Received: 24 September 2018 | Revised: 14 November 2018 | Accepted: 20 November 2018

DOI: 10.1111/iwj.13052

WILEY IWJ

ORIGINAL ARTICLE

Design and validation of a "Peristomal Lesion Scale" for peristomal skin assessment

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Many people in Italy undergo ostomy because of illness, and this can have negative psychological and physical effects. It is estimated that 15%–43% of ostomates suffer from skin complications in the peristomal area. During their life, many ostomates experience at least one peristomal lesion, and they turn to stomal therapy centres where trained nurses provide patient care and manage skin complications. To ensure a good quality of life for patients, and to take prompt action for the prevention and treatment of stomal lesions, it is essential to use appropriate assessment tools. The aim of this study was to develop a reliable peristomal skin assessment tool (Peristomal Lesion Scale [PLS]) for classifying lesions based on their severity; and to compare its validity with the most widely used peristomal tool in Italy, SACS. The new tool was designed by a team of experts, focusing on patients' demographics, clinical characteristics, and classification of the lesions by severity and topography. The results of this comparative validation study indicate that the PLS better discriminates lesions by their severity because of its level of detail, using a standardised terminology, and its completeness. The PLS is a valid tool for use in the daily work of stomal therapists.

KEYWORDS

ostomates, ostomy, peristomal skin assessment, scale development, validation study

1 | INTRODUCTION

Ostomy is a surgical procedure to create an abdominal hole (or stoma) for eliminating faeces or urine from the body by connecting the intestinal or urinary tract with the outside. There is no sphincter (or ring of muscle) to allow it to close, so faeces and urine come out without control.[1] This may have a negative psychological effect on patients, but it can be an effective solution for certain problems caused by trauma or disease. People with a stoma have a different, but manageable anatomical configuration, and they can lead a normal social life.[2] The main types of ostomy are the urostomy for the urinary tract, and the colostomy and ileostomy for the intestinal tract.[3]

As reported in the literature,[3–7] there may be complications associated with this type of surgery, causing pain and discomfort to the patient. The most common are parastomal hernia, prolapse, necrosis, mucocutaneous separation, retraction, stenosis, fistula, trauma, and peristomal skin problems.[3–7] Salvadalena, in reviewing the incidence of all the complications related to colostomy, ileostomy, or urostomy, found that the most common are the skin lesions.[8]

Among more than 70 000 people with a stoma in Italy (0.13% of the total Italian population), it is estimated that at least 15%–43% suffer from skin complications in the peristomal area.[9] It has been demonstrated that such skin complications interfere with patients' quality of life.[10,11] Having a stoma is a life-changing condition for patients and their relatives and/or caregivers as it increases the burden and cost of their health care.[12,13] It also carries a social cost because it increases the needs to access health services.[14,15]

During their life, the majority of ostomates experience at least one occurrence of peristomal skin complications that

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necessitate their referral as outpatients to a stomal therapy centre.[16] These centres have specialised health professionals, including surgeons, dermatologists, and stomal therapists (professional nurses specifically trained to manage skin complications caused by ostomies and/or the medical devices attached to a stoma).[1,17,18]

The protagonist during a patient's preoperative education, and postoperative training and rehabilitation is the stomal therapist, who will also follow up routinely the ostomate patient.[1] To ensure a good quality of life for ostomates, nurses must monitor, try to prevent, and promptly treat any skin complications in the peristomal area. To do so, it is essential to use appropriate tools to assess any peristomal skin variations correctly,[19] but in clinical practice there is paucity of reliable tools for peristomal skin assessment. In Italy, besides the most often used SACS instrument for assessing and classifying peristomal skin lesions, a few other instruments are available; however, nurses valued negatively the practicality and usefulness of such alternative tools.[2,20–27] In general, all such tools are covered by a copyright, or owned by medical companies and licensed free of charge to health institutions.

The limited availability of valid assessment tools, and the importance of monitoring the status of a patient's peristomal skin prompted a group of nurses to develop a more valid scale readily usable for assessing the peristomal skin area in the nursing care of ostomates. This gave rise to the independently developed "Peristomal Lesion Scale" (PLS) for classifying peristomal skin lesions based on several empirical aspects related to the specificity of the stomal therapist's examination.

