can be more complex in the long term. Patient quality of life can be negatively affected by the incidence of stoma related complications, such as leakage or sore skin. A new range of products, Aura Plus, distributed by CliniMed Ltd in the UK, were evaluated on more than 200 patients with a stoma and assessed for comfort, ease of application, security and leakage. Case studies highlight positive patient outcomes following the use of Aura Plus, and demonstrate how Aura Plus can benefit patients experiencing different needs with their stoma care, such as leakage, peristomal skin complications or a parastomal hernia.

Key words: Stoma ■ Leakage ■ Quality of life ■ Aura Plus

Being a community bladder and bowel nurse on a Crown dependency island with around 250 ostomates brings its own challenges. Ostomates on the Island suffer the same complications and frustrations as ostomates do worldwide. Evidence suggests that 20% of stoma patients found the anxiety of having a stoma affected their personal and work life (Black and Notter, 2021). Stoma-related complications such as parastomal hernias, stenosis, prolapse, and retraction are thought to affect up to 70% of ostomates (Ambe et al, 2018), with many of these issues leading to leakage and sore peristomal skin, which are complications in their own right and which can have a subsequent effect on the ostomate's quality of life.

In the author's day-to-day practice, the most frequent request for stoma advice and support is from ostomates who have sore skin or who have been struggling with leaks. The initial assessment involves the size and position of the stoma and the condition of the abdominal wall. Often the stoma has not been measured for some time and the flange no longer fits around it effectively. There are many causes of leakage and sore peristomal skin, including suboptimal product selection. Local ostomates do not get to see new products as easily as their mainland counterparts, due to there being fewer open days and less opportunity for stoma company territory managers to visit. Often patients try to manage leakage with a variety of samples of devices and skin care products that they have obtained themselves from the internet or by contacting a stoma care company.

Stoma care nurses can advise on appropriate products for patients who are experiencing complications. An experienced stoma care nurse will understand what is causing the complication and be able to recommend a solution. They will be aware of the novel stoma products that can help patients manage complications and will recommend if appropriate. However, the stoma care nurse must remember to keep the process of stoma care as simple as possible whilst maintaining pouch adherence and integrity.

There are a lot of novel stoma products that can help patients manage complications. This article will address complications specifically around leakage and will discuss the new Aura Plus range and how it has positively impacted patient outcomes.

Stomas

A stoma is a surgical opening on the abdomen used to divert the passage of faeces (colostomy or ileostomy) or urine (ileal conduit) into an external adhesive pouch on the abdomen (Hill, 2020). The stoma may be formed surgically for several reasons: colorectal cancer, bladder cancer, pelvic cancers, inflammatory bowel disease, trauma, familial adenomatous polyposis, diverticular disease, ischaemic colitis, radiation injury, fistula, faecal incontinence or because of a birth defect. There are more than 175 000 ostomates in the UK with an estimated 20 000 people having stoma surgery each year (Kettle, 2019; Burch et al, 2021; White, 2021).

In addition to collecting the stomal output, the pouch should contain odour and protect the stoma and peristomal skin. Ileostomy patients may choose to change a drainable bag daily or every 2-3 days as the output from an ileostomy will be a loose consistency and will need to be emptied before it becomes half full. Closed pouches are typically used by colostomy patients and may need to be changed several times throughout the day,

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as the output will be more formed which can mean it is not possible to empty the pouch. Urostomy patients wear pouches specifically designed to collect urine output, a tap is used to empty these pouches, with a pouch change every 1–3 days. It is important that an ostomate understands that if a leak should develop, the appliance must be changed as soon as possible to prevent peristomal skin damage. Leakage is a complication and patients should be aware that if they experience a leak, they should take steps to prevent this happening again in the future.

Initially after stoma surgery, the stoma care nurse will determine which type of appliance the ostomate needs. They will support patients post-operatively to advise and determine the appropriate appliance to support the patient living with a stoma. They will base their assessment on: the position and structure of the stoma; abdominal softness, creases, wrinkles and scarring; appliance wear time; output consistency; and patient choice and ability to manage the stoma (Hallowell, 2018). Improving patient outcomes is of great importance for all stoma care nurses (Association of Stoma Care Nurses UK, 2016).

