# Strategies to reduce treatment costs of peristomal skin complications

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# **Abstract**

Peristomal skin complications (PSCs) are common and troublesome and the consequences are substantial both for the patient and from a health-economic viewpoint. The purpose of this article is to demonstrate that early detection and treatment of PSCs, combined with the use of a correctly fitted and appropriate pouching system, can reduce treatment costs—in the UK, it is estimated to save £28.1m annually. A model for cost estimation of PSCs and a real-life global data set of people with stomas are used for the calculations. A high priority should be given to ensuring resources are available to provide education, guidance and assistance to people with a stoma. This would support increased awareness of the first signs of PSCs and enable self-management at an early stage.

**Key words:** Peristomal skin complications ■ Stoma care ■ Health economy ■ Ostomy skin tool

iving with a stoma is life-changing for the patient, his or her relatives and care givers. This change also impacts on society as a whole as it may be associated with increased absence from work due to illness or the need to permanently reduce working hours or stop working, all of which are significant health-economic burdens.

Peristomal skin complications (PSCs) are the most common complications for people with a stoma (Nybaek et al, 2010). Various studies have reported a PSC rate ranging from 18-60% (Colwell et al, 2001; Herlufsen et al, 2006; Nybaek and Jemec, 2010; Martins et al, 2011) and a previous survey revealed that skin problems account for more than one in three visits to stoma care nurses (SCNs) (Jemec and Nybaek, 2008). Early detection of PSCs and access to a qualified health professional can prevent the

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development of more serious complications, improve outcomes, and minimise unnecessary discomfort for the patient (Feldman et al, 1999; Griffiths et al, 2006). However, prevention and intervention strategies are not available to all patients with a stoma, and stoma-related skin complications may go untreated until they require definitive treatment and possible hospitalisation (Turnbull, 2003).

The wide variation in reporting PSCs may be owing to the less than systematic assessment of the peristomal skin by different groups of health professionals. In 2008, Martins et al developed the Ostomy Skin Tool (OST), a user-friendly and standardised approach to assessing PSCs (Martins et al, 2008). The OST has been validated and is now a recognised tool to help health professionals evaluate and monitor the condition of peristomal skin with a high level of reliability and accuracy (Martins et al, 2010; Jemec et al, 2011).

Recently, the OST was used as a reference to create a model for the cost-assessment of treating PSCs (Meisner et al, 2012). The model used a treatment algorithm based on a global understanding from experts applied to average PSC cases. The model estimates what it costs to treat a PSC for 7 weeks. In the study discussed in this article, this model is applied to a large-scale multinational study data set using the experiences of people living with a stoma (the Dialogue Study; Andersen et al, 2011).

The Dialogue Study found that the use of an ostomy appliance with double-layer adhesive (SenSura, Coloplast A/S), alongside regular visits to a SCN, led to improvement of PSCs after a 6-8 week treatment period (Porrett et al, 2011). The aim of the study discussed here was to investigate the possibility of reducing the costs associated with treating PSCs.

#### Materials and methods

#### Model for cost estimation of PSCs

The model for cost estimation of PSCs is described in detail by Meisner et al (2012). In the present study the model was used to estimate the costs of a 7-week treatment period at baseline and after 6-8 weeks' usage of a double-layer pouching system. Cost estimates and references used are presented in *Table 1*.

## Dialogue Study data

The Dialogue Study is the largest study ever undertaken in stoma care practice, with 18 countries participating and more than 3000 people with a stoma enrolled (Andersen et al, 2011). PSCs were assessed using the OST and information on leakage, stoma appliance performance and quality of life were collected. Only the subgroup of participants who reported 'regular' or 'when needed' visits to a SCN or doctor before enrolment were included in the present analysis in order to optimise baseline comparability. Baseline data of this subgroup of participants is presented in *Table 2* and *Table 3*.

#### The OST

The OST generates an objective score based on clinical observations of three domains: discoloration (D), erosion/ulceration (E), and tissue overgrowth (T). In the present study a simplified scale of the DET score was used with three levels of severity − mild (DET<4), moderate (DET≥4<7) and severe (DET≥7) (Martins et al, 2010).The OST also includes a full description of clinical signs for five diagnostic categories of PSC and a care guide for each of the categories.



