

Contributing factors associated with peristomal skin complications: a comprehensive literature review

ABSTRACT

Background Peristomal skin complications (PSCs) in the early post-operative period are commonly reported and considered largely preventable by many. Furthermore, they affect overall wellbeing and quality of life (QoL). As part of a study investigating the number, type and aetiology of PSCs experienced by a cohort of Western Australian ostomates, a comprehensive literature review was conducted to establish the contributing factors associated with PSCs.

Method The primary literature search was conducted from January 2000 – September 2021 and the secondary search was conducted from September 2021 – June 2023. Papers published prior to 2000 were included if they were seminal works or there were no other recent publications on the topic.

Results Internationally peristomal skin complications were reported to be 6–80% and commonly occurred during the early to late post-operative periods. The literature identified contributing factors related to the ostomate such as; obesity, geographical location and access to stomal therapy nurse (STN) follow-up and those related to the stoma, to be the primary causes of PSCs. Comprehensive assessment of PSC risk factors, pre and post-operative stoma care education, regular post-operative follow-up and appropriate selection of appliances and accessories were found to be the most effective prevention strategies.

Discussion The aetiology of PSCs are multifactorial and all contributing factors need to be considered by stomal therapy nurses (STNs). The results were used to inform a risk assessment tool that can guide STNs to identify ostomates most at risk of PSCs. Such knowledge informs the implementation of prevention interventions which are anticipated to reduce the overall incidence of PSCs.

Keywords peristomal, skin, complications, literature review.

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INTRODUCTION

Peristomal relates to the skin surrounding the stoma that is in contact with the adhesive skin barrier and parastomal relates to an area beside the stoma.¹ Peri/para stomal skin complications (PSCs) while generally thought to be preventable, are estimated to affect 6–80% of ostomates at some time post-

surgery.^{2,3} It is difficult to know the true prevalence or incidence of PSCs due to the inconsistency in terminology, the size and methods of studies conducted. However, a study which determined a consensus in PSC terminology was conducted in Australia in 2023 and the agreed terminology is found in Appendix 1.¹

The risk of PSCs is greater in the early post-operative period (first 12 weeks post-surgery) and can have significant financial implications due to readmission to hospital and incurred treatment costs.^{3,5} In addition, the development of a PSC can have a detrimental impact on quality of life (QoL) and participation in activities of daily living.⁶ In preparation for conducting a study designed to investigate the number, type and aetiology of PSCs experienced by a cohort of Western Australian ostomates, a comprehensive literature review was conducted to establish what was known about PSCs in regards to their contributing factors and their impacts on QoL. In addition, the information gained from the literature review was used to adapt an existing Peristomal Risk Assessment Tool (PRAT)⁷ for use in the study.

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METHODS

The primary search was conducted for literature published between January 2000 to September 2021 and a secondary search for literature published from September 2021 to June 2023. Papers published prior to 2000 were included if they were considered to be seminal works or if there were no recent sources identified. The following databases were searched: Summon, Medline, Cochrane, CINAHL and Scopus. The Medical Subject Heading (MeSH) of each key search term and the combinations was explored in every database. Boolean operators 'AND' and 'OR' were used to search the relevant studies. The key words that guided the searches were: *peristomal complications, stoma AND complications, peristomal skin guidelines, follow-up care AND stoma, stoma review, stoma AND moisture associated skin damage, stoma AND medical adhesive related skin injury, quality of life, wellness, AND wounds, self-efficacy.* A hand search of relevant textbooks, websites and reference lists from full text articles was also undertaken. Searches were restricted to literature written in the English language and studies performed on humans. Inclusion criteria were: full text articles, relevant to the topic, surgical procedures that resulted in formation of a urinary or faecal stoma, types of stomas being studied and related to adults. Exclusion criteria were: conference abstracts, case studies or conference proceedings and stomas on children.

