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An electronic approach to minimising moisture-associated skin damage in ostomy patients

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ABSTRACT

Marked developments in the design of ostomy appliances in recent years have revolutionised stoma care and management but the prevalence of peristomal skin complications continues to be problematic with incidence rates ranging from 10% to 70%. Despite requisite pre and post-operative education for new patients, complications continue to arise – even under the close supervision of specialist nurses. Prolonged exposure of the skin to high pH stoma effluent is widely accepted as a key contributor to the onset of moisture-associated skin disease and it is our hypothesis that a "smart wafer", employing electrochemical manipulation of local pH, could mitigate some of the issues currently plaguing ostomy management. Current electrochemical research strategies translatable to stoma care are presented and their possible implementations critically appraised.

Introduction

Despite numerous advances in the treatment and management of ostomies in recent years, the incidence of peristomal skin damage remains a perennial problem. An estimated one million patients, in the US alone, live with the routine of ostomy care and it is likely that a significant number will have experienced some form of peristomal skin complication (PSC) [1]. Statistics on the prevalence of the complaint are highly variable (ranging from 10% to 70%) [1–5] and reflect issues in the reporting procedures adopted by different healthcare systems [4,6]. What is clear however is that there is an abundance of evidence to support the conclusion that PSCs and their prevention remains problematic [1–5]. There have been considerable advances in the material design employed in the manufacture of the stoma appliances [7–9], but, in contrast, there has been relatively little innovation in terms of the technological options for actively preventing PSCs. The latter can be attributed, at least in part, to the rather unglamorous nature of research within this field such that there has been a long-recognised failure to attract both the interest of researchers and substantive funding from the main governmental research funders. A step change is needed in the technological approaches to ostomy management and it is our hypothesis that an opportunity for such change could be emerging. It is our assertion that the impetus may come, not from any renewed interest from the medical funders but, rather startlingly, as a consequence of investigations into energy harvesting – a field with undoubted global importance, but one which is wholly unrelated to the more immediate concerns of ostomy patients suffering with PSCs.

Inflammation and erosion of the skin surrounding the stoma site is remarkably common and can arise through a number of factors but, in the overwhelming majority of cases, it can be attributed to prolonged exposure to urine or stool [1–5]. The collection of effluent from the stoma is almost invariably achieved through the use of a pouch system, which is attached to the abdomen through an adhesive skin wafer (flange or faceplate) placed over the stoma [7,9]. A hole is cut in the wafer to allow the stoma to protrude with the surrounding wafer acting as a physical barrier preventing the stoma output from contacting the underlying skin [7–9]. Correct sizing of the wafer aperture is critical to minimise exposure of the unprotected skin [9–16] but, even with precise positioning, moisture from the stoma will eventually, inevitably, saturate the protective hydrocolloid barrier – particularly at the mucocutaneous junction and will lead to erosion of the adhesive [7]. The degree and rate of exposure will depend on a number of factors related to the stoma output (principally frequency, volume and composition). The presence of skin creases and the mechanical flexing of the wafer as a consequence of activity can greatly exacerbate the failure of the seal and allow ingress of moisture leading to irritation which, if left untreated, can rapidly develop into a PSC [1–5].

Inadequate seals at the skin-wafer interface are often attributed as a primary cause of peristomal moisture-associated skin damage (MASD) and there are many studies which confirm that those in the immediate post-operative period are most at risk [3,4]. It is

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tempting to suggest that patient inexperience is the root cause and that more extensive pre and post-operative patient education could alleviate the problem [10–16] but, while such programs certainly minimise the incidence of MASD, they cannot prevent the complication [3–5]. Neither heightened vigilance nor the availability of expertise would appear to preclude the possibility of PSCs occurring. As recent studies have noted, the clinical manifestation of MASD can arise in a large proportion of patients within hospital settings and while under the close supervision of specialist nursing staff [4].

A significant contributor to the apparent randomness of peristomal MASD is the fact that the aetiology and pathophysiology of peristomal MASD are only partly understood and can be profoundly dependent on the type of ostomy and the nature of the effluent produced [1,2]. The influence of demographic and clinical factors on MASD has been investigated and it has been found that patients with an ileostomy were significantly more likely to experience peristomal MASD than those with a colostomy [17–19]. It is widely recognised that the high moisture content (80–85%) and the presence of digestive enzymes in ileostomy effluent are (two) key factors that can trigger the onset of MASD [1–5], but it is important to note that changes in skin pH brought about by prolonged contact with moisture originating from the stoma will also have a significant role [20,21]. The pH of the skin lies within a narrow acidic region between 5 and 6 [21] and, historically, it was thought that the regulation of an acidic pH on the skin surface (the "acid mantle") was an antimicrobial defence [22]. Low pH can significantly inhibit the proliferation of pathogenic microbes (i.e. *Staphylococcus aureus*) [22,23], but it is now known that pH mediates a host of intrinsic functions which are vital for the maintenance of the Stratum Corneum's (SC) barrier properties [20,21].

