CONFLICTS OF INTEREST
No conflicts of interest were declared.

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METHODS
A cross-sectional study was conducted from September 2003 to September 2004. The study population included all persons with an ostomy living in Roskilde County, Denmark. The population of this county represented 4.4% of the total population of Denmark and is comparable with the national average, with regard to demographic variables, personal income, and days spent in hospital.

We attempted to include all persons with an ostomy by contacting the local municipalities administering individual aid.

An ostomy is an artificial excretory opening of the body, e.g., a colostomy or an ileostomy. The advent of the pouching system has made it possible for the majority of ostomy patients to maintain a normal lifestyle after an operation. Inability to use a pouching system can therefore seriously impair the health and wellbeing of the ostomy patient. The peristomal skin plays an important role in the functioning of the whole pouching system, by providing the surface to which it adheres, and skin complications often reduce the base-plates’ ability to attach to the skin; thus the quality of the peristomal skin is important.

Many different skin conditions are associated with ostomies. Complications are thought to be common, but the exact types, frequencies, and causes of these complications are unknown. Studies have reported a prevalence of peristomal skin complications of between 6% and 80% depending on the type of ostomy and type of skin complication described (1–8). This is a wide range. Generally, these studies have been single-centre-based studies reviewing the local experience in groups of patients ranging in numbers from 90 to 593.

Much of the literature concerning ostomy complications furthermore concerns mainly complications arising from surgery, e.g., necrosis, stenosis, retraction, prolapse, hernia, bleeding, or fistula formation. In fact several studies suggest that stoma complications within the first 2–3 weeks of surgery are more common (1, 9).

Different classifications of skin problems have been suggested, e.g., contact dermatitis (irritant/allergic), mechanical injuries, chemical injuries, fungal, bacterial, and disease-related skin problems, but there is no consensus on a standard definition of skin problems and no standard way of categorizing the severity of peristomal skin lesions, further complicating comparisons between studies.

Finally, the studies are generally retrospective analyses of records, or studies of patients with self-reported skin problems, rather than studies based on physical examination of all patients (2, 4, 7). A need to assess the role of previously suggested risk factors for peristomal skin complications therefore exists.

We have carried out a case-control study to re-assess the role of previously suggested risk factors in a cross-sectional sample of ostomy patients in a limited geographical area, rather than reviewing the experience of a single institution. All participants were examined by a dermatologist. The study population, collection procedure and methods have been presented previously (10). The aim of this study was to validate previously suggested risk factors.

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Danish law (law of Social Service Section 4 chapter 19 §97) states that every person with a chronic disease is entitled to reimbursement for any health-related expenses. For ostomy patients, this means that they are entitled to free stoma care products from selected retailers, without restriction to type or manufacturer of ostomy product. All ostomy patients are automatically enrolled in the database at the local municipality in order to receive reimbursement for product cost. It was therefore assumed that all ostomy patients were registered, as the law provides these benefits without restrictions, and self-payment for alternative purchases would involve substantial additional and unnecessary expenditure for the individual ostomy patient.

A letter was sent to every ostomy patient by the municipalities, inviting them to participate. The ostomy patients then returned a stamped addressed envelope with their reply. Ostomates were invited anonymously, which ensured the autonomy and protection of the participants, but limited the possibility of a non-responder study.

For all patients who accepted the invitation, a physical examination was scheduled. A careful physical examination was performed by a qualified dermatologist, a stoma care nurse specialist, and a resident. A detailed registration form was completed to provide standardized records of known risk factors and other data of possible pertinence to the investigation. The pouching system was examined, and the stoma placement assessed. The peristomal skin was examined and all abnormalities recorded. For further documentation the peristomal skin and the pouching system were photographed.

The majority of ostomy patients were seen at the dermatological department Roskilde University Hospital, but a few were seen at their homes due to advanced age or physical impairment.

Normal peristomal skin without complications was defined as complete absence of any visible skin change in the peristomal area. Skin complications were classified as mild, moderate or severe according to the following criteria: patients with mild skin complication had only slight skin changes, involving only a small portion of the skin (usually 0.1–0.5 cm around the stoma circumference) and requiring no adjustment of the pouching system or active treatment. Moderate skin complication was when definite skin change was seen, e.g., ulcers in the peristomal region, a larger area was involved (> 2 cm²) and adjustments of the pouching system and/or non-prescription treatment was suggested. Severe skin complication was defined as the condition in which immediate medical attention was needed, e.g., systemic steroids or anti-bacterial treatment (pouch refitting and management with mild topical steroids were not enough), often with substantial involvement of the whole skin surface beneath the pouching system and often complicating the pouch system’s adhesion to the skin (Fig. 1).

