Original article

A risk factor model for peristomal skin complications

ABSTRACT

For people living with an ostomy, leakage and peristomal skin complications (PSC) are common issues that often appear together. Better means of preventing these issues could improve the quality of life of these patients. The purpose of the research presented here was to identify and build a model of risk factors for PSC.

Risk factors were identified via discussion sessions with Coloplast's internal ostomy care experts, the Coloplast Skin Expert Panel, the Global Coloplast Ostomy Forum (COF), and 18 national COF boards, collectively representing more than 400 ostomy care nurses from around the world. Risk factors were identified by these expert groups, analysed, clustered into categories, and discussed in several stages, resulting in the risk factor model for PSC, comprising three overall categories and their related risk factors (n=24). Consensus on the model was achieved using a modified Delphi process involving over 4000 experts within ostomy care from 35 countries. In parallel, a systematic literature review of risk factors for PSC was performed to identify primary literature supporting the model. Relevant articles published from 2000 until August 2020 were included in the review, and 58 articles were found to support 19 out of the total 24 risk factors. The risk factor model for PSC was ratified by the Coloplast Skin Expert Panel and the Global COF and holds potential to be included in guidelines for healthcare professionals and to be used as a tool in daily clinical practice.

Keywords leakage, ostomy care, peristomal skin complications, risk factor model

For referencing Hansen AS et al. A risk factor model for peristomal skin complications. WCET® Journal 2022;42(4):14-30

DOI https://doi.org/10.33235/wcet.42.4.14-30

Submitted 2 September 2022, Accepted 23 November 2022

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INTRODUCTION

For people living with an ostomy, the risk of leakage and peristomal skin complications (PSC) are typical concerns. It has been estimated that 91% of people living with an ostomy worry about leakage and 76–77% have experienced leakage within the last 6 months[1,2]. Worrying about leakage may challenge everyday activities and social interactions; further, leakage is a major contributor for developing PSC.

In one study, four main diagnoses (faeces-induced erosion, maceration, erythema and contact dermatitis) accounted for

77% of all ostomy-related diagnoses, and these were all related to contact with ostomy effluent[3]. When the integrity of the skin is damaged, adherence between the skin and the ostomy product is challenged, potentially leading to further leakage[4]. As a result, pain, anxiety and a loss of confidence in the ostomy product may occur, leading to a risk of less participation in social activities and a negative impact on the individual's quality of life[1].

Lack of awareness of PSC seems to be common. A study reported that less than half (43%) of the individuals with PSC were aware of the problem[4]. Improving awareness of risks factors that may lead to leakage and PSC among people living with an ostomy has a great potential to help preventing PSC.

Several factors in addition to those inherent to ostomy products may predispose people living with an ostomy to PSC[4,5]. Some of these risk factors can be addressed at routine visits to the clinic to increase awareness in people living with an ostomy and initiate mitigating actions as part of a prevention strategy against PSC. Identification of these risk factors may also give rise to new interventions for preventing leakage and PSC in people living with an ostomy.

The concept of a consensus-based PSC risk factor model was identified as a potential solution to increasing the awareness of which risk factors can be intervened upon to prevent the development of PSC. The purpose of the research presented here was to develop consensus on the most important risk factors for PSC and incorporate them in a risk factor model, while simultaneously identifying evidence and gaps in the literature pertaining to these risk factors. The aim is to guide practice in ostomy care and support healthcare professionals and people living with an ostomy in the prevention of PSC. We hypothesised that the development process of a comprehensive PSC risk factor model to support daily practice in preventing PSC will highlight a gap of good or high quality evidence from the literature to support the model.

METHODS

Development of the risk factor model

The risk factor model for PSC was developed in collaboration with the Coloplast Skin Expert Panel (consisting of seven experts in the field of dermatology, wounds and ostomy care), the Global Coloplast Ostomy Forum (Global COF), an exclusive entity consisting of 13 internationally recognised experts, and the national COF boards. The national COF boards represent more than 400 ostomy care nurses from around the world, including Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Italy, the Netherlands, Norway, Poland, Slovakia, Sweden, the United Kingdom, and the United States of America.

The development of the risk factor model for PSC was a multistep process with four main stages, namely scoping, exploring, convergence and ratification (Figure 1).

In Step 1 (the scoping stage), an initial meeting was held with the Skin Expert Panel to brainstorm risk factors for PSC. The panel members individually made suggestions for risk factors; further discussions within the panel helped identify additional risk factors and risk factor categories. This process was repeated with the Global COF, the national COF boards, and internally at Coloplast with ostomy care experts from the Research and Development (R&D) and Marketing departments. In parallel, a literature search on PSC risk factors was conducted. The results of this search were shared with the Skin Expert Panel and the Global COF to guide the next steps.

In Step 2 (the exploring stage), an internal Coloplast skin project group categorised all data gathered from the different expert panels in the scoping phase into themes. These themes, with interlinked risk factors, were presented to the Skin Expert Panel, Global COF, and the national COF boards, and they were each tasked with further condensing these themes into overall risk factor categories.

In Step 3 (the convergence stage), the overall risk factor categories were presented to the Skin Expert Panel and the Global COF before discussion sessions were held within the national COF boards to align the content and nomenclature of these categories. The Coloplast internal skin project group updated the categories based on the input from the national COF boards and prepared a final draft. Agreement on this draft was obtained from the Skin Expert Panel and the Global COF before an international consensus process was conducted, resulting in the final version of the risk factor model[6,7]. The consensus process is described in detail in a

Figure 1. Method for development of the risk factor model for PSC.
A. *Step 1: Scoping stage. Meetings were held to brainstorm on risk factors for PSC with the Skin Expert Panel, Global COF, national COF boards and internally in Coloplast with experts in ostomy care from R&D and Marketing. Discussions with the Skin Expert Panel and Global COF based on a scoping literature review guided the further process Steps 2 and 3.*
B. *Step 2: Exploring stage. After all the data gathered in Step 1 had been grouped into 10 themes by the internal Coloplast skin project group, the Skin Expert Panel, Global COF, and national COF boards condensed the 10 themes even further, resulting in three overall categories to be outlined by the Coloplast skin project group.*
C. *Step 3: Convergence stage. The three categories were presented to the Expert Skin Panel and Global COF before discussions in the national COF boards aimed to align the content and name the three categories, and the Coloplast internal skin group adjusted the three categories to a final draft. In parallel, a systematic literature review was performed to support discussions and consensus building. The Skin Expert Panel and Global COF agreed to the final draft before an international consensus process resulted in the final version.*
D. *Step 4: Ratification stage. The final risk factor model for PSC was ratified by the Expert Skin Panel and the Global COF.*

separate publication[7]. Briefly, using a modified Delphi process, consensus was reached among ostomy care specialists across 35 countries. This stage was supported by a systematic literature review (see description below) to identify the level of evidence behind each identified risk factor. In Step 4 (the ratification stage), the final risk factor model was ratified by the Skin Expert Panel and the Global COF[7].

Literature review

A systematic review was performed during the convergence stage to support the discussions and consensus building and ascertain the level of evidence behind the identified risk factors. The literature search was performed by an information specialist using the PubMed (including Medline), Derwent World Patents Index, and CINAHL (Cumulative Index to Nursing and Allied Health Literature) databases. The searches were performed on 19 June 2020 (PubMed and Derwent) and 19 August 2020 (CINAHL).

The search timeline was restricted to articles published between 2000 and 2020 (August). The time interval was chosen based on receiving relevant published literature; 10 years was considered a too limited time interval to receive an optimal amount of relevant literature within ostomy care. The search was made sufficiently broad by searching for text words related to skin descriptors and combining these with skin issue and ostomy synonyms. Furthermore, search terms were mapped to the following Medical Subject Headings (MeSH) in Medline: skin, dermatitis, dermis, epidermis, dermatologic agents, ostomy, colostomy and ileostomy. The search strings generated were combined with Boolean operators (AND, OR) to arrive at the final results (Figure 2).

The study selection process is depicted via a PRISMA flow chart in Figure 3. Duplicates were identified manually based on titles and abstracts. These were removed, and thereafter the remaining references were independently screened by two authors based on titles and abstracts. The title or abstract would include words related to ostomy/stoma and problems or PSC to be included. The two independent screenings were compared, and a list of articles made based on the agreed selection. If there was doubt about the relevance of an article, a third author was consulted. The selected articles were evaluated based on exclusion criteria such as reviews, overviews, case studies/case series with less than 10 subjects,

	Search strings
1	Skin OR dermatitis OR dermis OR epidermis OR dermatologic
2	"risk factor*" OR damage* OR complication* OR problem* OR issue* OR discomfort OR trouble or impairment
3	Stoma OR stomas OR ostomies OR ostomy OR colostomy OR ileostomy or peristomal

The search strings were combined as:
(1 AND 2) OR (1 AND 3) OR (2 AND 3)

Figure 2. Method for the literature search: search strings.