A well-sited stoma can reduce the risk of complications such as leakage, and can make it easier for the patient to manage their stoma. This can lead to fewer lifestyle constraints and a positive quality of life for the patient. Kim et al (2021) found that preoperative stoma siting reduced the incidence of stoma complications by 53%. Moreover, the prevalence of peristomal skin damage decreased by 59%, increasing the independence with their stoma care. If the patient has not had the opportunity for the stoma to be sited before surgery, the surgeon will create the stoma while the patient is supine. This may result in the stoma being formed in a crease, fold or near a surgical incision. Peristomal skin needs to be without indentation in order to achieve the best surface for the bag to adhere to and therefore reduce the likelihood of leakage (Cruz et al, 2021). Stomal complications can have a lasting impact on an ostomates' physical and mental health (Krishnamurty et al, 2017). Around 85% of ostomates experience complications such as skin irritation/excoriation, blockage, stoma retraction, mucocutaneous separation, parastomal hernia, prolapsed stoma, stenosis, appliance leakage, constipation, diarrhoea and difficulty in attaching and removing appliances (Kettle, 2019).

Leakage

Leakage and sore skin are two of the most common stoma complications, and there can be a relationship between the two. The stoma care nurse can educate ostomates around these issues, emphasising that sore skin and regular leakage is not normal and that patients should take active measures to manage these complications if they arise. The stoma care nurse should also be available for ongoing clinical support, if necessary.

It is essential that ostomates have confidence in their appliance and believe they can carry on a normal life without fear of leaks or sore peristomal skin. A positive quality of life can be achieved while living with a stoma.

Stoma care nurses give ongoing support to patients and their carers. For example, they can provide educational tools that allow patients and carers to assess the patient's peristomal skin. In this way, the patients and carers can be confident and proactive in their stoma care.

The peristomal skin can be identified as the footprint of the adhesive flange, which attaches the stoma appliance to the abdomen (Nichols, 2018). Peristomal skin should not be discoloured; it should be the same colour as the rest of the abdominal skin.

To maintain a good base for the flange to adhere to, the peristomal skin needs to be healthy, as skin damage can affect the adhesion of the flange (O'Flynn, 2019; Evans and White, 2020). Ostomates may develop peristomal skin damage because of: leakage; poor appliance change technique; health problems and comorbidities; a lack of an education; and cultural influences (Bibi, 2019).

If patients are experiencing regular leakage, their peristomal skin may be exposed to repeated contact with chemical, mechanical and biological elements on a daily basis. This can lead to moisture-associated skin damage or contact dermatitis (Nichols, 2018). When peristomal skin encounters stoma effluent, the balance of the skin's natural acid mantle is disrupted, causing its pH to rise, which can impact the integrity of the peristomal skin (White and Evans, 2019).

If a patient is experiencing skin inflammation and they report faecal or urine output leaking onto this skin, leakage is the most likely cause of the inflammation. The stoma care nurse and ostomate should examine the skin side of the adhesive flange to observe for creases and signs of maceration or stoma effluent; this is most likely where the leak is occurring. Inappropriate aperture size of the flange may result in leakage as there may not be a good fit around the stoma. The stoma care nurse should ask the ostomates if the appliance always leaks in the same place and then examine this area on the abdominal skin to see if there are creases. Research shows that the main cause of peristomal skin complications is frequent leakage from the stoma appliance. Herlufsen et al (2006) found that 77% of peristomal skin damage resulted from leakage of stomal output onto the skin. Research over the last 15 years shows that the main cause of peristomal skin complications remains frequent appliance leakage (Nafees et al, 2018; Voegeli et al, 2020).

The Ostomy Life Study revealed that 91% of ostomates were anxious about leakage (Claessens et al, 2015). Moreover, international consensus shows that leakage, odour and pain cause ostomates stress, preventing nearly half of them (47%) from leaving their homes and causing them to withdraw from physical, leisure and social activities. Frequent appliance leaks may result in a disproportionate amount of time spent on stoma care, damage to clothing, stigma, social embarrassment and fear of accidents (De Campos et al, 2017; Colwell, 2019; O'Flynn, 2019). These distressing factors can affect an ostomate's physical and emotional wellbeing (Nafees et al, 2018; Hill, 2020).