Data analysed for this article were the frequency of subjective and objective skin complications, and the risk factors previously suggested in the literature: type of ostomy, leakage, sex, age, ostomy retraction, tobacco smoking, presence of postoperative hernia, and body mass index (BMI) (4, 6, 8, 11–19).

Descriptive statistics were used to summarize the data, and univariate statistical calculations were performed using the SAS program. Continuous data were grouped, e.g. BMI, the categorical data were analysed using χ² test. Odds ratios (OR) were calculated, where appropriate, and p-values were calculated for all considered risk factors.

RESULTS

Of a total of 630 invited ostomates, 338 persons responded, giving a response rate of 54%. Lack of data for the non-responders and the limited response rate precluded calculation of actual prevalence rates.

Of the 338 persons responding 139 declined to participate. The reasons for declining were mainly generally poor health, old age or a busy life.

A total of 199 persons, with a total of 202 ostomies were examined. Two ostomates had both a colostomy and an ileostomy and the colostomy were in these cases assumed to be blind (non-productive) and were along with one nephrostomy left out of the further analysis to prevent misrepresentation. This left a total of 199 ostomies for analysis. The ostomies were: colostomy (n = 98, 50%), ileostomy (n = 82, 41%) and urostomy (n = 19, 9%). The mean age of all patients was 63 years (range 29–90 years). The sex distribution of the sample of ostomies was even (M/F: 99/100) as each ostomy was analysed separately.

A total of 90 (44.8%) ostomies were found to have a peristomal skin complication (see Table I). The changes observed by the nurse or physician were recorded. To include subclinical informations as well the patients were asked if they had subjective symptoms such as burning or itching. The frequency of self-reported skin complications was significantly lower than skin complications diagnosed by the junior doctor, dermatologist or stoma care nurse. Only 39 of the 90 (43%) patients diagnosed with a skin complication had noticed the

Fig. 1. Mild, moderate and severe peristomal skin problem.
abnormality themselves, and only 14 (16%) had sought medical assistance to deal with their skin problem.

The types of stoma and the frequency of skin complications are shown in Table II. This shows a significant relationship between frequency of skin complications and the type of ostomy ($p = 0.0341$) due to a higher frequency of skin problems in ileostomy patients compared with colostomy patients (OR = 2.34), 95% confidence interval (1.28–4.26), $p = 0.0052$. Leakage was related to frequency of skin complications (OR = 2.10), 95% CI (1.18–3.71), $p = 0.0107$, but not to the type of stoma ($p = 0.323$).

BMI correlated significantly with skin complication. The frequency of skin complications for different BMI groups is shown in Fig. 2. Patients with a BMI over 30 had more skin complications than patients with BMI under 30 (OR = 2.54), 95% CI (1.27–5.10), $p = 0.0074$.

Several of the studied variables showed no significant relationship to the frequency of skin complications: Sex ($p = 0.826$), age ($p = 0.0864$), retraction of the stoma ($p = 0.0971$), tobacco smoking ($p = 0.877$) and the presence of a peristomal hernia ($p = 0.1263$).

**DISCUSSION**

The results of this study support the view that ostomy type and leakage are major risk factors for skin complications. Ileostomy patients were found to be at significantly greater risk of developing skin complications than patients with a colostomy. This observation is in good agreement with consensus throughout the literature. It is suggested that the pathogenesis of this is the absence of large bowel function which causes more frequent stool, thereby causing more skin irritation than that of colostomies (4). Similarly, patients with urostomies may be at higher risk of skin complications. This study only included 19 urostomy, but 9 (47%) of these had skin complications suggesting that non-specific irritants, such as water or other urine contents, may also play a role. The difference in complication rates for urostomy patients did not, however, reach statistical significance, most likely due to the small number of patients.

One of the most discussed risk factors for peristomal skin complications is leakage. Leakage can be a complication in two ways. It is, in itself, the cause of major social and psychological problems due to smell, soiling, etc. In addition it can cause physical problem, e.g. faecal contact dermatitis. The underlying mechanism is unknown. It has been suggested that leakage is an independent risk factor for skin barrier erosion, although proof is lacking (20). In our study over 50% of the diagnosed skin complications were associated with leakage. Leakage was significantly associated with skin complications (OR = 2.10) 95% CI (1.18–3.71), $p = 0.0107$. Leakage was not associated with stoma type and may therefore be an independent risk factor.