The aims of this study were: (a) to develop a reliable and easy-to-use peristomal skin assessment scale for classifying lesions based on their severity; and (b) to compare the validity of the new scale with the one currently most often used, the SACS.[20]

Key Messages

- most of the ostomates experience at least one peristomal lesion during their life. Adequate monitoring of the status of the skin in the peristomal area requires the use of an appropriate scale for assessment
- none of the currently available peristomal skin assessment scale have reached a sufficient level of international acceptance to be considered as a gold standard
- compared with the SACS, our new PLS better discriminates stomal lesions by severity, and provides more details for nursing assessments and monitoring of peristomal skin complications

2 | STUDY DESIGN AND METHODS

The study adopted a cross-sectional exploratory design with a convenience sample.

The variables considered are observable characteristics that can adequately describe the state, location, and dimension of changes in the peristomal skin. The system of measurement adopted makes it feasible to compare the validity of the PLS vs the SACS.

The PLS was developed between January 2016 and October 2017. The initial multidisciplinary focus group identified the set of crucial variables for assessing the peristomal skin. This group also compared and assessed the overall quality of existing tools for describing and measuring peristomal skin lesions. The MEASURE Evaluation method[28] was adopted for this comparison as this algorithm has been recommended for the development of best practices for assessing lesions, their variability in size, appearance, exudate, pain, and margins. According to MEASURE, skin lesions should be periodically reassessed and reclassified by the subtype.

Based on the abovementioned outcomes, the group of experts derived a description and measurement model that it could use to develop a new instrument.

Phase two was dedicated to developing a logical and empirical system of elements forming an observation grid with an appealing graphical layout. The third and last phase was dedicated to comparing the PLS with the SACS Instrument by means of a multicentre cross-sectional study in Italy.

2.1 | Focus group

The multidisciplinary focus group's mandate was to explore the existing literature on peristomal skin alterations and specific systems for assessing them. The group consisted of experts from different clinical fields and geographical areas of Italy, who met in Bologna in 2016. Group members were recruited by the AIOSS (Technical-Scientific Association of Stomatherapy and Rehabilitation of the Pelvic Floor) and AISLeC (Nursing Association for the Study of Skin Lesions) nursing associations collaborating on the project and included a general surgeon, a dermatologist, 14 stomal therapists, a wound care nurse, two generic professional nurses, and a professor of nursing who served as coordinator.

A full-day meeting was dedicated to comparing existing scales, their validity, and their application protocols. The strengths and weaknesses of each tool were identified, and a set of necessary variables and measures that were still lacking was defined. The patient's features that the experts wanted such tools to assess were as follows: (a) diagnosis, age, and gender; (b) general state of health; (c) systemic diseases, disorders, and complications; (d) therapies (related to skin lesions); (e) type of ostomy and devices in use; (f) characteristics of peristomal skin lesion (type, size with scale, and appearance); (g) localisation/extension of the lesion; and (h) classification of the lesion. The tool should be suitable

for use in repeated assessments, and for monitoring the evolution of a lesion. It should be applicable to single stomas, producing clear and accurate data suitable for inputting in a computer program. It should be quick and easy for any nurse to use.

2.2 | Literature review

In January and September 2016, the PubMed, Cinahl, and RNAO electronic databases were searched for instruments measuring peristomal skin complications, using the following keywords: assessment of peristomal skin, colostomy, ileostomy, management of peristomal skin, ostomy assessment, ostomy management, urostomy, ostomy skin tool, quality of life, and skin complication. It emerged that several instruments for peristomal skin evaluation have been tested and described. The most cited are: the Scale for the Classification of Peristomal Skin Disorders (SACS),[2,20,21] and SACS 2.0[18,29]; the Ostomy Skin Tool (OST)[2,22,23]; the ABCD Stoma[24]; the LSD score[25]; the Stoma Care Ostomy Research Index[26]; and the Classification of Peristomal Skin (CPS).[27]

The validity of the ABCD Stoma[24] and the LSD score[25] has not been reported in the literature, so these two instruments were excluded from the analysis. The CPS[27] is a tool for classifying microscopic peristomal skin changes in faecal and urinary stomas, was described by Haugen and Ratiff[19] as needed to undergo further testing. The Stoma Care Ostomy Research Index[26] identifies common skin problems in ostomates, assigning scores on digital photographs of peristomal skin complications. This index was derived from the Ostomy Observation Index,[5] and the authors provided no data on its reliability and statistical validity.[5,19] The OST provides a standardised description of three peristomal skin changes, discoloration (D), erosion (E), and tissue overgrowth (T). Each parameter facilitates the assessment of the peristomal area, and the evaluation of the severity of any lesions. A score of 0 to 5 is attributed to each parameter, for a total in the range of 0 to 15. The OST has a "moderate to good" inter-rater reliability and a high consistency (K test = 0.84). OST validation studies have been conducted in Denmark and Spain,[2,19,22,23] but not in Italy, and it is almost unknown to Italian nurses.