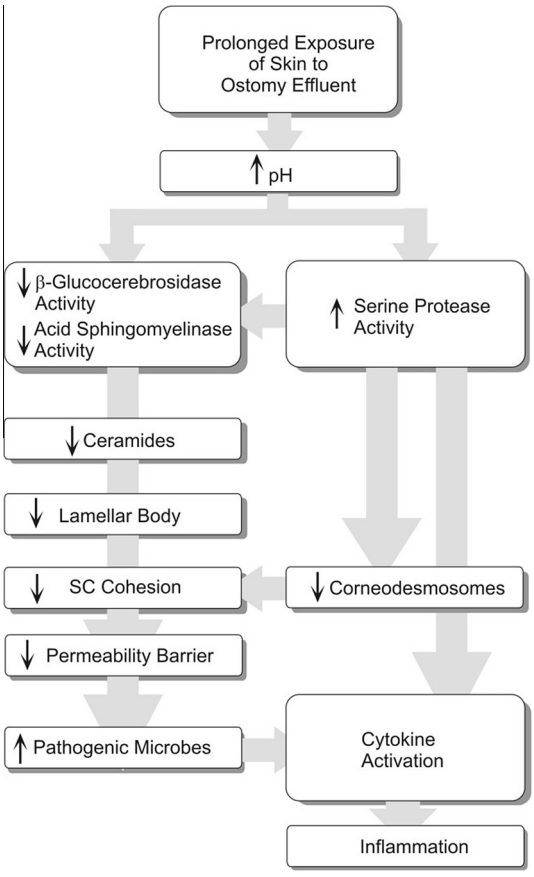

Fig. 1. Influence of increased pH on skin homeostasis.

The structure of the SC is a complex composite of corneocytes encased in an envelope of cross-linked protein and lipid and held together by modified desmosomes – all of which are organised in a dense lamellar structure to provide a hydrophobic barrier [20,21]. Healthy skin function requires the intricate interplay of numerous components to ensure balance between desquamation and the formation of the cornified envelope barrier such that skin homeostasis is maintained. The underlying processes are heavily dependent upon pH and thus it is of little surprise that the prolonged exposure to more alkaline solutions arising from the stoma will compromise the integrity of the barrier and lead to the onset of inflammation as indicated in Fig. 1 [20,21]. The formation of the core lipophilic components that constitute the envelope (typically ceramides) involves a complex interplay between a series of pH dependent enzymes – principally β-glucocerebrosidase and acidic sphingomyelinase. These have pH optima of 5.6 and 4.5, respectively and any increase in the pH as a consequence of exposure to the stoma effluent will have an impact on their emollient effects [24]. In particular, there is a 10-fold reduction in the activity of β-glucocerebrosidase at pH 7.4 [25]. Additionally, the activity of serine proteases and tryptic enzymes (Kallikriens 5 and 7) which are linked to desquamation (through degradation of the corneodesmosomes) will be increased [26–28].

The hypothesis

Exposure of the peristomal skin to effluent and the consequent change in pH therefore has the combined effect of reducing the integrity and cohesion of the SC's barrier ability through disruption of the lamellar structure and corneocyte adhesion [27,28]. The result is inflammation which, if left unchecked, will precipitate the onset of irritant dermatitis and allow the ingress of pathogenic microbes [23,24]. Could maintaining the local pH at the immediate skin surface minimise potential complications? It could be envisaged that by controlling pH at the skin surface, the detrimental cascade highlighted in Fig. 1 could be minimised. Adopting such a strategy is not new and there have been numerous attempts to create acidic barriers [21], but the continuing issue with MASD would suggest that these are ineffective when dealing with stoma effluent. The hypothesis posed here relates to whether it is appropriate or indeed technically possible to consider the application of an electronic "smart" wafer system (Fig. 2) which can actively measure the pH and respond accordingly. The electrochemical control of processes that involve either the production of protons (H^+) or their consumption (and hence enable pH manipulation) have been successfully demonstrated in a number of electroanalytical [29,30] and electroporation systems [31–34] but the underpinning reactions are now being extensively researched in solar conversion and hydrogen fuel cell technologies [35–41]. Our contention is that these processes which, in principle, can lead to changes in pH profile at the electrode, could be harnessed to control the pH at the skin surface.

The evidence base

Ancillary evidence for the efficacy of maintaining an acidic barrier comes from studies targeted at irritant diaper dermatitis where prolonged exposure to urine and faeces similarly leads to elevated skin pH, the magnitude of which can be directly correlated to the severity of the consequent dermatitis [44–46]. It has been demonstrated that the application of diapers modified with an acidic cellulose component can maintain a lower pH (in the region of pH 4.5–5.5) and have been effective in resolving pre-existing skin lesions [46]. However, there is an issue with this approach as regards the frequency with which the diaper is