



# Use of Convexity in Ostomy Care

## Results of an International Consensus Meeting

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### ABSTRACT

Ostomy skin barriers that incorporate a convexity feature have been available in the marketplace for decades, but limited resources are available to guide clinicians in selection and use of convex products. Given the widespread use of convexity, and the need to provide practical guidelines for appropriate use of pouching systems with convex features, an international consensus panel was convened to provide consensus-based guidance for this aspect of ostomy practice. Panelists were provided with a summary of relevant literature in advance of the meeting; these articles were used to generate and reach consensus on 26 statements during a 1-day meeting. Consensus was achieved when 80% of panelists agreed on a statement using an anonymous electronic response system. The 26 statements provide guidance for convex product characteristics, patient assessment, convexity use, and outcomes.

**KEY WORDS:** consensus, convex, convexity, ostomy barrier.

### INTRODUCTION

One of the guiding principles of ostomy care is to establish and maintain a secure and predictable seal.<sup>1</sup> Products that incorporate convexity are often considered an important tool for achieving this goal. Convexity is defined as A curvature on the skin side of the barrier or accessory.<sup>2</sup> Convex products are frequently cited as the preferred means to manage flat or retracted stomas and to compensate for irregular peristomal planes such as creases or folds.<sup>1,3-7</sup> Although a variety of convex products are available with different depths and shapes, there is little supporting evidence to guide their selection and use.<sup>2</sup>

The origins of convex product development are not known. Limitations in early ostomy product availability and the need to cope with poorly constructed stomas or irregular body contours were historically addressed by creative use of pastes, belts, rings, and medical adhesives.<sup>6,8,9</sup> During the 1980s and early 1990s, multiple ostomy product manufacturers designed

and released firm convex skin barriers designed for both 1- and 2-piece pouching systems.<sup>2</sup> More recently, manufacturers have introduced additional accessories with convex features such as barrier rings and soft convex skin barriers.<sup>2</sup>

Although the terms “convex” and “convexity” are consistently used to describe the curvature on the adhesive side of the skin barrier or accessory, other descriptors remain undefined.<sup>2</sup> There are no industry standards for the depth, profile, tension, firmness, softness, and flexibility of products with a convex feature.<sup>2</sup> Research and clinical practice guidelines for product selection are lacking, which leaves the determination of matching stomal protrusion and peristomal contours to appropriate barriers to the individual knowledge and skill of the clinicians.

In order to address these gaps, an international group of expert ostomy care nurses was convened to discuss key aspects of convexity use and to identify areas of agreement. The panel generated 26 statements focusing on the assessment, use, and characteristics of convexity. Funding for the meeting was provided by Hollister Incorporated (Libertyville, Illinois).

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### METHODS

Using structured processes as outlined by Murphy and colleagues,<sup>10</sup> 15 nurse panelists from 9 countries were convened to review, discuss, and vote on a group of proposed consensus statements designed to provide a basis for clinical decision making when selecting an ostomy pouching system or accessories that incorporate convexity. The group was led by a facilitator with expertise in group moderation for purposes of building consensus (M.G.). Panelists were selected from a broad range of practice settings (Box 1), including private practice, community, and acute care; all worked with adult patients and had familiarity with convex products and their use. Clinician experience ranged from 4.5 to 38 years, with a median of 15.9 years.

A consensus process was chosen for this topic based on the lack of an evidence base guiding selection of ostomy pouching

**BOX 1.****Convexity Consensus Panel Members**

Name and Credentials	Country
Mieke Bolmer-Sinnema, Stoma Consultant	The Netherlands
Pascale Cassier, Infirmiere Liberale	France
Marco Della Sanità, Clinical Specialist, Ostomy, Continence, Colorectal Disease Management	Italy
Yves Depaifve, Registered Nurse, Clinical Nurse Specialist	Belgium
Colleen Drolshagen, RN, CNS, CWOCN	United States
Werner Droste, ET Nurse	Germany
Anne Marie Frandsen, RN, MCN, WOC Therapist, Clinical Nurse Specialist	Denmark
Rosemary Hill, BSN, RN, CWOCN, CETN(C)	Canada
Jill Marshall, Stoma Care Nurse Specialist	United Kingdom
Laurie McNichol, MSN, RN, GNP, CWOCN, CWON-AP, Clinical Nurse Specialist	United States
Kitty Peeten, MANP, OCN	The Netherlands
Sue Pridham, RN, Clinical Nurse Specialist	United Kingdom
Henriette Skov, Stoma Nurse, Stoma Therapist, Clinical Nurse Specialist	Denmark
Margarete Wieczorek, Clinical Specialist, WOC Nurse	Germany
Jo Hoeflok, MA, BSN, RN(EC), CETN(C), CGN(C), Nurse Practitioner	Canada

systems or accessories with convex features. The consensus process provides a formalized process for constructing statements that integrate clinical experience from a geographically and professionally diverse group of individuals with expertise in ostomy care.<sup>10</sup> Participants were selected based on their clinical expertise, practice settings, and countries of origin. Panel members practice in the United States, Canada, France, the Netherlands, the United Kingdom, Italy, Germany, and Belgium. The meeting was conducted in English and held in Europe.