The SACS is a tool developed by Bosio and colleagues[20] to assess peristomal skin in connection with a patient's health status and the site of any skin alterations. The SACS considers five types of lesion: (L1) hyperemic (peristomal erythema without loss of substance); (L2) erosive (open lesion with loss of substance, not extending into subcutaneous tissue); (L3) ulcerative (open lesion extending into subcutaneous tissue); (L4) ulcerative (full-thickness skin loss with dead tissue, fibrinous/necrotic lesion); and (LX) proliferative (abnormal growths present, ie hyperplasia, granulomas, neoplasia, and oxalate deposit).[2,19,20] In a recent review of the SACS,[18,29] a group of experts added "L5" as a further level of severity with ulcerative lesions involving planes beyond the muscle fascia, with or without fibrin, necrosis, pus, or fistula. The SACS divides the peristomal area into four topographic quadrants ($T_{I\text{-}IV}$) arranged clockwise around the stoma, with the additional T_V to indicate that all four quadrants are affected.[20] The SACS is currently the only instrument validated for peristomal skin assessment and classification in Italy, the United States and Turkey.[2] It has a high interobserver consistency and its validity is rated as "very good" ($K = 0.91$).[19] It has some important limitations, however, in that it only applies to intestinal ostomies, and it provides a qualitative description without any scores or weighted measurements. The SACS is also unable to classify lesions by intensity, or to assess peristomal skin changes over time.[20]

From the literature review it emerged that, despite the ample availability of scales for peristomal skin assessment, none of these tools has reached a sufficient degree of clinical acceptance and scientific validation. There is consequently no particular tool that can be seen as a reference, or used as a gold standard for peristomal skin assessment on an international scale. In short, there is still no sufficiently valid and reliable scale available for assessing peristomal skin complications that meets nurses' needs in their clinical practice.

2.3 | Structure of the PLS for assessing and scoring peristomal skin complications

The Peristomal Lesion Scale (PLS) contains three sections and covers 50 variables measured on nominal, ordinal, and continuous scales. The three sections concern: (a) patient demographics, with a subsection on health status; (b) classification of peristomal lesions; and (c) topography of peristomal lesions. Each variable was selected in the light of the literature[3–7,18,20] and the focus group's clinical expertise.

The "Demographics" section contains information about the patient's age, gender, weight, and height. The subsection "Health status" is for recording details about the reason for the ostomy (neoplasia, chronic inflammatory intestinal diseases, and diverticulitis), any comorbidities (neoplasia, autoimmune diseases, diabetes), and ongoing therapies (immunosuppressants, antibiotics, chemo/radiotherapy, and anticoagulants/antiaggregants). This is followed by a description of the type of ostomy (colostomy, ileostomy, jejunostomy, cecostomy, ureteroileal cutanostomy, or ureteral cutanostomy), the related devices (flat or convex plates with adhesive edges), and accessories (paste with or without alcohol, protective film, ring, belt, and patches). The experts' meeting generated a consensus on the importance of certain further information, including the surgical modality (urgent or elective), the date of the procedure, and the site of the stoma. After reviewing the type of postoperative complications that occurred, space was provided for indicating the characteristics of lesions: retraction, mucous-cutaneous

detachment, hernia, and fistula. The number of ostomies has to be specified in this section too, because these details have to be provided separately for each ostomy and peristomal lesion.

The second section deals with the assessment of the peristomal skin. It describes the characteristics of the lesion considered the most severe. The experts in the focus group agreed on a classification of the lesion as: elementary, ulcerative, or with overgrowth. If the lesion is of elementary type, any erythema, papules, pustules, vesicles, or bubbles should be recorded. If it is ulcerative, it should be stated whether it is an erosion or an ulcer. In the case of ulcers, the floor (granulation tissue, necrosis, slough, biofilm, purulent, or haemorrhagic exudate), margins (active, undercut or locked), and edge (dark red, well defined or irregular) are described. In the event of multiple lesions, the set of information must be provided separately for each lesion.

