

# Understanding Convexity; A Compendium of Key Studies



# Why is convexity important?



Primary goal in ostomy care is to establish a secure seal between the peristomal skin and the baseplate of the stoma, because:

Ostomy is associated with a **high rate of complications**<sup>2,3</sup>. A systematic literature review of 23 studies identified the range of peristomal complications in ostomy patients to be between **36.3 and 73.4%**<sup>3</sup>.

**Peristomal skin complications** as a result of leaked effluent are common<sup>3</sup>. **Leakage** has been reported to occur up to **87%** of the time within the first 2-years after ostomy surgery<sup>4</sup>.

**Flat baseplates** may not be best suited to all patients, especially those with flush or retracted stomas, skin creases or folds<sup>5</sup>.

Estimated number of people living with stomas<sup>1</sup>:



USA: 1 million



China: 1 million



Europe: 700,000

1. Goodman, W., Downing, A., Allsop, M. et al. Quality of life profiles and their association with clinical and demographic characteristics and physical activity in people with a stoma: a latent profile analysis. *Qual Life Res* 31, 2435–2444 (2022).
2. Malik T, Lee MJ, Hari Krishnan AB. The incidence of stoma related morbidity - a systematic review of randomised controlled trials. *Ann R Coll Surg Engl*. 2018 Sep;100(7):501-508. doi: 10.1308/rcsann.2018.0126. Epub 2018 Aug 16. PMID: 30112948; PMCID: PMC6214073.
3. D'Ambrosio F, Pappalardo C, Scardigno A, Maida A, Ricciardi R, Calabrò GE. Peristomal Skin Complications in Ileostomy and Colostomy Patients: What We Need to Know from a Public Health Perspective. *Int J Environ Res Public Health*. 2022 Dec 21;20(1):79.
4. Indrebø KL, Aasprang A, Olsen TE, Andersen JR. Factors associated with leakage in patients with an ostomy: A cross-sectional study. *Nurs Open*. 2023 Jun;10(6):3635-3645.
5. Colwell, Janice C.; Stoa Davis, Janet; Emodi, Krisztina; Fellows, Jane; Mahoney, Mary; McDade, Bethany; Porten, Sima; Raskin, Elizabeth; Sims, Terran; Norman, Holly; Kelly, Matthew T.; Gray, Mikel. Use of a Convex Pouching System in the Postoperative Period: A National Consensus. *Journal of Wound, Ostomy and Continence Nursing* 49(3):p 240-246, May/June 2022

# Current Thinking on Convexity



The big questions surrounding convexity relates to how it is defined and how to select the right convex barrier to achieve desired clinical outcomes. The following summarized publications all serve to help reduce this “complexity of convexity” and pave the road to bring consensus and guidance to convexity product definition, selection, and use.

Historically, the use of convexity was seen as controversial due to: risk of complications<sup>1</sup>, such as:

- Mucocutaneous separation (MCS)
- Peristomal pressure injury

Scientific literature suggests that the rate of MCS complications is low, between 3.7 and 9.7%<sup>2</sup>, and pressure injuries are rare<sup>3</sup>

Evidence supports the use of convexity, with the aim to prevent leaking, as the most important consideration to prevent peristomal complications<sup>1</sup>, with a low risk of MCS and peristomal pressure injuries<sup>1</sup>

1. Colwell JC, Stoia Davis J, Emodi K, Fellows J, Mahoney M, McDade B, Porten S, Raskin E, Sims T, Norman H, Kelly MT, Gray M. Use of a Convex Pouching System in the Postoperative Period: A National Consensus. *J Wound Ostomy Continence Nurs.* 2022 May-Jun 01;49(3):240-246.  
2. Tsujinaka S, Tan KY, Miyakura Y, Fukano R, Oshima M, Konishi F, Rikiyama T. Current Management of Intestinal Stomas and Their Complications. *J Anus Rectum Colon.* 2020 Jan 30;4(1):25-33.  
3. Brindle, T, et al, Selecting Convex Products in the Immediate Post-Operative Period: the journey from consensus recommendations toward an evidence-based clinical approach to ostomy care, *J. Wound Ostomy Continence*, Nov. 2024 (In Press)

# Recent Evidence on Convexity



## Hoeflok J, et al. 2017 Consensus paper

Due to the necessity for practical guidelines on the use of convex ostomy products, a panel of international experts convened and agreed on 26 comprehensive statements covering product characteristics, patient assessment considerations, indications for convexity, and expected outcomes.