Guidelines suggest that marking the best stoma site preoperatively can minimise stoma-related complications, including appliance leakage (Rat et al, 2018). Preoperative stoma site marking is essential; ideally, the site of the stoma needs to be away from surgical and other scars, bony prominences and abdominal creases (Smith et al, 2020). However, stoma

siting may not be possible due to emergency surgery. When siting the stoma, the stoma care nurse must pay attention to clothing, the waistband and abdominal bends and creases, as siting the stoma in these areas may cause complications.

To determine the correct appliance for a patient initially after stoma surgery, the stoma care nurse must first make a thorough patient assessment. This must include stomal output, stoma location, stoma size, abdominal tone and creases.

The most important factor in stoma care is to ensure that the stoma appliance provides a secure, reliable seal. Historically, poorly fashioned stomas or abdominal creases were corrected with the use of rings, pastes, belts and medical adhesives (Hoeflok et al, 2017). Considering that the cost of stoma accessories worldwide in 2021 was £370 million with a predicted increase to £719 million by 2031 (Persistence Market Research, 2021), the role of stoma care nurses is crucial in avoiding inappropriate or excessive use of stoma appliances and accessories (Montesinos Gálvez et al, 2020). Advancements in stoma appliances can help patients manage their stoma and may reduce the risk of complications such as leakage, and the use of such products may help to reduce the use of additional stoma accessories.

Advances in stoma products to provide security and reduce the risk of leaks

The majority of skin barriers use a hypoallergenic, hydrocolloid adhesive. Recent advances include adhesive flanges permeated with skin-friendly ingredients such as Manuka honey, aloe vera, ceramide and vitamin E (Sica, 2018). Developments in stoma technology result in appliances that are more secure and skin friendly, control moisture, can be worn for longer and are atraumatic on removal (Lager and Loxdale, 2021).

A stoma care nurse has clinical knowledge and experience, which enables them to identify issues that the ostomate is experiencing and be able to rectify it using their knowledge of solutions and new products. The Nursing and Midwifery Council (2018) *Code* states that nurses must 'always practise in line with the best available evidence and make sure that any information or advice given is evidence-based including information relating to using any health and care products or services'.

Stoma care, being a worldwide discipline, encompasses the latest bioengineering technology. Advances in stoma care means appliances can provide a secure and reliable seal, which can reduce the risk of complications such as leakage, whilst the inclusion of skin-friendly ingredients in the adhesive flange may help to reduce the risk of peristomal skin complications. These advances can improve patient outcomes, increase or maintain patient quality of life, and can reduce the cost of stoma care.

Aura Plus

The Aura Plus range has been designed with a unique plus shaped flange for even greater security, with the flange designed to conform around any body shapes which surround the stoma. Aura Plus is available in a choice of pouch colour, sand and black, with a clear pouch also available (*Figure 1*). The adhesive flange is the Hyperflex® hydrocolloid formulation which contains medical grade Manuka honey. Aura Plus is available in a range of pouch and flange sizes, so there are options to suit the individual needs of different stoma patients.

Figure 1. CliniMed Aura Plus range

The unique plus shaped flange is specifically designed to reduce the risk of leaks. The cutaway areas which form the plus shape help the flange conform around the body, which increases security for the patient, especially when the patient is moving. The flange also reduces the risk of creases forming when the pouch is applied, which reduces the risk of leaks due to the decrease in potential leakage channels.

It has been reported that Manuka honey has antimicrobial properties, and it has been found to have antibacterial properties against a wide range of bacteria (Woodward, 2019). Manuka honey is widely used in wound care and research and evidence suggests that Manuka honey can promote skin healing (White, 2016). The addition of medical grade Manuka honey to a hydrocolloid stoma flange can help to promote healthy skin around the stoma. White and Evans (2019) found that 94% of patients reported an improvement in their peristomal skin condition within 7 days of changing to a stoma pouch containing Manuka honey, following the patient being observed to have a peristomal skin complication by a stoma care nurse from an independent centre. Martin-Skurr (2019) also found that using a flange which included Manuka honey promoted the healing of a peristomal pyoderma gangrenosum, a rare condition characterised by painful ulcerations which surround the stoma.

