Leakage and peristomal skin complications influences user comfort and confidence and are associated with reduced quality of life in people with a stoma

ABSTRACT

Objective The purpose of the research was to investigate how leakage of stomal effluent and peristomal skin complications (PSC) affects the quality of life (QoL) of people living with a stoma.

Method Data were collected from an online questionnaire sent out to approximately 20,000 people living with a stoma. The validated Ostomy-Q scale was used to measure changes in QoL.

Results More than 4,200 people from 13 countries completed the study between 30 August and 3 October 2016. Leakage had a statistically significant impact on the QoL for participants who experienced leakage four times (or more) out of ten baseplates changes. All four domains in the Ostomy-Q scale – confidence in stoma appliance, comfort, discretion and socialising – were affected. Also, people with PSC had a significantly lower QoL than those who had not experienced PSC in the 6 months before the survey. PSC impacted the confidence and comfort domains significantly. The discretion and socialising domains were also significantly affected by PSC but were below the pre-defined limit for a minimal important difference.

Conclusion The data support that leakage and PSC have a significant physical and psychological impact on people living with a stoma.

Keywords stoma, leakage of stomal effluents, peristomal skin complications, quality of life

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INTRODUCTION

Leakage is a major concern for people living with a stoma. Up to 87% experience leakage of stomal effluent (output) underneath their baseplate[1,2]. The consequences of leakage are two-sided, with both a psychological and physical impact on everyday life. The psychological impact is seen by the fact that the majority of people with a stoma (91%) worry about leakage[2]. The physical burden includes irritant contact dermatitis (ICD) which is one type of peristomal skin complication (PSC)[3]. PSC is associated with a general feeling of discomfort[4]. Stoma care nurses in the UK reported that more than 60% of their patients showed signs of PSC and 86% of these cases were due to leakage problems[4]. Stomal effluents in contact with the peristomal skin is believed to cause ICD[3]. ICD is a very common problem among people with a stoma as seen in a recent survey, where 49% reported incidents of ICD[5].

Reducing leakage and improving peristomal skin health was observed to increase quality of life (QoL) in stoma patients suffering from PSC caused by leakage[6]. A thorough understanding of which underlying parameters are directly associated with QoL remains to be established. The aim of this research was to investigate the relation between output leakage, PSC and QoL and explore if the stoma-related QoL domains – confidence, comfort, discretion and socialising – contribute to these associations.

METHODS

Survey methodology was described by Voegeli et al.[5] In brief, an online, retrospective, self-reported questionnaire was sent to 19,555 people with a stoma in 13 countries on four continents. Data were collected from 30 August to 3 October 2016. The inclusion criteria were age above 18 years, and having at least one stoma of any type. Respondents who did not complete the survey, who answered 'Don't know' to more than 30% of the questions, or who completed all questions very quickly (within 15 minutes) were excluded from the population. Besides demographics and data on the incidence of PSC (reported by Voegeli et al.[5]), the survey contained questions on QoL, leakage frequency (leakage incidence within the respondents' last ten changes of baseplate), and worry of leakage (using a five point Likert scale) that has not been reported previously. The Ostomy-Q scale was used to estimate product-related QoL, a scale which consists of four domains – confidence, comfort, discretion and socialising[7]. Out of the study population of 4,235 included in the survey (response rate of 22%), 3,638 respondents completed the Ostomy-Q questionnaire (final response rate of 19%).