CONTRIBUTING FACTORS FOR PSC RELATED TO THE OSTOMATE AND THE STOMA

The contributing factors for PSC were divided into those related to the ostomate and the stoma. Those related to the ostomate were; obesity, disability, age, intrinsic and extrinsic factors, time since surgery, stomal therapy specialist follow-up and geographical location. Those related to the stoma were; positioning of the stoma, type of stoma, high output stoma and stoma characteristics.

OSTOMATE CONTRIBUTING FACTORS

The World Council of Enterostomal Therapists® (WCET™)⁸ stated the risk of PSCs is likely to increase by 75% if the ostomate is obese or has a disability. Common causes of PSCs found in the literature included: flush, retracted, prolapsed or poorly sited stomas; poorly fitting or leaking appliances; allergy to appliance components; pathergy or pathophysiological conditions.⁹ Blessy et al¹⁰ in their integrative literature review added mechanical trauma; the type of surgery; and individual demographics as additional PSC risk factors.

Other authors reported that PSCs are most common in patients with loop ileostomies.^{11,12,13} Cottam et al⁹ confirmed this finding in their audit of nearly 4000 ostomates across 93 hospitals in the United Kingdom (UK) where loop ileostomies were associated with the most common complications. However, the authors found a variance in complications between different hospitals which could indicate surgical technique or the quality of follow-up care may have been associated with some PSCs.

OBESITY-RELATED PERISTOMAL COMPLICATIONS

A body mass index (BMI) greater than 25 can lead to an increased risk of PSCs due to increased risk of stoma retraction and necrosis, parastomal hernia, and stomas sited in folds or creases.^{14,15} Harilingam et al¹⁶ stated that as obesity is a major risk factor for PSCs, they proposed the need for a specific pre and post-operative care plan that includes siting several abdominal areas for the stoma placement, frequent follow-up post-operatively and introduction of a weight loss programme. However, despite these reports Cottam's et al⁹ study of nearly 4000 ostomates found 34% (n=1350) had a PSC, but did not find that an increased BMI was a contributing factor.

DISABILITY AND PERISTOMAL SKIN COMPLICATIONS

The risk of developing PSCs for those with an existing physical disability increases and makes self-management of a stoma more challenging.⁸ In particular, disabilities which include: visual impairment, decreased manual dexterity and reduced mobility or activity can hinder self-care rehabilitation post-ostomy surgery,^{17,18} as can mental health issues, such as depression and anxiety, that further inhibit self-management.^{19,20} In addition a learning disorder or cognitive impairment can predispose an ostomate to difficulties in understanding self-care instructions.²¹ It is therefore recommended that carers of ostomates with learning or cognitive impairment participate in stoma care education provided by the attending STN and those with disabilities receive increased post-discharge follow-up.

AGE RELATED PERISTOMAL COMPLICATIONS

Voegeli et al⁵ conducted a survey of over 4000 ostomates and found that older people were less likely to report a PSC or seek help compared to their younger counterparts. Conversely, Pittman et al,¹⁴ in their survey of 239 war veteran ostomates aged less than 60 years, discovered that they tended to have more peristomal severe skin irritation, severe leakage problems and greater difficulty adjusting to life with a stoma than participants aged 80 years or over. Both Pittman et al¹⁴ and Voegeli et al⁵ collected their data using questionnaires which were completed by ostomates who assessed their own peristomal skin, which may have made the results less reliable since the ostomates may have varied in their ability to identify complications. Conversely, Whiteley and Sinclair¹⁵ had clinicians follow-up 672 ostomates for two to four weeks post-surgery, and found ostomates who were 40 years of age and younger at the time of surgery were significantly more likely to have developed a PSC ($p \leq 0.001$). Whiteley and Sinclair¹⁵ proposed that ostomates under 40 years of age were more likely to have their stoma formed due to inflammatory bowel disease (IBD) which affects other organs such as the skin and which can lead to painful peristomal ulcers such as pyoderma gangrenosum or Crohn's ulcers.²² However, it can also be argued that ageing skin is known to have less turgor and hydration and is therefore predisposed to damage from removal of adhesives.^{23,24}