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Resources	Unit	Cost (£)	Reference	
SCN (first visit)	Visit	94.48	60 mins. Stoma care F2F1	
SCN (general visit)	Visit	47.24	20–30 mins. Stoma care F2F1	
SCN/specialist conference	Session	14.71	10–15 mins. Stoma care. Non-F2F <sup>1</sup>	
Additional home care	Visit	32.00	Community nurse home visit (£64/hr x7) <sup>2</sup>	
Dermatologist (first visit)	Visit	136.14	30 mins. Dermatology (First attendance) <sup>1</sup>	
Dermatologist (general)	Visit	109.73	10–15 mins. Dermatology (Follow-up) <sup>1</sup>	
Gastro surgeon (first visit)	Visit	96.82	30 mins. Gastro surgeon (First attendance) <sup>1</sup>	
Gastro surgeon (general)	Visit	119.07	10–15 mins. Gastro surgeon (Follow-up) <sup>1</sup>	
Local surgical revision	Case	1099.26	Day case. Intermediate skin procedures.  Category 1. Without CC <sup>1</sup>	
Re-surgery (re-siting of stoma)	Case	2443.73	FZ10B <sup>3</sup> Non-elective, short stay. Distal colon procedures. Without major CC <sup>1</sup>	
Hospital stay	Day	247.99	Non-elective inpatient stays (short stay) <sup>1</sup>	
Wound dressing	Once	2.10	Allevyn Gentle Border 10x10cm <sup>4</sup>	
Topical corticosteroids	Regiment	2.25	Betamethasone 30g 0.1% cream <sup>4</sup>	
Prednisolone	Regiment	1.21	Prednisolone 5mg tablets, 28 pcs <sup>4</sup>	
Topical anti-fungal drug	Regiment	4.70	Terbinafine 1% spray, 15ml <sup>4</sup>	
Systemic anti-fungal drug	Regiment	4.98	Fluconazole 200mg capsules 7 pcs <sup>4</sup>	
Systemic antibiotics	Regiment	1.20	Amoxicillin 500mg capsules, 21 pcs <sup>4</sup>	
Tacrolimus	Regiment	50.50	Tacrolimus 500 microgram capsules 50 pcs <sup>4</sup>	
Cyclophosphamide	Regiment	20.20	Cyclophosphamide 50mg tablets, 100 pcs <sup>4</sup>	
Infliximab	Regiment	5035.44	Weeks 0, 2 and 6. 80kg <sup>4</sup>	
Weak opioids, systemic	Week	1.14	Tramadol 50mg capsules, 30 pcs <sup>4</sup>	

F2F – face-to-face; CC – complications and comorbidities; pcs – pieces

- Department of Health, 2011
- Personal Social Services Research Unit, 2012
- <sup>3</sup> Health Resource Group <sup>4</sup> BMJ Publishing Group, Royal Pharmaceutical Society of Great Britain, 2012

#### Statistical methods

The baseline and end of study PSC treatment costs are analysed using a linear normal analysis of covariance. The treatment costs of PSCs are further analysed using a logarithmic transformation providing relative instead of absolute differences after exponentiation of estimated differences.

The covariates considered were:

- Type of stoma
- One- or two-piece appliance
- Convex or non-convex baseplate
- Frequency of clinic visits to SCN or doctor before enrolment
- Baseline frequency of leakage (on a threelevel scale)
- Reason for stoma creation
- Permanency of stoma (temporary or permanent)
- Sex
- Country and centre treating the patient
- Time span since stoma creation (years)
- Age (years).

The significance level used was the standard

5% and all analyses were performed using SAS software, version 9.2.

#### Sensitivity analysis

A sensitivity analysis was conducted to test the robustness of the health economic model with a ±20% change in resource cost (including salaries, overhead cost, time utilisation, administration, education, and so on).

The estimated cost of 7 weeks' treatment of an average case of PSCs at all levels of severity are listed in Table 4 (overleaf). Severe PSCs are 2-4 times more expensive to treat than mild PSCs. The difference in costs between mild and moderate cases ranged from £,12 to £,194 with disease-related PSCs at the top end.

The overall mean DET score was 2.5±2.8 range [0-15] at baseline, which was reduced to  $1.6\pm2.2$  range [0-15] at the end of the Dialogue Study. This reduction was highly significant (p<0.0001). Overall, 39% of the participants (n=993) had normal peristomal skin whereas

Table 2. Dialogue Study – baseline characteristics					
		Participants (N)	%		
C	Male	1252	49		
Sex	Female	1308	51		
Type of	Colostomy	1715	67		
	Ileostomy	802	31		
Stoma	Urostomy*	44	2		
Permanent	Yes	2202	86		
stoma	No	352	14		
PSC	Yes	1562	61		
	No	993	39		
*People wit	h urostomies	were not enrol	led in		

Table 3. Dialogue Study – patient characteristics				
	Mean ± SD			
Mean age (years)	63.2 ± 14.3			
Time since surgery (years)	5.3 ± 7.0			

the remaining 61% (n=1562) showed PSCs at baseline with a mean DET score of 4.1. At the end of the study, only 46% of the participants had PSCs with a mean DET score of 2.4. The present study focused only on participants with PSCs. The estimated mean reduction in treatment costs for PSCs from baseline to the end of study was £62 (from £160 to £98) for a 7-week treatment period.