Table 1. Participant demographics

Participant demographics	**Women (n=1813)**		**Men (n=2163)**		
	n	**Distribution**	**n**	**Distribution**	**P-value**
Age					<0.001
18–29 years old	50	2.8%	18	0.8%	
30–39 years old	133	7.3%	82	3.8%	
40–49 years old	249	13.7%	164	7.6%	
50–59 years old	423	23.3%	327	15.1%	
60–69 years old	573	31.6%	727	33.6%	
70+ years old	385	21.2%	845	39.1%	
Stoma type					
Urostomy	190	10.4%	399	18.4%	<0.001
Colostomy	738	40.5%	999	46.0%	<0.001
Ileostomy	825	45.3%	697	32.1%	<0.001
More than one stoma	59	3.2%	54	2.5%	
Don't know	11	<1%	24	1.1%	
Leakage: Frequency of output observed on baseplate from the last ten appliance changes					
Never (0 times out of 10)	208	12.2%	361	17.7%	<0.001
Rarely (1–3 times out of 10)	576	33.8%	723	35.4%	
Sometimes (4–6 times out of 10)	378	22.2%	416	20.4%	
Often (7–9 times out of 10)	316	18.5%	297	14.5%	0.0012
Always (10 times out of 10)	228	13.4%	245	12.0%	
PSC*					<0.001
Yes	1402	76.9%	1514	69.7%	
No	421	23.1%	659	30.3%	

* Based on recall of at least one PSC experience within the last 6 months[5]

For statistical analysis, JMP® (Version 13.1. SAS Institute Inc., Cary, NC, 1989–2019) was used. Tukey-Kramers HSD test was used for leakage, and Student's t-test was used for PSC when analysing statistical difference between levels. Besides statistical difference ($p<0.05$), a threshold for clinical relevance, the so-called minimal important difference (MID), was defined, so any difference in total QoL between two levels had to be >5.75; and, for the domains, >2.75 for comfort, >2.51 for confidence, >2.54 for discretion and >2.60 for social life[7].

Ethical considerations

The survey was a market research study approved by an internal review board. Participation was on a voluntary basis with informed consent. The patients' data were treated with confidentiality in compliance with the EU General Data Protection Regulation, and data analysis was performed with aggregated anonymous data. There was no intervention nor change in treatment.

RESULTS

The survey population included 46% women, and 66% of the respondents were 60 years or older (Table 1). Colostomy (44%) was the most common type of reported stoma, followed by ileostomy (38%) and urostomy (15%) (Table 1). Output under the baseplate (i.e. leakage) observed during the last ten baseplate changes was reported among 83% of respondents, with 26% reporting leakage during their last seven baseplate changes (Table 1). Furthermore, 73% of the respondents reported to have experienced PSC within the last 6 months (Table 1; also reported in Voegeli et al.[5]).

Leakage and QoL

Overall, a stepwise decline in total QoL by each increase in leakage frequency was observed until a plateau was reached, i.e. for those who often or always experienced leakage (seven times or more out of the last ten baseplate changes) (Figure 1). Though the decline in QoL by increased frequency in leakage was statistically significant, the decline in QoL was only clinically relevant when four or more times out of ten baseplates showed signs of leakage (Figure 1).

Of the four domains in Ostomy-Q scale, the domain on confidence in stoma appliance was significantly impacted when the frequency of leakage to baseplate was higher than three times out of ten baseplate changes as compared to 'never' ($p<0.0001$; Figure 2A). Leakage also impacted the Ostomy-Q domains of comfort, discretion and socialising; the comfort and discretion domains were impacted when respondents experienced leakage more than six times during the last ten baseplate changes (Figures 2B&C). Leakage also had an impact on social life, but only in groups of respondents who reported having leakage 'often' or 'always' on recent baseplate changes (Figure 2D).

PSC and QoL

Respondents who reported skin issues had significantly lower QoL than those who did not experience skin issues during the previous 6 months before the survey ($p<0.001$; Figure 3).

PSC impacted the confidence and comfort domains significantly ($p<0.001$; Figures 4A&B). Likewise, PSC impacted the discretion and socialising domains significantly ($p<0.001$), although the difference was below the pre-defined limit for a minimal important difference (Figures 4C&D).

DISCUSSION

Our data show that there is a clear relation between leakage incidences and reported QoL; subjects who experience

Figure 1. The influence of output under baseplate (leakage) on total QoL

Respondents reported if they experienced output underneath their baseplate during their last ten baseplate changes and completed the Ostomy-Q questionnaire (n=3,638).