INTRINSIC AND EXTRINSIC RISK FACTORS

Boyles and Hunt²³ identified intrinsic and extrinsic factors which potentially can affect the skin and can be associated with PSCs. Apart from ageing, other intrinsic factors reported to impact peristomal skin changes were: diabetes, renal failure, immunosuppression, hypertension, smoking, low haemoglobin, psoriasis, eczema, peristomal varices, hyperhidrosis and malnutrition.^{12,14,15,23,25,26} Darker skin tones may also compromise assessment of signs of inflammation or pressure damage such as erythema.²⁷ Burch et al²⁶ agreed that the majority of PSC research has been conducted among Caucasians and that assessment of darker skin could be more challenging. Black et al²⁷ said that as erythema is not clinically visible on dark skin, the likelihood of these individuals developing more severe pressure injuries than those with light skin is increased. Therefore, STNs need to be efficacious in identifying early signs of skin damage in dark skinned people, so appropriate prevention and early treatment interventions can be employed.²⁸ Extrinsic factors that impact skin health, such as desiccation, maceration due to incontinence or leaking appliances, radiation-induced injury, pressure and friction from the appliance or clothing and use of adhesive products can also make the skin more susceptible to PSCs.²³

TIME POST-SURGERY

Peristomal skin complications are often grouped into those that occur early, within one month post-surgery or late, for those occurring more than a month post-surgery.²⁹ However, discrepancies in this classification exist. Bosio et al³⁰ classify the early period as within 15 days and late complications as occurring more than 15 days post-surgery. Regardless, several authors describe increased incidence of PSCs during the first two to three months following surgery.^{5,31,32,33} Ratliff's³¹ prospective study which followed 89 ostomates for the first two months post-surgery found 47% ($n=42$) of them developed PSCs. In comparison, the multinational survey conducted by Voegeli et al⁵ collected data from over 4000 ostomates who had their stomas for 10 years or longer and found ostomates were at least one and a half times more likely to have a PSC in the first two years after surgery, but by five years they concluded that time since surgery was not predictive of PSCs. Contrastingly, Meisner et al³⁴ proposed that PSCs were most common in the first five years however, they described the risk of complications as lifelong.

STOMAL THERAPY SPECIALIST FOLLOW-UP

Research has indicated that ostomates often do not recognise they have developed a PSC and therefore do not seek assistance or review from their STN. Herlufsen et al³⁵ recruited 202 ostomates with permanent stomas and found 38% ($n=77$) of those diagnosed with a PSC conceded they had a problem and of those, over 80% ($n=66$) did not seek assistance. Interestingly, Voegeli et al⁵ reported ostomates who had their stoma for some time were less likely to seek advice,

whilst Blesy et al¹⁰ found that lack of awareness or the ability to recognise the early symptoms increased the ostomates risk of PSCs. Similarly, Williams et al³⁶ reviewed 80 ostomates and reported that almost all had a skin issue at some point and they proposed this was in part due to lack of ostomate awareness, which led them to recommend a need for more education and annual reviews. Conversely, Pringle and Swan³⁷ reported 43% of ostomates had PSCs within the first year after surgery and they recommended six monthly reviews in the first year extending to annual thereafter. Pringle and Swan³⁷ suggested that drop-in nurse-led clinics could be a possible answer to ensuring timely review by an STN. However, Salvadalena³³ observed 43 ostomates for 3 months post-operatively and found that despite regular reviews, a high proportion (63%) $n=27$ still acquired PSCs. Salvadalena³³ proposed that regardless of follow-up frequency some still acquired a PSC and this indicates the need for further investigation into preventative interventions.

Unfortunately, many ostomates in Australia do not have equitable access to a STN due to their remote location and possible language barriers.³⁸ Burch et al²⁶ described how those with poor English or health literacy have poorer health outcomes when compared with the general population as they are unable to verbalise their perceived health needs or cultural or religious preferences.