Figure 1 (overleaf) shows the mean estimated cost of treating mild, moderate and severe PSCs at baseline and at the end of the study. The data show that severe PSCs are more expensive to treat than mild and moderate cases. In fact, at baseline, the estimated mean cost of treating severe PSCs is twice as expensive (£303) as treating moderate cases (£151). The improvement in peristomal skin from a DET score of 4.1 (baseline) to a DET score of 2.4 (end of study) led to a significant reduction (p<0.0001) in estimated costs for a 7-week treatment period. The cost of treating severe PSCs was reduced by almost half (from £,303 to £,155) and the cost of treating mild and moderate PCSs was reduced by 41% and 30% respectively at the end of the study.

Frequency of appliance leakage is associated with the severity of PSCs and Figure 2 shows that there is a reduction in the related estimated cost in the range of 34-42% from baseline to the end of the study, with the highest reduction seen in the group who experience leakage 'sometimes'. For the five diagnostic categories, the highest estimated

Table 4. Cost of managing PSCs depending on cause and severity							
Diagnostic category	Mild	Moderate	Severe				
Irritant contact dermatitis	£113.38	£132.88	£290.45				
Allergic dermatitis	£196.81	£267.36	£371.84				
Mechanical trauma	£106.29	£118.38	£219.60				
Disease related	£142.73	£336.36	£618.69				
Infection	£151.84	£184.41	£385.87				

Mild = DET score <4; Moderate = DET Score  $\ge 4$  and <7; Severe = DET score  $\ge 7$ 

DET = discoloration, erosion/ulceration, tissue overgrowth

Cost estimations are based on UK unit cost in 2012

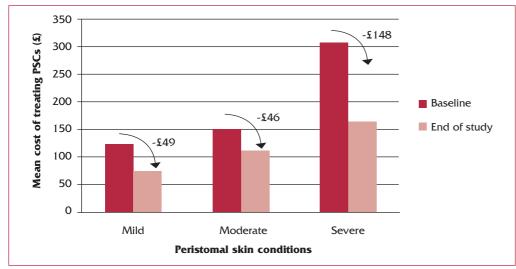


Figure 1. Mean estimated cost of treating mild, moderate and severe PSCs for a 7-week period

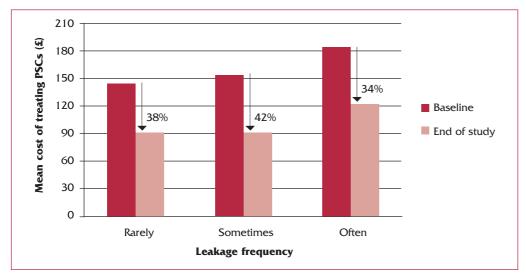


Figure 2. Mean estimated cost of treating PSCs with various leakage frequencies for a 7-week period

reduction in cost of treating PSCs was seen for infection-related peristomal skin disorders from £212 at baseline to £59 at the end of the study (*Figure 3*); however, only a small number of the participants had this type of peristomal skin disorder. Overall, 45% of the participants suffered from irritant contact dermatitis, and in this group the estimated reduction in costs from baseline (£149) to the end of study (£91) was 38%.

In participants with a temporary stoma, treatment costs reduced by 46% from baseline to study end (from £168 to £91), which was more than for those with a permanent stoma whose treatment costs were estimated to have been reduced by 37% (from £158 to £99).

A sensitivity analysis of a  $\pm /-20\%$  change in the costs associated with the 11 healthcare resources (resources in *Table 1* excluding medical treatment) was performed to assess

the robustness of the model and the estimated cost. The results are presented in *Figure 4* and show that the estimated costs are most sensitive to the costs associated with the first visit to a SCN. The PSC treatment costs changed 0.5% for a 1% change in the cost of the first visit to a SCN and less in any of the other 10 categories. The PSC cost estimate, however, is robust to changes in the 11 tested categories.

A covariance analysis was performed to test for factors influencing the treatment costs of PSCs at baseline. There was no significant impact on the treatment costs when the different variables were tested (data not shown).

