Journal of
Composites Science

MDPI

Review

Evolution of Ostomy Pouch Design: Opportunities for Composite Technologies to Advance Patient Care

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Abstract: Stoma surgery can be critical in helping to restore the well-being of patients suffering from gastrointestinal disease or injury but it inevitably comes with numerous psychological and physiological complications. Disposable pouch systems which enable the collection of bowel waste have revolutionized stoma care but providing robust, discreet devices that can efficiently meet the requirements of the patient can be challenging. Pouches must securely store a microbially active waste whilst preventing leakage, protecting the underlying skin from inflammation and minimizing odor. All of this needs to be achieved within the design constraints of a pouch that is easy to manage and yet still maintains a discreet body contour. Stoma collection has moved from the waste being collected in butyl rubber pouches to much more elaborate systems incorporating assemblies of polyvinylidene chloride, ethylene vinyl acetate, ethyl vinyl alcohol and polyvinyl alcohol with new, skin-friendly adhesive such as hydrocolloid and silicones impregnated with ceramides and aloe. Moreover, 3D printing has emerged as a means of providing personalized stoma pouches that can potentially address the age-old issue of leakage. Despite such advances, stoma pouches have evolved slowly over the past 70 or so years. A survey of the literature reveals an abundance of quality-of-life studies but a dearth of reports addressing the key technological challenges. Consequently, this narrative review considers current stoma pouch technology and highlights the issues that continue to afflict stoma patients. Research and patent literature is critically appraised in terms of current pouch technology and the potential opportunities for new composite materials are identified.

Keywords: stoma; ileostomy; colostomy; pouch; peristomal; leakage

Citation: Gilpin, V.; Magee, N.; Scott, C.; Pourshahidi, L.K.; Gill, C.I.R.; Simpson, E.E.A.; McCreadie, K.; Davis, J. Evolution of Ostomy Pouch Design: Opportunities for Composite Technologies to Advance Patient Care. *J. Compos. Sci.* **2024**, *8*, 388. https://doi.org/10.3390/jcs8100388

Academic Editors: Dong-Wook Han and Francesco Tornabene

Received: 22 August 2024
Revised: 16 September 2024
Accepted: 24 September 2024
Published: 27 September 2024

1. Introduction

The formation of an intestinal stoma (ostomy) is a common surgical procedure performed as a consequence of treating gastrointestinal injury and disease [1]. Inflammatory bowel disease (IBD), trauma and colorectal cancer (CRC) can often lead to stoma formation and it has been estimated that there are some 205,000 ostomates in the United Kingdom (700,000 throughout Europe and 1 million in the United States/Canada) [2]. The stoma can be either a temporary intervention to allow the bowel to heal or become a more permanent modification to the patient's physiology. A stoma is formed through bringing a healthy section of the bowel through the abdominal wall and stitching it in place to create an artificial opening through which fecal matter can pass [1]. The nature of the latter will vary depending on the position at which the stoma is created with those introduced into the small bowel (ileostomy) resulting in a liquid discharge [2] whereas those located within the colon (colostomy) are typically more solid [3]. In either case, the waste is collected in a disposable pouch which adheres to the skin surrounding the stoma [1–5] as indicated in Figure 1.

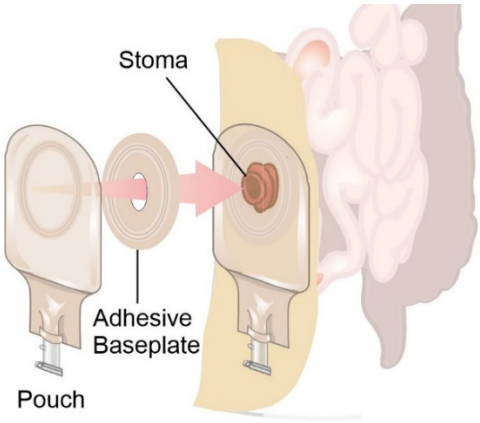

Figure 1. Example of a 2-piece drainable ileostomy pouch and its application.

Stomas can be critical in improving health, restoring function and removing pain with quality-of-life (QoL) surveys confirming dramatic improvements in well-being post surgery [6–11]. Nevertheless, the presence of the stoma brings numerous physical and psychological challenges. The day-to-day management of the pouch can be problematic where device failure will directly impact on the well-being of the wearer. The potential for leakage is a persistent worry for many, which, when combined with unpleasant odor, noise and issues of body image, can lead to anxiety and distress [8,9,12,13]. These factors can impact relationships and social activities and, when the patient returns to work, induce considerable worry over employer, colleague and customer perceptions [14]. Unfortunately, peristomal skin complications characterized by changes in the underlying skin morphology can cause significant pain and discomfort [15–21]. Moreover, the degradation of the skin surrounding the stoma can affect the adhesion of the stoma appliance leading to leakage and thereby greatly exacerbate those psychological conditions.

Thus, far from being a simple waste container, the pouch must meet the demanding requirements of patient accessibility and acceptability whilst also acting as a secure containment vessel for a waste product that will be microbially active [1,3]. This is an important consideration given that a pouch system must adhere securely to the skin throughout a multitude of everyday activities, collecting waste until the point at which the bag can be safely emptied or disposed of. Therefore, the materials employed in the design of a pouch system are crucial to meeting the needs of patients. This review will critically assess the complex interaction of material selection and device design and highlight emerging developments that seek to redress the limitations of current commercial systems.

2. Stoma Characteristics

A description of the surgical options relating to stoma construction are beyond the scope of this review and the reader is directed to more comprehensive works [1,22,23]. It is, however, beneficial to briefly consider the key features of the bowel, how they process the waste and hence the implications for pouch design and material selection. A summary of the core components of the bowel and sites at which stomas are commonly introduced is shown in Figure 2. After digestion of food and drink has begun in the stomach, it will pass into the small bowel (duodenum, jejunum and ileum) where the nutrients and fluid are actively and passively absorbed. The further that digesta passes along the intestine, the greater the amount of fluid is absorbed and the less liquid like the output from a stoma is liable to be. The most common position for the formation of an ileostomy is the ileum but this will be dependent on the nature of the surgery. In general, the output will have a liquid or porridge-like consistency. Those suffering from short bowel syndrome (SBS), where the intestinal length is typically less than 1.5 m, have an absorptive capacity that is much diminished and the stomal output can be largely fluid [24]. Moreover, it is common for SBS patients to experience high output volumes (>1.5 L/24 h) which, again, can place significant demands on the pouch, its adhesion to the skin and its

drainage [25–27]. The large intestine (caecum, ascending, transverse, descending and sigmoid colon) is responsible for thickening the fecal matter into soft stools for passage through the rectum and anus, excluding its extensive gut microbiota-derived metabolic activity [28,29]. Colostomies are normally formed at the descending or sigmoid portions and will result in a much more solid output when compared to an ileostomy.

