

Managing leakage with confidence: clinical insights into a soft convex pouching system

ABSTRACT

Aims To investigate effects of SenSura Mio Convex Soft on stoma-leakage and leakage-related quality of life (QoL).

Methods The study was an interventional, single-arm, open-label, multicentre trial conducted in Great Britain, the Netherlands, Norway and USA. The sample comprised individuals with leakage-issues when using flat baseplates. Participants used their own flat pouching system in a 2-week baseline period and subsequently SenSura Mio Convex Soft for 12 weeks. The primary endpoint was leakage area underneath the baseplate-adhesive. Secondary outcomes were leakage incidents outside the baseplate and leakage-related QoL using the validated Ostomy Leak Impact (OLI) tool, which consists of three domains capturing the impact of leakage on emotional aspects, engagement in usual and social activities and ability to cope and being in control. Primary comparisons between 12-week data with SenSura Mio Convex Soft and baseline flat baseplates were evaluated using mixed repeated measures models and a logistic regression model for correlated data.

Results Statistical analyses included 74 participants (Intention-to-treat population). After 12 weeks, use of SenSura Mio Convex Soft resulted in less leakage underneath the baseplate-adhesive than with flat pouching systems (estimated mean difference=-2.4 cm squared; $P=0.001$). Participants experienced fewer incidents of leakage outside the baseplate when using SenSura Mio Convex Soft (with 2.2% of the baseplates) versus flat pouching systems (7.0%) ($P<0.001$). Participants also reported significant improvements in all three domains of the OLI tool. Adverse events were comparable between the baseline and intervention periods, mainly affecting the peristomal skin.

Conclusions Study findings indicate that using SenSura Mio Convex Soft resulted in less leakage underneath the baseplate, fewer soiling incidents and higher leakage-related QoL compared to using flat pouching systems.

The study was registered on ClinicalTrials.gov (ID-NR: NCT02517541).

Keywords convexity, leakage, peristomal body profile, quality of life, soft convex baseplate, stoma.

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INTRODUCTION

One of the cornerstones of ostomy care is to select a pouching system that ensures a secure seal between the baseplate and the peristomal skin.¹ An ill-fitting baseplate is a common cause for effluent to seep underneath the baseplate, which may ultimately result in soiling of clothes or bed sheets.² Leakage of stomal effluent can lead to embarrassing situations and is always inconvenient for the afflicted, leaving many with the mental burden of worrying if and when it might occur.³ In this way, leakage can have negative implications on quality of life (QoL) and may ultimately lead to social isolation.^{3,4} Stoma care nurses (SCNs) consider complicated peristomal body profiles and incorrect product usage as key risks for experiencing leakage.⁵

Assessment of the peristomal body profile is critical for selection of a pouching system that can provide a secure seal.¹ Baseplates with convex curvatures pushing into the abdominal wall are often used to increase stomal protrusion for people with stomas settled below or at level with the surrounding abdomen, and to help flatten uneven peristomal skin with creases and folds ensuring better skin contact.⁶ A wide range of convex baseplates are available on the market, and selection of a convex baseplate requires consideration of multiple convexity characteristics, including depth and slope of the dome, compressibility, flexibility and tension location.^{7,8} For example, deep convex baseplate shapes provide more pressure to the peristomal skin to help attain protrusion of retracted stomas and to fill in deep folds or creases in the abdomen, however they are more rigid and inflexible than soft or light convex baseplates. Soft convex baseplates on the other hand exert gentler pressure on the peristomal skin, and they are intended for when the baseplate needs to conform securely to minor abdominal curvatures and are most often used when the stoma is above skin level.^{6,9} SCNs need to balance pressure required to obtain a secure seal with the patient's comfort.

The aim of this clinical study was to evaluate the impact of the SenSura® Mio Convex Soft one-piece pouching system on leakage and QoL in a population struggling with leakage issues when using flat baseplates.

METHODS

Study design

The study was an interventional, single-arm, open-label, multicentre trial enrolling patients for a total of 14 weeks. Data were collected from September 2015 to February 2016 in Great Britain, the Netherlands, Norway and USA. The study sites consisted of four National Health Service (NHS) hospitals across the UK, one university hospital in USA, and a local private research organisation (CRO) in Norway and the Netherlands. The study was registered on ClinicalTrials.gov (ID-NR: NCT02517541).