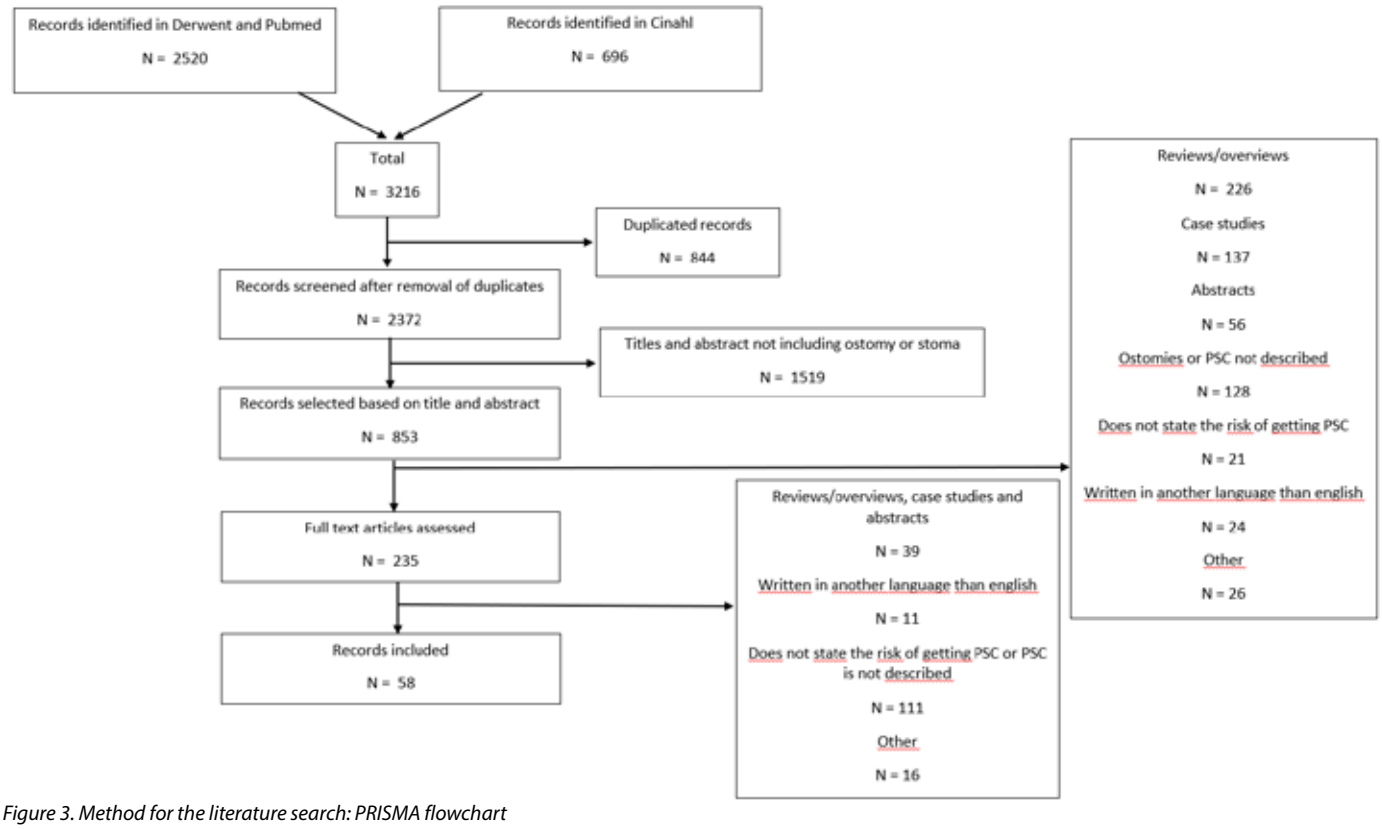

Figure 3. Method for the literature search: PRISMA flowchart

opinion pieces, editorials, conference abstracts, and book chapters; the aim was to find published primary literature providing clinical evidence to support the risk factor model. Articles written in languages other than English were also excluded. Thereafter, the full-text versions of the remaining articles were read and studies included if evidence for the identified PSC risk factors were described and both reviewers agreed on the inclusion. Lastly, the evidence quality of the selected articles was evaluated using a 3-point scale adapted from John Hopkins evidenced-based practice methodology[8]. The selected articles found to support the risk factor model were consolidated and approved by the Coloplast skin expert panel and the Global COF.

RESULTS

Risk factor categories from the risk factor model

In Step 1 (the scoping stage) of the PSC risk factor model development, more than 100 risk factors were identified. In Step 2 (the exploring stage), these were condensed into 10 ensuing themes: skin-related; user characteristics; resources; environment; mental compliance and adaption; stoma and body profiles; output properties; product usage, compliance, and routines; product performance; and training and education. These 10 themes with interlinked risk factors were condensed further with the help of the expert panels (the Skin Expert Panel, Global COF and the national COF boards) resulting in three suggestions for the overall risk factor categories – Healthcare system, Individual with an ostomy, and Ostomy product (Figure 4).

In Step 3 (the convergence stage), the content and nomenclature of the three categories were refined further, resulting in 24 risk factor subcategories (Figure 4). In Step 4 (the ratification stage), these risk categories and subcategories were ratified by the Skin Expert Panel and the Global COF to constitute the final risk factor model.

Literature search results

Based on the combined searches, 3216 references were found (Figure 3). After removing 844 duplicates, 2372 articles were screened by title and abstract, and 235 read and screened for the final selection. It was not possible to retrieve four articles; they were therefore excluded. Four articles[9–12] did not display any statistics but were included because of their relatively large sample sizes, ranging from 18–796 subjects. In total, 58 articles were included in the review, supporting 19 of the 24 risk factor subcategories identified. Of the included articles, 27 were found to fit into the Healthcare system category[11,13–38] (with 32 citations within this category), 43 into the Individual with an ostomy category[4,5,9,12–19,22,24–28,30–32,34–37,39–57] (74 citations), and 13 into the Ostomy product category[9,10,25,39,41,55,58–64] (16 citations); several articles were found to fit into two or more categories or subcategories. The articles were divided into three evidence levels[8]: Level I (high), five articles[38,51,54,61,64]; Level II (good), 43 articles[4,10,12–22,24–37,41,44–50,52,53,55–60]; and Level III (low), 10 articles[5,9,11,39,40,42,43,62,63]. A list of the individual studies supporting each identified risk factor within each risk factor category is available in Appendix 1.

Risk factor categories

Healthcare system

The Healthcare system category included seven system level PSC risk factors related to contact, guidance and input from the healthcare system (Figure 4). In the literature review, 27 articles[11,13–38] (one Level I[38], 24 Level II[13–22,24–37], two Level III[11,23]),

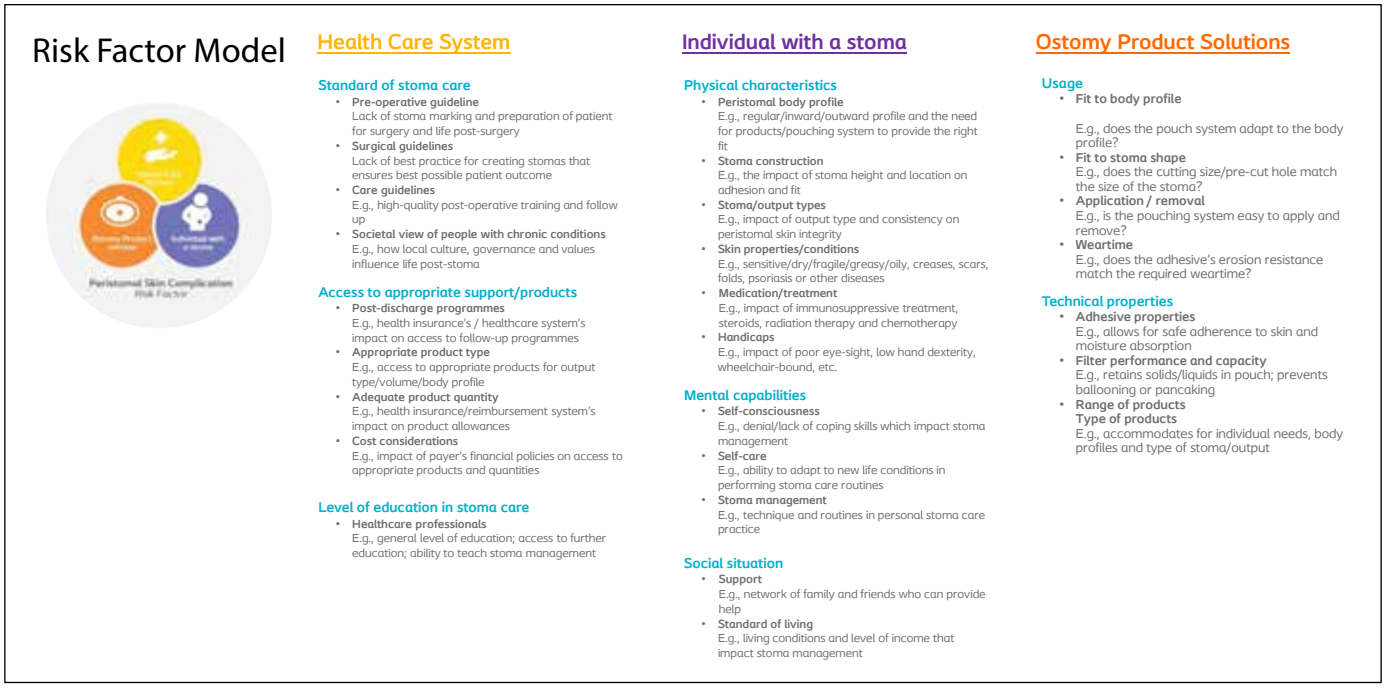

Figure 4. The risk factor model for PSC

with 32 within-category citations, were found supporting five of these seven risk factors (Appendix 1).

Among the individual risk factors in this category, preoperative guidelines include guidance on preparing the patient for the surgical procedure, marking the spot for the ostomy, and advising the patient on life with an ostomy post-surgery; seven articles[14,16,21,27–29,33] (all Level II) were found to support the importance of preoperative ostomy site marking as a risk factor for developing PSC.

Surgical guidelines include best practices for creating ostomies for the best possible patient outcome; 19 articles[13–15,17–20,22,24–27,30–32,34–37] (all Level II) were found providing clinical evidence for surgical techniques and indicating the importance of selecting a surgical procedure that reduces the risk of getting PSC. Care guidelines include high quality postoperative training and follow-up; three articles[21,23,38] (Level I, II and III: one each) were found pertaining to guidelines for ensuring the quality of postoperative training of the patients. Post-discharge programs include whether health insurances and healthcare systems provide access to follow-up programs; two clinical trials[29,38] (Level I and II: one each) were found to provide evidence on the importance of adequate access to post-discharge programs and demonstrated that support from healthcare professionals post-discharge as well as pre-surgical education of the patient decreased the risk of developing PSC.

Healthcare professionals as a risk factor subcategory include the general level of education, access to further education, and the type of care and surgical procedures undertaken; one qualitative study[11] (Level III) discussed the importance of the level of education of healthcare professionals to provide optimal support to the patient. Other risk factors in this category were access to appropriate ostomy product types and quantity to cover any needs, and societal view of people with chronic conditions; no supporting evidence was found for these subcategories.

Individual with a stoma

In this category, a total of 10 individual level risk factors for PSC were identified (Figure 4). The literature review identified 43 articles[4,5,9,12–19,22,24–28,30–32,34–37,39–57] (two Level I[51,54], 35 Level II[4,12–19,22,24–28,30–32,34–37,41,44–50,52,53,55–57], six Level III[5,9,39,40,42,43]), cited 74 times, supporting nine of these 10 risk factors (Appendix 1). One of these, peristomal body profile, includes whether the peristomal area has a regular, inward or outward (bulging) profile and informs the selection of the most appropriate ostomy products to provide the right fit and a secure seal. Nine articles[9,15,27,32,35,40,42,48,56] (six Level II, three Level III) were found to support peristomal body profile, including a high body mass index (BMI) and parastomal hernias, as an important risk factor for PSC. Ostomy construction indicates how ostomy height and location may impact the adherence and fit of the ostomy product; 18 articles[9,12,13,17–19,22,24,27,30,31,34–37,41,47,50] (17 Level II, one Level III) were found dealing with the importance of ostomy construction in terms of appropriate diameter and height as well as the optimal surgical technique. Ostomy output type is a PSC risk factor depending on the output consistency and volume; 20 articles[4,5,12,14,16,18,25–28,39,41,43,45,46,49,52–54,57] (one Level I, 16 Level II, three Level III) found evidence that an ileostomy increases the risk of PSC when compared with other ostomies.