The third and last section focuses on the location of the lesion and its size. To locate the lesion, the method used by the SACS instrument,[20] with the quadrants T1, T2, T3, T4, and T5, was combined with the method based on the proximal/distal areas A, B, and C used in the ABCD-stoma tool,[24] where A indicates a lesion in the circumstomal area (from the ostomy up to 2 cm away), B a lesion on the skin covered by the plaque (up to 7 cm away), and C a lesion beyond the plaque. An indication of the size of a lesion was judged to be crucial; the size must be measured in centimetres on the two major axes of the lesion. The scale is administered to faecal and urinary ostomies repeatedly to track the wound over time.

The PLS scoring system has been designed to weight each lesion according to its severity, assigning a score from 1 to 10 to each type of lesion. Similarly, the score for the topography of the lesion depends on the quadrant involved and the extent of the area affected - one point for each area involved. The total PLS scores derive from the sum of the scores obtained in the second and third sections of the scale, generating a final score ranging from 2 to 22. The patients' total scores on the PLS were classified based on the following threshold values dividing the total distribution in quartiles:

- "low" = less than 8 included;
- "medium" = 9 and 10 included;
- "high" = 11 and 12 included;
- "very high" = more than 12.

The same scoring system was applied to the SACS to enable a comparison between the outcomes of the two scales (PLS and SACS). In fact, the total score in SACS comes from adding the score by type of lesion (from 1 to 5) with the score for quadrants involved (from 1 to 4). The total score can vary between 2 and 9. To compare SACS and PLS, the categories of severity in SACS have been derived dividing the total score distribution of the observed subjects, into quartiles. Each quartile represents a level of severity according to its rank in the distribution, both for SACS and PLS, as follows:

Quartile 1—Low severity—SACS: less than 5 included; PLS: less than 8 included;

Quartile 2—Medium severity—SACS = 6; PLS: 9 and 10 included;

Quartile 3—High severity—SACS = 7; PLS: 11 and 12 included;

Quartile 4—Very severity—SACS more than 7; PLS more than 12.

Section 1 of the PLS (Demographics and Health status) is currently used only for descriptive purposes, although in future it may provide useful information about potential predictors of the risk of peristomal complications.

2.4 | Tool validation: Setting and sample

The study sample was collected at four Italian stomal therapy centres in northern Italy, in the cities of Padua and Venice (Veneto region), and Modena (Emilia Romagna region), between June and September 2017. The sample was collected using a systematic recruitment model. The study was conducted on outpatients attending the stomal therapy centres, and in hospital wards with stomal therapists on the staff. All patients treated at the participating centres were considered eligible for observation and assessed. Patients with healthy ostomies were excluded. The eligibility criteria were: (a) age over 18 years; (b) the presence of one or more colostomy, ileostomy, jejunostomy, cecostomy, ureteroileal cutanostomy, or ureteral cutanostomy; (c) the presence of one or more peristomal skin lesions; (d) ability to provide informed consent.

A meeting was arranged at each recruiting centre to provide staff with specific guidelines on patient assessment and data collection, and to give participants the opportunity to ask any questions before giving the consent.

2.5 | Data collection and analysis

Patients' demographic and clinical data and their peristomal skin findings were collected using both the PLS and the SACS. The data were collected by stomal therapists on a paper form during patient follow-ups in the wards or at the outpatient clinics. The same stomal therapist observed each patient using the two instruments and recorded both results with a unique code for each patient.

Data from these paper forms were input in an electronic database and analysed using STATA v13.0.

For both the PLS and the SACS, the various partial scores were combined to obtain a total score, which was divided into quartiles to obtain four classes of severity ("low", "medium", "high", and "very high"). These four

classes were then compared using double-entry cross-tabulations.

2.6 | Ethical considerations

The validation study was approved by the institutional ethics committees. Patients' participation was voluntary and informed consent was obtained from all patients recruited. The confidentiality of the data and patients' anonymity were guaranteed by a coding system in accordance with the ethical guidelines of the 1975 Declaration of Helsinki. The original list of names and the corresponding codes were kept under the study supervisor's control, inside the hospital or outpatient clinic. All data accessible to the researchers had been previously anonymised.