The study consisted of a two-week baseline period, where participants applied their own one-piece flat pouching system, followed by a 12-week intervention period, where participants applied SenSura Mio Convex Soft one-piece (Coloplast A/S,

Denmark). Participants attended an information meeting, and if eligible, they proceeded to Visit 1 (V1) for consent signing and baseline data collection. At Visit 2 (V2), adverse events (AEs) from the baseline period were recorded, and participants were instructed on using SenSura Mio Convex Soft for the intervention period. SenSura Mio Convex Soft was provided by the sponsor via the investigators at the respective sites. Visit 3 (V3) marked the termination of the study, which included documentation of AEs during the intervention period (Figure 1). Participants completed questionnaires available on a bespoke clinical study app every second week.

Selection of study participants

At the respective hospital sites, potential study participants were identified by specialist SCNs screening patient journals. At the respective CROs, potential study participants were identified via patient lists retrieved from national databases maintained by Coloplast. Only individuals who had consented to receiving information about clinical investigations were contacted by either letter, e-mail or phone as first contact. At the CROs, screening of individuals was undertaken by site personnel being either specialist SCNs or research nurses. Individuals who were interested and found eligible based upon study inclusion/exclusion criteria were consecutively enrolled into the investigation. The study sites recruited patients independently from the sponsor.

Inclusion criteria identified those being >18 years of age, who had been living with an ileostomy or a colostomy for at least three months, who had intact peristomal skin and experienced faecal effluent seeping underneath the baseplate at least three times during the preceding two weeks. Potential participants had to use a one-piece flat product (open or closed), be able to use a custom cut product and be evaluated to be suitable for a soft convex pouching system.

Potential participants were excluded if they were currently receiving or had received chemotherapy or radiation therapy within the preceding two months, if they had received topical steroid treatment to the peristomal skin area in the preceding month, if they participated in other concurrent interventional clinical trials, and if they were pregnant or breastfeeding.

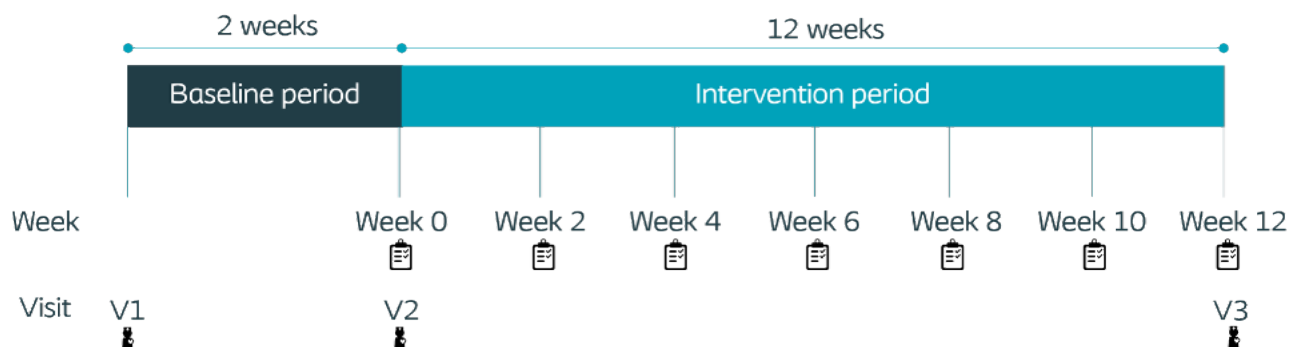


Figure 1. Study design. V = Visit with a study nurse. The Week 0 questionnaire covers the baseline period, the Week 2 questionnaire covers the first two weeks of the intervention period, and the Week 12 questionnaire covers week 11 and 12 of the intervention period.

Patient demographics and endpoints

Patient demographics and pertinent clinical data were recorded at baseline (V1) by study investigators using a questionnaire specifically developed for the study.