(–) Levels compared to Never observing leakage.
(–) Levels compared to Rarely observing leakage.
*Statistically significant difference observed ($p<0.001$), but with a magnitude less than the clinically relevant MID (<5.75)
*** Difference observed is statistically significant ($p<0.001$) and greater that the clinically relevant MID (>5.75).

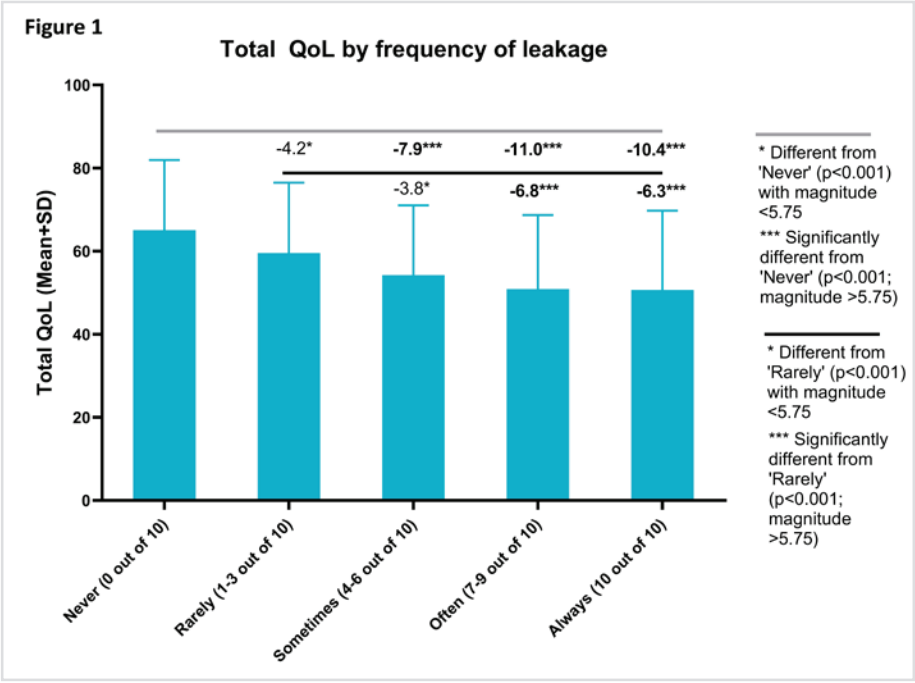
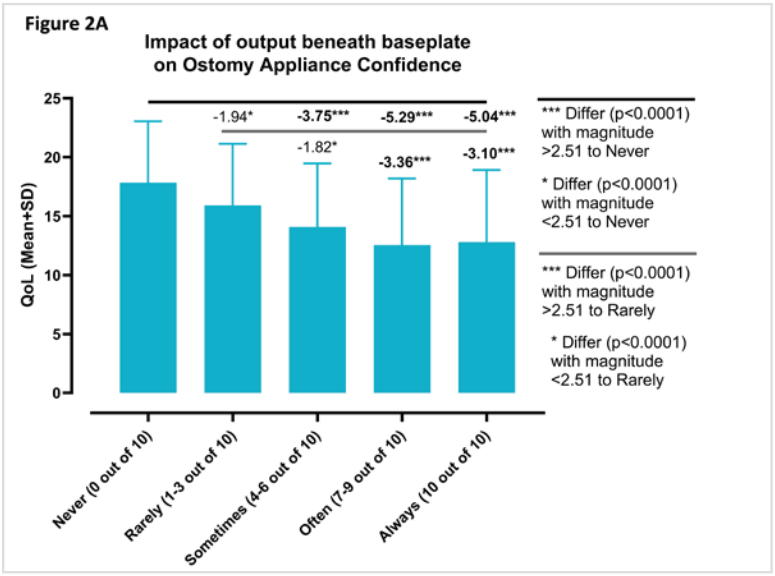
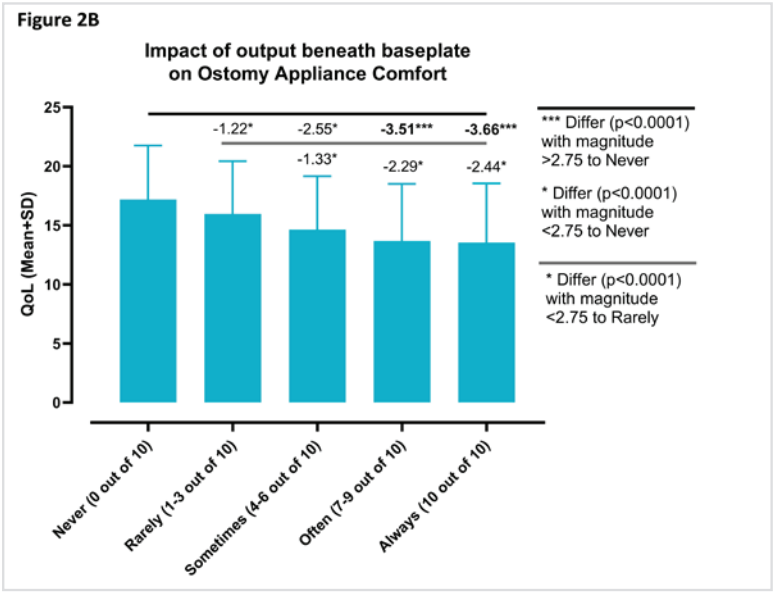