## McNichol L, et al. 2021 Consensus paper

Building on the previous consensus paper, another international panel of experts met with the objective of defining the fundamental characteristics of convex skin barriers and providing guidance on the clinical selection of convex products.

- 5 characteristics of convexity were agreed on: depth, compressibility, flexibility, tension location and slope.
- 18 clinical application statements were included as guidance for the use of the five characteristics in clinical practice.



## Colwell JC, et al. 2022 Consensus paper

A scoping review identified a lack of standardisation in the best practice for clinicians using convexity during the postoperative period.

- An expert panel recommended considering convexity during the immediate post-operative period. The type and characteristics of convexity should be chosen based on its ability to provide a secure seal, prevent leakage, and maintain or restore optimal peristomal skin health, while exerting minimal pressure on the mucocutaneous junction.



## Waller J, et al. 2024 FEA analysis

While the consensus papers highlight the key characteristics of convex products, data regarding the amount and location of tension applied on the abdomen by convex baseplates was lacking.

This study used finite element analysis (FEA) to assess the impact of stoma baseplate convexity on tension and compression around the stoma site

- First study to demonstrate the interaction of convex baseplates with the abdominal wall
- Relationship of tension location and depth allows clinicians to understand how these convex characteristics may guide product selection with attention to forces applied around the stoma.




Click on icon link to view the full article.



# Use of Convexity in Ostomy Care

## Results of an International Consensus Meeting

 Hoeflok J, Salvadalena G, Pridham S, Droste W, McNichol L, Gray M. *J Wound Ostomy Continence Nurs.* 2017;44(1):55-62.

### Study Overview

- Expert panel reviewed, discussed, and voted on proposed consensus statements to provide a basis for clinical decision making when selecting an ostomy pouch system and/or accessories that incorporate convexity
  - 15 nurses, 9 countries
  - Median years of experience in ostomy care: 15.9 years
- A scoping review was carried out before the meeting

### Results

Consensus was reached on 26 statements, grouped into 4 categories:

#### Product characteristics

1. Some convex products are firm
2. Some convex products are soft
3. A belt can be used to enhance the effect of convexity
4. The effect of convexity can be enhanced if placed close to the base of the stoma

#### Outcomes

5. Use of convexity can extend wear time

#### Patient assessment

6. To best assess the need for convexity, the pouching system must be removed
7. The best position for assessment for convexity is the sitting position
8. Assessment for convexity includes type of output (such as formed, semi-formed, and loose or liquid)
9. Assessment for convexity includes the location of the stoma opening, stoma height, whether the stoma telescopes, and location of distal lumen in the loop or double-barrel stoma.
10. Assessment for convexity includes abdominal tone, contour of peristomal region, and the presence of peristomal skin disorders
11. An ostomy patient using convexity must be reassessed based on individual needs
12. An ostomy patient using convexity must be reassessed based on clinician judgment
13. Assessment of harmful effects of convexity (such as ulceration, pain) is needed with each pouching system change

#### Indications

14. Convexity can be used with colostomy, ileostomy, and urostomy
15. Liquid output can be an indicator for convexity to prevent or manage leakage
16. Stoma opening at the level of the skin can be an indicator for convexity
17. A protruding stoma can require convexity
18. With a firm peristomal region, soft convexity can be a better option than firm convexity
19. With a soft peristomal region, firm convexity can be a better option than soft convexity
20. People with peristomal skin disorders can require convexity
21. In the immediate postoperative period, convexity can be considered
22. The stoma care nurse is best prepared to advise patients and health care providers on the appropriate use of convexity
23. Loop stomas with the distal opening at skin level can be an indicator for convexity
24. Stoma opening that is off-center can be an indicator for convexity
25. A stoma opening below the level of the skin can be an indicator for convexity
26. Convexity can be used to manage enterocutaneous fistulae

### Conclusion

The 26 consensus statements provide information for the use of convexity in clinical practice

# Characteristics of Convex Skin Barriers and Clinical Application

## Results of an International Consensus Panel

McNichol L, Cobb T, Depaifve Y, Quigley M, Smitka K, Gray M. *J Wound Ostomy Continence Nurs.* 2021;48:524–532.