During the baseline and intervention periods, patients filled in questionnaires on the bespoke clinical study app that was available on mobile phones provided by the sponsor. The primary endpoint was leakage area (in cm squared) underneath the baseplate, recorded for each product change. This was objectively assessed by photos taken of the used baseplates with the bespoke clinical study app. At every product change, participants also recorded if effluent had progressed outside the baseplate, for example soiling clothes (secondary endpoint). Leakage-related QoL was assessed every second week using the validated Ostomy Leak Impact (OLI) tool (secondary endpoints).¹⁰ The OLI tool consists of 22 questions, which summarise the burden of leakage in three domains: *Emotional impact*, *Usual and social activities* and *Coping and in control*. Each domain was scored on a scale ranging from 0 to 100, with higher scores reflecting better QoL (for example lower impact of leakage). This report only presents outcomes related to leakage and leakage-related QoL.

Adverse events (AEs) were recorded at V2 and V3 by the investigators at the respective sites. Participants were also advised to inform investigators about any AEs during the baseline and intervention periods, and the investigator assessed whether rescheduling of the next meeting was needed to monitor and resolve the AE. Final evaluation of each AE (whether being serious or non-serious, and the intensity of each event) and whether it was related to the participants' own products or SenSura Mio Convex Soft was made by the principal investigator at each site. Intensity of each AE was graded accordingly: 1) Mild: the intensity of the event is mild with no further action or intervention. 2) Moderate: the intensity of the event will lead to an action or intervention to solve the event. 3) Severe, the intensity of the event will lead to follow up on the action or intervention, as the effect of the action or intervention may not decrease the symptoms.

Statistics

The intention-to-treat (ITT) population consisted of all eligible participants with valid informed consent and valid information on at least one product with respect to either primary or secondary endpoints. The safety population consisted of participants who had given informed consent and had applied at least one product.

The primary endpoint (leakage area assessed at each baseplate) was analysed using a mixed repeated measures model. The mean structure depended on the interaction between type of stoma and time period (Week 0, 2, 4, 6, 8, 10, 12), thereby allowing the time course to be different for people with an ileostomy than for people with a colostomy. The model considered that observations corresponding to different participants were independent, whereas observations corresponding to the same participants were correlated. From

this model, the mean difference in leakage area between week 12 and the baseline period (week 0) was estimated assuming an equal distribution of people with an ileostomy and a colostomy, and a test of no difference was performed. The mean leakage area for a baseplate at week 12 and week 0 was estimated similarly.

The domain scores (*Emotional impact*; *Usual and social activities*; and *Coping and in control*) from the OLI tool were analysed and presented similarly to the longitudinal data analysis of the primary endpoint.

The binary endpoint leakage outside the baseplate (Yes/No) was analysed using a logistic regression model allowing for data corresponding to the same participant to be correlated. As for the quantitative data described above, the model included an interaction between type of stoma and time period. From this model, the odds ratio (OR) between week 12 and the baseline (week 0) was estimated together with the corresponding 95% confidence interval, as above, assuming equal distribution of people with an ileostomy and a colostomy. The proportion of baseplates with leakage at week 12 and 0 respectively, was estimated similarly. Further, a test of no difference (OR = 1) was performed.

For all statistical analyses, a 2-sided significance level of 5% was applied. Statistical analyses were conducted in SAS version 9.4 (SAS Institute Inc., Cary, North Carolina, USA).

RESULTS

Study participants

A total of 79 participants were enrolled into the study between September 2015 and February 2016. Five participants had not received appropriate training in using the mobile phone containing the bespoke clinical study app, so they decided to withdraw from the study within the baseline period. They were considered as screening failures and were not included in the ITT population. From the ITT population (n=74), n=13 (18%) did not complete the study as planned due to either AEs (n=3; 4%), lack of effectiveness (n=2; 3%), protocol deviation (n=2; 3%), wish to discontinue (n=4; 5%) or other reasons (n=2; 3%). Data from the ITT population (n=74) were included in the statistical analyses.

The participants were recruited from Great Britain (42%), the Netherlands (36%), Norway (15%) and USA (7%). The mean age of the participants was 62.5 years and on average they had their stoma surgery 6.9 years before enrolment. Fifty-four percent had an ileostomy, and 46% had a colostomy (Table 1).