Previous studies have suggested obesity as a risk factor for early skin excoriation. Patients with skin complications had an average BMI of 27.3, whereas the patients without skin complications had a BMI of 26.0. A threshold appears to occur when BMI exceeds 30, beyond which peristomal skin complications are more likely to occur (see Fig. 2). We found that a BMI over 30 was directly associated with having a skin complication (with OR = 2.54, 95% CI (1.27–5.10), $p = 0.0074$).

Ileostomies were not more common in the obese group. From a clinical standpoint obesity could be expected to impair the use of the ostomy bags, and therefore give rise to leakage and peristomal skin complications. Similarly, obesity may affect the positioning of the ostomy before surgery. In view of the association between psoriasis and the metabolic syndrome this observation warrants further study.

Similarly retraction has been implied as a risk factor. With a borderline $p$-value ($p = 0.0971$), retraction of the stoma did not statistically correlate with skin problems. The $p$-value is, however, most likely influenced by the

### Table I. Classification of peristomal skin problems according to cause and severity

<table>
<thead>
<tr>
<th></th>
<th>Mild n</th>
<th>Moderate n</th>
<th>Severe n</th>
<th>Total n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faecal dermatitis</td>
<td>30</td>
<td>9</td>
<td>4</td>
<td>43 (47.7)</td>
</tr>
<tr>
<td>Mechanical dermatitis</td>
<td>19</td>
<td>14</td>
<td>2</td>
<td>35 (38.8)</td>
</tr>
<tr>
<td>Folliculitis</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>5 (5.5)</td>
</tr>
<tr>
<td>Psoriasis</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>2 (2.2)</td>
</tr>
<tr>
<td>Nummular eczema</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2 (2.2)</td>
</tr>
<tr>
<td>Pyoderma gangrenosum</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1 (1.1)</td>
</tr>
<tr>
<td>Allergic contact dermatitis</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1 (1.1)</td>
</tr>
<tr>
<td>Fissura</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2 (2.2)</td>
</tr>
<tr>
<td>Total</td>
<td>52</td>
<td>29</td>
<td>9</td>
<td>90 (100)</td>
</tr>
</tbody>
</table>

### Table II. Ostomy type and skin complications

<table>
<thead>
<tr>
<th>Type and number of stoma</th>
<th>Ostomies with skin problems n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colostomy, n=100</td>
<td>35 (35)</td>
</tr>
<tr>
<td>Ileostomy, n=82</td>
<td>46 (56)</td>
</tr>
<tr>
<td>Urostomy, n=19</td>
<td>9 (47)</td>
</tr>
</tbody>
</table>

Fig. 2. Frequency of skin complications for different body mass index (BMI) groups. The number of patients in each BMI group is shown in parentheses.
fact that only 27 (13.5%) of the studied patients had retraction of their ostomy; while 59% of the people with a retracted ostomy experienced a skin disorder vs. 42% among those without retraction. The observation is not in agreement with clinical experience and it may therefore be speculated that the low absolute number may have influenced the statistical analysis.

A number of other factors have been suggested to play a role in peristomal skin problems. Tobacco smoking impairs healing, and may play a role in perioperative skin complications (17, 18). We found no correlation, as the study population contained only older permanent ostomies. Similarly, herniation may cause functional problems in the stoma, and often represents a challenge to the practical application of a pouching system (15, 16). We did not find a correlation between peristomal hernia and skin complication. It may be speculated that this may be due to the abilities of the individual patient to adapt the pouching system to his or her anatomy.

Finally, the results indicate that simple demographic variables do not appear to be independent risk factors for peristomal skin complications. Earlier literature suggested a trend of higher prevalence among the older age groups (4, 19), and it is speculated that these observations were epiphenomena reflecting other characteristics of the treatment and the patients at the time when the studies were done. The study is, however, limited by the low response rate (54%), and the absolute numbers of participants (numbers of ostomies = 199).

The prevalence of peristomal skin complications reported in the literature varies greatly (1–8). One reason may be that some studies are based on self-reported data. Importantly, our study shows that patients appear to have a significantly higher threshold for noticing abnormalities in the skin. This may reflect the frequency of skin complications, i.e. patients get used to some form of skin complication, or have a lack of education regarding skin complications. The assessment of skin problems by patients themselves often differs from that of dermatologists (21). Of the participants who were diagnosed with a skin complication only 43% recognized that they had a skin disorder, and only 16% of the patients with a skin complication sought professional help. This strongly suggests that self-reported skin problems cannot be used to estimate actual prevalence.

The authors declare no conflicts of interest.

REFERENCES