Aside from the focus on promoting security and healthy skin around the stoma, Aura Plus is available in a range of colours which provides added choice for patients, which may help to increase patient confidence when adapting to life with a stoma as patients can choose a pouch colour which suits them the most.

In the UK, 203 patients (58% male, 42% female) evaluated Aura Plus by comparing it to the stoma pouch with a flat flange that they were currently using. The inclusion criteria

were patients over the age of 18, who were using a flat stoma flange, and who did not have an allergy to honey. Patients evaluated Aura Plus by completing a comparative questionnaire.

Of the respondents, 79% found the flange was easier or the same to apply to the skin compared to the appliance they were currently using. Patients reported that the flange was easy to apply without any gaps or creases forming. Patients who have a parastomal hernia reported that the plus shape flange was easier to fit around the hernia.

'Very easy to apply the flange—no gaps.'
Mrs KT, Mid-Glamorgan

'My stoma has turned into a hernia, and I found that the cut outs on the new pouch help fit around this.'
Mr NE

87% of respondents reported that the Aura Plus flange was either more comfortable or the same level of comfort compared to the pouch they were currently using at the time. Patients reported that the flange fitted and moved well without pulling on the skin and that overall, the pouch was unobstrusive. Patients also reported that the pouch material was soft and comfortable, and that the water repellency was excellent which avoided any disruption for the user.

'Really liked this pouch, particularly the way the flange fitted my tum—fewer wrinkles.'
Mrs CB

'My skin felt much more comfortable and not so itchy.'
Mrs AS, Buckinghamshire

'Felt like it moved more with my movements and did not pull on the skin.'
Mrs BT, County Durham

'Loved the softness and didn't crackle and laid nice under my clothes.'
Mrs LL, South Yorkshire

80% found that the Aura Plus flange was more secure or the same level of security compared to the pouch they were currently using at the time. Patients reported that the flange remained secure throughout the day, without any compromise to security when twisting and moving. Patients reported that the flange did not come away at the edge and that as it felt more secure for the user, the user didn't feel the need to keep checking the pouch as often.

'I was gardening and doing lots of twisting and still felt very secure.'
Mrs LJ, Worcestershire

'It was very secure and lasted the night.'
Mr SN, Lincolnshire

70% of patients reported that they experienced no leakage when using Aura Plus. Overall, the instances of patients experiencing leakage reduced following the use of Aura Plus (from 46% to 30%).

'The cross of Aura Plus seems a lot more sensible than a complete adhesive circle or oval, as it leaves space for the skin to fold and wrinkle when exercising or sitting down or when bending to do housework, gardening etc.'
Mrs MD

'Felt more secure, performed better, and didn't have any accidents.'
Mrs SM, Lancashire

Overall, the feedback received highlighted how Aura Plus has helped stoma patients resolve some of the problems they have been facing with complications such as leakage, as well as helping patients feel more confident whilst going out to work, socialising with friends and family and even just leaving the house without a backup pouch due to the pouch feeling more secure for the user.

Case studies

The benefits of the Aura Plus pouches are explored through two case studies of people who used the product. **All names have been changed*

Case study 1. Long-term ostomate

Mrs Smith* is a 70-year-old ileostomate, whose stoma was formed when she was 18 years old for Crohn's disease. She has managed her stoma without issue for many years. She sourced her own stoma supplies so that even her GP was unaware that she had a stoma. Mrs Smith's ileostomy is 20mm, round with a small spout, her abdomen is flat with no creases; however, she has an occasional parastomal 'bulge', which was causing the edges of the flange to lift and for her bag to leak. This made Mrs Smith feel very self-conscious and caused her to order twice the amount of bags she had been allocated. Because of this, a review of Mrs Smith was requested. Mrs Smith claimed that frequent changes were required as her skin was stinging around the stoma and the edges were peeling up and she was experiencing some leaks. On examination, the stoma was found to be pink and healthy and her peristomal skin was intact, she also had a firm flat abdomen. Reassurance was given and no explanation for the stinging could be found.