Prior to the meeting, panelists reviewed current literature relevant to convexity in ostomy care (Table 1). The literature summary was generated from a scoping review of articles indexed in the CINAHL and MEDLINE electronic databases. All articles published within a 15-year period prior to the meeting date (October 2015) and written in the English language were included. Search terms included “ostomy,” “product assessment,” “convex,” “convexity,” “barrier,” “flange,” “appliance,” and “pouching system.” All article types were included in the review; they included articles reporting original research, all review articles (systematic, scoping, and integrative), and best practice guidelines. Grey literature sources such as conference abstracts were excluded. Twenty-five articles were initially retrieved; a combined title and abstract search identified 15 papers that met inclusion criteria. These papers are summarized in Table 1. In addition, panel members were encouraged to provide any relevant literature in their own languages for translation and review prior to the consensus meeting. No additional articles were identified that met inclusion criteria using this method.

An integrative review article was located that identified multiple gaps in the evidence related to convexity, including a lack of consistent terminology and no standardization in product

descriptions or use.<sup>2</sup> No randomized controlled trials or non-randomized clinical trials were found evaluating the efficacy of various pouching products that incorporate convexity. Several studies were found that described proportions of subjects using 1 or more convex options.<sup>11-19</sup> In a large prospective study, Davis and colleagues<sup>20</sup> analyzed convexity as a covariate and determined it was not a factor related to health-related quality of life. McPhail and colleagues<sup>14</sup> reported findings from a single group study in 2014; subjects compared a single product that incorporated convexity to their current pouching system. The study product was preferred by 62% of participants. Beitz and Colwell<sup>21</sup> reported results of a nurse survey of important uses for convexity. Several consensus documents were located relevant to the topic of convexity in relationship to stoma conditions or peristomal skin conditions.<sup>22-24</sup> The paucity of research-based literature concerning assessment for and optimal use of convex ostomy products underscored the need for development of consensus-based statements, providing guidance for clinical decision until additional research is conducted.

Draft statements were written in advance of the meeting to allow maximum time for discussion by the panelists; in addition, panelists were encouraged to propose their own statements during the latter part of the meeting. Participants used an electronic audience response system that enabled them to provide anonymous feedback concerning statements. Each statement was read by the moderator and briefly discussed by panel members. An initial vote was taken, and the statement deemed consensus based if 80% or more of panelists agreed to the statement as written. If consensus was not reached, the moderator led a discussion designed to revise the statement so that consensus could be reached and a second vote was taken. Up to 3 rounds of discussion were undertaken in an attempt to reach consensus; if agreement could not be reached after 3 rounds, the statement was identified as “unable to reach consensus” and discussion was discontinued. Upon completion of voting for each of the statements, the panel reviewed all final statements to confirm their work.

## CONSENSUS STATEMENTS

The panelists reached consensus on 26 statements (Table 2). These statements were later grouped by the authors into the following 4 categories: (1) product characteristics, (2) patient assessment, (3) indications for convexity, and (4) outcomes.

### Product Characteristics

Consensus was reached for 4 statements that focused on convex product characteristics. Two of these 4 statements focused on physical properties: “Some convex products are firm” and “Some convex products are soft.” Convex product evolution has witnessed the development of multiple products to obtain secure and predictable seals. While no standardized product definitions exist, integrated firm convex products are thought to support and stabilize abdominal contours through their rigidity while soft convex barriers are known for their flexibility and patient comfort.<sup>1,2</sup> Convex products extend beyond those with integrated features and include barrier rings and inserts that may be used to provide a primary source of convexity (by adding onto a flat barrier) or as an adjunct to existing convex barriers, enhancing the depth.<sup>1,23</sup>

The 2 other statements categorized by the authors as pertaining to product characteristics were concerning techniques for enhancing convexity. One statement focused on use of a