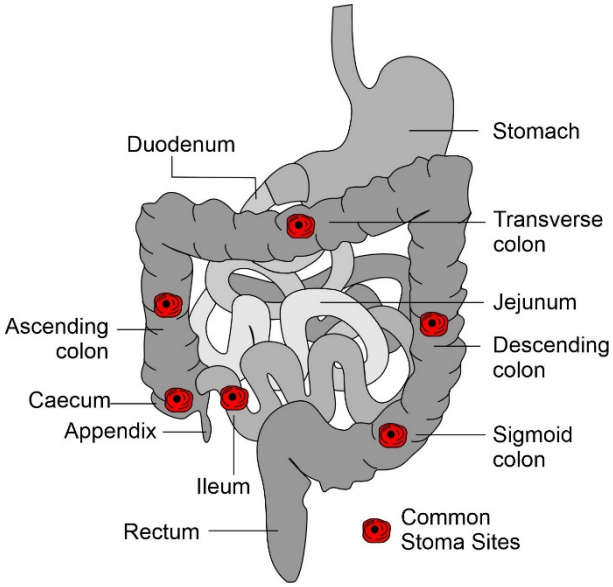

Figure 2. Structure of bowel and typical ostomy sites.

The absence of sphincter muscles at the opening of the stoma means that patients will generally have no conscious control over output though there are strategies which can be employed, at least in some instances, that can moderate the frequency and timing. The greater volume associated with ileostomies will typically require the pouch to be drained 4–6 times per day while, in contrast, the preconcentrated output of the colostomy patient may only need emptying 2–3 times daily [2,30]. There have been a number of surgical innovations in relation to the creation of a "continent" colostomy or ileostomy and their development have been reviewed by Doughty (2008) [1]. In terms of the former, the patient can proactively irrigate the stoma to stimulate evacuation of the stool and thereby offers an option for moderate continence [31]. Most patients, however, will be dependent on the pouching system to provide a more secure means of control over inadvertent leakage.

3. Stoma Pouch Origins and Development

The first record of a successful stoma surgery dates to 1793 where a colostomy was performed on a 3-day year old infant and, despite the questionable approach to asepsis at the time, the patient was reported to have survived to their 45th year [1]. Sadly, their approach to the daily management of the stoma is not recorded. While the prevalence of stoma surgery increased in later years with advances in anesthesia and infection control, in the absence of any commercial pouch system, more rudimentary approaches to waste collection would have been prevalent. These typically involved the compression of a suitable receptacle (glass, porcelain or metal) to the skin by means of a belt [1,32–34]. The first major advance in stoma pouch systems is attributed to the rubber Koenig Rutzen bags. These arose in 1944 and were designed to be re-usable pouches held to the skin by a latex adhesive. The first practical disposable pouch is attributed to Elise Sørensen (1953) which led to a colostomy bag whose design, although materially simpler, is not unlike the systems currently in use [35,36]. Rather than physical compression, pouches are typically held in place with a suitable adhesive with original Coloplast (Humlebæk, Denmark) zinc oxide paste having given way to more dermatologically acceptable variants such as Karaya gum [37] and now, almost universally, hydrocolloid. The latter was an

adventitious discovery where it had previously been used as dental adhesive but which is now the main interface between skin and pouch [4,5,38].

Stoma pouches tend to be classified as 1-piece, 2-piece, closed or drainable, with more recent developments introducing toilet flushable systems [3,4]. Examples of some of the different types of pouch/baseplate are shown in Figure 3. The 1-piece system integrates the pouch and the baseplate (also referred to as a "flange") which adheres the system to the abdomen. These are typically closed systems common to colostomies and the entire unit is removed and replaced at the time of emptying. Two-piece closed systems require only the pouch to be discarded at the time of emptying. The baseplate is left on the skin and can have a typical wear time of 3–5 days [30]. As the baseplate/skin interface is left undisturbed, the 2-piece system can be more beneficial for those with sensitive skin or for those prone to peristomal skin damage [39]. Moreover, it is also a potentially cheaper option as only the pouch component is discarded rather than the entire appliance. The higher output frequency associated with ileostomies will generally require a drainable pouch system. The 2-piece system can either be attached to the baseplate via an adhesive ring or via a plastic interlocking ring—the latter providing a reassuring "click" when connected. However, the mechanical nature of this type of assembly does require a greater degree of manual dexterity when affixing a new pouch [40].

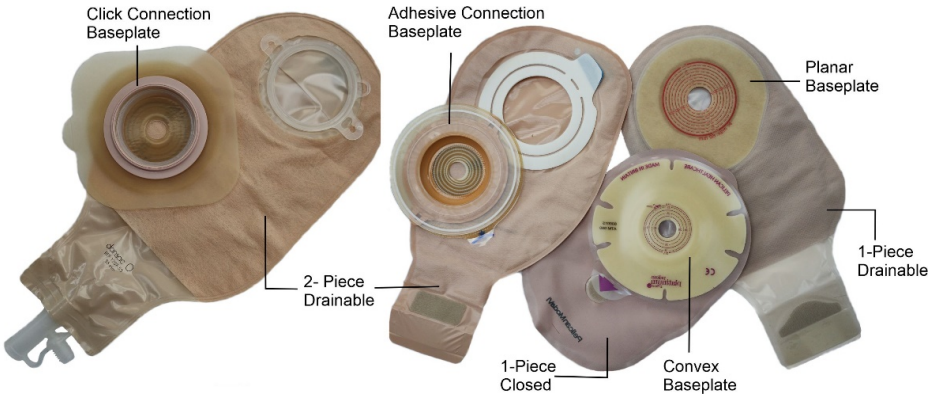

Figure 3. Common stoma pouch designs.