GEOGRAPHICAL LOCATION

It has been found that people living in rural communities have poorer health outcomes than their metropolitan counterparts, and are likely to die sooner following a cancer diagnosis due to inequitable access to cancer treatment and support.³⁹ Frequently those who reside in rural areas delay admitting they have a problem and or are reluctant to seek a medical review. Character traits of 'optimism', 'stoicism' and 'machismo' have been cited as reasons for the delay among this cohort, coupled with delays in diagnosis, lack of primary care support and access to treatment centres.³⁹

In Western Australia (WA) there are approximately 1000 rural ostomates who do not have ready access to an STN. To address this gap the 'Bowel & Stoma Health WA Program' was established in 2014 and provides a consultation service funded and coordinated by the Western Australia Ostomy Association (WAOA), for the specific purpose of providing support to rural ostomates. As part of this service an STN visits rural and remote WA towns at least annually and conducts clinics to review ostomates and provide education to health professionals working in the area. To date over 500 ostomates have been reviewed and data obtained from 100 of these rural ostomates, found 86% ($n=86$) of them had PSCs which were associated with wrongly sized appliances leading to leakages, granulomas and parastomal hernias and 30 out of the 100 ostomates reported sexual dysfunction, personal relationship issues and depression.³⁶

STOMA CONTRIBUTING FACTORS

Positioning of stoma

Pre-operative stoma siting is highly recommended and is usually performed by a STN or surgeon; it determines the best place for positioning the stoma on the abdomen.¹⁷ According to Blessy et al¹⁰ patients who do not have a pre-operative stoma site marked are more likely to develop a PSC due to a poor fitting and leaking appliances should the stoma be sited on an irregular abdominal plane or in a crease or scar. A study by Persson et al¹¹ conducted among 100 ostomates measured the incidence of PSCs and associated impacts on reduced QoL when half their study participants had received pre-operative education and stoma siting and the other half did not. There was a significant difference in post-operative PSCs ($p=0.01$) which included peristomal hernias and appliance leakages in the group that didn't have a stoma sited and this group also scored much lower of the QoL scores.

Ambe et al⁴² in their systematic review and meta-analysis of 27 papers related to pre-operative stoma siting found there was a high risk of bias among the studies, which were mainly observational and conducted at single centres, where more ostomates underwent planned surgery compared to emergent surgery. In addition, major stoma complications (such as prolapse, retraction, stenosis and mucocutaneous dehiscence) were frequently identified due to poor stoma siting or lack thereof.⁴² However, the authors of the review concluded that despite the low quality of evidence, a stoma which is sited in a visible position for the ostomate and avoids scars and skin folds has a direct influence on preventing leakage and reducing associated skin complications.

Type of stoma

An earlier study that reviewed 1616 ostomates between 1976–1995 found that 75% of stoma and PSCs complications occurred among ostomates with a loop ileostomy.⁴³ A loop stoma is formed when a loop of small or large bowel is exteriorised onto the abdomen and an incision into the bowel reveals a proximal and distal aperture.⁴⁴ Persson et al¹¹ discovered that patients with loop ileostomies experienced 13% more PSCs than those with end or terminal ileostomies. Steinhagen et al¹² reported PSCs occurred in 25–43% of patients with ileostomies and in 7–20% of those with colostomies. Not surprisingly, loop ileostomies appeared to be associated with an increased risk of PSCs as they result in a high volume of watery effluent, making leakages more likely, especially if the stoma is flush to the skin rather than spout-shaped.⁸

High stoma output

After ileostomy surgery the initial effluent output is quite watery, but this will generally thicken over time dependent upon dietary intake.⁴⁵ An ostomy appliance generally holds around 400–600mls of effluent and it is advisable that it be emptied when a third full.⁵ Initially the ostomate may be emptying their pouch eight to 10 times a day with reduced

occurrences of four to six times daily after three months.⁴⁵ Sometimes the output continues to be watery, particularly for ostomates who have had a large portion of their small intestine removed and this can rapidly lead to dehydration, and if not treated promptly kidney damage can occur.⁵ Steinhagen et al¹² reported 17% of ileostomates were re-hospitalised due to dehydration from high output stomas. Furthermore, a high output stoma can also increase the risk of appliance leakages leading to contact irritant dermatitis due to the erosive nature of uncontrolled output.¹⁵