The individual's skin properties/conditions may also have an impact on PSC as the skin can be sensitive, dry, fragile, greasy, or oily, or have creases, scars, folds, wounds or underlying diseases; three articles[41,42,54] (Level I, II and III: one each) alluded to skin properties/conditions as risk factors for developing PSC, particularly in terms of impaired mechanical quality of the barrier, skin creases, or age of the patient. Medication/treatment as a PSC risk factor includes side effects from immunosuppressive treatment, steroids, radiation therapy and chemotherapy; six articles[15,26,32,36,55,57] (all Level II) showed chemotherapy and conditions such as diabetes to be risk factors for PSC. Both age and disabilities were identified as risk factors. Disabilities that may potentially and adversely impact on PSC are factors such as poor eyesight, low hand dexterity, or being a wheelchair user; nine articles[5,18,25,28,35,36,40,48,57] (seven Level II, two Level III) identified age as a risk factor for PSC.

Self-consciousness/self-care was also deemed to have an impact on PSC as denial or lack of coping skills could affect ostomy management and the ability to adapt to new life conditions; five articles[5,14,18,31,35] (four Level II, one Level III) related to this subcategory were found, particularly those dealing with gender as a risk factor for PSC. Ostomy management is a risk factor depending on the individual's ability to perform ostomy care techniques and routines in personal ostomy care practice; three articles[9,41,51] (Level I, II and III: one each) showed the importance of ostomy management skills. Support from family or the individual's social network to provide help was identified as another risk factor as was the individual's standard of living, e.g., living conditions, level of income, hydration and nutrition, which may impact ostomy management; one article[44] (Level II) supported standard of living as a risk factor displaying an impact of social restriction. No articles providing evidence for support from family/social network were found.

Ostomy product

The consensus development process identified seven product level PSC risk factors (Figure 4). In the literature review, 13 articles[9,10,25,39,41,55,58–64] (two Level I[61,64], seven Level II[10,25,41,55,58–60], four Level III[9,39,62,63]), cited 16 times, were identified as supporting five of these seven risk factors (Appendix 1).

An identified risk factor, fit to the ostomy shape, highlights the fit between the pre-cut hole in the wafer and the ostomy; two articles[9,41] (Level II and III: one each) were found providing evidence for this risk factor subcategory. Wear time is a risk factor for PSC, including how the chosen ostomy product will match the recommended and preferred wear time; three articles[39,41,55] (two Level II, one Level III) were found dealing with issues related to wear time. The range and type of products accommodating individual needs, peristomal body profiles,

and the type of ostomy output are considered PSC risk factors; three articles[25,39,63] (one Level II, two Level III) were found describing, for example, the importance of accommodating individual needs to minimise PSC risk (e.g., by using a convex product).

The adhesive property of the ostomy product is a risk factor as it impacts adherence to the skin, moisture absorption and erosion; seven articles [9,10,58–61,64] (two Level I, four Level II, one Level III) were found describing how different components in the adhesives affect the peristomal skin. Filter performance and capacity of the ostomy product are also risk factors determining the ability of the ostomy product to retain solids and liquids and prevent ballooning or pancaking; only one relevant article[62] (Level III) was found in this category. The fit to the body profile, which concerns how the ostomy products adapt to the peristomal body profile, and the ease of application or removal of the ostomy product, were also identified as PSC risk factors; however, no supporting articles were found in the literature.

DISCUSSION

The research presented here depicts the development of an international consensus-based risk factor model for PSC which resulted in 24 risk factors organised in three overall categories, namely those at the system level (Healthcare system), individual level (Individual with an ostomy), and product level (Ostomy product). A systematic literature review identified 58 articles providing evidence for 19 of the 24 risk factors; it also highlighted the gap in good or high quality evidence for specific risk factors included in the model.

In recent years, ostomy products have been the subject of innovation and development to improve the fit or the performance of the ostomy pouching system. However, recent research showed that leakage and PSC are still impacting peoples' lives and causing worries among people with an ostomy[65,66]. In a broader perspective, risk factors other than those inherent to ostomy products may offer unexplored opportunities to prevent leakage and skin issues by other means.

The consensus-based risk factor model for PSC gives an insight into which risk factors should be considered in the prevention of leakage and PSC. This risk factor model was developed in collaboration with ostomy care specialists, dermatologists and professors in wound and skin care representing 13 different countries. International consensus was reached among ostomy care specialists across 35 countries using a structured modified Delphi process. The large number and geographic diversity of the participants make this risk factor model unique in the field of PSC, allowing for regionally appropriate emphasis and implementation variations based on system requirements and patient expectations.

A systematic literature review demonstrated the evidence base for the identified risk factors, further strengthening and consolidating the model. For this systematic review, a broad search was conducted in several databases, and study selection was performed independently and thereafter aligned by two different reviewers, making the process robust and the quality of the review sound. By excluding study designs furnishing low levels of evidence, including case studies/series with <10 subjects, the quality of evidence of the included studies seems reasonable. The included studies were also quantitative in nature (except four articles[9–12]), providing statistical evidence for the risk factors. Therefore, the identified primary articles are believed to display an adequate level of clinical evidence (majority classified as Level II) to support the risk factor model, particularly in a field that is believed to be sparse on clinical evidence.

Among the three overall categories in the model, Individual with an ostomy had the most supporting evidence with 43 articles[4,5,9,12–19,22,24–28,30–32,34–37,39–57] (74 citations). In general, most of the individual level risk factors included in this category were well supported by good quality evidence (mostly Level II), including BMI or hernia (peristomal body profile)[9,15,27,32,35,40,42,48,56], age (disabilities)[5,18,25,28,35,36,40,48,57], ostomy height/diameter (ostomy construction)[9,12,13,17–19,22,24,27,30,31,34–37,41,47,50], and surgery type (ostomy construction[9,12,13,17–19,22,24,27,30,31,34–37,41,47,50]; these citations overlapped with surgical guidelines)[13–15,17–20,22,24–27,30–32,34–37]; ileostomy (ostomy/output type)[4,5,12,14,16,18,25–28,39,41,43,45,46,49,52–54,57], as patients with an ileostomy have a higher risk of developing PSC; and gender (self-consciousness/self-care, though gender as a risk factor could be conditioned by cultural differences rather than a difference in genders alone)[5,14,18,31,35]. In addition, at least Level II evidence was found for an individual's ostomy management skills[9,41,51], medication/treatment status[15,26,32,36,55,57] (e.g., chemotherapy, diabetes), skin properties/conditions[41,42,54], and standard of living[44] being risk factors for PSC.

The Healthcare system was the next most supported risk factor category with 27 articles[11,13–38] (cited 32 times within the category) providing evidence for five of the seven system level risk factors included in this category. These articles primarily described clinical evidence for surgical techniques[13–15,17–20,22,24–27,30–32,34–37] or preoperative guidelines[14,16,21,27–29,33], indicating the importance of accurate ostomy site marking and choosing the appropriate surgery technique.

In contrast, very few articles[21,23,38] could be found related to care guidelines for ensuring the quality of the postoperative training of the patients. Only two articles supplied evidence on how the healthcare system could provide support for the patient post-discharge[29,38]. Nevertheless, these articles did show that support from healthcare professionals post-discharge and pre-surgical education of the patient decreased the risk of developing PSC[29,38].

In the Ostomy product category, five of the seven product-related risk factors were accompanied by evidence from the literature (13 articles[9,10,25,39,41,55,58–64] being cited 16 times). Apart from the 'adhesive properties' of the ostomy product

(which was backed by seven articles[9,10,58–61,64] providing mostly Level I[61,64]/II[10,58–60] evidence), the rest of the identified risk factors were supported by three or fewer studies. Since these risk factors were identified by healthcare professionals and scientists as important for developing PSC, one could wonder why the clinical evidence on these aspects of ostomy product development is sparse. Nonetheless, the few articles identified in this risk factor category do indicate that both the type[25,39,63] and composition of an ostomy product[9,10,58–61,64] are important in PSC development.

Overall, the risk factors pertaining to surgical technique ('surgical guidelines'), ostomy output type, and ostomy construction had the most evidence from the literature with 19[13–15,17–20,22,24–27,30–32,34–37], 20[4,5,12,14,16,18,25–28,39,41,43,45,46,49,52–54,57], and 18[9,12,13,17–19,22,24,27,30,31,34–37,41,47,50] related articles respectively. However, the majority of the articles in the surgical guidelines and ostomy construction categories overlap. Another 11 risk factors from the three overall categories (namely, preoperative ostomy site marking [preoperative guidelines], postoperative training of patients [care guidelines], peristomal body profile, the individual's skin properties and conditions, his/her medication/treatment status, age [disability], self-consciousness/self-care ability, ostomy management skills, range and type of ostomy products, adhesive property of the product, and product wear time) are also sufficiently described in the literature with evidence coming from three to nine studies.

Only five out of the 24 consensus-based risk factors identified in the model lacked any evidence from the literature. These include: system level factors such as access to appropriate ostomy product types and quantity, and the societal view of people with such a condition; individual level support from family or social network; and product level factors such as fit to the body profile and ease of application or removal of the ostomy product. While these factors are not supported by evidence from the literature, they are considered relevant and are internationally recognised based on expert opinion and experience. Combined with the five risk factor subcategories that were only supported by only one to two studies (namely, access to post-discharge programs[29,38], level of education of healthcare professionals[11], an individual's income/standard of living[44], fit of the ostomy product to the ostomy shape[9,41], and filter performance and capacity of the ostomy product[62]), these represent areas where further research is particularly needed.

It is a goal that the risk factor model for PSC can be used as a tool in daily practice in ostomy care. Some of the identified risk factors can be addressed at an early stage when the patient is discharged from the hospital and can save the patients from some of the initial issues they may face with a trial-and-error approach to self-care. The extensive and geographically diverse process of development of the model make it reasonably generalisable to population of individuals living with an ostomy and allow for regionally appropriate implementation variations. The model thus has the potential to be included in a healthcare professional assessment, intervention and monitoring guide to promote a holistic approach to ensure peristomal skin health and quality of life for people with an ostomy.