4. Stoma Pouch Market Evolution

Pouch systems are myriad and costs have increased markedly in England over the last decades rising from GBP 198 m (2010) to GBP 368 m in 2021–2022, based on annual prescription cost analysis data (PCA) [41]. This substantial rise highlights the increasing prevalence of ostomy formation, attributed in part to the growing incidence of inflammatory bowel disease and colorectal cancer—both of which are common causes for ostomy surgery. A study by King et al. (2020) has indicated that ulcerative colitis and Crohn's disease cases in the United Kingdom have been increasing over the past two decades at a rate of 2–3% per annum with similar figures common across the western nations [42]. These figures are also being supplemented by changing lifestyles of the Asian, Latin American and Middle Eastern countries where the prevalence of IBD, which has hitherto been relatively low, is now recognized as increasing in prevalence [43]. Similarly, colorectal cancer is predicted to increase as populations age but it is also noted that the incidence of CRC within younger populations has also started to increase. It is perhaps of little surprise that the global market for ostomy products in 2023, valued at $3.9 bn, is predicted to rise to $6.1 bn by 2033 [44].

Despite the availability of an enormous portfolio of pouch options, patients continue to encounter a variety of physical problems (skin irritation/inflammation, leakage). This is reflected in the PCA where adhesive discs, pastes, fillers and skin protectants account for over GBP 64 m (~19% of the annual cost) [41]. A common issue relates to the fact that the skin surrounding the stoma is neither flat nor static and this uneven topography creates

opportunities for the bowel fluid to pool [22,23]. It is important to note that bowel waste is a highly active substance containing a multitude of digestive enzymes (e.g., proteases, carbohydrases and lipases) and an ever-changing microbial population [45]. Such an enzymatically complex milieu degrades unprotected skin leading to peristomal inflammation and subsequent physical transformation that further diminishes pouch adherence to the skin, generating a self-propagating cycle of problems which ultimately increase the anxiety of the ostomate.

The myriad of pouch systems results from differences in the size of the baseplate (diameter of the stoma), composition (flexible, skin protection), shape (flat or convex) and connection (1- or 2-piece). Pouches can be closed, drainable, flushable and can be transparent (typically post surgery—hospital use) or opaque (post discharge) [2,31]. Convex baseplates, where the hydrocolloid is designed to press into the recessed skin around the stoma and reduce the potential for pooling, are available for most of the pouch configurations but these are not a universal solution as the skin contours surrounding the stoma are seldom uniform. This can be very painful for those with an ileostomy where the output is largely liquid and any defect in the adhesive seal will lead to exposure of the skin to the digestive enzymes. Abdominal movement can also be problematic and serve to further undermine the seal—especially where there is a skin crease and mechanical flexing of the skin leads to the partial delamination of the baseplate from the skin and thereby allows the ingress of bowel fluid. Given this environmental dynamism, finding a suitable solution that mitigates against changes in peristomal skin shape and condition often requires a trial-and-error approach. Employing stronger adhesives to ensure a stronger skin seal is limited as the need to regularly remove the pouch/baseplate (especially for 1-piece systems) can lead to skin-stripping, exacerbating the problem further [38]. It can be argued that the use of the secondary adhesives, fillers and pastes will give rise to similar problems and can further complicate the management processes where the removal of residual adhesive particles can require more aggressive abrasion or the use of remover solutions that can damage peristomal skin. Historically, the baseplate has been structurally firm and less responsive to dynamic changes in abdominal shape but newer designs have attempted to provide a higher degree of mechanical flexibility such that they better match the body's contours. Nevertheless, despite the availability of such products, leakage or the potential for leakage remains a considerable source of worry for ostomates [8,9,12].

5. Material Limitations and Opportunities

The diversity of materials that have been employed in the development of ostomy pouches is highlighted in Figure 4. Much of the material information is derived from the patent literature where the precise composite formulations tend to be proprietary and commercially sensitive. Nevertheless, the main material components tend to be universally employed and are discussed in turn within the following sections.

5.1. The Baseplate

Irrespective of the supplier, the pouch will be held to the abdomen via an adhesive baseplate which comes either directly integrated with a given pouch or individually with the pouch fixed to a flange through either an adhesive collar or mechanical clip (Figure 3). Historically, the baseplate would have been composed of Karaya gum (KG) which is a natural product produced by Sterculia urens trees and is composed of a partially acetylated, ramnogalacturonane-type polysaccharide exhibiting a high viscosity that creates the adhesive tack necessary for securing the pouch [37]. While KG is still available, it has largely given way to proprietary hydrocolloid formulations based on a composite composed of moisture-absorbing carboxymethylcellulose, gelatin, pectin and polyisobutylene [46]. A polyethylene (PE) or polyurethane (PU) outer layer completes the assembly serving as an external moisture barrier. An example of a hydrocolloid baseplate (Dansac Nova 2^{TM}, Wokingham, UK) after being worn for a period of 24 h is detailed in Figure 5. Prior to application, hydrocolloid base plates will typically have a uniform consistency

(Figure 5A) but sustained exposure to fluid from the ileostomy will induce swelling of the adhesive layer and the gradual erosion of the protective barrier around the site of the stoma (Figure 5B) leaving only the top PE or PU outer film [47]. It is important to note that the simple absorption of water is not in itself sufficient to lead to the breakdown of the film but rather induces swelling [18,19]. It can be seen from Figure 5B that prolonged exposure to the bowel fluid can lead to an annulus of eroded hydrocolloid around the stoma site which will result in the underlying skin being directly exposed to the hydrolytic enzymes and could lead to peristomal complications.

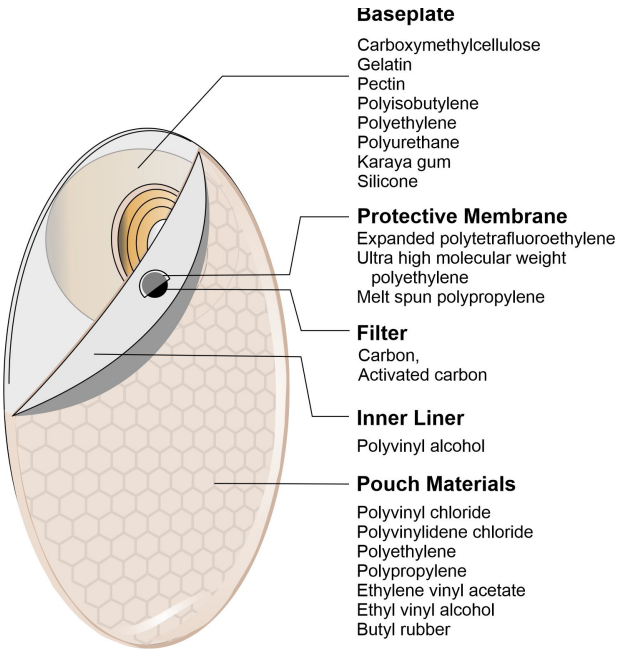

Figure 4. Common material components that have been used in the production of stoma pouches.