Stomal characteristics

Urostomy and ileostomy stomas are usually created by the surgeon to be a 'spout' shape (at least 2cm above surrounding skin level) which facilitates effluent drainage into the appliance. If the stoma is retracted (below skin level) or flush (level) with the surrounding skin, PSCs such as irritant dermatitis due to leakage are more likely to occur.¹⁴ In another study, almost all patients with a colostomy stoma height ≤ 5 mm or an end-ileostomy and loop-ileostomy with a height ≤ 20 mm experienced leakage and skin problems.¹¹ However, even when the stoma is spouted above 20mm the ostomate may still experience leakage problems, if the stoma opening points downwards.¹⁷

APPLIANCE AND ACCESSORY-RELATED ISSUES

Appliances

The most frequently reported PSC is contact irritant dermatitis which may be referred to as peristomal moisture associated skin damage (PMASD), and which arises from prolonged skin exposure to effluent.^{5,32,41,46,47} An ill-fitting appliance is the most likely cause of leakage and subsequent erosion and ulceration of the skin due to impaired skin barrier function associated with frequent or extended contact with effluent.⁵ In a follow-up review of 80 ostomates, 44% ($n=35$) were found to have 'irritated' skin and of those 21% had an ill-fitting appliance.¹⁵ Once the skin is eroded or ulcerated it becomes difficult to adhere an appliance, which creates a vicious cycle of leaking appliances leading to further skin damage.^{15,49}

Blessy et al¹⁰ investigated the contributing factors for PSCs and found that 61% of PSCs were caused by leaking appliances. There are over 3700 different types of ostomy appliances on the government funded Stoma Appliance Scheme (SAS) in Australia, and these are manufactured by six different companies.⁵⁰ The variety and choice of available appliances is largely due to the recognition that there are many variations in clinical stoma presentations and abdominal profiles and as yet no one appliance is able to suit all. However, as mentioned previously, one of the key roles of a STN is to ensure that the ostomate has a correctly fitting and secure appliance and that their selection is based on assessment of body profile and stoma type. Buckle⁵¹ introduced a stoma assessment tool to assist with appliance selection according to body profile and stoma characteristics, which was based on findings from a study that recruited over 3000 ostomates across 18 countries.

This same study predicted that with regular specialist follow-up and the correct appliance selection the incidence of PSCs could be reduced by 36% and unplanned bag changes by 25% with a coexisting reduction in use of accessories by 30%.⁵¹

Poorly fitting appliances can also lead to the development of mucosal or mucocutaneous granulomas which are raised, irregular shaped tissue around the mucocutaneous junction or on the stoma mucosa. Granulomas may be prone to bleeding which adds to difficulty in appliance adhesion.^{50,53} Additionally, chronic exposure to faecal effluent can cause the skin to develop raised papules and plaques and sometimes bowel metaplasia, which can appear as a red, eroded or ulcerated plaque continuous with the stoma.⁵⁴ Chronic exposure to alkaline urine can cause the development of wart-like papules or hyperplasia, which is referred to with synonymous terms, such as chronic papillomatous dermatitis, pseudo epitheliomatous hyperplasia⁵⁴ or pseudoverrucous lesions.⁵²

Furthermore, if an appliance is 'pulled off' the skin rather than gently removed, skin stripping can occur and this is sometimes referred to as peristomal medical adhesive-related skin injury (PMARSI).⁵⁵ Hair on the peristomal skin (particularly in hirsute men) can adhere to the appliance and cause trauma on removal resulting in inflammation of the hair follicle and folliculitis.⁵⁶ Due to the risk of potential skin damage when changing an appliance, it is therefore essential that ostomates are educated regarding gentle removal.