CONCLUSIONS

The purpose of developing a risk factor model on PSC was to explore existing evidence- and experience-based risks leading to PSC, with the purpose of providing a valid assessment method to guide individualised recommendations and decision making in ostomy care. The intention is to help prevent PSC.

By conducting a comprehensive literature research and by working with specialists in the field of ostomy care we have obtained a solid knowledge base upon which the risk factor model on PSC has been developed.

With the personalised risk factor assessment including quality of life, peristomal body profile and peristomal skin, hand in hand with a professional holistic judgement, a trial-and-error approach should be avoided to save the individual patient from severe negative impact on health and quality of life.

CONFLICTS OF INTEREST, SOURCE OF FUNDING

This work was supported by Coloplast A/S. Anne Steen Hansen, Cecilie Jæger Leidesdorff Bechshøft, Zenia Størling and Lene Feldskov Nielsen were employed by Coloplast A/S when the model was developed, and the manuscript was prepared.

Lina Martins, Jane Fellows, Birgitte Dissing-Andersen, Gillian Down, David Voegeli, Tonny Karlsmark and Gregor Jemec are members of the Coloplast Skin Expert Panel and have received honoraria for participating in different Coloplast Advisory Boards. They have not received compensation for involvement in this publication.

All authors were involved in the writing, reviewing and editing of the manuscript, gave final approval and agreed to be accountable for all aspects of the work. Anne Steen Hansen and Lene Feldskov Nielsen were responsible for the risk factor model for PSC and Cecilie Jæger Leidesdorff Bechshøft for the literature review. References were screened independently by Cecilie Jæger Leidesdorff Bechshøft and Lene Feldskov Nielsen.

ACKNOWLEDGEMENTS

The authors would like to thank the members of the COF and the Coloplast Skin Expert Panel who participated in discussions and shared their invaluable experience about PSC – Gemma Gascón Guitart who was part of the workshops in the beginning of the process and started the literature search in collaboration with Information Specialist Jette Brandt, M.L.I Sc, Library and Information Science, who conducted the literature searches, as well as Louise C. Rosenberg Christ, PhD and Kaushik Sengupta, PhD (Larix A/S, Copenhagen, Denmark) for editorial and medical writing services which were funded by Coloplast A/S.

REFERENCES

1. Claessens I, Probert R, Tielemans C, et al. The Ostomy Life Study: the everyday challenges faced by people living with a stoma in a snapshot. Gastrointest Nurs 2015;13(5):18–25. doi:10.12968/gasn.2015.13.5.18
2. Coloplast. Perception of leakage: data from the Ostomy Life Study 2019. In Press.
3. Herlufsen P, Olsen AG, Carlsen B, et al. Study of peristomal skin disorders in patients with permanent stomas. Br J Nurs 2006;15(16):854–862. doi:10.12968/bjon.2006.15.16.21848
4. Nybæk H, Knudsen DB, Laursen TN, Karlsmark T, Jemec GBE. Skin problems in ostomy patients: a case-control study of risk factors. Acta Dermato-Venereologica 2009;89(1):64–67. doi:10.2340/00015555-0536
5. Voegeli D, Karlsmark T, Eddes EH, et al. Factors influencing the incidence of peristomal skin complications: evidence from a multinational survey on living with a stoma. Gastroint Nurs 2020;18(Supplement 4):S31-S38.
6. James-Reid S, Bain K, Hansen AS, Vendelbo G, Droste W, Colwell J. Creating consensus-based practice guidelines with 2000 nurses. Br J Nurs 2019;28(22):S18-S25. doi:10.12968/bjon.2019.28.22.S18
7. Bain KA, Bain M. Clinical preventative-based best practices to reduce the risk of peristomal skin complications – an international consensus report. Publication in progress.
8. Dearholt SL and Dang D. (2012) Johns Hopkins Nursing Evidence-Based Practice: Models and Guidelines. 2nd Edition, Sigma Theta Tau International, Indianapolis, IN.
9. Colwell JC, McNichol L, Boarini J. North America wound, ostomy, and continence and enterostomal therapy nurses current ostomy care practice related to peristomal skin issues. J Wound Ostomy Continence Nurs 2017;44(3):257–261. doi:10.1097/WON.0000000000000324
10. Cressey BD, Belum VR, Scheinman P, et al. Stoma care products represent a common and previously underreported source of peristomal contact dermatitis. Contact Dermatitis 2017;76(1):27–33. doi:10.1111/cod.12678
11. Foa C, Bisi E, Calcagni A, et al. Infectious risk in ostomy patient: the role of nursing competence. Acta Biomed 2019;90(11-S):53–64. doi:10.23750/abm.v90i11-S.8909
12. Persson E, Berndtsson I, Carlsson E, Hallen AM, Lindholm E. Stoma-related complications and stoma size: a 2-year follow up. Colorectal Di 2010;12(10):971–6. doi:10.1111/j.1463-1318.2009.01941.x
13. Almosallam OI, Aseeri A, Shanafey SA. Outcome of loop versus divided colostomy in the management of anorectal malformations. Ann Saudi Med 2016;36(5):352–355. doi:10.5144/0256-4947.2016.352
14. Arolfo S, Borgiotto C, Bosio G, Mistrangelo M, Allaix ME, Morino M. Preoperative stoma site marking: a simple practice to reduce stoma-related complications. Tech Coloproctol 2018;22(9):683–687. doi:10.1007/s10151-018-1857-3
15. Arumugam PJ, Bevan L, Macdonald L, et al. A prospective audit of stomas-analysis of risk factors and complications and their management. Colorectal Dis 2003;5:49–52.
16. Baykara ZG, Demir SG, Karadag A, et al. A multicenter, retrospective study to evaluate the effect of preoperative stoma site marking on stomal and peristomal complications. Ostomy Wound Manage 2014;60(5):16–26.
17. Carannante F, Masciana G, Lauricella S, Caricato M, Capolupo GT. Skin bridge loop stoma: outcome in 45 patients in comparison with stoma made on a plastic rod. Int J Colorectal Dis 2019;34(12):2195–2197. doi:10.1007/s00384-019-03415-x
18. Carbonell BB, Treter C, Staccini G, MajnoHurst P, Christoforidis D. Early peristomal complications: detailed analysis, classification and predictive risk factors. Ann Ital Chir 2020;91(1).
19. Dziki L, Mik M, Trzcinski R, et al. Evaluation of the early results of a loop stoma with a plastic rod in comparison to a loop stoma made with a skin bridge. Polski Przeglad Chirurgiczny 2015;87(1):31–34.
20. Fagundes RB, Cantarelli JC, Fontana K, Motta GL. Percutaneous endoscopic gastrostomy and peristomal infection: an avoidable complication with the use of a minimum skin incision. Surg Laparosc Endosc Percutan Tech 2011;21(4):275–277.
21. Folguera-Arnau M, Gutiérrez-Vilaplana JM, González-María E, et al. Implementation of best practice guidelines for ostomy care and management: care outcomes. Enfermería Clínica (English edition) 2020;30(3):176–184. doi:10.1016/j.enfcle.2019.10.008
22. Hayashi K, Kotake M, Hada M, et al. Laparoscopic versus open stoma creation: a retrospective analysis. J Anus Rectum Colon 2017;1(3):84–88. doi:10.23922/jarc.2016-014
23. Karadag A, Mentes BB, Üner A, Irkörkücü O, Ayaz S, Özkan S. Impact of stomatherapy on quality of life in patients with permanent colostomies or ileostomies. Int J Colorectal Dis 2003;18:234–238.
24. Klink CD, Lioupis K, Binnebosel M, et al. Diversion stoma after colorectal surgery: loop colostomy or ileostomy? Int J Colorectal Dis 2011;26(4):431–6. doi:10.1007/s00384-010-1123-2
25. Martins L, Samai O, Fernandez A, Urquhart M, Hansen AS. Maintaining healthy skin around an ostomy: peristomal skin disorders and self-assessment. Gastrointest Nurs 2011;9(2)(Supplement):9–13.
26. Nagano M, Ogata Y, Ikeda M, Tsukada K, Tokunaga K, Iida S. Peristomal moisture-associated skin damage and independence in pouching system changes in persons with new fecal ostomies. J Wound Ostomy Continence Nurs 2019;46(2):137–142. doi:10.1097/WON.0000000000000491
27. Parmar KL, Zammit M, Smith A, et al. A prospective audit of early stoma complications in colorectal cancer treatment throughout the Greater Manchester and Cheshire colorectal cancer network. Colorectal Dis 2011;13(8):935–8. doi:10.1111/j.1463-1318.2010.02325.x
28. Pittman J, Rawl SM, Schmidt CM, et al. Demographic and clinical factors related to ostomy complications and quality of life in veterans with an ostomy. JWOCN 2008;35(5):493–503.
29. Robatmily A, Anboohi Z, Shirinabadi Farahani A, Nasiri M. Effect of Providing Ostomy Care Education to Mothers of Neonates with Peristomal Skin Complications. Adv Nurs Midwifery. 2018;27(3):6-10. doi:10.21859/ANM-027033
30. Sakai Y, Nelson H, Larson D, Maidl L, Young-Fadok T, Ilstrup D. Temporary transverse colostomy vs loop ileostomy in diversion. Arch Surg 2001;136:338–324.
31. Scarpa M, Ruffolo C, Boetto R, Pozza A, Sadocchi L, Angriman I. Diverting loop ileostomy after restorative protocolectomy: predictors of poor outcome and poor quality of life. Colorectal Dis 2009;12:914–920.
32. Shiraishi T, Nishizawa Y, Nakajima M, et al. Risk factors for the incidence and severity of peristomal skin disorders defined using two scoring systems. Surg Today 2020;50(3):284–291. doi:10.1007/s00595-019-01876-9
33. Stokes AL, Tice S, Follett S, et al. Institution of a preoperative stoma education group class decreases rate of peristomal complications in new stoma patients. JWOCN 2017;44(4):363–367. doi:10.1097/WON.0000000000000338