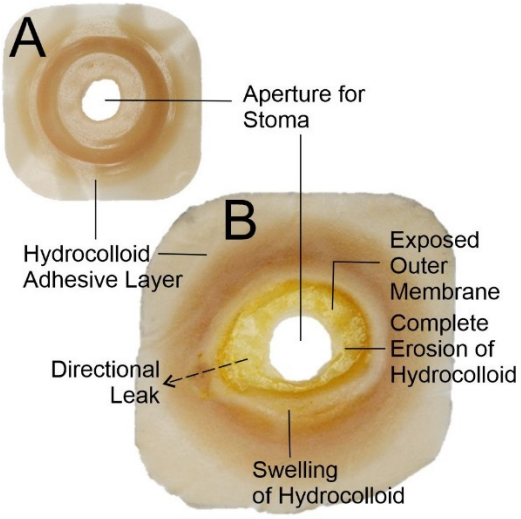

Figure 5. Dansac Nova 2^{TM} hydrocolloid baseplate (**A**) before use and (**B**) after being worn for 24 h. (adapted from Ref. [47]).

Moisture management at the peristomal skin site is critical as the failure to disperse accumulated water effectively can lead to a number of skin complications. Water diffuses through the skin from the hydrated lower layers of the dermis to the stratum corneum where it will exit either via the sweat glands or as transepidermal water loss (TEWL). A fine balance of TEWL is required to maintain skin health and the addition of an adhesive

barrier can have a great impact. It can easily be envisaged how an occlusive device (low water permeability) will lead to moisture buildup in the stratum corneum. The latter has a considerable absorptive capacity (up to 400% of its dry weight) [19] and in healthy skin, removal of the barrier will result in the accelerated evaporation of the accumulated water until equilibrium is restored. As such, it could be expected that short-term occlusions, even if repetitive, should not induce any adverse effects [48,49]. In contrast, prolonged occlusion could lead to maceration of the skin ultimately compromising the skin's barrier function and lead to moisture-associated skin damage (MASD) [50,51].

In the case of a hydrocolloid baseplate, its initial hygroscopic nature typically draws moisture away from the skin. Unfortunately, as more moisture is absorbed, the hydrocolloid layer swells in volume (Figure 4), becomes deformed and can increase in adhesive strength. Once saturated, however, the hydrocolloid wafer loses the capacity to manage moisture and can, if left untreated, lead to the onset of MASD. This, along with enzyme hydrolysis of the hydrocolloid, leads to degradation of the baseplate integrity resulting in a marked reduction in its adhesive function reducing wear time and increasing the likelihood of leakage. As such, hydrocolloid formulations used in baseplate production need to exhibit a balance between being sufficiently adhesive that they can secure attachment of the pouch to the patient's skin but not so much that the pouch cannot be removed without causing excoriation. Skin stripping at the peristomal site can arise when the bond between the baseplate/pouch and the skin is stronger than the bond between the cells at the peristomal skin interface. Unfortunately, repeated excoriation can greatly increase the pain associated with stoma management with the skin damage making attachment of subsequent baseplates difficult. Importantly, it makes the skin more vulnerable to infection and disease. Frequent removal of adhesive devices from the stoma site can lead to a greater risk of skin tearing, known as medical adhesive-related skin injury (MARSI) [52].

Baseplates are distributed in a non-sterile form but can, in some instances, be supplied in airtight packaging to maintain the consistency of the hydrocolloid layer. Moisture loss from the exposed periphery of the baseplate when worn is common—leading to a hard edge which, when the underlying skin flexes with movement, can cause painful abrasion. Framing the border of the baseplate with tape (i.e., zinc oxide or a flange extender) is often used as a strategy to help minimize leaks but also to reduce exposure to the dehydrated edge.

Historically, the baseplates have been relatively rigid, particularly around annulus that defines the stoma site and, as such, delamination from the skin could occur upon movement of the abdomen. More recent designs have attempted to address this issue through increasing the mechanical flexing of the base adhesive. Coloplast's Sensura® (Coloplast, UK) family of baseplates attempted to address this issue by providing a much more flexible baseplate and have recently deviated from the more normal circular/elliptical design and have released their Sensura Mio® (Coloplast, UK) pouch systems which have a unique five-petal design. These baseplates are of a softer composition which is intended to improve the ability of the base plate to conform to the contours of the abdomen. The Sensura family, like most other brands, incorporates a convex variant as a means of countering recessed stomas but, significantly, the increased mechanical flexibility of the baseplate enables a concave conformation [53]. This mechanical flexibility across the baseplate can be particularly advantageous where the convex shape allows initial placement around the stoma with the baseplate allowed to transition to a concave conformation when the stoma is positioned on a bulged or curved portion of the abdomen. While such designs can assist adhesion across larger surface variations in the body morphology, smaller defects in the skin (typically creases caused by scar tissue around the stoma arising from the original surgery) can still be problematic. Where the overlying baseplate crosses a narrow skin valley, the walls of the crease can remain untouched by the adhesive and hence can still act as a channel for the stoma fluid to enter thereby increasing the risk of leakage. It must be acknowledged that most pouch manufacturers have also recognized the need for softer baseplates and have followed suit with their own variants demonstrating

improved flexibility (i.e., Salts Healthcare's Confidence BE® (Birmingham, UK) family of pouches).

In most cases, the hole through which the stoma emerges will either be cut to a specific size/shape prior to dispatch to the ostomate or the ostomate will manually cut the hole themselves prior to fitting. In either case, there can be issues with the cut shape following the perimeter of the stoma accurately and can lead to areas of the peristomal skin being unprotected. Moldable hydrocolloid rings have been available as a stoma accessory for many years and typically employed as a means of countering the issues of recessed and non-uniformly shaped stomas which can assist in protecting the peristomal skin. ConvaTec (Reading, UK) have launched Esteem+™ baseplates that have directly incorporated this strategy into their baseplates. Rather than attempting to cut a hole in the baseplate that accurately mimics the outline of the stoma, the hole is manually manipulated or "worked" by the patient to provide a tightly fitting collar around the stoma and thereby proffers a one-step seal that better protects the underlying skin.

