

Kevin,
Uses SenSura® Mio
Concave



Curved fit for curved areas

New clinical evidence supporting SenSura® Mio Concave!

SenSura® Mio Concave

A recent clinical study in Canada¹ demonstrated that SenSura® Mio Concave performed significantly better than non-concave appliances for people with outward peristomal body profiles* in key clinical areas, such as:

- *Wear time*
- *Leakage & skin problems*
- *Fit of the barrier*
- *Ease of application*
- *Feeling of security*
- *Feeling of comfort*



***An Outward Peristomal Body Profile (OPBP)** is when the area surrounding the stoma typically covered by the skin barrier, rises above the level of the surrounding abdomen.

1. St-Cyr, D., Gilbert, D., Dionne, Il, & Kameka, N. (2022). Evaluation of SenSura® Mio Concave vs. non-concave appliances in people with outward peristomal body profiles (OPBP). NSWOC 41st National Conference. Sponsored by Coloplast.

Study design:

1. Pre-evaluation visit
20 people enrolled in study

2. Trial with SenSura[®] Mio
Concave for 4-6 weeks

3. Post-evaluation visit
17 people completed study

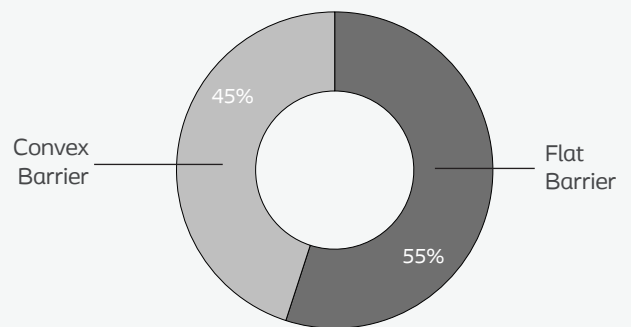
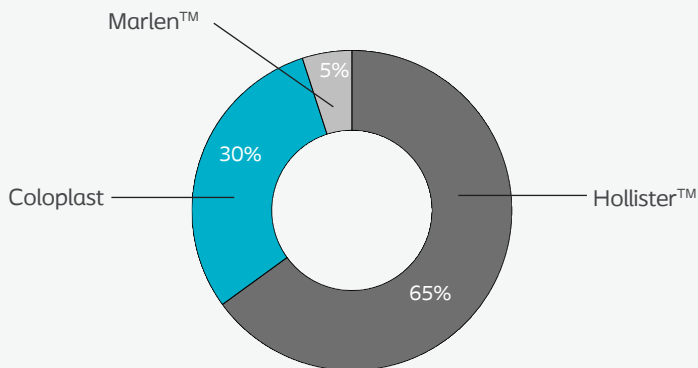
Inclusion criteria:

- Outward peristomal body profile
- 18 years of age or older
- Has a protruding stoma with a colostomy, ileostomy, urostomy or has a flush stoma with a colostomy with non-liquid output
- Willing to contact clinician once per week during study period
- Independent with ostomy appliance changes

Exclusion criteria:

- Has a retracted stoma or a flush stoma with liquid output
- Uses irrigation during the study
- Pregnant or breastfeeding
- Currently receiving or had received within the last four weeks radiation, chemotherapy, or steroid medication in the peristomal area

Pre-evaluation appliances:



Results



5.0 days wear time
with SenSura[®] Mio Concave
compared to 4.1 days wear time
with non-concave appliances,
 $p = 0.024$



42% reduction in DET score*
with SenSura[®] Mio Concave
DET Score was 1.19 for SenSura Mio
Concave and 2.05 for non-concave
appliances, $p = 0.009$

* The DET score is a standardized and professionally-administered method for assessing **peristomal skin health**. DET stands for Discolouration, Erosion, and Tissue overgrowth. Within each domain, both the area of peristomal skin affected and the severity of the skin changes are taken into account.