34. Sun X, Han H, Qiu H, et al. Comparison of safety of loop ileostomy and loop transverse colostomy for low-lying rectal cancer patients undergoing anterior resection: a retrospective, single institution, propensity score-matched study. Asia Pac J Clin Oncol 2020. Journal of BUON: Official Journal of the Balkan Union of Oncology 24(1): 123-129; 2019 ISSN/ISBN: 1107-0625 PMID: 30941960 doi:10.1111/ajco.13322
35. Sung YH, Kwon I, Jo S, Park S. Factors affecting ostomy-related complications in Korea. JWOCN 2010;37(2):166–172.
36. Uchino M, Ikeuchi H, Bando T, Chohno T, Sasaki H, Horio Y. Is an ostomy rod useful for bridging the retraction during the creation of a loop ileostomy? A randomized control trial. World J Surg 2017;41(8):2128–2135. doi:10.1007/s00268-017-3978-7
37. Wu X, Lin G, Qiu H, Xiao Y, Wu B, Zhong M. Loop ostomy following laparoscopic low anterior resection for rectal cancer after neoadjuvant chemoradiotherapy. Eur J Med Res 2018;23(1):24. doi:10.1186/s40001-018-0325-x
38. Zhou H, Ye Y, Qu H, Zhou H, Gu S, Wang T. Effect of ostomy care team intervention on patients with ileal conduit. JWOCN 2019;46(5):413–417. doi:10.1097/WON.0000000000000574
39. Bourgois M, Evers G, Filez L. Satisfaction of ileostomy and colostomy patients with their ostomy collection devices. WCET J 2001;21(3):16–20.
40. Bulkley JE, McMullen CK, Grant M, Wendel C, Hornbrook MC, Krouse RS. Ongoing ostomy self-care challenges of long-term rectal cancer survivors. Support Care Cancer 2018;26(11):3933–3939. doi:10.1007/s00520-018-4268-0
41. Carlsson E, Fingren J, Hallen AM, Petersen C, Lindholm E. The prevalence of ostomy-related complications 1 year after ostomy surgery: a prospective, descriptive, clinical study. Ostomy Wound Manage 2016;62(10):34–48.
42. Cowin C, Redmond C. Living with a parastomal hernia. Gastrointest Nurs 2012;10(1):16–24.
43. Goldstine J, Hees RV, de Vorst DV, Skountrianos G, Nichols T. Factors influencing health-related quality of life of those in the Netherlands living with an ostomy. Br J Nurs 2019;28(22)(Stoma supplement):S10-S17.
44. Gooszen AW, Geelkerken RH, Hermans J, Lagaay MB, Gooszen HG. Quality of life with a temporary stoma. Dis Colon Rectum 2000;43(5):650–655.
45. Jayarajah U, Samarasekara AM, Samarasekera DN. A study of long-term complications associated with enteral ostomy and their contributory factors. BMC Res Notes 2016;9(1):500. doi:10.1186/s13104-016-2304-z
46. Lin Z, Yu W, Shi J, Chen Q, Tan S, Li N. Temporary decompression in critically ill patients: retrospective comparison of ileostomy and colostomy. Hepato-Gastroenterol 2014;64:647–651.
47. Lindholm E, Persson E, Carlsson E, Hallen AM, Fingren J, Berndtsson I. Ostomy-related complications after emergent abdominal surgery: a 2-year follow-up study. JWOCN 2013;40(6):603–10. doi:10.1097/WON.0b013e3182a9a7d9
48. Mahjoubi B, Moghimi A, Mirzaei R, Bijari A. Evaluation of the end colostomy complications and the risk factors influencing them in Iranian patients. Colorectal Dis 2005;7(6):582–7. doi:10.1111/j.1463-1318.2005.00878.x
49. Manzenreiter L, Spaun G, Weitzendorfer M, et al. A proposal for a tailored approach to diverting ostomy for colorectal anastomosis. Minerva Chirurgica 2018;73(1):29–35.
50. Miyo M, Takemasa I, Ikeda M, et al. The influence of specific technical maneuvers utilized in the creation of diverting loop-ileostomies on stoma-related morbidity. Surg Today 2017;47(8):940–950. doi:10.1007/s00595-017-1481-2
51. Park S, Lee YJ, Oh DN, Kim J. Comparison of standardized peristomal skin care and crusting technique in prevention of peristomal skin problems in ostomy patients. J Korean Acad Nurs 2011;41(6):814–20. doi:10.4040/jkan.2011.41.6.814
52. Pearson R, Knight SR, Ng JCK, Robertson I, McKenzie C, Macdonald AM. Stoma-related complications following ostomy surgery in 3 acute care hospitals: a cohort study. JWOCN 2020;47(1):32–38. doi:10.1097/WON.0000000000000605
53. Pittman J, Bakas T, Ellett M, Sloan R, Rawl SM. Psychometric evaluation of the ostomy complication severity index. JWOCN 2014;41(2):147–57. doi:10.1097/WON.0000000000000008
54. Salvadalena G, Colwell JC, Skountrianos G, Pittman J. Lessons learned about peristomal skin complications: secondary analysis of the ADVOCATE trial. JWOCN 2020;47(4):357–363. doi:10.1097/WON.0000000000000666
55. Salvadalena GD. The incidence of stoma and peristomal complications during the first 3 months after ostomy creation. JWOCN 2013;40(4):400–6. doi:10.1097/WON.0b013e318295a12b
56. Shiraishi T, Nishizawa Y, Ikeda K, Tsukada Y, Sasaki T, Ito M. Risk factors for parastomal hernia of loop stoma and relationships with other stoma complications in laparoscopic surgery era. BMC Surg 2020;20(1):141. doi:10.1186/s12893-020-00802-y
57. Whiteley I, Sinclair G. A review of peristomal complications after the formation of an ileostomy, colostomy or ileal conduit. WCET J 2010;30(3)
58. Al-Niaimi F, Beck M, Almaani N, Samarasinghe V, Williams J, Lyon C. The relevance of patch testing in peristomal dermatitis. Br J Dermatol 2012;167(1):103–9. doi:10.1111/j.1365-2133.2012.10925.x
59. Banu T, Talukder R, Chowdhury TK, Hoque M. Betel leaf in stoma care. J Pediatr Surg 2007;42(7):1263–5. doi:10.1016/j.jpedsurg.2007.02.025
60. Caroppo F, Brumana MB, Biolo G, Giorato E, Barbierato M, Belloni Fortina A. Peristomal allergic contact dermatitis caused by ostoma pastes and role of Gantrez ES-425. G Ital Dermatol Venereol 2019;154(1):1–5. doi:10.23736/S0392-0488.18.05957-6
61. Colwell JC, Pittman J, Raizman R, Salvadalena G. A randomized controlled trial determining variances in ostomy skin conditions and the economic impact (ADVOCATE trial). JWOCN 2018;45(1):37–42. doi:10.1097/WON.0000000000000389
62. Klok-Vonkeman SI, Douw G, Janse AJ. Pancaking: an underestimated problem among ostomates. WCET J 2013;33(4):16–25.
63. Ratliff CR. Factors related to ostomy leakage in the community setting. JWOCN 2014;41(3):249–53. doi:10.1097/WON.0000000000000017
64. Welser M, Riedlinger I, Prause U. A comparative study of two-priece ostomy appliances. Br J Nurs 2009;18(9):530–538.
65. Martins L, Andersen BD, Colwell J, Down G, Forest-Lalande L, Novakova S, Probert R, Hedegaard CJ, Hansen AS. Challenges faced by people with a stoma: peristomal body profile risk factors and leakage. Br J Nurs. 2022 Apr 7;31(7):376-385. doi: 10.12968/bjon.2022.31.7.376. PMID: 35404660.
66. Coloplast. The emotional impact of stoma leakage: data from the Ostomy Life Study 2019. In press.

Appendix 1. Literature supporting the identified risk factors.

Risk factor / No. supporting articles (n) / Citation	Type of study (evidence Level I, II or III)	No. participants	Major findings/applicability for the risk factor model
HEALTHCARE SYSTEM (n=32)			
Standard of stoma care (n=29)			
1. Preoperative guidelines (n=7)			
Pittman et al. (2008)[28]	Descriptive cross-sectional design (II)	239 veterans	Patients (168 veterans) who did not receive preoperative instructions reported severe skin irritations (p=0.009) compared to patients who did.
Parmar et al. (2011)[27]	Prospective study (II)	192 stomas	Preoperatively marked stomas (30 out of 150 patients) had a lower risk of developing a problematic stoma (including skin problems) than those not marked (19 out of 34 patients) (p<0.001).
Arolfo et al. (2018)[14]	Retrospective analysis (II)	1076 patients	1055 stoma complications were recorded in 797 patients. Preoperative stoma marking displayed a protective role for developing stoma complications such as skin lesions (p=0.017).
Baykara et al. (2014)[16]	Retrospective analysis (II)	748 patients	Peristomal complications developed in 248 persons. Stoma complications such as parastomal skin problems were more evident in the non-preoperative marking of the stoma site group compared to preoperative marking (22.9% vs. 46.0%, p<0.001).
Folguera-Arnau et al. (2020)[21]	Postquasi experimental multicentre test (II)	3084 patients	Implication of Registered Nurses' Association of Ontario (RNAO) Ostomy care and management guidelines minimised the risk of PSC. PSC dropped from 17% to 14% to 11% (p<0.05).
Robatmily et al. (2018)[29]	Clinical trial (II)	48 mothers	30 days post-discharge of the infants (40 participants) there was a significantly higher occurrence of PSC in the control group compared to the experimental group (mothers receiving ostomy care education) (p=0.013).
Stokes et al. (2017)[33]	Retrospective analysis (II)	218 participants	Preoperative stoma education resulted in a reduction from 44.7% to 20.2% in PSC (p=0.002) in 124 patients.
2. Surgical guidelines (n=19)			
Arumugam et al. (2003)[15]	Prospective study (II)	97 patients	49 out of 97 stomas had one or more complications after 1 year. Emergency surgery was linked to late skin excoriation (p=0.045) post-surgery.
Shiraishi et al. (2020)[32]	Retrospective analysis (II)	333 cases of temporary loop stomas	PSC was diagnosed in 262 patients. Operation duration was found to increase the risk of severe PSC (71 patients, p=0.012) compared to non-severe PSC (191 patients).
Sung et al. (2010)[35]	Retrospective analysis (II)	1170 patients	The incidence of irritant contact dermatitis was significantly higher in the end stoma group (778 stomas) compared to those with loop stoma (390 patients, p=0.013).
Carbonell et al. (2020)[18]	Retrospective analysis (II)	111 patients	Emergency surgery was a significant predictor for PSC 30 days post-surgery (p=0.035).
Martins et al. (2011)[25]	Non-comparative, multinational post-marketing study (II)	3017 patients	Permanent surgery had a lower baseline Discoloration, Erosion/Ulceration, Tissue overgrowth (DET) score compared to temporary surgery (p=0.012).
Parmar et al. (2011)[27]	Prospective study (II)	192 stomas	Emergency surgery (41 out of 191 patients) was a significant risk factor for developing a problematic stoma (including skin problems) 6 months post-surgery (p=0.002) compared to elective surgery (150 out of 191 patients).
Almosallam et al. (2016)[13]	Retrospective study (II)	104 patients	Skin excoriations were higher in the divided colostomy group compared to loop (17 vs. 10, p=0.04).
Carannante et al. (2019)[17]	Prospective study (II)	90 patients	A higher occurrence of peristomal dermatitis was observed in the plastic rod group compared to the skin bridge group (30 vs. 9, p=0.08) 3 weeks post-surgery.
Hayashi et al. (2017)[22]	Retrospective study (II)	50 patients	Five patients experienced skin problems in the laparoscopic group compared to 11 patients in the open stoma group (p=0.03).
Klink et al. (2011)[24]	Retrospective clinical study (II)	200 patients	A higher incidence of dermatitis was observed in the loop ileostomy group (15% vs. 0%, p<0.001) compared to loop transverse colostomy.
Sakai et al. (2001)[30]	Retrospective case-matched study (II)	126 patients	Skin problems around the stoma were significantly more common in the transverse colostomy group compared to the loop ileostomy group (15.9% vs. 3.2%, p<0.04).
Scarpa et al. (2009)[31]	Prospective study (II)	44 patients	10 out of 21 patients with a standard rod developed peristomal dermatitis compared to four out 23 who had a ring rod (p=0.050).