Mrs Smith was admitted to hospital a few weeks later with severe abdominal pain. An abdominal ultrasound scan revealed that she had a large pelvic complex multiloculated cyst measuring 10x8x9 cm. She was discharged home and declined further treatment.

Since returning home, Mrs Smith had experienced a lot of pain, and her analgesia increased significantly over a few weeks. She continued to complain of pain and stinging around the stoma and found that the peristomal area was 'tender'. Mrs Smith continued to change her pouch several times each day as she reported that it was leaking and causing her pain and discomfort.

Over the next few weeks, Mrs Smith tried using different

pouches with no great improvement, so we decided to sample the new Aura Plus range. Mrs Smith's initial response was that the flange was soft and due to the unique plus shape, it fitted better on her abdomen and did not crease. She stated that it was easy to cut so did not aggravate her stoma. She felt that the softness of the flange helped with the pain and she did not feel the need to change the appliance during the day. Although she still has pain she feels more confident in the new Aura Plus appliance.

Case study 2. Parastomal hernia

Mrs Brown* is an 85-year-old woman who had a colostomy formed in 2016 secondary to anal fissures. Mrs Brown developed a parastomal hernia, which was repaired in 2017. In 2019 Mrs Brown had a small bowel obstruction, which was stuck to a further parastomal hernia. Mrs Brown is of short stature with a large soft abdomen and a very large (the size of a rugby ball) and heavy parastomal hernia. The weight of the hernia causes her back pain and makes her unsteady when she walks. Unfortunately, she is unable to have a further parastomal hernia repair because of her comorbidities. It has been difficult to get a flange to fit securely around the hernia because the edges of the appliance lift when Mrs Brown moves. The lack of an effective seal has caused leakage and subsequent peristomal skin damage. Mrs Brown was suffering from a reduced quality of life due to anxiety and the fear of leakages led to a reduced confidence. She was admitted to the hospital early in 2021 with parastomal cellulitis and erythema around her stoma across her abdomen.

Mrs Brown tried many different appliances over the last few months to see if she could get an effective seal with secure edges that envelope around the hernia. We have used convex, concave and shaped flanges; however nothing has been 100% secure. I introduced Mrs Brown to the new Aura Plus range, initially she was quite anxious and felt that there was not enough flange to be secure. I reassured her that the unique plus shape had been designed to be more secure.

After a week she reported that the Aura Plus range did not come away at the edge and was easy to apply, and the flange's adhesive base is much easier to fit round her hernia and is more secure. This means her leakage problem has been solved and her quality of life has improved. She is now more confident to live life to the full. Her peristomal skin is intact and she now no longer needs flange extenders. Although she still has a large parastomal hernia she feels more confident that her skin will not become sore again.

Conclusion

Stomal complications can have a detrimental effect on ostomates both physically and psychologically. It is therefore of utmost importance to ensure the correct appliance for each individual.

Experienced stoma care nurses will understand that no two patients are the same, let alone two stomas. Stoma care nurses need to be aware of new products that might benefit their patients. The new Aura Plus range was evaluated on several ostomates in my care with good results. Patients experienced a reduction in leakage and sore peristomal skin. This led to the patients having an increase in confidence and wellbeing. **BJN**

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Sica J. Helping ostomates choose the right appliance for their stoma.

KEY POINTS

- Experiencing stoma related complications, such as leakage, can result in a reduced quality of life
- One of the most common causes of peristomal skin damage is a leaking appliance
- A securely fitting appliance is essential to prevent leaks
- A good quality of life needs to be maintained in people with a stoma through support from the stoma specialist nurse
- Stoma care nurses need to be aware of the advances in stoma appliances. Finding the correct appliance can make a significant difference to a patient's quality of life

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CPD reflective questions

- What do stoma care nurses base their assessment on to determine the correct appliance?
- How is the peristomal skin affected by stoma effluent?
- Why would the nurse examine the skin side of the adhesive flange?