3 | RESULTS

During the 4 months of data collection, 120 subjects were recruited, but only 110 were analysed; eight patients were excluded because they had more than one lesion (6.7%), two because they had two or more ostomies (1.7%). Overall, 10 subjects have been excluded from the analysis.

Details of the sample's demographics and health status are outlined in Table 1.

The sample consisted of 57 males (51.8%) and 53 females (48.2%), with a mean age of 69 years (range 19-90 years). There was a majority of males among the 71- to 80-year-olds (37.5% of all the males), and a majority of females among the 61- to 70-year-olds (35.9% of all the females). When the different age groups were stratified by gender, most of the women were into the class 61 to 70, whilst most of the men were into the class 71 to 80. This is an intriguing result bearing in mind that women's greater life expectancy should produce a more rightward-skewed curve for female patients. Stratifying age by PLS severity the patients' age distribution resulted evenly divided between the four severity classes. However, gender distributed differently between the "high" and "very high" classes of severity: in the "high" class, the males were almost twice (17.3%, 19) the females (9.1%, 10), whilst in the "very high" class there were more females (14.5%, 16) than males (8.2% 9).

The average BMI was 26.5 (min 18.7, max 39.5), with a significant proportion of overweight patients (71, 64.5%).

The sample included 61 subjects (55.4%) with no comorbidities, 40 (36.4%) with one, and 9 (8.2%) with more than one. Cancer was disregarded as a comorbidity if it was also the main reason for the ostomy because cancer was identified as the most frequent reason for ostomy (52.7%) and as a comorbidity. Of all the other conditions leading to ostomy, 10% were because of occlusion and intestinal perforation.

As for patients' therapies, the most common were "anticoagulants" (20.9%), antibiotics (10%), and antihypertensive agents (9.1%). The mean time elapsing since the ostomy was 3 years. The most common type of ostomy in our sample was ileostomy (47.3%), followed by colostomy (38.2%), and then other types of procedures (14.5%).

TABLE 1 Patient demographics and clinical information

Variable	N.	%
Sex		
Male	57	51.8
Female	53	48.2
Total	110	100
Age		
<60	25	22.7
61–70	30	27.3
71–80	34	30.9
>80	20	18.2
Missing	1	0.9
Total	110	100
Comorbidity		
0	61	55.4
1	40	36.4
>1	9	8.2
Total	110	100
Comorbidity[a]		
Cancer	24	49
Autoimmune disease	9	18.4
Diabetes	11	22.5
Other[b]	15	30.6
Main pathology		
Cancer	58	52.7
Chronic intestinal inflammatory	10	9.1
Diverticulitis	9	8.2
Other[c]	33	30
Total	110	100
Treatment		
Immunosuppressants	5	4.6
Antibiotics	11	10
Chemotherapy/radiotherapy	7	6.4
Anticoagulants	23	20.9
Other[d]	17	15.5

[a] Percentages are calculated on the sample of subjects with at least one comorbidity (49, 44.5%), so they may be summative or not mutually exclusive.
[b] "Other" includes: hypertension, cardiopathy and valvulopathy, intestinal perforation, arthritis, pressure ulcers, chronic renal failure, viruses (HIV, HCV), and liver disease.
[c] "Other" includes: rectal ulcerative colitis, intestinal ischaemia and recto-vaginal fistula, polyposis, occlusion, and perforation.
[d] "Other" includes: analgesics, diuretics, antihypertensive agents, allopurinol, antiviral agents, oral hypoglycemic drugs, statins, thyroid hormones, and anti-inflammatory drugs.

The two most adopted devices were flat (50%) or convex (48.2%) plates in association with various accessories such as pastes (with or without alcohol), dust, and belts.

Complications involving the stoma are related to some degree to the surgical procedure (whether it is performed urgently or electively). In our sample, 61.8% of participants were identified as having at least one stomal complication (see Table 2), the most common being retraction of the

stoma itself (66.2%). Peristomal skin alterations are considered much more common by several authors, however, and they were found in 100% of our sample.[5–8]

Using the PLS, peristomal skin lesions can be grouped into three main descriptive typologies: elementary, ulcerative, or with overgrowth. Of the elementary alterations, erythema is the most frequent (17.3%, 19). The ulcerative type of lesion was the most common condition (63.7%, 70) in our sample (see Table 3), and more than half of these patients had erosions (32.7%, 36), whilst the remainder (31%, 34) had more or less severe ulcers. However, overgrowth of tissue was reported in a significant proportion of our sample, (12.7%, 14).