Risk factor / No. supporting articles (n) / Citation	Type of study (evidence Level I, II or III)	No. participants	Major findings/applicability for the risk factor model
Arolfo et al. (2018)[14]	Univariate and multivariate analysis on retrospective data (II)	1076 patients	1055 stoma complications were recorded in 797 patients. Emergency and open surgery were significant predictors for developing stoma complications such as skin lesions (p=0.010 and p<0.001).
Dziki et al. (2015)[19]	Retrospective study (II)	40 patients	18 out of 20 patients (90%) operated with a plastic rod developed peristomal dermatitis compared to 0 out of 20 patients (0%) operated using a skin flap.
Fagundes et al. (2011)[20]	Retrospective study (II)	120 patients	A significant difference between group 1 (47 patients, 10mm skin incision) and 2 (46 patients, skin incision up to 5mm) (p=0.01) for skin incision size to have an effect of peristomal infection.
Nagano et al. (2019)[26]	Retrospective study (II)	89 patients	Patients with temporary versus permanent stomas were more likely to develop moisture-associated skin damage (52 vs. 37 stomas, p=0.017).
Sun et al. (2020)[34]	Retrospective study (II)	288 patients	The loop ileostomy group had a significant higher rate of irritant dermatitis than the loop transverse colostomy group (82 vs. 206 patients, p<0.01).
Uchino et al. (2017)[36]	Prospective randomised study (II)	320 patients	Dermatitis around the ostomy site was observed in 124/308 patients (40.3%), and it was significantly higher in the group operated with a rod (84 out of 154 patients) compared to surgery without a rod (40 out of 154 patients, p<0.001).
Wu et al. (2018)[37]	Prospective study (II)	186 patients	Loop transverse colostomies displayed less dermatitis compared to loop ileostomies (15 vs. 5 patients, p=0.001).
3. Care guidelines (n=3)			
Folguera-Arnau et al. (2020)[21]	Postquasi experimental multicentre test (II)	3084 patients	Implication of RNAO Ostomy care and management guidelines minimised the risk of PSC. PSC from 17% to 14% to 11% (p<0.05).
Zhou et al. (2019)[38]	Randomised controlled trial (I)	48 patients	Patients were randomised to a control or intervention group. Both groups received routine postoperative ostomy nursing. The intervention group further followed a multicomponent intervention delivered by an ostomy care team post-discharge. After 6 months, occurrence of PSC were significantly lower in intervention group compared to the control group (4.35% vs. 30.43%, p=0.047).
Karadag et al. (2003)[23]	Questionnaires (III)	43 patients	The patients were invited to a stoma therapy unit 1, 3, and 6 months after an initial rehabilitation program, and then on a yearly basis. They were encouraged to contact whenever they needed help. Skin problems decreased in all ostomy groups and in total (26 before, four after receiving guidelines, p<0.001).
4. Societal view of people with chronic conditions (n=0)			
–	–	–	
Access to appropriate support/products (n=2)			
5. Post-discharge programs (n=2)			
Robatmily et al. (2018)[29]	Clinical trial (II)	48 mothers	30 days post-discharge of the infants (40 participants, 20 in each group), there was a significantly higher occurrence of PSC in the control group compared to the experimental group where mothers were receiving ostomy care education (14 vs. 4 infants, p=0.013).
Zhou et al. (2019)[38]	Randomised controlled trial (I)	48 patients	Patients were randomised to a control or intervention group. Both groups received routine postoperative ostomy nursing. The intervention group further followed a multicomponent intervention delivered by an ostomy care team post-discharge. After 6 months, occurrence of PSC were significantly lower in intervention group compared to the control group (4.35% vs. 30.43%, p=0.047).
6. Appropriate product type and quantity (n=0)			
–	–	–	
Level of education in stoma care and surgical procedures (n=1)			
7. Healthcare professionals (n=1)			
Foa et al. (2019)[11]	Qualitative study with retrospective data (III)	55 nurses	40 nurses completed the study. Higher education of the nurses gives low incidence of peristomal skin infections (bacterial) leading to risk reduction.

Risk factor / No. supporting articles (n) / Citation	Type of study (evidence Level I, II or III)	No. participants	Major findings/applicability for the risk factor model
INDIVIDUAL WITH AN OSTOMY (n=74)			
Physical characteristics (n=65)			
8. Peristomal body profile (n=9)			
Colwell et al. (2017)[9]	Questionnaires (III)	796 nurses	77.7% of the nurses indicated that 26–100% of their patients developed some type of PSC during their time with a stoma. The nurses indicated that obesity could result in creases and retracted stomas which could affect the fitting of the pouching system, leading to dermatitis.
Arumugam et al. (2003)[15]	Prospective study (II)	97 patients	49 out of 97 stomas had one or more complications after 1 year. BMI was associated with early skin excoriation (p=0.042).
Shiraishi et al. (2020)[32]	Retrospective analysis (II)	333 cases of temporary loop stomas	PSC was diagnosed in 262 patients. Parastomal hernia was found to increase the risk of severe PSC (79 patients, p=0.007) compared to non-severe PSC (183 patients).
Sung et al. (2010)[35]	Retrospective analysis (II)	1170 patients	The incidence of irritant contact dermatitis was significantly higher in the obese and overweight group (517 patients) compared to those with underweight and normal weight (606 patients, p=0.001).
Bulkley et al. (2018)[40]	Cross sectional study, survey (III)	313 surveys mailed	Survey was completed by 177 respondents of rectal cancer survivors with ostomies. Participants reporting skin problems had a significantly higher BMI (29.6) than those without (26.0, p=0.002).
Cowin & Redmond (2012)[42]	Questionnaires (III)	1876 costumers placing an order for support garments	322 (17%) respondents were diagnosed with parastomal hernia. Before onset of hernia, 20% of the 322 respondents had significant problems with their skin. This increased to 32% after the hernia developed.
Mahjoubi et al. (2005)[48]	Retrospective cross-sectional study (II)	330 patients	330 patients with end colostomy were divided into two groups, within 1-month post-surgery and later than 1-month post-surgery. BMI >25kg/m^2 was associated with early dermal irritation (OR 2.08, 95% CI 1.12–3.84).
Shiraishi et al. (2020)[56]	Retrospective study (II)	153 consecutive patients with loop stomas	Parastomal hernia was developed in 77 cases (50.3%). PSC were significantly associated with parastomal hernia (p=0.049).
Parmar et al. (2011)[27]	Prospective study (II)	192 stomas	Higher BMI was a significant risk factor for developing a problematic stoma (including skin problems) 6 months post-surgery (p=0.043).
9. Stoma construction (n=18)			
Colwell et al. (2017)[9]	Questionnaires (III)	796 nurses	77.7% of the nurses indicated that 26–100% of their patients developed some type of PSC during their time with a stoma. 325 (49%) of the nurses indicated that 50% of the planned surgery patients had a preoperative stoma marking. 249 nurses (34%) indicated that 25% or less of their patients had preoperative stoma marking.
Persson et al. (2010)[12]	Prospective study (II)	180 elective patients	Most complications occurred 2 weeks after discharge in all types of stomas. Most common complication was PSC. Almost all patients with an ileostomy and loop-ileostomy with stoma heights lower than 20mm had leakage and skin problems (4/4 and 13/14). Colostomies with stoma height less than 5mm experienced skin problems in 10/20 cases.
Sung et al. (2010)[35]	Retrospective analysis (II)	1170 patients	The incidence of irritant contact dermatitis was significantly higher in the end stoma group (778 stomas) compared to those with loop stoma (390 patients, p=0.013).
Carbonell et al. (2020)[18]	Retrospective analysis (II)	111 patients	Loop stoma was a significant factor for developing PSC 30 days post-surgery (p=0.030).
Parmar et al. (2011)[27]	Prospective study (II)	192 stomas	Mean stoma length was shorter for problematic stomas (including skin problems) (10.6 ± 14.9mm) 6 months after surgery (p=0.006) compared to stomas without problems (17.17±14.2mm).
Almosallam et al. (2016)[13]	Retrospective study (II)	104 patients	Skin excoriations was higher in the divided colostomy group compared to loop colostomy (17 vs. 10, p=0.04).
Carannante et al. (2019)[17]	Prospective study (II)	90 patients	A higher occurrence of peristomal dermatitis was observed in the plastic rod group compared to the skin bridge group (30 vs. 9, p=0.08) 3 weeks post-surgery.
Hayashi et al. (2017)[22]	Retrospective study (II)	50 patients	Five patients observed skin problems in the laparoscopic group compared to 11 patients who experienced skin problems in the open stoma group (p=0.03).
Klink et al. (2011)[24]	Retrospective clinical study (II)	200 patients	A higher incidence of dermatitis was observed in the loop ileostomy group (15% vs. 0%, p<0.001) compared to loop transverse colostomy.