Appliances are available in either a one or two-piece format. A one-piece appliance has the adhesive skin barrier attached to the bag, while a two-piece has the adhesive skin barrier separate to the bag and this is often referred to as a base plate.⁵⁰ The ostomate's personal preference usually dictates the selection of appliance, but generally a two-piece appliance will have a more durable skin barrier which can reduce the frequency of base plate changes, although there is little evidence to guide the ideal wear time for appliances. Colwell et al⁴⁷ discussed practice guidelines for appliance selection and frequency of follow-up post-discharge but they did not make recommendations for frequency of bag changes. Burch⁵⁷ compared both the one and two-piece systems and related wear time preferences of ostomates, proposing that a two-piece system can stay in situ for one to three days, but that in the USA the recommendation may be for up to seven days due to cost constraints among self-funding ostomates. Interestingly Burch et al⁵⁷ only discussed the use of one-piece appliances and recommended that for both ileostomies and urostomies the appliance should be changed every other day or daily and for colostomies up to three times a day. It was unclear as to why two-piece appliances were not discussed by these authors.

Blessy et al¹⁰ stated that the more frequently a skin barrier was removed, the speed in which it was removed, and excessive rubbing during cleaning could all contribute to PSCs, and they recommended that the appliance be worn for between three and seven days. However, Bourgois et al.⁵⁸ in their cross-sectional study which endeavoured to determine ostomate

satisfaction with their appliances, found that a rash was the most commonly reported PSC and that there was a significant increase in skin problems with those who left their appliance on for up to 3 days, compared with those who changed more frequently ($p=0.03$). Salvadalena³³ followed-up 43 ostomates for three months post-surgery and reported a median wear time of 3.5 days but didn't stipulate whether it was a one or two-piece appliance that was worn. This author noted that there was a direct correlation between the absence of erosion and a longer wear time. Generally access to, and cost of, appliances may dictate the frequency of change regime.

The majority of ostomy companies infuse additives into their barriers which are promoted to improve skin condition, such as aloe vera, ceramide and honey. Comparisons of these medicant-infused skin barriers were not explored in this literature review.

Accessories

In addition to appliances, ostomy product accessories which include pastes, seals, powders and skin barrier wipes are sometimes required to ensure optimal skin protection, appliance security and treatment products for PSCs. O'Flynn⁴⁹ recommended using skin cleansers and barrier sprays or wipes to protect the peristomal skin against contact with effluent. Conversely Bibi⁵⁹ and a panel of nine STNs and clinical consultants reported they preferred a correctly fitting appliance rather than barrier accessories unless there was skin erosion or ulceration. It is the author's experience that excessive use of skin barrier products can interfere with appliance adhesion and thus increase problems while adding to the financial burden for individuals and health agencies.

CONCLUSION

This literature review provided insight into the prevalence and type of PSCs and identified the need for a definitive diagnosis and identification of the aetiology of PSCs to inform prehabilitation preventative and post-operative interventional strategies. The review highlighted the difficulties in assessing peristomal skin changes in dark skintoned individuals and underscored the value of pre and post-operative stoma care education and regular post-discharge clinical reviews. The need for appropriately fitting appliances to prevent leakage of effluent and associated loss of skin integrity was highlighted. Moreover the literature review emphasised the need for comprehensive assessment of risk factors and the use of a validated PSC risk assessment instrument. The need for further research is proposed to determine a consensus on type and frequency of preventative interventions, in order to improve outcomes for ostomates.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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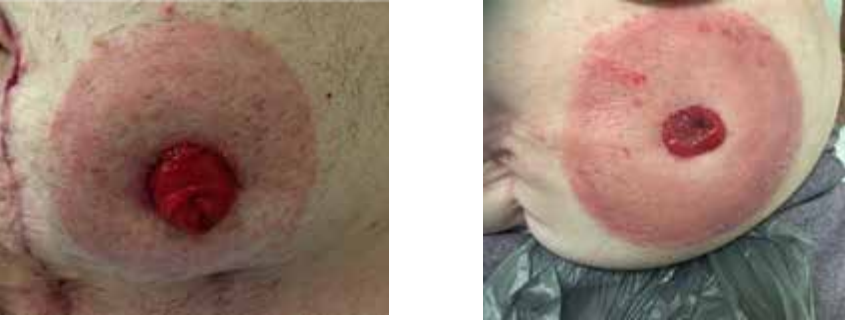