Ostoform (Mullingar, Ireland) have released a novel baseplate design based on their FlowAssist™ technology where a moldable hydrocolloid collar is combined with a non-absorbent spout which aims to direct the stoma output away from the stoma/hydrocolloid junction [54]. The latter is a prime location for irritation and hence it could be envisaged that when in an upright stance, it should help control the flow direction into the bottom of the pouch and minimize peristomal skin complications. It is less clear what happens when the ostomate is asleep and the body is horizontal. Pooling of the stoma output can be envisaged and will render the spout ineffective though the additional hydrocolloid collar could help increase the absorptive capacity of the baseplate.

While baseplate formulations are invariably proprietary recipes, most employ much the same components with discrete variations intended largely to optimize manufacturability and the resulting adhesive properties of the wafer. As mentioned, a core issue with hydrocolloid baseplates relates to the fact that as they absorb moisture, they become tacky and more adhesive and require a greater peel force to remove and hence are more likely to result in pain and discomfort. The situation can be further complicated where parts of the hydrocolloid may be excessively swollen and leave sporadic residues across the peristomal site that require additional abrasion to remove [55]. More recently, there has been considerable innovation in the composition to enhance the dermatological properties with the addition of skin protectants such as aloe vera (Salts Healthcare, Birmingham, UK), ceramides (Hollister Corporation, Libertyville, IL, USA) or Manuka honey (Clinimed, High Wycombe, UK) [15,56]. It could be argued, however, that the introduction of silicone products is one of the more significant advances in recent years and represents the first true shift away from the more conventional hydrocolloid systems [19]. While silicone sprays have long been used as skin-friendly barrier films, filler gels and adhesive removers, issues with moisture management have historically prevented the extrapolation of the material to the production of baseplates. However, composite systems have now arisen that take advantage of the softness of the material, its hypoallergenic nature and intrinsic mechanical flexibility that enhances its ability to conform easily to body shape. It also possesses a low surface energy that facilitates an adhesive "tack" to the skin without compromising the skin surface upon removal.

The majority of manufacturers employ hydrocolloid baseplates and the slow development trajectory of silicone baseplates can be attributed to the hydrophobic nature of the material. While this property is ideal from the perspective of a protective film designed for short duration effect—it can be much more problematic when considering moisture management within the baseplate. The formation of a silicone composite containing hydrophilic components, however, can introduce a tunable micro/nano porosity that can facilitate the transport of water. The composition can be manipulated to enable the transit of water vapor whilst still also acting as a barrier to liquid water where the active principle is for the water to negotiate a pathway through the hydrophilic domains. Wang and colleagues (2017) have provided a more comprehensive discussion of the interplay between the components and

the nuances needed for control of TEWL [57]. In contrast to the hydrocolloid systems, the water is not absorbed by the silicone composite baseplate and hence the baseplate does not undergo the swelling that impacts on adhesion. Investigations comparing the peel force of hydrocolloid and silicone systems have found that skin stripping is more prominent in the former. As such, it could be expected that such systems could offer greater protection from both MASD and MARSI that can afflict users of hydrocolloid baseplates. Swift et al. (2020, 2023) have provided an eloquent discussion of the evolution of silicone technology in wound and ostomy care and it is notable that at present, of the many ostomy product manufacturers, only Trio Healthcare (Atlanta, GA, USA) have released a silicone ostomy range (Genii^{TM}) [18,19].

5.2. Standard Pouch Designs

Traditionally, pouch systems have used little more than a single-layer film to encapsulate the fecal waste but modern systems are much more complex assemblies that can incorporate flatus filters, viewports and drains. While a transparent pouch is initially used immediately post surgery in order to aid visual assessment of the stoma function, this will normally be replaced by an opaque system and, in most cases, an outer, non-woven textile layer is normally included for aesthetic purposes to remove the "plastic feel" of the pouch. The latter will be comprised of a thin occlusive film (typically 25–150 micron) comprised of polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyethylene (PE, LDPE), polypropylene (PP), ethylene vinyl acetate (EVA) or ethyl vinyl alcohol (EVOH) either as distinct components or composite layers and thermally bonded at the periphery to provide the sealed pouch system. The pouches are invariably multilayer with spot welds used to create distinct internal compartments (i.e., for gas exchange). Despite the many advances in polymer film technology, the original Koenig Rutzen rubber pouches remain available on U.K. prescription and it is noteworthy that their inherent re-usability provides a much more environmentally sustainable option than modern designs. The use of synthetic polymer-based films have encountered issues over the use of plasticizers but there is a notable shift from Di-(2-ethylhexyl) phthalate to the terephthalate derivative (ConvaTec). A typical 1-piece drainable pouch system (Oakmed, Northampton, UK) is shown in Figure 6 where the cross-section highlights the configuration of the multiple polymeric layers.

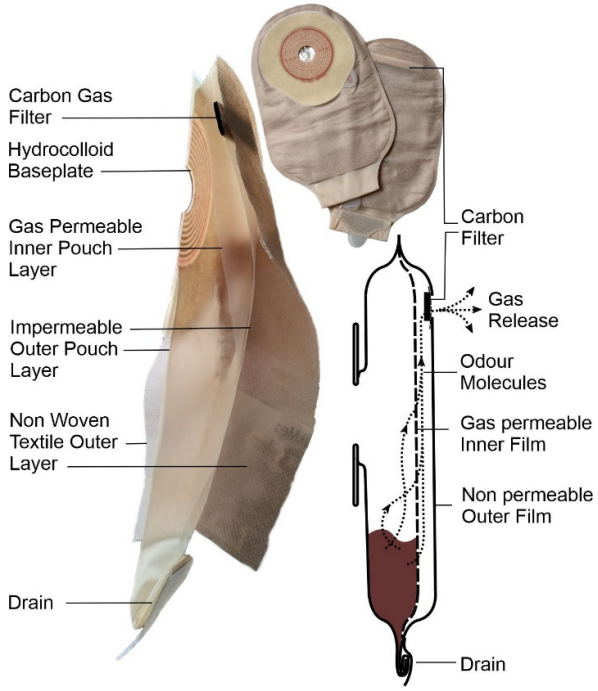

Figure 6. Components and function of an Oakmed drainable pouch.