Assessment of the participants' peristomal body profiles revealed that 54% had an outward peristomal body profile, 42% had a regular peristomal body profile and 4% had an inward peristomal body profile (Table 2). Most had a soft abdomen around the stoma (84%), with no or only superficial creases (93%). For 77% of the participants, the stoma opening was above the skin surface.

Eighty-five percent of the participants used a one-piece flat pouching system from Coloplast during the baseline period,

Table 1. Demographics of the intention-to-treat (ITT) population.

Parameter	Total (n=74)
Age (years): Mean ± SD (range)	62.5 ± 11.1 (31; 81)
Sex: n (%)	
Females	29 (39.2%)
Males	44 (59.5%)
Did not answer	1 (1.4%)
Time since stoma surgery in years: Mean ± SD (range)	6.9 ± 8.0 (0; 42)
Type of stoma: n (%)	
Ileostomy	40 (54.1%)
Colostomy	34 (45.9%)
Reason for stoma creation: n (%)	
Ulcerative colitis	20 (27.0%)
Cancer	33 (44.6%)
Crohn's disease	7 (9.5%)
Cancer + Crohn's disease	1 (1.4%)
Crohn's disease + ulcerative colitis	2 (2.7%)
Other	11 (14.9%)

Table 2. Assessment of peristomal body profiles.

Parameter	Total (n=74)
Form around stoma and variation	
Inward uniform	0 (0.0%)
Inward variable	3 (4.1%)
Outward uniform	32 (43.2%)
Outward variable	8 (10.8%)
Regular uniform	25 (33.8%)
Regular variable	6 (8.1%)
Abdominal firmness	
Firm	12 (16.2%)
Soft	62 (83.8%)
Skin curvatures	
Deep folds	5 (6.8%)
No creases or superficial creases	69 (93.2%)
Stoma location	
Above bending line	11 (14.9%)
At bending line	22 (29.7%)
Below bending line	41 (55.4%)
Level of stoma opening	
Above skin surface	56 (75.7%)
In level with skin surface	13 (17.6%)
Below skin surface	4 (5.4%)
Missing information	1 (1.4%)

while the remaining 15% of the participants used a one-piece flat pouching system from other manufacturers (Convatec, Dansac, Hollister, B. Braun, Salts and others) or had used products from multiple manufacturers.

Leakage

The leakage area underneath the baseplate was significantly lower with SenSura Mio Convex Soft at week 12 versus the

comparator flat baseplates at baseline (estimated mean 8.7cm squared versus 11.1cm squared; estimated mean difference=-2.4 cm squared, 95% CI [-3.8 to -1.0]; P=0.001) (Figure 2).

Participants recorded whether leakage had progressed outside the baseplate, which was the case for 2.2% with the SenSura Mio Convex Soft baseplates at week 12 compared with 7.0% of

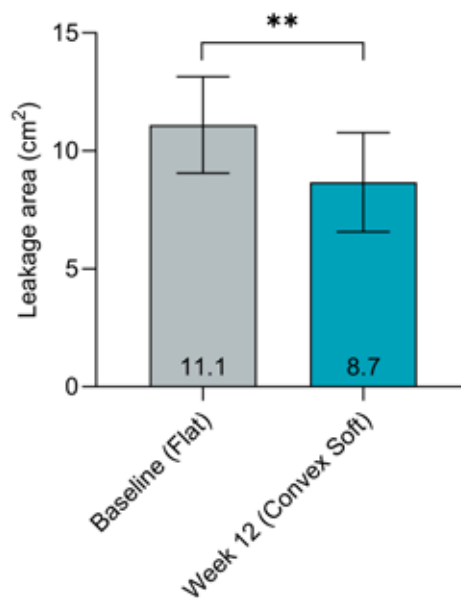


Figure 2. Leakage area (in cm squared) underneath the baseplate with SenSura Mio Convex Soft at week 12 and flat baseplates at baseline. Data are presented as estimated means, and error bars represent the 95% confidence intervals. P<0.01 (**).