Using the SACS, the findings in our sample differed very little from those obtained with the PLS (see Table 3). In particular, peristomal skin erosion was found in 35.5% of the cases (39 patients) using the SACS as opposed to 32.7% (36) using the PLS. Erythematous lesions without loss of substance were identified in 20% of the sample with the SACS and in 23.6% with the PLS.

The SACS classifies the site of peristomal lesions in one of four quadrants whilst the PLS considers 4 quadrants and 12 areas (3 areas per quadrant). Using the PLS by areas, 30.9% (34) of the patients had lesions covering two areas, and 49.1% (54) had lesions covering four areas. Using the PLS by quadrants, more quadrants were involved, and the lesions resulted more extensive than using SACS. According to PLS, 6 patients (5.5%) had severe lesions involving all four quadrants (12 areas), whilst 8 (7.3%) had only small lesions located in just one quadrant (1 area). In comparison, as SACS uses only four quadrants, 34.5% subjects resulted having two quadrants involved, 47.3% had lesions in all four quadrants, and 13.6% had lesions in just one. Comparing the topographic classifications obtained with the two scales, all but one of the patients with lesions located in the first quadrant according to the SACS were similarly located in the first quadrant according to the PLS, but in distinct areas (A, B, or C). The results concerning the site of the lesions obtained with the PLS and the SACS are outlined in Table 4.

The patients' total scores on the PLS were classified in "low" (less than 8); "medium" (between 8 and 10 included); "high" (between 11 and 12 included); and "very high" (more than 12).

The resulting distribution of the values ranged from 2 to 19, where the theoretical distribution was expected to range from 2 to 22.

The SACS scores were similarly processed to obtain four classes of overall severity for the purposes of a comparison with the PLS scores. The resulting distributions of the observed and theoretical values overlapped completely, ranging from 2 to 9 (see Table 5).

Comparing the two instruments in terms of their capacity to discriminate the sample by the overall severity of their peristomal lesions, the SACS places more patients in the "low" (49.1%) and "high" (29.1%) groups than the PLS, which stratifies the sample quite evenly across the four classes. Interestingly, the highest agreement between both instruments refers to the "low" (24.6%) and "high" severity classes (18.2%). In contrast, the two scales have a little

TABLE 2 Patients' ostomy complications

Variable	N.	%
Type of operation		
Urgent	43	39.1
Elective	63	57.3
Missing	4	3.6
Total	110	100
Preoperative design		
Yes	23	20.9
No	75	68.2
Missing	12	10.9
Total	100	100
Type of ostomy		
Colostomy	42	38.2
Ileostomy	52	47.3
Jejunostomy	1	0.9
Cecostomy	2	1.8
UICS	9	8.2
UCS	2	1.8
Other	1	0.9
Missing	1	0.9
Total	110	100
Device		
Flat	55	50
Convex	53	48.2
Plate with adhesive edge	2	1.8
Total	110	100
Accessories		
Paste	23	20.9
Paste with alcohol	16	14.6
Film	4	3.7
Ring	5	4.6
Belt	9	8.2
Patch	1	0.9
Other	10	9.1
Ostomy complications		
0	42	38.2
1	62	56.4
>1	6	5.4
Total	110	100
Type of complication (if complication > 0)		
Retraction	45	66.2
Detachment of mucocutaneous junction	16	23.5
Hernia	9	13.2
Fistula	2	2.9
Other	4	3.7

TABLE 3 Classification and distribution of peristomal skin complications in PLS vs SACS

Wound classification in PLS	Fr.	%	Wound classification in SACS	Fr.	%
Elementary			L1	22	20
Erythema	19	17.3	L2	39	35.5
Papules	2	1.8	L3	22	20
Pustules	2	1.8	L4	11	10
Vesicles	2	1.8	LX	15	14.5
Bubbles (>0.5 mm)	1	0.9			
Overgrowth	14	12.7			
Ulcerative					
Erosion	36	32.7			
Healing ulcer	5	4.6			
Mixed ulcer	21	19.1			
Worsening ulcer	8	7.3			
Total	110	100.0	Total	110	100.0

Abbreviation: PLS, Peristomal Lesion Scale.