88% reported no leakage

with SenSura[®] Mio Concave

compared to 35% when using non-concave appliances

p = 0.008



82% reported no skin problems

compared to 35% when using non-concave appliances

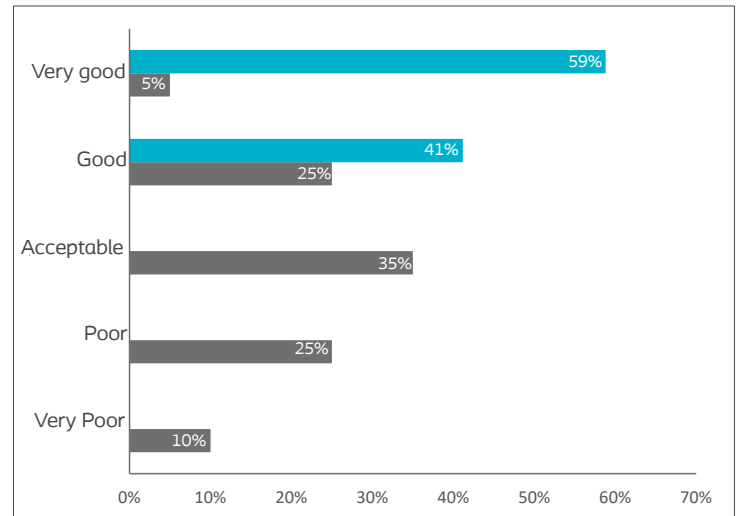
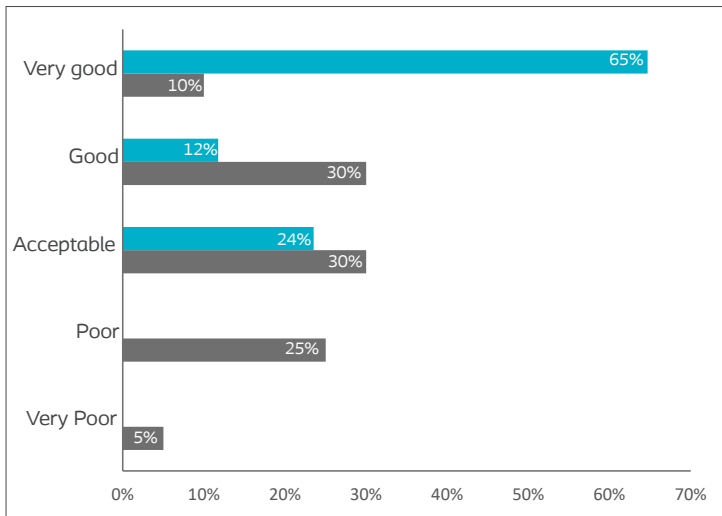
p = 0.021

 = SenSura[®] Mio Concave

 = Non-Concave appliances

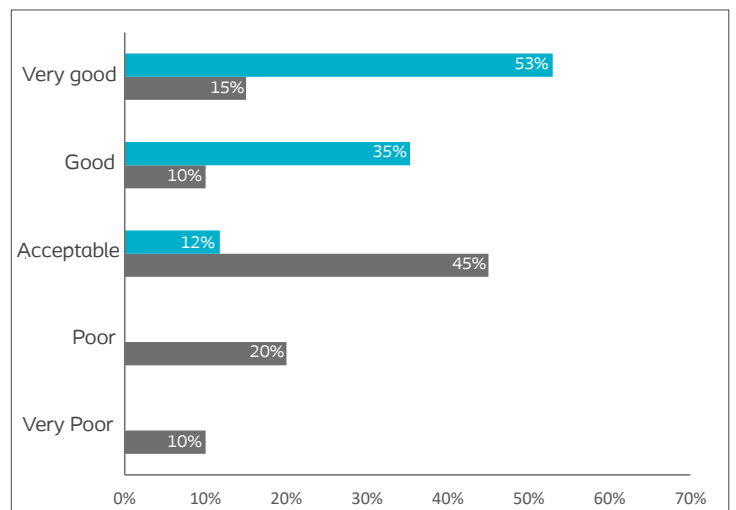
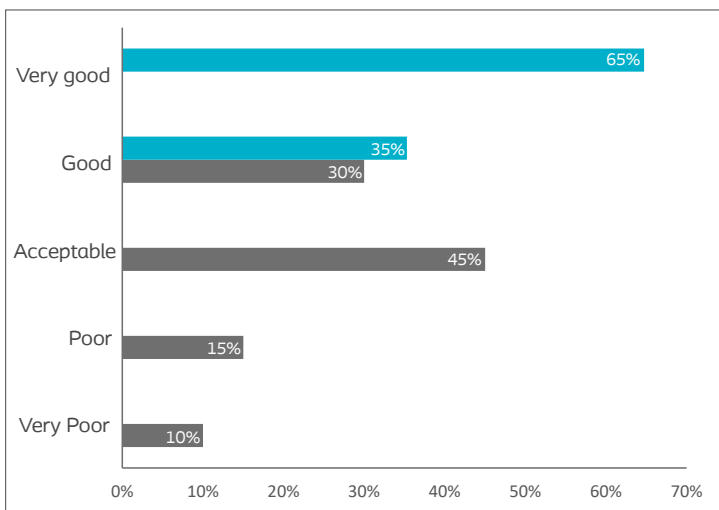
77% evaluated SenSura[®] Mio Concave to be Very good or Good at **providing feeling of security** (p = 0.002)