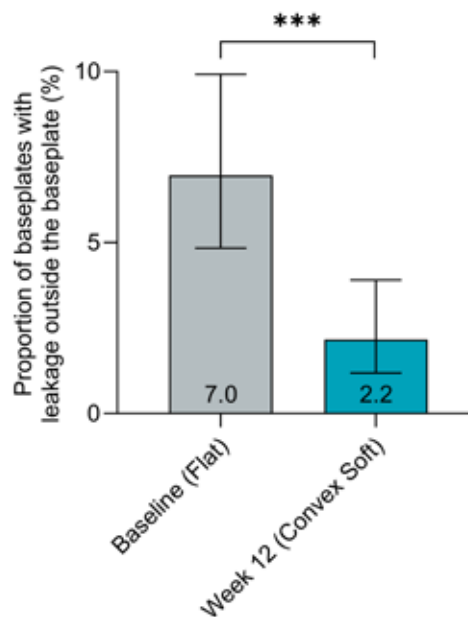


Figure 3. Estimated proportion of baseplates with leakage progressing outside the baseplate with SenSura Mio Convex Soft at week 12 and flat baseplates at baseline. P<0.001 (***).

the flat baseplates at baseline (OR=0.30, 95% CI [0.15 to 0.57]; P<0.001) (Figure 3).

Quality of life

Leakage-related QoL was assessed using the validated OLI tool.¹⁰ When using SenSura Mio Convex Soft, participants reported a significantly higher *Emotional impact* domain score compared with the flat baseplates at baseline (estimated mean 92.3 versus 72.1; estimated mean difference=20.3; 95% CI [14.7 to 25.8]; P<0.001). When using SenSura Mio Convex Soft, participants also reported a significantly higher *Usual and social activities* domain score compared with the flat baseplates at baseline (estimated mean 96.3 vs. 90.0; estimated mean difference=6.3; 95% CI [2.1 to 10.5]; P=0.004). Finally, when using SenSura Mio Convex Soft, participants reported a significantly higher *Coping and in control* domain score compared with the flat baseplates at baseline (estimated mean 93.3 versus 75.1; estimated mean difference=18.2; 95% CI [11.2 to 25.2]; P<0.001) (Figure 4).

Safety

A total of n=96 AEs from 32 participants were reported during the study. One participant reported a serious AE (hospitalisation due to hypokalemia) that was not related to use of pouching systems. Ninety-five of the reported AEs were categorised as non-serious, of which, n=81 from 29 participants were related to use of pouching systems.

A total of n=20 related AEs were reported, from 17 out of 74 participants, while they were using their own pouching systems during the 2-week baseline period. Of these, n=19 were mild in intensity and n=1 was moderate in intensity. All the AEs related to participants' own pouching systems concerned the peristomal skin: erythema (n=1), itching (n=15), erythema and itching (n=1), pain (n=1), sore skin (n=1) and an unclassified peristomal skin complication (n=1). The five screening failures did not report any AEs in the baseline period.

A total of n=61 related AEs, from 26 of the 71 participants, were reported during the 12-week study period with SenSura Mio Convex Soft. Of these, n=53 of the AEs were mild in intensity, n=7 were moderate and n=1 was severe (the participant had red/irritated peristomal skin with increasing severity). A total of n=59 of the 61 AEs related to SenSura Mio Convex Soft concerned peristomal skin: erythema (n=3), itching (n=38), erythema and itching (n=1), pain (n=7), sore skin (n=8) and unclassified peristomal skin complications (n=2). For the two remaining related AEs, one concerned a viral infection and one concerned a gastrointestinal disorder with changes in stoma height. Both of these were categorised as unlikely to be related to use of SenSura Mio Convex Soft.

With a substantially longer intervention period than the baseline period, more AEs were to be expected. The reported AEs were similar in the two test periods, and most were mild peristomal skin complications.

DISCUSSION

An important aspect of ostomy care is selection of a pouching system that ensures a secure seal between the baseplate and the peristomal skin.¹ In the present study, a population struggling with leakages, when using flat baseplates, trialled SenSura Mio Convex Soft to help obtain a more secure seal through better fit to reduce the risk of leakage incidents. The participants experienced less leakage underneath the baseplate when using SenSura Mio Convex Soft than with their own flat baseplates, as well as significantly fewer episodes of leakage progressing outside the baseplate. Concomitantly, participants scored significantly higher in all three domains of the OLI tool with SenSura Mio Convex Soft compared with flat baseplates at baseline. The magnitudes of the improvements were of clinical relevance, with the improvements being similar to or higher than the minimally clinically important differences (MCID) previously established for this tool (*Emotional impact*