5.3. Pouch Filters

Pouches invariably contain a carbon flatus filter located at the top of the pouch but, in contrast to the near uniformity of the external pouch shape, their composition and integration can be variable. As the bowel fluid enters the pouch, gaseous products from the microbial flora within the waste can build up leading to the ballooning of the pouch. This can be distressing for those wishing to conceal the presence of the bag but the inflation can also undermine the integrity of the adhesive seal. The subsequent pressure from stoma gas within the pouch can lead to the seal between the skin and baseplate being breached resulting in leakage of bowel fluid. A gas-permeable barrier film covers the filter but its design can vary significantly from one type of pouch to another. The filter itself is invariably carbon based (fiber, particle or foam) and electron micrographs detailing the surface morphology of two examples extracted from two different commercial pouches are detailed in Figure 7. Irrespective of manufacturer and design, the intention is to present a large surface area with a torturous path to enable adsorption of odor chemicals prior to venting to the outside.

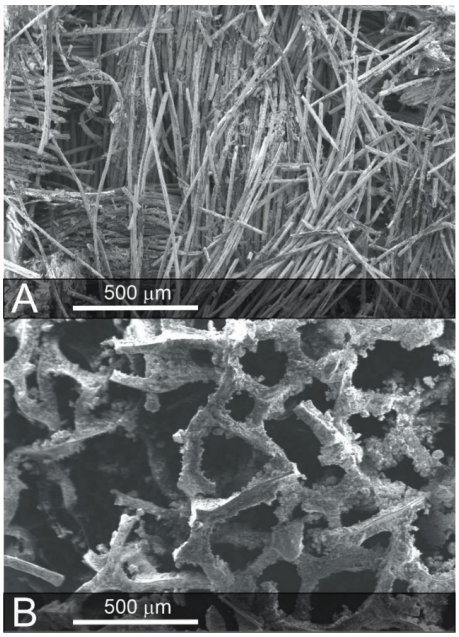

Figure 7. Scanning electron micrograph of carbon filters extracted from (**A**) Oakmed and (**B**) Coloplast pouch systems.

Issues arise where the inward face of the filter becomes contaminated by fecal matter and block the transport of gas leading to ballooning. Placing a gas-permeable membrane—typically expanded polytetrafluorethylene (ePTFE) or ultra-high-molecular weight polyethylene (UHMW PE) over the filter can reduce the non-specific adsorption but it is common to use a pre-exchange barrier to assist in screening out the liquid waste. It has been estimated that the ePTFE component accounts for almost 50% of the component cost of the filter assembly and it is of little surprise that there is interest in spun-melt materials (i.e., polypropylene) being potentially more cost-effective alternatives [58]. In the case of the Oakmed design shown in Figure 6, a pre-separation barrier film is used to cover an entire side of the pouch providing a large surface area for gaseous exchange prior to reaching the filter vent. Nevertheless, quality-of-life surveys continue to highlight ballooning as a concern and there has been substantial activity within the patent literature. In most cases, the approach has been to address the problem through design strategies rather than material advances. Some of the former are considered in Figures 8 and 9. Hollister have proposed creating a natural barrier through simply folding the top portion of the pouch over to create a crease (Figure 8A) that aims to reduce the transport of fecal matter

towards the filter [59]. Entrenous (Chicago, IL, USA) proposed a manual vent port [60] as indicated in Figure 8B and while the absence of any filter may be very effective in releasing gas, it does not counteract the inevitable odor. One solution is to have a disposable filter (Figure 8C) that can adsorb the odor chemicals and which can be replaced as soon as ballooning arises. The filter can be "renewed" through insertion into the vent and where the previous (blocked filter) is forced directly into the pouch.

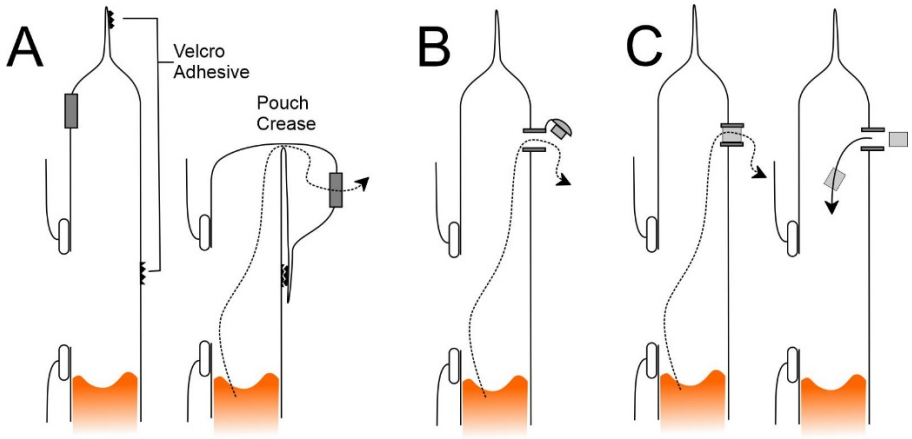

Figure 8. Proposed strategies for improving filter operation. (**A**) Hollister fold-over pouch and Entrenous vent port in the absence (**B**) and presence (**C**) of replaceable filter.

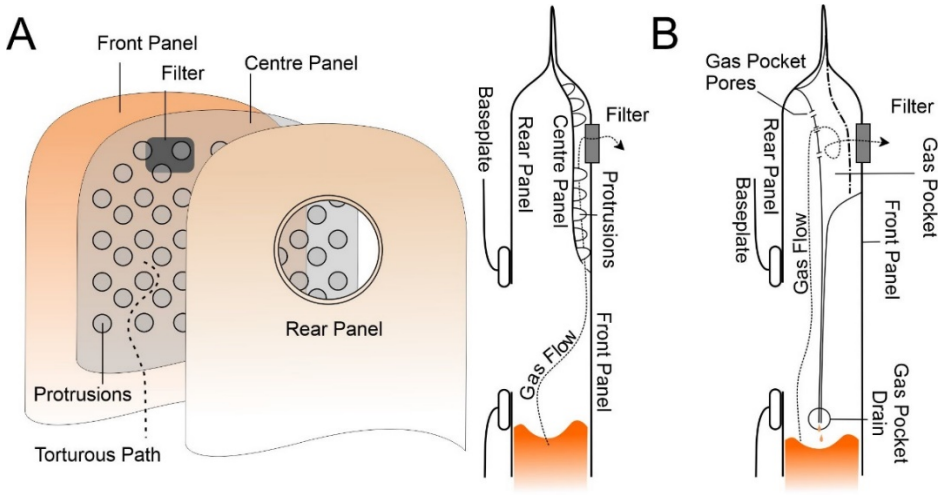

Figure 9. Film barrier approaches to improved filter operation. (**A**) ConvaTec 3D pleated/protrusions [61] and (**B**) Salts Healthcare Active Filter system [62].