Risk factor / No. supporting articles (n) / Citation	Type of study (evidence Level I, II or III)	No. participants	Major findings/applicability for the risk factor model
Sakai et al. (2001)[30]	Retrospective case-matched study (II)	126 patients	Skin problems around the stoma were significantly more common in the transverse colostomy group compared to the loop ileostomy group (15.9% vs. 3.2%, p<0.04).
Scarpa et al. (2009)[31]	Prospective study (II)	44 patients	10 out of 21 patients with a standard rod developed peristomal dermatitis compared to four out 23 who had a ring rod (p=0.050).
Carlsson et al. (2016)[41]	Prospective study (II)	207 patients	207 patients undergoing surgeries for different ostomies were followed for 1 year. 11% had PSC. The construction of the ostomy (stenosis, sliding ostomy, ostomy opening) were related to PSC.
Lindholm et al. (2013)[47]	Prospective study (II)	144 patients	144 patients were followed to 2 years post-surgery. Patients with low ostomy had PSC ranging from 21–57% in the period.
Miyo et al. (2017)[50]	Retrospective study (II)	279 patients	279 patients with an ileostomy participated in the study during a 1-year period. Most common complication was parastomal dermatitis (132 patients). Distance from the ileocecal valve (<30cm) had a significant effect on the development of parastomal dermatitis compared to >30cm (p<0.001).
Dziki et al. (2015)[19]	Retrospective study (II)	40 patients	18 out of 20 patients (90%) operated with a plastic rod developed peristomal dermatitis compared to 0 out of 20 patients (0%) operated using a skin flap.
Sun et al. (2020)[34]	Retrospective study (II)	288 patients	The loop ileostomy group had a significantly higher rate of irritant dermatitis than the loop transverse colostomy group (82 vs. 206 patients, p<0.01).
Uchino et al. (2017)[36]	Prospective randomised study (II)	320 patients	Dermatitis around the ostomy site was observed in 124/308 patients (40.3%), and it was significantly higher in the group operated with a rod (84 out of 154 patients) compared to surgery without rod (40 out of 154 patients, p<0.001).
Wu et al. (2018)[37]	Prospective study (II)	186 patients	Loop transverse colostomies displayed less dermatitis compared to loop ileostomies (15 vs. 5 patients, p=0.001).
10. Stoma/output types (n=20)			
Nybæk et al. (2009)[4]	Cross-sectional study (II)	630 ostomates	199 persons with 202 ostomies were examined. 90 persons (44.8%) had PSC diagnosed by a nurse. There was a significant difference in PSC between ostomy types (colostomy 35/100 persons, ileostomy 46/82 persons, and urostomy 9/19 persons, p=0.0341).
Voegeli et al. (2020)[5]	Retrospective questionnaire (III)	19555 surveys	4235 persons with an ostomy responded from 13 countries. Ileostomies had a higher risk of developing PSC compared to colostomies (p<0.0001) and urostomies (p=0.0003).
Persson et al. (2010)[12]	Prospective study (II)	180 elective patients	Most complications occurred 2 weeks after discharge in all types of stomas. Most common complication was PSC. After 2 weeks, 33 colostomies and 12 end-ileostomies and 25 loop-ileostomies experienced skin problems.
Pittman et al. (2008)[28]	Descriptive cross-sectional design (II)	239 veterans	Veterans with a colostomy reported less severe skin problems than veterans with an ileostomy (p=0.006, 168 out of 239 veterans with skin problems).
Carbonell et al. (2020)[18]	Retrospective analysis (II)	111 patients	Loop stoma was a significant factor for developing PSC 30 days post-surgery (p=0.030).
Martins et al. (2011)[25]	Non-comparative, multinational post-marketing study (II)	3017 patients	Colostomy patients had a lower baseline DET score compared to ileostomy (p=0.004).
Whiteley & Sinclair (2010)[57]	Prospective study (II)	672 patients	Overall PSC rate was 42.7%. PSC were found to be the highest for patients with ileostomies (55%) (p<0.001), followed by ileal conduits (40.3%) and colostomies (26.5%).
Parmar et al. (2011)[27]	Prospective study (II)	192 stomas	Colostomy (31.7%) was a significant risk factor for developing a problematic stoma (including skin problems) 6 months after surgery (p<0.05) compared to ileostomy (18.3%).
Carlsson et al. (2016)[41]	Prospective study (II)	207 patients	207 patients undergoing surgeries for different ostomies were followed for 1 year. 11% had PSC. 23 patients had PSC; nine of the patients had a colostomy whereas 12 had an ileostomy (p=0.002), indicating that PSC occurs more often when having an ileostomy.
Arolfo et al. (2018)[14]	Univariate and multivariate analysis on retrospective data (II)	1076 patients	1055 stomas complications were recorded in 797 patients. Ileostomy was a significant predictor for developing stoma complications such as skin lesions (p=0.004).
Nagano et al. (2019)[26]	Retrospective study (II)	89 patients	Patients with ileostomies versus colostomies were more likely to develop moisture-associated skin damage (52 vs. 37 stomas, p=0.017).
Baykara et al. (2014)[16]	Retrospective analysis (II)	748 patients	Peristomal complications developed in 248 persons, where 136 developed PSC. Complications were found to be higher in patients with an ileostomy or with more than 1 stoma compared to colostomies and urostomies (p=0.002).

Risk factor / No. supporting articles (n) / Citation	Type of study (evidence Level I, II or III)	No. participants	Major findings/applicability for the risk factor model
Bourgois et al. (2001)[39]	Cross-sectional study, questionnaire (III)	340 patients	One of the most frequent complaints was rash under the baseplate 50% (170 out of 337). Ileostomy patients experienced more itching under the baseplate compared to colostomy patients (p<0.005).
Goldstine et al. (2019)[43]	Cross-sectional survey (III)	4500 patients	Of the 2127 who responded, 55% indicated that there peristomal area has some degree of skin problem. Of the 543 that reported leakage, 54% experienced some degree of skin problems.
Jayarajah et al. (2016)[45]	Retrospective study (II)	192 patients	Analysis of patients who underwent ostomy creation over a 5-year period. Skin excoriation was significantly higher in ileostomies compared to colostomies (p=0.0001).
Lin et al. (2014)[46]	Retrospective study (II)	63 patients	Data from 35 patients with a temporary ileostomy and 28 patients with a temporary colostomy were analysed. The rate of dermatitis was significantly higher in the ileostomy group (31.4%) compared to the colostomy group (7.14%, p=0.017).
Manzenreiter et al. (2018)[49]	Retrospective study (II)	167 patients	Data from 37 patients with a loop ileostomy and 130 patients with a loop colostomy were analysed. Skin irritation was significantly higher in the ileostomy group compared to the colostomy group (p=0.003).
Pearson et al. (2020)[52]	Prospective study (II)	3509 stoma surgeries	3509 stomas were followed for 2 years, and 435 had their 2-year follow-up. Skin excoriation was more than twice as common after 2 years in the ileostomy group (23.9% vs. 10.5%, p<0.0010) compared to the colostomy group.
Pittman et al. (2014)[53]	Prospective study (II)	71 patients	Patients were followed 60 days in the postoperative period, and 58 completed the study. Ostomy type correlated with peristomal moisture-associated dermatitis (p=0.05), meaning that patients with ileostomies had a higher severity score.
Salvadalena et al. (2020)[54]	Randomised controlled study (I)	153 participants	153 participants were divided into two groups, those that did not experience PSC and those that did. The PSC group was further examined for risk factors. Participants with an ileostomy were approximately 10 times more likely to experience a severe PSC than patients with a colostomy (OR 9.8, 95% CI 2.2–43.7).
11. Skin properties/conditions (n=3)			
Cowin & Redmond (2012)[42]	Questionnaire (III)	322 subjects	The 322 respondents were a subset of a larger study corresponding to 17% of the dataset. 20% reported problems with the skin before the development of a hernia. This increased to 32% after the development of the hernia. A thinning of the skin was reported after development of the hernia (from 4% to 35%, p=0.05).
Carlsson et al. (2016)[41]	Prospective study (II)	207 patients	207 patients undergoing surgeries for different ostomies were followed for 1 year. 11% had PSC. Peristomal skin diseases (unspecific dermatitis around the ostomy, candidiasis, Pyoderma gangrenosum, no obvious reason, skin irritation of the outer part of the ostomy appliance) were related to PSC.
Salvadalena et al. (2020)[54]	Randomised controlled study (I)	153 participants	153 participants were divided into two groups, those that did not experience PSC and those that did. The PSC group was further examined for risk factors. Participants with skin creases in the peristomal area were 3 times more likely to have PSC compared to those without (OR 2.9, 95% CI 1.3–8.1).
12. Medication/treatment (n=6)			
Arumugam et al. (2003)[15]	Prospective study (II)	97 patients	49 out of 97 stomas had one or more complications after 1 year. Diabetes was associated with late skin excoriation (p=0.045).
Shiraishi et al. (2020)[32]	Retrospective analysis (II)	333 cases of temporary loop stomas	PSC was diagnosed in 262 patients. Adjuvant chemotherapy was found to increase the risk of severe PSC (71 patients, p=0.004) compared to non-severe PSC (191 patients).
Whiteley & Sinclair (2010)[57]	Prospective study (II)	672 patients	Overall PSC rate was 42.7%. There was a statistically significant relationship between age at surgery and development of PSC (p<0.001) with younger patients (1–40 years) having more PSC.
Nagano et al. (2019)[26]	Retrospective study (II)	89 patients	Patients receiving post-surgical chemotherapy were more likely to develop moisture-associated skin damage (19 vs. 13, p=0.084, tendency), compared to those who did not.
Uchino et al. (2017)[36]	Prospective randomised study (II)	320 patients	Dermatitis around the ostomy site was observed in 124/308 patients (40.3%) and administered prednisolone was found as a predictor for developing dermatitis (p=0.04).
Salvadalena (2013)[55]	Prospective repeated measure design (II)	47 patients	47 patients were followed for 3 months postoperatively, and complications were recorded on 43 patients. 27 out of the 43 experienced PSC (63%). Use of non-steroidal anti-inflammatory medication had an impact on ulceration (p=0.01).
13. Disabilities (n=9)			
Voegeli et al. (2020)[5]	Retrospective questionnaire (III)	19555 surveys	4235 persons with an ostomy responded from 13 countries, The older the respondent, the lower the rate of reported PSC compared to the older age groups.