Figure 2. The influence of output under baseplate (leakage) on the domains of Ostomy-Q: (A) confidence, (B) comfort, (C) discretion and (D) socialising

Respondents reported if they experienced output underneath their baseplate during their last ten baseplate changes and completed the Ostomy-Q questionnaire (n=3,638).
(–) Levels compared to Never observing leakage.
(–) Levels compared to Rarely observing leakage.
* Statistically significant difference observed (p<0.001), but with a magnitude less than the clinically relevant MID
*** Difference observed is statistically significant (p<0.001) and greater that the clinically relevant MID.





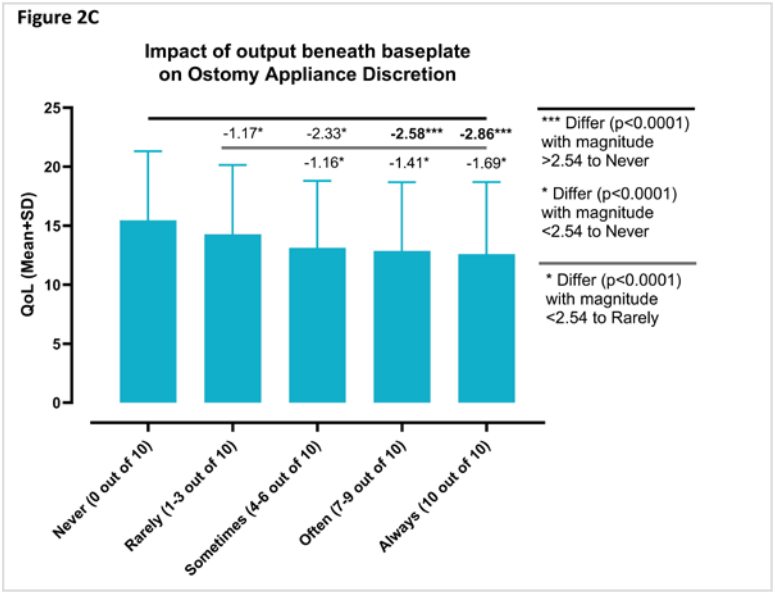


Figure 2 continued. The influence of output under baseplate (leakage) on the domains of Ostomy-Q: (A) confidence, (B) comfort, (C) discretion and (D) socialising