### Study Overview

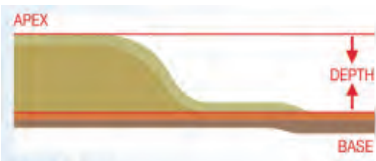
- Expert panel reviewed, discussed, and reached consensus on proposed statements designed to provide standard definitions of convex skin barrier characteristics and their clinical applications
- 12 nurses, 11 countries (across Australia, Europe, North America and the UK)
- Median years of experience in ostomy care: 19.5 years
- Literature review carried out before meeting

### Results

27 draft statements were presented, consensus on 5 definitions of fundamental convex skin barrier characteristics.

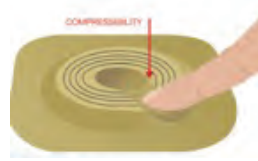
#### Depth

- measurement from the apex of the dome to the base



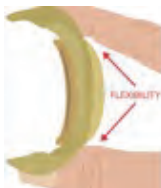
#### Compressibility

- capacity of the convex dome to be displaced or flattened



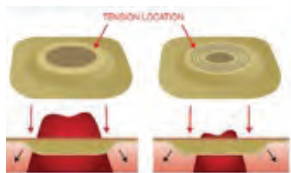
#### Flexibility

- how easily the convex skin barrier can bend



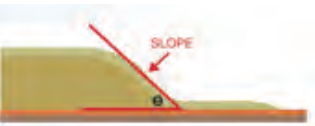
#### Tension location

- position in which the convex dome exerts downward and outward forces on the peristomal topography



#### Slope

- angle from the base of the convex skin barrier to the apex of the dome




### Conclusion

The five consensus statements provide a framework for clinicians to select the most appropriate convex skin barrier

Images adapted from: McNichol, Laurie MSN, RN, CNS, GNP, CWOCN, CWON-AP, FAAN; Cobb, Terri BSN, RN, CWOCN; Depaifve, Yves MSN, RN; Quigley, Mary RGN, RM, ET, Dip Onc, PGrad; Smitka, Kimberly RN, WON; Gray, Mikel PhD, RN, FNP, PNP, CUNP, CCCN, FAANP, FAAN. Characteristics of Convex Skin Barriers and Clinical Application: Results of an International Consensus Panel. *Journal of Wound, Ostomy and Continence Nursing* 48(6):p 524-532, November/December 2021

# Use of a Convex Pouching System in the Postoperative Period

## A National Consensus

 Colwell JC, Stoia Davis J, Emodi K, Fellows J, Mahoney M, McDade B, Porten S, Raskin E, Sims T, Norman H, Kelly MT, Gray M. *J Wound Ostomy Continence Nurs.* 2022;49(3):240-246.

### Study Overview

- Expert panel reviewed, discussed, and reached consensus on the use of convex products in the post-operative period
  - 10 healthcare providers with expertise in managing patients with an ostomy in inpatient, outpatient and home care settings in the United States
- Scoping review carried out before meeting

### Results

- Scoping review revealed a lack of standardization regarding the best practice for clinicians using convexity during the postoperative period
- Consensus was reached on 8 statements for the use of convexity in the immediate postoperative period and throughout the first 6 months, as well as goals for choosing the best pouching system

Primary goal for choosing an ostomy pouching system is a reliable seal, predictable wear time, and optimal quality of life for the patient

If a change in the pouching system is made, reassessment should be conducted by an ostomy nurse specialist.

A pouching system belt should be introduced when convexity alone does not provide a secure seal

- A convex pouching system may be necessary if:
- The patient is experiencing leakage
  - There are peristomal skin complications due to leakage
  - The area around the stoma pulls or dips inward, recesses into the abdomen, is concave, or there is a moat around the stoma
  - The abdomen is soft and/or the peristomal area has creases, folds, or scars
  - The position of the stoma opening is level with or below the peristomal skin, allowing the effluent to undermine the seal

Convex ostomy pouching systems can be used regardless of when the stoma was created

Follow-up by an ostomy nurse specialist should occur within the first 2 weeks after hospital discharge following stoma creation/revision

Convexity can be used in the immediate postoperative period. Type and characteristics should be based on the ability to secure a seal and exert the least amount of pressure on the mucocutaneous junction

A full assessment of the patient's ostomy needs should be conducted in each stage of the postoperative periods:

- Immediate postoperative period (days 0-8)
- Postoperative period (days 9-30)
- Transition phase (day 31-6 months)

### Conclusion

The expert panel agreed that convexity can be used anytime after surgery, achieving a secure seal with no leakage is the key goal of ostomy management, and that routine follow-up visits with an ostomy nurse should be made within 2 weeks after discharge and when pouching system changes are made