**TABLE 1.**  
**Literature Review**

Reference	Type and Country	Number of Participants	Study Overview and Findings Related to Convexity
Beitz JM, Colwell JC. Stomal and peristomal complications: prioritizing management approaches in adults. <i>J Wound Ostomy Continence Nurs.</i> 2014;41(5):1-10.	Cross-sectional descriptive questionnaire United States	281	Stoma care nurses ranked interventions for managing stoma and peristomal complications. Use of a convexity was the most highly ranked intervention for managing stoma retraction. Use of convexity was the second highest ranking intervention for management of stoma fistula.
Colwell JC, Ratliff CR, Goldberg M, et al. MASD part 3: peristomal moisture-associated dermatitis and periwound moisture-associated dermatitis: a consensus. <i>J Wound Ostomy Continence Nurs.</i> 2011;38(5):541-553.	Consensus	Not applicable	Structured process of consensus statement development was used with a group of expert stoma care nurses. Convexity should be considered when the stoma lumen is not above the skin level and when the area around the stoma demonstrates creases or folds in the sitting or standing position. Convexity, a rounded outward protrusion of the skin barrier, can apply peristomal pressure to push the stoma lumen above the skin barrier edge, allowing the stoma output to drain into the pouch. Convexity can stabilize the peristomal area when creases or folds are there, preventing undermining and leakage.
Davis JS, Svavarsdóttir MH, Pudlo M, et al. Factors impairing quality of life for people with an ostomy. <i>Gastrointest Nurs.</i> 2011;9(2)(suppl):14-18.	Prospective, repeated-measures. Treatment; no control 18 countries	2924 (visit 1) 2710 (visit 2)	Described demographics, skin condition, product type, and QOL at baseline and again 8 wk after the stoma care nurse provided product fitting, study product, and instructions on usage. QOL scores at baseline were similar between those using a convex barrier (661) and those using a nonconvex barrier (2202). Convexity was not found to be a factor related to QOL.
Gray M, Colwell JC, Doughty D, et al. Peristomal moisture-associated skin damage in adults with fecal ostomies: a comprehensive review and consensus. <i>J Wound Ostomy Continence Nurs.</i> 2013;40(4):389-399.	Consensus Canada and the United States	Not applicable	Structured process of consensus statement development was used with a group of expert stoma care nurses. Abdominal contour should be examined for creases and folds in the sitting, standing, and lying positions in order to evaluate its influence on the seal between the skin barrier and the peristomal skin. If the peristomal area remains flat in all positions, the peristomal area is managed with a flat barrier. If creases are identified that are likely to cause the solid flat skin barrier to pull away from the uneven areas, panel members advocate the use of convexity. In addition, panel members recommended the use of a belt to further stabilize the pouch seal and apply gentle pressure to the convexity.
Gray M, Colwell JC, Goldberg MT. What treatments are effective for the management of peristomal hernia? <i>J Wound Ostomy Continence Nurs.</i> 2005;32(2):87-92.	Review Review	Not applicable Not applicable	Authors found no reports of specific cases or studies documenting complications related to the use of convexity with peristomal hernias.
Hoeflok J, Kittscha J, Purnell P. Use of convexity in pouching: a comprehensive review. <i>J Wound Ostomy Continence Nurs.</i> 2012;40(5):506-512.	Review Review	Not applicable Not applicable	Authors found convexity terminology was inconsistent; not standardized; insufficient evidence was found for convexity use; and outcomes of convexity use were not consistently reported.
Lindholm E, Persson E, Carlsson E, Hallén AM. Ostomy-related complications after emergent abdominal surgery: a 2-year follow-up study. <i>J Wound Ostomy Continence Nurs.</i> 2013;40(6):603-610.	Prospective, repeated-measures observational Sweden	144	Stoma nurses evaluated stoma complications, stoma configuration, and product use over a 2-y period after surgery. Use of convexity increased over time for all stoma types; 12.2% immediately postoperatively/on the ward, to maximum of 28.2% at 6 mo. Loop ileostomy patients had the highest use of convexity; 67% at 6 mo. 12/51 (29%) patients with end colostomy were using convexity at 1 y postsurgery.

(continues)