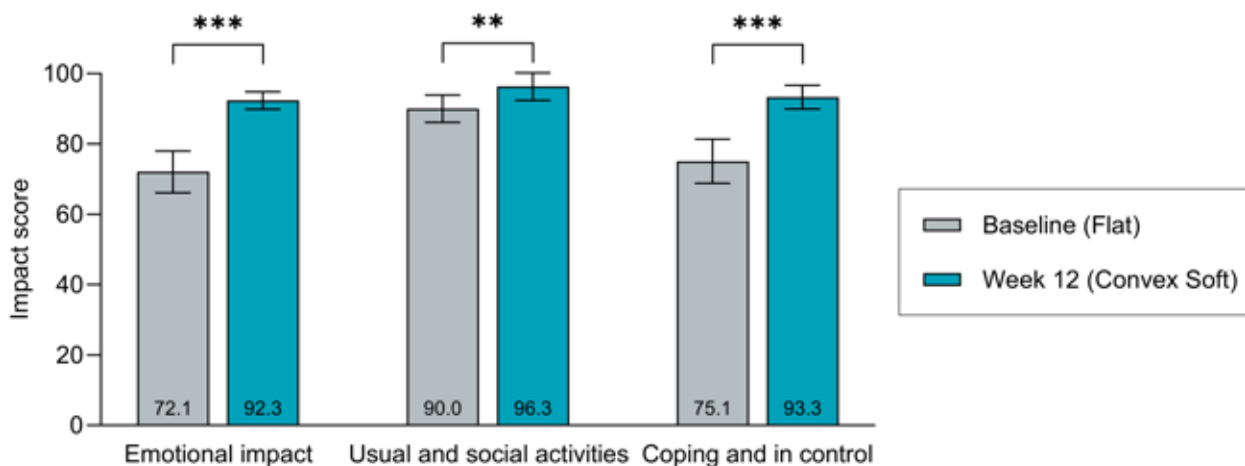


Figure 4. The OLI tool captures the burden of leakage in three domains: Emotional impact; Usual and social activities; and Coping and in control. Each domain sums into a total score ranging from 0 to 100. A higher score reflects improved leakage-related QoL. Data are presented as estimated means, and error bars represent the 95% confidence intervals. P<0.01 (**), and P<0.001 (***).

$\Delta 7.6$; *Usual and social activities* $\Delta 6.6$; *Coping and in control* $\Delta 7.2$).^{10, 11} It should be noted that the *Usual and social activities* domain score was already high at baseline (estimated mean 90.0; on a scale of 0–100), and even with this ceiling effect, use of SenSura Mio Convex Soft was associated with a significant improvement in this domain of $\Delta 6.2$ points. These data indicate that SenSura Mio Convex Soft provides a meaningful change for the participants and based on the constituents of the domains indicate that participants felt less embarrassment, less frustration, improved engagement in social activities, and felt better in control of their situation.

Other reports based on case studies¹² and a non-comparative clinical study¹³ have also highlighted benefits of using baseplates with soft convex curvatures from other manufacturers to help resolve leakage issues and complications associated with leakage. Only one randomised-controlled, cross-over trial has reported comparative clinical data on two soft convex products (SenSura Mio Convex Soft and Pelican Select Convex) and users own flat baseplates.¹⁴ The randomised-controlled, cross-over trial showed that use of both soft convex products reduced leakage underneath the baseplate to a similar degree compared with users own flat baseplates. Patient-reported outcomes however showed that feeling of security while wearing the product and feeling of comfort were higher when using SenSura Mio Convex Soft compared with Pelican Select Convex. A higher proportion of the participants reported that SenSura Mio Convex Soft had a good or very good ability to follow body movements than with Pelican Select Convex (84% versus 36%). The wear time was also significantly higher when using SenSura Mio Convex Soft than with Pelican Select Convex and the participants reported an overall preference for SenSura Mio Convex Soft over Pelican Select Convex.¹⁴ Together these data indicate that use of baseplates with soft convex curvatures can be a solution to help resolve leakage issues, however differences in properties between soft convex products can affect user comfort, feeling of security and preference, and have implications on wear time.