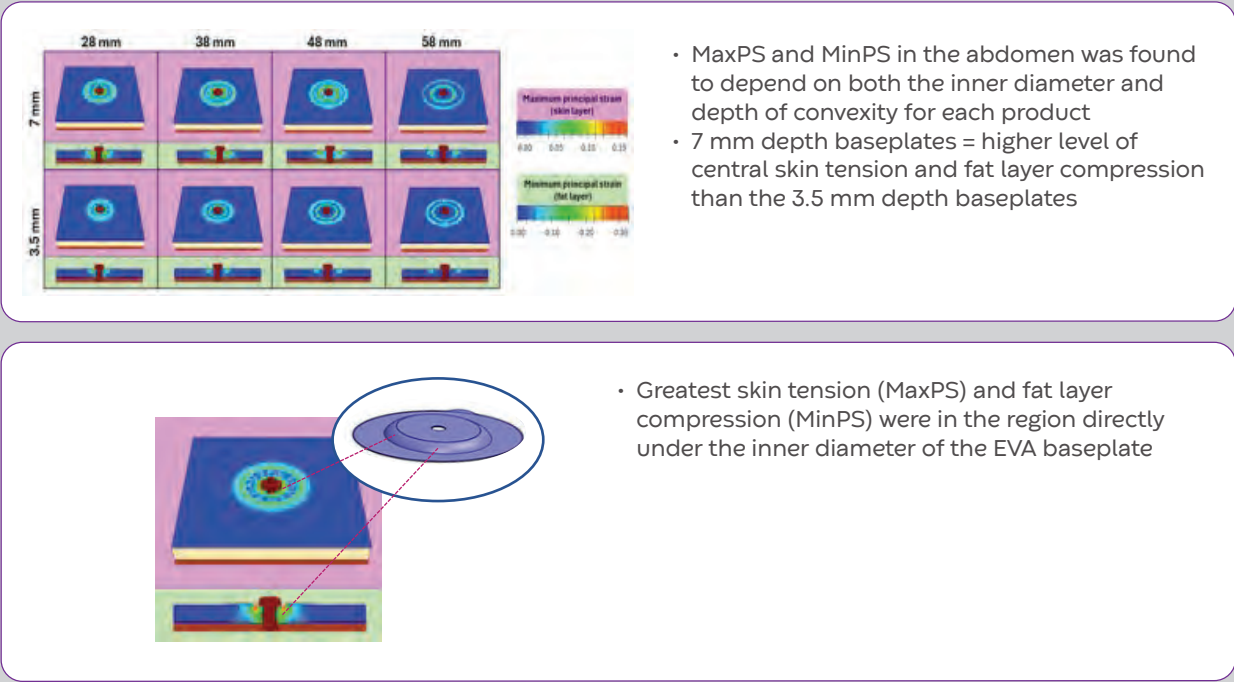
# Impact of Stoma Baseplate Convexity on Tension and Compression Around the Stoma Site: a Finite Element Analysis

Waller J, et al. Cureus 2024;16:e5112.

## Study Overview

- A finite element analysis (FEA) simulating the application of convex baseplates with different geometries and flexibilities to an idealised, flat abdomen (representing skin, subcutaneous tissue and musculature layers) was conducted
- Eight different baseplates, with depths of either 3.5mm or 7mm and inner diameters between 30mm and 60mm were assessed
- MaxPS has been used to measure the outwards effect of the baseplate on the abdomen skin layer. Elements in the skin layer of the FE model are coloured according to the level of greatest tension or stretch experienced across each one. MinPS has been used to measure the downwards effect of the convex baseplate on the abdomen fat layer<sup>1</sup>

## Results



## Conclusion

The findings illustrate the role of convexity in ostomy care and the value of having a range of baseplate geometries to address patient-to-patient variation in stoma type and peristomal skin.

Images adapted from Waller J, Gowans P, Lord S, et al. (January 11, 2024) Impact of Stoma Baseplate Convexity on Tension and Compression Around the Stoma Site: A Finite Element Analysis. Cureus 16(1): e52112. doi:10.7759/cureus.52112

1. Waller J, Gowans P, Lord S, et al. (January 11, 2024) Impact of Stoma Baseplate Convexity on Tension and Compression Around the Stoma Site: A Finite Element Analysis. Cureus 16(1): e52112. doi:10.7759/cureus.52112





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