Risk factor / No. supporting articles (n) / Citation	Type of study (evidence Level I, II or III)	No. participants	Major findings/applicability for the risk factor model
Sung et al. (2010)[35]	Retrospective analysis (II)	1170 patients	The incidence of irritant contact dermatitis could be higher in patients above 65 years of age (1336 patients) compared to those younger than 65 years of age (45 patients, p=0.061).
Bulkley et al. (2018)[40]	Cross sectional study, survey (III)	313 surveys mailed	Survey was completed by 177 respondents of rectal cancer survivors with ostomies. Participants reporting skin problems were approximately 4–5 years younger (average 71.8 years) than those without skin problems (average 76.1 years, p=0.021).
Mahjoubi et al. (2005)[48]	Retrospective cross-sectional study (II)	330 patients	330 patients with end colostomy were divided into two groups, within 1-month post-surgery and later than 1 month post-surgery. Age >40 years was associated with early dermal bleeding (OR 3.14, 95% CI 1.56–6.32).
Pittman et al. (2008)[28]	Descriptive cross-sectional design (II)	239 veterans	Age was a significant predictor for skin problems (p=0.006) in 168 veterans with skin problems.
Carbonell et al. (2020)[18]	Retrospective analysis (II)	111 patients	Age was a significant factor for developing PSC 30 days post-surgery (p=0.004).
Martins et al. (2011)[25]	Non-comparative, multinational post-marketing study (II)	3017 patients	Age had a small but a significant effect on the DET score (p=0.025). For every year, the DET score increased by 0.009.
Whiteley & Sinclair (2010)[57]	Prospective study (II)	672 patients	Overall PSC rate was 42.7%. A diagnosis of inflammatory bowel disease was a predictor for PSC (p=0.005), including when compared with all other diagnoses (p=0.007).
Uchino et al. (2017)[36]	Prospective randomised study (II)	320 patients	Dermatitis around the ostomy site was observed in 124/308 patients (40.3%) and age >42 years was found to be a predictor for developing dermatitis (p=0.03).
Mental capabilities (n=9)			
14. Self-consciousness/Self-care (n=5)			
Voegeli et al. (2020)[5]	Retrospective questionnaire (III)	19555 surveys	4235 persons with an ostomy responded from 13 countries. Women reported PSC more often than men (p<0.0001).
Sung et al. (2010)[35]	Retrospective analysis (II)	1170 patients	The incidence of irritant contact dermatitis could be higher in males (93 patients) compared to females (88 patients, p=0.077).
Carbonell et al. (2020)[18]	Retrospective analysis (II)	111 patients	Female sex was a significant factor for developing PSC 30 days post-surgery (p=0.030).
Scarpa et al. (2009)[31]	Prospective study (II)	44 patients	Peristomal dermatitis was correlated with male sex (regression model, p<0.001) in patients with ileostomies.
Arolfo et al. (2018)[14]	Univariate and multivariate analysis on retrospective data (II)	1076 patients	1055 stomas complications were recorded in 797 patients. Male sex was a significant predictor for developing stoma complications such as skin lesions (p=0.032).
15. Stoma management (n=3)			
Colwell et al. (2017)[9]	Questionnaires (III)	796 nurses	77.7% of the nurses indicated that 26–100% of their patients developed some type of PSC during their time with a stoma. The nurses indicated that short inpatient stay afforded little time for the patients to acquire necessary self-management skills.
Carlsson et al. (2016)[41]	Prospective study (II)	207 patients	207 patients undergoing surgeries for different ostomies were followed for 1 year. 11% had PSC. Appliance or routine-related issues (pressure from convexity, ostomy appliance worn for too long, rich hair growth, leakage, or the ostomy opening was too large) were related to PSC.
Park et al. (2011)[51]	Randomised controlled study (I)	81 participants	Participants were divided into two groups. 45 patients in the standardised peristomal skin care group and 36 patients in the crusting group. DET score was evaluated at 1, 2 and 3 months post follow-up. DET score was higher in the crust group (47.2%) compared to the standardised group (22.2%) after 3 months (p<0.05).
Social situation (n=1)			
16. Support (n=0)			
–	–	–	
17. Standard of living (n=1)			
Gooszen et al. (2000)[44]	Prospective study (II)	76 patients	37 patients with loop ileostomies and 39 patients with loop colostomy. Skin irritation occurred more often in patients living in total isolation compared to patients living in partial isolation (p<0.013).

Risk factor / No. supporting articles (n) / Citation	Type of study (evidence Level I, II or III)	No. participants	Major findings/applicability for the risk factor model
OSTOMY PRODUCT (n=16)			
Usage (n=8)			
18. Fit to body profile (n=0)			
–	–	–	
19. Fit to stoma shape (n=2)			
Colwell et al. (2017)[9]	Questionnaires (III)	796 nurses	77.7% of the nurses indicated that 26–100% of their patients developed some type of PSC during their time with a stoma. The nurses indicated that inappropriate use of pouching system contributed to the development of PSC.
Carlsson et al. (2016)[41]	Prospective study (II)	207 patients	207 patients undergoing surgeries for different ostomies were followed for 1 year. 11% had PSC. Appliance or routine-related issues (pressure from convexity, ostomy appliance worn for too long, rich hair growth, leakage, or the ostomy opening was too large) were related to PSC.
20. Application/removal (n=0)			
–	–	–	
21. Wear time (n=3)			
Carlsson et al. (2016)[41]	Prospective study (II)	207 patients	207 patients undergoing surgeries for different ostomies were followed for 1 year. 11% had PSC. Appliance or routine-related issues (pressure from convexity, ostomy appliance worn for too long, rich hair growth, leakage, or the ostomy opening was too large) were related to PSC.
Bourgois et al. (2001)[39]	Cross-sectional study, questionnaire (III)	340 patients	One of the most frequent complaints was rash under the baseplate 50% (170 out of 337). Patients replacing their flanges less frequently (once every 3 days or less) experienced more itching than those replacing it more frequently (p=0.03).
Salvadalena (2013)[55]	Prospective repeated measure design (II)	47 patients	47 patients were followed for 3 months postoperatively, and complications were recorded in 43 patients. 27 out of the 43 experienced PSC (63%). Wear time was a predictor for erosion (p=0.0254).
22. Range and type of products (n=3)			
Martins et al. (2011)[25]	Non-comparative, multinational post-marketing study (II)	3017 patients	Flat baseplate users had a lower baseline DET score compared to convex baseplate users (p=0.002).
Bourgois et al. (2001)[39]	Cross-sectional study, questionnaire (III)	340 patients	One of the most frequent complaints was rash under the baseplate 50% (170 out of 337). Users of a 2-piece system have significantly more complaints of skin problems (p=0.021) than 1-piece system users.
Ratliff (2014)[63]	Descriptive cross-sectional study (III) survey	198 participants	107 persons completed the survey (55%). A 2-piece pouch (less likely to be in a frequent leakage group) was individually a significant predictor for leakage (p=0.015). Participants with peristomal skin irritation seem to be more likely to be in the frequent leakage group (p=0.056).
Technical properties (n=8)			
23. Adhesive properties (n=7)			
Colwell et al. (2017)[9]	Questionnaires (III)	796 nurses	77.7% of the nurses indicated that 26–100% of their patients developed some type of PSC during their time with a stoma. The nurses indicated that inappropriate use of pouching system contributed to the development of PSC.
Cressey et al. (2017)[10]	Retrospective study (II)	54 patients	18 patients out of 54 were identified with peristomal dermatitis. 12 patients had peristomal contact dermatitis. Several stoma skin care products were identified as triggers to allergic reactions, e.g., Cavilon™ No Sting Barrier Film.
Al-Niaimi et al. (2012)[58]	Cohort study (II)	525 cases	65 patients were identified from the 525 cases of peristomal dermatitis with unexplained dermatitis. Separate ingredients could not be sourced, therefore, the product was applied as it was. Patients also undertook a use test, testing the product on the abdominal side, changing the appliance on same time points as the stoma's appliances. All patients went prick testing on cotton, pectin, latex, gelatine, carboxymethylcellulose polyacrylamide and polyisosorbate (no positive results). The participants were reacting to Gantrez™ copolymer (four cases), limonene (two cases), fragrances or preservatives (five cases).

Risk factor / No. supporting articles (n) / Citation	Type of study (evidence Level I, II or III)	No. participants	Major findings/applicability for the risk factor model
Banu et al. (2007)[59]	Prospective study (II)	623 patients	623 paediatric patients (age: 2 days to 12 years) had exteriorisation of the bowel. 495 patients using betel leaf to cover the ostomy experienced only 13 (2.6%) skin excoriation and no allergic reactions. Of the 128 who used an ostomy bag, 52 (40.5%) experienced skin excoriation with small ulcerations and bleedings, and 24 (18.75%) experienced allergic reactions such as rashes and itching.
Caroppo et al. (2019)[60]	Prospective study (II)	26 patients	26 patients with dermatitis were enrolled in the study. All patients were screened for a series of 52 allergens and with specific products for ostomates. Products were tested as they were. Gantrez™ ES-425 was also tested on 13 patients and on 20 healthy volunteers. 10 out of 13 patients were positive to Gantrez™. The most common sensitisations were ConvaTec paste (10 patients), Coloplast paste (10 patients), Adapt Hollister paste (10 patients), and Dansac paste (9 patients).
Colwell et al. (2018)[61]	Randomised controlled study (I)	153 participants	153 participants were followed for a 12-week period post-surgery. 73 patients developed PSC. Significantly more patients in the treatment group with ceramide in the barrier were very satisfied with the overall barrier performance (75% vs. 55.2%, p=0.033). The same was observed in terms of leakage (63.3% vs. 37.9%, p<0.01) and itching (53% vs. 31%, p=0.016). Incidence of PSC was lower in the treatment group.
Welser et al. (2009)[64]	Comparative crossover randomised study (I)	73 participants	73 people were enrolled in a closed-end bag study (60 completed), and 75 people were enrolled in a drainable bag study (72 completed). For people living with an ileostomy and using drainable bag, the PSC (0–4cm from the stoma) were improved after using SenSura Click (p<0.05). For people living with a colostomy using a closed bag, the PSC (0–2cm from the stoma) improved after using SenSura Click (p<0.05), compared to its competitors.
24. Filter performance and capacity (n=1)			
Klok-Vonkeman et al. (2013)[62]	Questionnaires (III)	380 participants	195 out of 380 questionnaires were analysed. Ileostomies experience skin irritation caused by stool on the backside of the skin barrier nearly two times more often than (37%, n=64) than colostomies (19%, n=131). Pancaking ileostomies have 2.4 times more skin irritation than non-pancaking ileostomies. Skin irritation is more common in ostomates with pancaking (p=0.028).