Peristomal body profiles vary from individual to individual and the abdominal topography may change over time. Assessment of the peristomal body profile is important for selection of the most suitable pouching system. The Peristomal Body Profile Assessment Tool is a multistep guide that has been developed by Coloplast to help with the selection of pouching systems based on the individual's stoma characteristics and abdominal topography. This tool is based on consensus guidelines¹⁵ and is open access with no specific permission needed to use it.¹⁶ When nurses used this tool to aid selection of appropriate pouching systems, the participants of the study experienced significantly fewer leakage incidents and reported concomitant improvements in leakage-related QoL.² The association between leakage control and improved QoL is supported by multiple clinical studies that have demonstrated more secure seals when using pouching systems with different convex^{13, 17, 18} or concave features^{19, 20} for people with complicated stomas and abdominal topographies.

Soft convex pouching systems are often recommended for individuals with firm abdomens.⁸ However, the majority of participants in the present study had soft abdomens. SCN experts have provided consensus guidelines stating that soft convex baseplates may better bend and move with the body than firm options particularly when a soft abdomen has creases that might cause a rigid convex pouching system to lift off the skin.⁸ Overall, study participants presented with great variation in their peristomal body profiles, which highlights that soft convexity may be considered to help resolve leakage-issues across different peristomal body profiles, and that individualised assessment is important for pouching system selection.

In the present study, enrolled participants had been living with their stoma for at least three months (inclusion criterion), but soft convex pouching systems have also been reported to be successfully used in the immediate post-operative period to help achieve a secure seal and improve patient confidence.⁶

STRENGTHS AND LIMITATIONS

Study results should be interpreted considering limitations of the study design. The study was an open-label, single-arm investigation, which might influence the subjective evaluations of the investigational product. In single-arm studies it is difficult to discriminate between the effects of the trialled product and study effects. However, similar positive leakage-results with SenSura Mio Convex Soft were also obtained in a randomised-controlled, cross-over trial.¹⁴ A strength of the study was that the primary endpoint was objectively evaluated based on pictures of used baseplates.

CONCLUSION

The findings of this study show that SenSura Mio Convex Soft reduced leakage area and soiling incidents, and participants reported significant improvements to QoL. We recommend that SCNs consider a baseplate with a soft convex feature for individuals who have difficulty in obtaining a secure seal when using flat baseplates after appropriate assessment of individuals' peristomal body profiles.

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ROLE OF THE FUNDING SOURCE

The study was funded by Coloplast A/S. The sponsor was involved in study design, analysis and interpretation of data, in writing the report, and in the decision to submit the paper for publication. The site investigators conducted screening, planned visits, and investigated AEs independently from the sponsor. Study participants filled in questionnaires independently from both the sponsor and site personnel. All study sites were contractually compensated by the sponsor for their time and resources spent on the study.

CONFLICT OF INTEREST

TR has previously been a consultant for Coloplast, however, he did not receive remuneration for contributions to this manuscript. ASH, AB, CH and MV are employees of Coloplast A/S.

ETHIC STATEMENT

The study was conducted in accordance with the Declaration of Helsinki, ISO 14155:2011, and European Medical Device Directive (2007/47/EC). Study procedures were reviewed and approved by ethic committees or boards in Norway (Regionale komiteer for medisinsk og helsefaglig forskningsetik; 2015/989 REK sør-øst B), Great Britain (Research Ethics Committee of Yorkshire & The Humber - Bradford Leeds; IRAS Project-ID: 181462), the US (The University of Chicago Biological Sciences Division; IRB15-1172) and the Netherlands (Stichting Beoordeling Ethiek Biomedisch Onderzoek; NL53366.056.15).

The study was registered on ClinicalTrials.gov (ID NR: NCT02517541). All patients were fully informed about the study, both verbally and in writing, and all gave written informed consent to participate in the study. Participation in the study was voluntary, and participants could withdraw from the study at any time.

FUNDING

The study was funded by Coloplast A/S, Denmark.

DATA AVAILABILITY STATEMENT

Anonymous data that underlie the results of this study, as well as the study protocol and the informed consent form, are available from the corresponding author upon reasonable request.

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