One of the issues with using a simple internal barrier film is that once contaminated, it can often become physically laminated against the filter interface further reducing the opportunity for gas transport. The general approach to counter this issue has been to introduce internal pockets within the pouch to facilitate gaseous separation and prevent liquid fecal matter reaching the filter interfaces. ConvaTec have proposed pleated barrier films or films with shaped 3D protrusions to aid in increasing surface area and to maintain a gaseous void between film and filter (Figure 9A) [61].

Salts have employed an innovative pocket system in their Confidence BE pouches (Figure 9B) which aims to reduce the ingress of liquid matter to the filter and through the judicious use of spot heat welds, the internal films are physically separated from the outer walls such that when stoma fluid enters the pouch, the gas pocket is preserved [62]. As such, when gas accumulates within the pocket, manual compression can be used to relieve pressure through the filter. It is noteworthy that both ConvaTec and Salts Healthcare exploit

designs that rely largely on imposing a physical impediment to the transport of the liquid as the solution to maintaining an active filter.

Virgin-Elliston and colleagues (2023) took an innovative approach to the filter system by placing the pre-filter (gas separation stage) close to the stoma site [63]. A 360 degree/full-circle design (Figure 10) was investigated with both colostomy and ileostomy patients and compared to a partial/dual filter system. The frequency of ballooning was found to be significantly lower with the circular design and, given the contrasting position of the filter to conventional approaches, could spur alternative designs in the future.

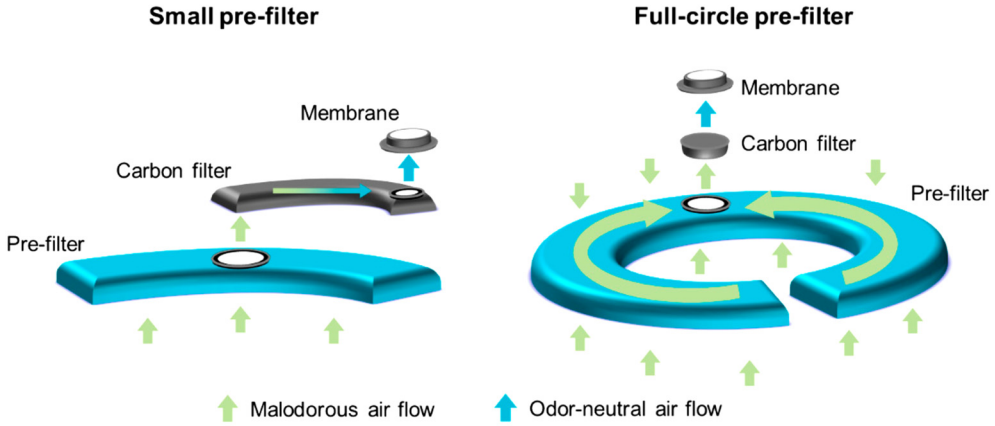

Figure 10. Schematic of the small pre-filter (used in the dual filter system) and the full-circle pre-filter (reproduced from Ref. [63]).

The use of gelling agents with anti-odor components (i.e., ConvaTec Diamonds™, Trio Pearls™) is an alternative strategy to counter odor for those with an ileostomy. These are added directly to the pouch when a new pouch is applied and serve to increase the viscosity of fluid waste. In principle, such sachets can aid in reducing the likelihood of leakage through simply reducing the mobility of the fluid and its ability to attack the hydrocolloid of the baseplate. However, it can be envisaged that their ability to combat odor will be dependent on the nature of the fluid itself. In contrast to the particulate carbon within the flatus filter, the carbon elements delivered by sachet will be in direct contact with fluid and could easily be saturated by the adsorption of hydrophobic molecules from the bowel fluid, of which only a few may be odorous.

5.4. Biodegradable Pouches

Those with an ileostomy will tend to use pouches with a drain and will typically empty the contents 3–6 times daily, depending on the nature of their condition. It can be expected that the pouch itself would be replaced on a daily basis as a means of avoiding the buildup of odor as mentioned in the previous section. In contrast, colostomy pouches are typically closed and discarded each time it is necessary to empty the contents. In either case, the contents are disposed of via the toilet but the plastic pouch (and baseplate in the case of a 1-piece system) will normally be placed within a sealed bag (often impregnated with an anti-odor agent) and discarded into the domestic trash. The use of 2-piece configurations can simplify the process where only the pouch is removed. While it can be appreciated that the drainable nature of ileostomy fluid helps to minimize contact with bodily waste, the greater solidity of the colostomy output can make disposal more problematic [64].

In most cases, manipulation of the stoma pouch, baseplate and cleaning of the peristomal skin can be performed without the need for gloves where there are adequate hand-washing facilities. Patients regularly report emptying the pouch to be most difficult and, as Berry (2005) notes, some 16% of respondents reported becoming distressed if pouch excreta touched their hands [64,65]. Colostomy pouch liners (Welland Freestyle Flushable™ (Welland Medical, Crawley, UK) and Dansac Nova Life 2™) have been promoted as a means of easing the cleaning process where the stool is passed into a disposable biodegrad-

able inner liner held within a more conventional, non-degradable, outer pouch [3,4,66]. Temporary removal of the latter allows the liner (complete with stool) to be discarded directly via the toilet where it is expected that sustained contact with water leads to a breakdown in the integrity of the liner film thereby releasing its contents. As with the pouch material, formulations are proprietary and commercially sensitive. Nevertheless, surveying the patent literature reveals that the inner liner will typically be based on polyvinyl alcohol (PVA) which is water soluble but, through blending with various polymers (i.e., starch, cellulose), it is possible to impart a degree of water resistance [67–69]. There has been substantial interest in the development of moisture-resistant films based on composite PVA formulations for the food packaging sector and it is likely that some of that knowledge could be directly transferable to stoma product design [69,70]. There is obviously a fine balance to be struck between a liner that holds its structure long enough to allow the capture of the stool and aid manipulation during disposal and one which will readily degrade upon entering the sewage system. A critical constraint in the application of the degradable inner liner is that the stool must be well formed such that the absorption of water by the liner is minimized. Where the output is particularly liquid, swelling of the film will occur, leading to a loss in structural integrity which could inadvertently lead to the pouch failing. It must be noted that, in such cases, the outer pouch would still retain the bowel contents thereby preventing a catastrophic uncontrolled leakage event.