100% evaluated SenSura[®] Mio Concave to be Very good or Good at **providing feeling of comfort** (p < 0.001)



100% evaluated SenSura[®] Mio Concave to be Very good or Good at **following body movements** (p < 0.001)

88% evaluated SenSura[®] Mio Concave to be Very good or Good at **avoiding wrinkles and folds** (p = 0.008)



Curves are complicated but **SenSura® Mio Concave** has solutions!

Challenge 1

On curved areas, a flat skin barrier does not fit without forming creases and folds.



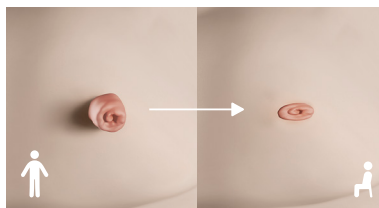
Solution 1



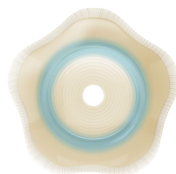
The petals of the **curved star-shape** hug the body with significantly less creasing and folding.

Challenge 2

The peristomal area changes when the body moves.²



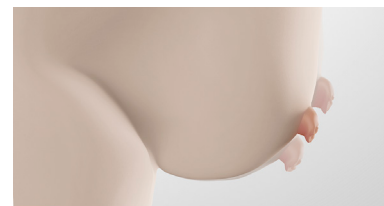
Solution 2



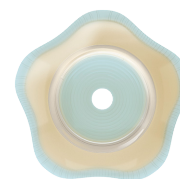
The **built-in stability ring** stabilises the centre zone, giving the peristomal area the necessary support.

Challenge 3

Outward curves move a lot. The barrier needs to stay secure.³



Solution 3



The **fit zones** on the outer rim grip down on the belly and follow its movements. The fit zones at the centre provide flexibility close to the stoma.

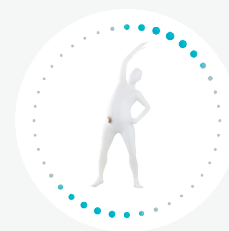
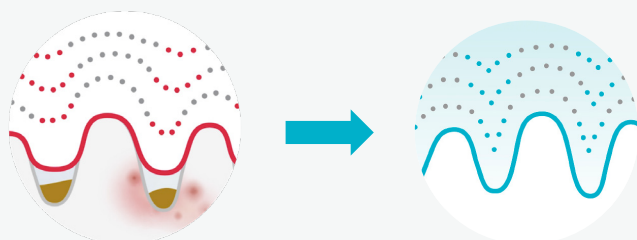
BodyFit Technology is the foundation for getting the right fit

SenSura® Mio barriers are designed with BodyFit Technology, a unique elastic adhesive technology that provides:

Secure **body** contact for protection

&

Flexible **fit** during movement



2. Bible, J. E., Biswas, D. et al. Normal Functional Range of Motion of the Lumbar Spine During 15 Activities of Daily Living. J Spinal Disord Tech. Vol. 23, Number 2, April 2010.

3. Coloplast Ostomy Life Study, 2016, Data on file; 2Ostomy Life Study 2016/17, Review (p 13).

Ostomy Care / Continence Care / Wound & Skin Care / Interventional Urology

Prior to use, refer to product "Instructions for Use" for intended use and relevant safety information.