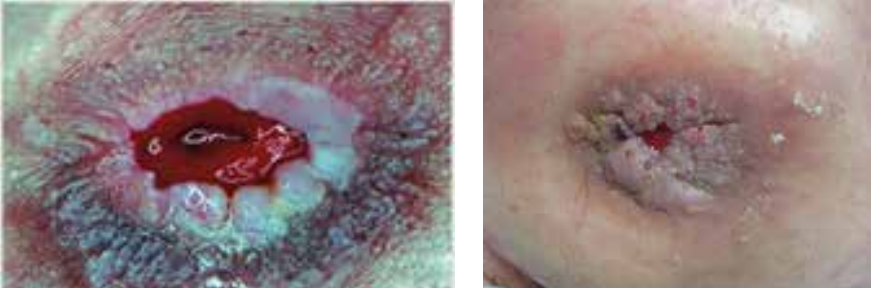


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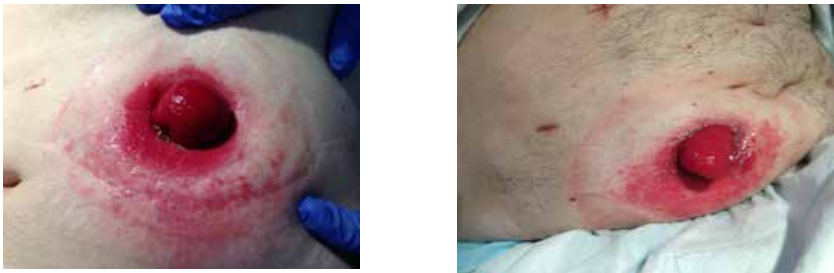



APPENDIX

Australian consensus glossary terms for stomal complications.

Australian Consensus Glossary Terms for Stomal Complications

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<p>Peri/parastomal contact allergic dermatitis</p>	<p>Peri/parastomal contact allergic dermatitis is an inflammatory and typically demarcated skin reaction due to hypersensitivity or allergy resulting from contact with a product.</p> 
<p>Peri/parastomal irritant dermatitis</p>	<p>Peri/parastomal irritant dermatitis is inflammation, erosion or ulceration due to sustained contact with stomal effluent.</p> 
<p>Pseudoverrucous lesions</p>	<p>Pseudoverrucous lesions are moist or dry hyperkeratosis occurring due to sustained exposure to urine (usually alkaline).</p> 
<p>Granuloma</p> <ul style="list-style-type: none">• Mucocutaneous granuloma• Mucosal granuloma	<p>A granuloma is friable, papular hypergranulation due to an inflammatory response to localised and often prolonged irritation.</p> <p>A granuloma may be located on the stoma (mucosal granuloma) or at the junction between the mucosa and skin (mucocutaneous granuloma).</p> <p>Mucocutaneous:</p>  <p>Mucosal:</p> 

<p>Peri/parastomal erosion</p>	<p>Peri/parastomal erosion is partial or total loss of epidermis due to moisture, trauma or allergic response.</p> 
<p>Peri/parastomal excoriation</p>	<p>Peri/parastomal excoriation is epidermal or partial dermal loss with a linear or punctated appearance that occurs due to scratching or injury.</p> 
<p>Peristomal mucosal cell implants</p>	<p>Peristomal mucosal cell implants are the transplantation of mucosal cells to peristomal skin during suturing when constructing the stoma.</p> 
<p>Peri/parastomal medical adhesive related skin injury (MARS)</p>	<p>Peri/parastomal medical adhesive related skin injury (MARS) is persistent erythema, vesicle, bulla, erosion, ulceration or tears that occur as a result of application or removal of adhesive products. The term refers to conditions that are related to application and/or removal of medical adhesive products, such as tension blisters and skin stripping.</p> 
<p>Skin stripping Tension blister</p>	<p>These terms were removed from the terminology. The experts considered that the umbrella term medical adhesive related skin injury was more appropriate and should replace tension blister and skin stripping. One rationale was that it was unclear whether the injury to the skin occurred due to the process of applying or removing the medical adhesive product.</p>