Given the ~205,000 ostomates currently within the United Kingdom, disposal of the pouch will clearly lead to a considerable amount of waste. Even assuming a modest replacement of 1 pouch per day would lead to some 73 million pouches being discarded each year. Assuming a 1-piece system weighs around ~20 g per unit while a 2-piece system is typically just over double due to the baseplate, a simple estimate would equate ~1500 tonnes annually. In context, of 2.5 million tonnes of U.K. plastic waste annually generated, this is a small proportion but there is a growing awareness of the need to reduce waste where possible. Flushable liners may ease the handling and disposal of colostomy output and can be expected to reduce the number of outer pouch changes but the physical/chemical constraints pertaining to the moisture content of the stool prevent them from more widespread use. The challenge of developing a truly biodegradable pouch applicable across the spectrum of stoma types and morphologies remains elusive and is complicated by the fact that the enzyme and microbial constituents of the stoma output are key actors in the biodegradative process. As yet, there is no universal pouch system that successfully balances a liquid (and hydrolytically active) output with rapid sewage system dispersibility. The two would appear to be incompatible and compromises, such as the flushable liner, are liable to be the more practical pathway, at least in the short term, to reducing waste.

6. 3D Printing and Personalized Pouch Systems

There is a spectrum of pouch/baseplate systems available from which a patient can choose and therein hopefully acquire a system that suits their needs. However, as mentioned earlier, stoma morphology is complicated and for a significant proportion of patients, leakage and the complications that come with it remain problematic. At present, the only recourse is to employ barrier creams, fillers and pastes to accommodate variations in the skin surrounding the stoma, such that a uniform base is created. Advances in 3D printing, however, could offer a new approach to personalized baseplates whereby the shape of the latter is directly tailored to the contours of an individual's stoma. The use of 3D models for visualizing anatomical structures prior to surgery is well known and usually constructed from CT scan data [71–73]. Similar techniques have been used to help inform stoma patients [74,75] but it could be envisaged that similar technology could be employed to map the peristomal contours and allow the printing of a customized baseplate. The obvious issue has been the need for the acquisition of CT scan data but Zahia and colleagues (2022) found that handheld scanners produce topological data that are of equal or better accuracy and avoid the issues with X-ray techniques and their availability [76].

The demonstration that handheld scanners can reliably inform the production of personalized baseplates is of particular importance in terms of accessibility. It could be envisaged that a peristomal map could be obtained by a stoma care nurse during the initial consultations post surgery which can then be fed directly to a stoma care company. In some respects, there already exists some justification for the practicality of this approach where, at present, the shape of the stoma outline can be sent to the pouch manufacturer and the baseplate hole automatically cut and supplied to the patient. It is important to note that even this relatively simple step could be enhanced through the use of 3D printing technology where a tailored template is employed to aid ostomates in cutting their own baseplate [75].

An issue with the direct production of personalized baseplates relates to the number required and the ability of 3D printing to satisfy volume production which will easily reach the multiple million levels per annum—even for nations with relatively low numbers of ostomates. While it could be anticipated that printed baseplates would be more expensive than traditional systems—they could be reserved for use with stomas that are particularly prone to leakage. This could be a more cost-effective option when considering the total cost (i.e., fillers and treatment of clinical complications that can arise as a consequence of frequent leakage). A second problem has traditionally been the limited range of materials available for 3D printing and the ability to reproduce the soft formats that are common to conventional baseplates. This is an ever-evolving field and there continue to be advances in the nature of the materials available and their optimization such that they retain the softness needed to adjust to movement of the abdomen [77]. The use of scanner technology to produce customized 3D-printed silicone baseplates has been proffered by Odapt (Barcelona, Spain) [78]. While the silicone may be flexible, it is unclear how the management of the TWEL is achieved (cf. Trio Genii™ baseplates) and the system is still in the development stage. Nevertheless, the ability to print soft, wearable baseplates [77,78] highlights how far 3D printing has progressed and shows clear signs of innovation that could significantly improve the QoL for those with problematic stomas.

7. Conclusions

Stoma surgery presents a tremendous physical and psychological challenge to patients and the provision of a truly effective pouch system would dramatically improve their quality of life and facilitate a return to normal social and occupational activities. While early systems were rudimentary collection devices physically pressed to the skin, recent years have seen substantial advances in skin adhesives and polymers to minimize leakage and provide unobtrusive devices. There have been substantial improvements in adhesives—moving from karaya gum and cyanoacrylates to more skin-friendly hydrocolloids and silicones. The transformation of pouches has also been significant where unwieldy butyl rubber may have once resembled a clumsy appendage, pouches are now much more discreet and comfortable which is in part due to the intricate combination of a variety of polymer systems. Designs have embodied a multitude of proprietary combinations of PVC, PVDC, EVA and EVOH. The use of engineered PVA has also seen the development of flushable liners which has greatly improved the ease with which colostomy patients can manage their pouch. Advances in 3D printing and scanner technologies offer yet further opportunities for personalized healthcare through customized baseplate production or the provision of barriers that could improve the adhesion of conventional products—ideally removing the need for fillers and pastes.

The adoption of new materials has been central to pouch development and, in many cases, these have revolutionized daily stoma management. Nevertheless, leakage, odor, peristomal complications and disposal continue to present challenges and, as patient numbers continue to increase, it is clear that much remains to be done. Pouches are quintessentially a composite product and hopefully, the perspective presented here will stimulate new interest within a field that has been starved of material advances.

Author Contributions: Conceptualization, V.G., N.M., C.I.R.G. and J.D.; methodology, V.G., C.S. and J.D.; investigation, V.G., N.M. and C.S.; resources, C.S., L.K.P. and J.D.; data curation, V.G., N.M. and J.D.; writing—original draft preparation, V.G., C.S. and J.D.; writing—review and editing, V.G., N.M., L.K.P., C.I.R.G., K.M., E.E.A.S. and J.D.; supervision, L.K.P., C.I.R.G. and J.D.; project administration, J.D. and C.S.; funding acquisition, J.D., C.I.R.G., L.K.P., K.M. and E.E.A.S. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded by the UK Medical Research Council (MRC), grant number MR 1/029561/1.

Data Availability Statement: No new data were created in the course of the narrative review.

Conflicts of Interest: The authors have received funding from the UK Medical Research Council to develop a leak detection system for stoma pouches. Neither the funders nor any collaborating partner to the project had any role in the design of the present study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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