Respondents reported if they experienced output underneath their baseplate during their last ten baseplate changes and completed the Ostomy-Q questionnaire (n=3,638).
(–) Levels compared to Never observing leakage.
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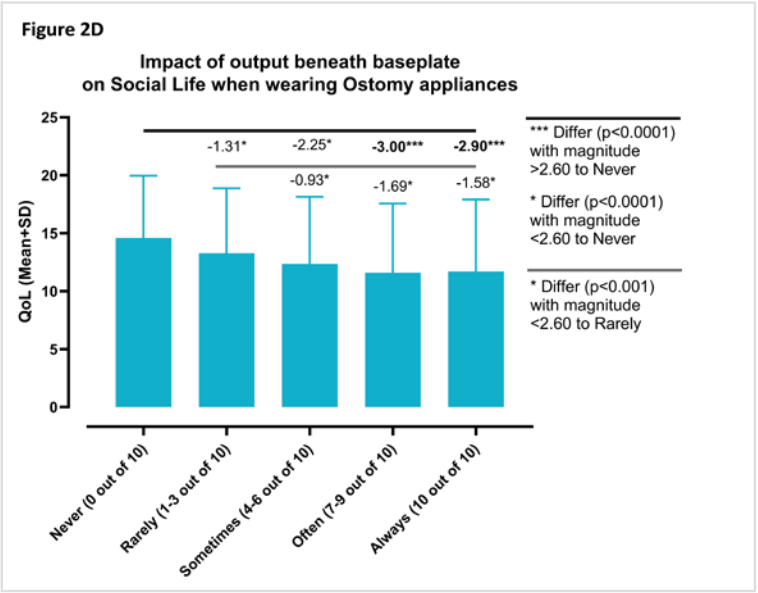


leakage to four or more baseplates out of the last ten baseplate changes had a significantly lower total QoL. Leakage has previously been reported to have both emotional and physical implications – the emotional impact was recorded by Nafees et al.[8] in which the authors developed a scale for measuring the impact of leakage on domains such as emotional, socialising, and coping and control – but people's experience and its impact is not well understood.

This study aimed to establish a definition of leakage through clinical and user input. This information was used to develop and validate a new measurement tool to understand the impact of leakage for people using a stoma appliance in the UK, US, France and Denmark. Participants were recruited from a panel of users, hosted by Coloplast, that included people who currently use Coloplast products. Six clinicians and 41 users took part in concept elicitation interviews. The qualitative findings were used to draft items. A panel of clinical experts was organised to develop and validate items (n=6). The impact of leakage became significantly more important when stomal output reached outside the baseplate area and onto the participants' clothes[8]. As our data suggests, even if the output stays inside the baseplate area it appears to have an impact on QoL as the users lose confidence in their stoma appliances.

It is not known whether the high reporting of leakage incidences is influenced by a lack of compliance or knowledge of users in how to avoid leakages. However, if the numbers do reflect that users struggle with managing their stoma appliance, there may be room for preventing poor QoL by advising users on good stoma care practice. The lack of comfort and confidence may also be impacted by the physical

Figure 3. The influence of PSC on total QoL

Respondents reported if they had experienced PSC during the 6 months prior to completing the Ostomy-Q questionnaire (n=3,638).
(–) Levels (PSC no/yes) compared to each other.
*** Difference observed is statistically significant (p<0.001) and greater that the clinically relevant MID (>5.75).