#### **Discussion**

Stoma-related complications such as stoma necrosis, retraction, prolapse and stenosis, as well as parastomal hernia and peristomal skin diseases, are common (Persson et al, 2010). PSCs are the most common complication following creation of a stoma and the risk is highest in the first 5 years after the operation (Londono-Schimmer et al, 1994).

PSCs range from a mild peristomal dermatitis to ulceration or necrosis. It is vital that people with a stoma regularly check the peristomal skin and seek professional advice in a timely manner if deterioration in skin condition is observed. However, several studies have shown that a high percentage of patients with PSCs are not aware of their condition (Scarpa et al, 2004; Martins et al, 2011; Erwin-Toth et al, 2012) and, even worse, patients who recognise their PSCs do not always seek professional care. This is of concern as the severity of PSCs may increase if left untreated. The consequences of PSCs are substantial, both for the patient and from a health-economic viewpoint.

Meisner et al (2012) presented a model for cost estimation of PSCs. In the present study, this model was used to estimate the treatment costs related to PSCs. The estimated reduction in costs for a 7-week treatment period was £62 for an average case and significantly more for patients with severe PSCs, where the estimated costs were reduced by almost half (from £303 to £155) for a 7-week treatment period. It is therefore reasonable to state that significant cost savings could be made if the focus was on methods to:

- Prevent or minimise the risk of developing a PSC
- Detect PSCs at an early stage
- Provide optimal treatment thereby avoiding long-term, debilitating and expensive complications.

About 100 000 people in the UK and Ireland have a stoma (Lyon, 2001) and, assuming that



### **KEY POINTS**

- PSCs are common and the consequences are considerable for the patient and from a health-economic point of view
- A model for estimating the cost of treating PSCs has been established
- Treatment costs of PSCs increase with severity level
- High focus on early treatment
- Education and guidance of the patient to perform self-management should be prioritised

there is no further improvement or deterioration in the PSC level and that 61% of the population have a PSC, a £,62 cost reduction would make a £461 annual saving per patient and a total annual saving of £28.1m in the UK.

The use of an appropriate appliance and accessories will also save money in the long term. In the global Dialogue Study, the number of accessories (excluding belts) used by participants was significantly reduced from 4682 at baseline to 3214 at the end of the study (p<0.0001) (Porrett et al, 2011). Depending on the country, there are a limited number of free stoma appliances, accessories or consultations, and the model used in the present study does not take into account the costs incurred by the patient.

The actual cost of treating PSCs is important to quantify, but the frequency and severity of PSCs also has a major impact on a patient's quality of life and overall standard of daily living, which is difficult to quantify but is equally important. The authors' recommendations are that efforts should be made to educate and guide patients to become aware of the first signs of PSCs and enable self-management at an early stage. This will require increased access to a SCN, who should also help with correct fit and adjustment of an appropriate pouching system.

#### **Conclusion**

The extent and consequences of PSCs necessitates awareness of and action to be taken by patients and health professionals in order to avoid long-term and expensive treatments. The present study demonstrates that significant savings can be made by following evidencebased stoma care nursing practice and using a double-layer adhesive appliance.

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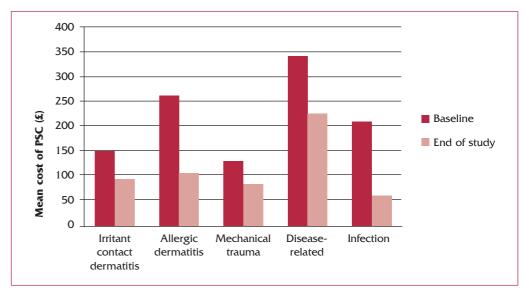


Figure 3. Mean estimated cost of treating PSCs in five diagnostic categories for a 7 week period

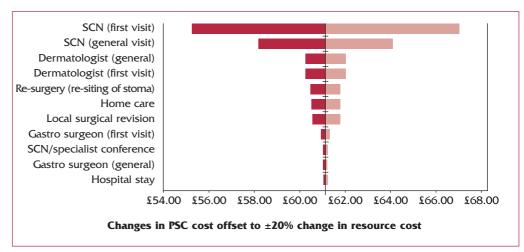


Figure 4. Sensitivity analysis on ±20% unit cost variation

(Coloplast A/S) provided health economic input for the analyses. James Clark (Oxford Outcomes, UK) did the UK unit cost collection. Zenia M. Størling (Trial Form Support Aps, Denmark) contributed with medical writing of the manuscript.

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