TABLE 4 Localisation of lesions in PLS areas vs SACS (T)

Localisation of lesions in PLS	Fr.	%	Localisation of lesions in SACS (T)	Fr.	%
1 area	8	7.3	T1	15	13.6
2 areas	34	30.9	T2	38	34.6
3 areas	1	0.9	T3	5	4.5
4 areas	54	49.1	T4	52	47.3
6 areas	2	1.8			
8 areas	5	4.5			
12 areas	6	5.5			
Total	110	100.0	Total	110	100.0

Abbreviation: PLS, Peristomal Lesion Scale.

TABLE 5 Concordance between PLS and SACS by classes of severity

	TOT SACS				
TOT PLS	**LOW**	**MEDIUM**	**HIGH**	**VERY HIGH**	**TOTAL**
LOW	27 24.6%	1 0.9%	1 0.9%	0 0%	29 26.4%
MEDIUM	18 16.4%	8 7.3%	1 0.9%	0 0%	27 24.6%
HIGH	5 4.5%	2 1.8%	20 18.2%	2 1.8%	29 26.4%
VERY HIGH	4 3.6%	4 3.6%	10 9.1%	7 6.4%	25 22.7%
TOTAL	54 49.1%	15 13.6%	32 29.1%	9 8.2%	110 100%

Abbreviation: PLS, Peristomal Lesion Scale.

agreement for the "medium" (7.3%) and "very high" (6.4%) classes.

4 | DISCUSSION

There are many tools available to nurses to facilitate their peristomal skin assessment. Our literature review showed that six are widely used around the world—SACS,[2,18,20,21] OST,[2,22,23] ABCD Stoma,[24] LSD score,[25] Stoma Care Ostomy Research Index,[26] and CPS.[27]

This validation study compared two scales, SACS and the new PLS, for their capacity to describe and classify skin alterations in the peristomal area.

Our recruited sample proved to be comparable, in terms of gender and age, with other validation studies, and specifically Bosio for the SACS study,[20] and Antonini of the SACS 2.0.[18,29]

More than half of our sample (55.4%) had no comorbidities. Among those who had at least one comorbidity, 49%

of them had cancer. Cardiopathy and hypertension were slightly more common in our sample (20.4%) than what reported by Bosio (17.1%).[20] The same applied to the percentage of diabetic patients (22.5% in our sample vs 11.2% in the Bosio's study). On the other hand, only 6.4% of patients in our sample were receiving chemotherapy, compared with 30% in Bosio's study.

A study conducted by Arumugam in 2003 on the risk factors for peristomal skin complications[30] found correlations between stoma retraction and obesity ($P = 0.036$), late skin excoriation, and diabetes ($P = 0.02$), emergency ostomies, and stomas placed in a crease ($P = 0.022$). The relationship between obesity and retraction ($P = 0.051$) emerged in our sample too, and a significant relationship was observed between diabetes and ulcerative lesions ($P = 0.038$).

As for the different types of ostomy, our sample included a larger proportion of ileostomies (47.3%) than in Bosio's study (28.6%), where the majority of patients had colostomies (71.4%).[20,29]

In the literature, the complications of ostomy procedures and involving the peristomal skin include edema, ischaemia and necrosis, haemorrhage, malpositioning, retraction, prolapse, fistula stenosis, hernia, granuloma, abscess, folliculitis, mucocutaneous skin detachment, dermatitis, and pyoderma gangrenosum.[3–5,7,8,29] In our sample, there was some degree of retraction in two out of three patients (66.2%). The other most common complications were mucocutaneous skin detachment (23.5%), and hernia (13.2%). Antonini[18,29] reported ulcerative fibrinous/necrotic lesions as the most frequently encountered skin alteration in ostomates, unlike the findings in the Bosio study[20] and our own.

Our results indicate a 56.4% agreement between the PLS and the SACS[20] in classifying patients by severity. As for any correlations between the variables, there were no statistically significant associations between gender and total PLS scores ($P = 0.173$), or between age and total PLS scores ($P = 0.441$).