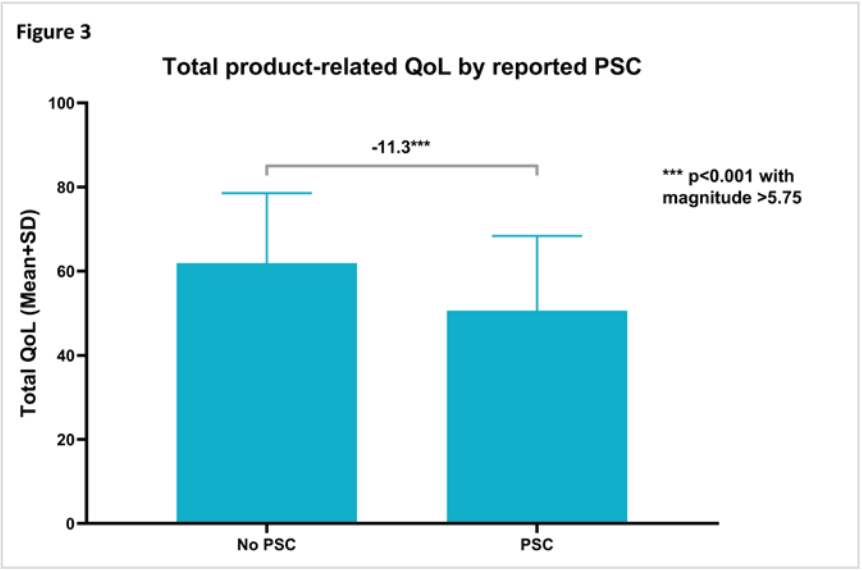


Figure 4. The influence of PSC on the domains of Ostomy-Q: (A) comfort, (B) confidence, (C) discretion and (D) socialising

Respondents reported if they had experienced PSC during the 6 months prior to completing the Ostomy-Q questionnaire (n=3,638).
(–) Levels (PSC no/yes) compared to each other.
*** Difference observed is statistically significant ($p<0.001$) and greater that the clinically relevant MID (>5.75).