Comparing the two instruments in terms of their capacity to discriminate the sample by the overall severity of their peristomal lesions, the SACS places more patients in the "low" (49.1%) and "high" (29.1%) groups than the PLS, which stratifies the sample quite evenly across the four classes. Interestingly, the highest agreement between both instruments refers to the "low" (24.6%) and "high" severity classes (18.2%). On the opposite, the two scales have a little agreement for the "medium" (7.3%) and "very high" (6.4%) classes (see Figure 1).

In summary, the PLS identified patients' complications as more severe than SACS, that is, cases classified as "medium severity" with the PLS were classified as "low severity" with SACS, and cases classified as "very high severity" with PLS were classified as "high severity" with SACS. These results highlight the better discriminatory

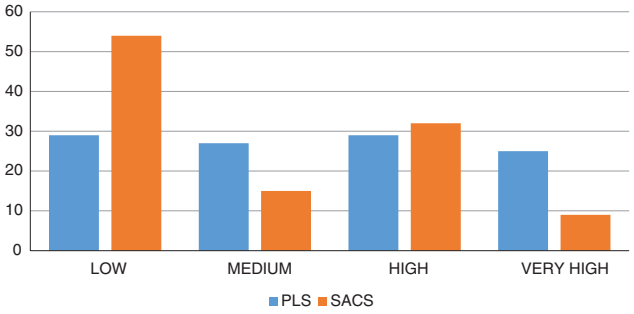

FIGURE 1 Frequency of cases by classes of severity—Peristomal Lesion Scale (PLS) vs SACS

capacity of the PLS in judging the characteristics of a lesion in relation to the overall severity of the patient's condition. The PLS makes it easier to measure and describe the types of skin lesion (elementary, overgrowth, and ulcerative) and their extent. In particular, it can provide information that enables a comparison of findings over time during a patient's follow-up and thus support clinical decision-making. In fact, the idea behind the PLS was to devise a simple, easy-to-use tool for assessing peristomal skin alterations that does not require any extra measurements, and that can be used with ease by any nurses with minimal training.

A limitation of our study stems from the fact that the SACS taken for comparison with the PLS is not a weighted scale; it only provides a description and the approximate localisation of a lesion. This made it necessary for us to apply the same weighted and scoring models to the SACS as to the PLS to make the two instruments comparable in terms of a total score of overall severity.

A second limitation relates to the subjective nature of the nurses' observations, despite the standardisation of the scale. A third limitation concerns the sample size, which was small to enable any generalisation of our findings. The study should be replicated at multiple centres and on an international sample to obtain more representative data. Assessments should also be performed in a blind fashion by two health professionals to test for inter-rater validity. The adoption of the PLS for other types of ostomy should also be considered, including tracheostomies and percutaneous endoscopic gastrostomies (PEG).

Peristomal skin assessment is a significant issue for ostomates because any peristomal lesions can have a severely detrimental influence on their quality of life. For stomal therapists, maintaining skin integrity and managing complications effectively demands the use of appropriate tools designed to integrate the available information about a patient's health status, ostomy, and related devices and accessories, and capable of providing a valid classification of the peristomal skin lesions.

By comparison with existing scales, the PLS proved more accurate in describing and measuring skin alterations and is therefore a more valid tool for monitoring the peristomal skin area. In addition, as it classifies lesions by overall

severity, the PLS has great potential for use in repeated comparative assessments throughout the follow-up process.

ACKNOWLEDGEMENTS

This study was made possible by AIOSS (Technical-Scientific Association of Stomatherapy and Rehabilitation of the Pelvic Floor) and AISLeC (Nursing Association for the Study of Skin Lesions), who provided support in all phases of the study. G.E., R.V., and L.N. were involved in instrument development and testing; and M.Z., M.M., D.D.N., and L.C. performed the data collection.

CONFLICTS OF INTEREST

The authors have no conflict of interest to disclose. This research received no specific grants from any funding agency in the public, commercial, or not-for-profit sectors.

The authors have no financial interests in the product (PLS) mentioned in the manuscript.

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How to cite this article: Menin G, Roveron G, Barbierato M, Peghetti A, Zanotti R. Design and validation of a "Peristomal Lesion Scale" for peristomal skin assessment. *Int Wound J*. 2018;1–9. https://doi.org/10.1111/iwj.13052