Figure 4A

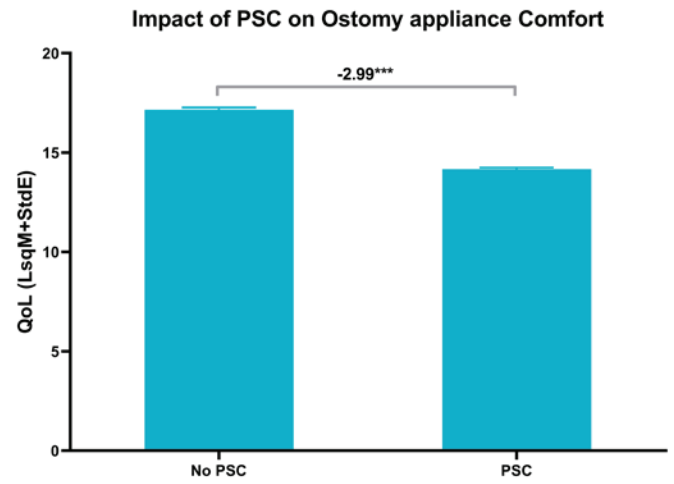


Figure 4B

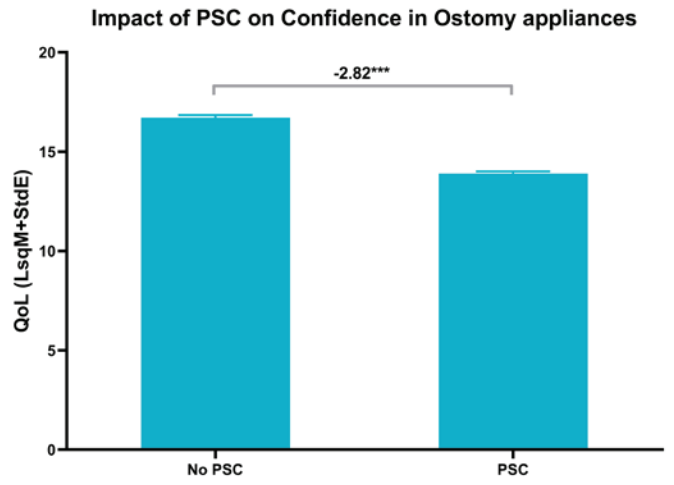


Figure 4C

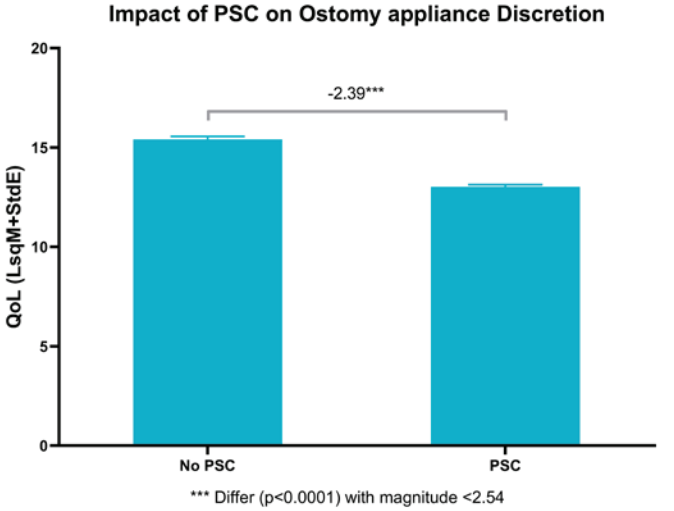
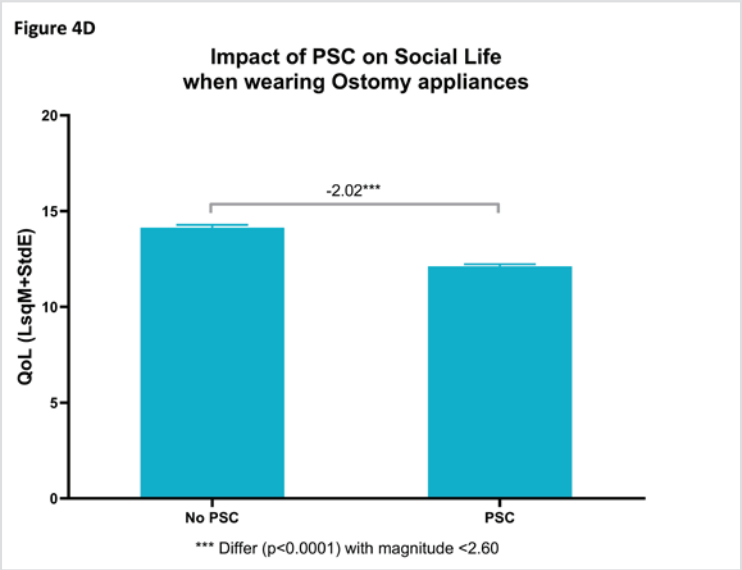


Figure 4 continued. The influence of PSC on the domains of Ostomy-Q: (A) comfort, (B) confidence, (C) discretion and (D) socialising

Respondents reported if they had experienced PSC during the 6 months prior to completing the Ostomy-Q questionnaire (n=3,638).
(–) Levels (PSC no/yes) compared to each other.
*** Difference observed is statistically significant (p<0.001) and greater that the clinically relevant MID (>5.75).



implications of the leakage. As the output from ostomies contain digestive enzymes[9–11], faeces can cause ICD which is the most common type of PSC[5,12]. Thus, leakage and PSC appear to negatively impact total QoL by impacting the domains of confidence in and comfort of the stoma appliance. In the present study, users were asked to recall any skin issue during the last 6 months to ensure to capture all users who struggle with skin problems from time to time, and QoL was only measured at one timepoint. Thus, due to the limitations of the present study with cross-sectional data collection, it is not possible to point to a causal relationship between PCS and QoL. However, in a previous prospective study, lower QoL was also observed in patients suffering from PSC[6].

CONCLUSION

The data support that leakage has a significant physical and psychological impact on people living with a stoma. Thus, prevention of leakage incidents has the potential to improve QoL, including the domains of comfort and confidence, as well as reduce PSC. Moreover, as almost all respondents expressed a worry of leakage, and as leakage impacts confidence in stoma appliances, these results warrant for solutions that can enforce confidence by reducing the worry of leakage.

ETHICS

The survey was carried out as market research and was approved by an internal review board.

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CONFLICT OF INTEREST

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