**TABLE 1.**  
**Literature Review (Continued)**

Reference	Type and Country	Number of Participants	Study Overview and Findings Related to Convexity
Lyon CC, Smith AJ, Beck MH, et al. Parastomal pyoderma gangrenosum: clinical features and management. <i>J Am Acad Dermatol.</i> 2000;42:992-1002.	Prospective, descriptive, cross-sectional United Kingdom	26	Described clinical findings for patients diagnosed with PPG from a larger study of patients evaluated with peristomal skin complications. Convexity was used in 6/26 cases; 6/8 had recurrent lesions underneath the convex surface. Healed scars were also a location of PPG development (6/26), and in 12 cases no local trauma or scarring was identified.
Martins L, Samai O, Fernández A, et al. Maintaining healthy skin around an ostomy: peristomal skin disorders and self-assessment. <i>Gastrointest Nurs.</i> 2011;9(2)(suppl):9-13.	Prospective, repeated-measures. Treatment; no control 18 countries	2924 (visit 1) 2710 (visit 2)	Described demographics, skin condition, product type, and QOL at baseline and again 8 wk after the stoma care nurse provided product fitting, study product, and instructions on usage. Participants who were changed from flat to convexity at baseline (n = 129) had greatest improvement in skin condition by week 8 assessment.
McPhail J, Nichols T, Menier M. A convex urostomy pouch with adhesive border: a patient survey. <i>Br J Nurs.</i> 2014;23(22):1182-1186.	Open-label product sampling and survey United Kingdom	47	Respondents used study product and described satisfaction with the features and security of the product. All participants used convexity (before the study and during the study). 62% reported the study product was more secure than their usual pouch.
Ratloff CR. Factors related to ostomy leakage in the community setting. <i>J Wound Ostomy Continence Nurs.</i> 2014;41(3):249-253.	Questionnaire United States	107	Respondents who were within 2 y of stoma creation described their stoma, skin, product use, and leakage occurrence. 87% overall reported leakage. 35% of respondents reported using convexity.
Ratloff CR. Early peristomal skin complications reported by WOC nurses. <i>J Wound Ostomy Continence Nurs.</i> 2010;37(5):505-510.	Prospective, observational United States	89	Stoma care nurses described stoma, type of complications, and product use of patients evaluated within 2 mo of surgery. 42 patients had peristomal complications. Of the 42 patients with peristomal complications, 11 were wearing convexity. Of the 47 patients without complications, 8 were wearing convexity.
Ratloff CR, Scarano KA, Donovan AM. Descriptive study of peristomal complications. <i>J Wound Ostomy Continence Nurs.</i> 2005;32(1):33-37.	Cross-sectional, observational United States	220	Stoma care nurses reported type of complications present when evaluated 2 mo after stoma creation. Total of 35 patients (17%) had complications described as: <ul style="list-style-type: none"> <li>• irritant dermatitis (24)</li> <li>• pressure areas from convexity (7)</li> <li>• Candida infection (3)</li> </ul>
Redmond C, Cowin C, Parker T. The experience of fecal leakage among ileostomists. <i>Br J Nurs.</i> 2009;18(17):S12-S17.	Marketing survey United Kingdom	1035	Respondents with ileostomy described stoma, product use, leakage, and strategies for reducing leakage. Convex and flat barrier users reported leakage (65% vs 55%). 25% overall used convexity. Convexity users were more likely to have retracted stomas. 49% using convexity reported red, irritated skin. 39% using flat barriers reported red, irritated skin.
Whiteley I, Sinclair G. A review of peristomal skin complications after formation of an ileostomy, colostomy or ileal conduit. <i>World Council Enterostomal Ther J.</i> 2010;30(3):23-25, 29.	Retrospective, descriptive, correlational analysis Australia	672	Database of stoma clinic records was used to describe and measure possible relationships between demographics, stoma type, product use, and complications. Stoma height was found not to be a predictor for the development of complications. Convex product users had fewer peristomal skin complications; 78% of patients discharged from hospital with a retracted stoma were using convexity.

Abbreviations: PPG, peristomal pyoderma gangrenosum; QOL, quality of life.



**TABLE 2.**  
**Consensus Statements**

<p><b>Product characteristics</b></p> <ul style="list-style-type: none"> <li>Some convex products are firm</li> <li>Some convex products are soft</li> <li>A belt can be used to enhance the effect of convexity</li> <li>The effect of convexity can be enhanced if placed close to the base of the stoma</li> </ul>
<p><b>Patient assessment</b></p> <ul style="list-style-type: none"> <li>To best assess the need for convexity, the pouching system must be removed</li> <li>The best position for assessment for convexity is the sitting position</li> <li>Assessment for convexity includes type of output (such as formed, semi-formed, and loose or liquid)</li> <li>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</li> <li>Assessment for convexity includes abdominal tone, contour of peristomal region, and the presence of peristomal skin disorders</li> <li>An ostomy patient using convexity must be reassessed based on individual needs</li> <li>An ostomy patient using convexity must be reassessed based on clinician judgment</li> <li>Assessment of harmful effects of convexity (such as ulceration, pain) is needed with each pouching system change</li> </ul>
<p><b>Indications</b></p> <ul style="list-style-type: none"> <li>Convexity can be used with colostomy, ileostomy, and urostomy</li> <li>Liquid output can be an indicator for convexity to prevent or manage leakage</li> <li>Stoma opening at the level of the skin can be an indicator for convexity</li> <li>A protruding stoma can require convexity</li> <li>With a firm peristomal region, soft convexity can be a better option than firm convexity</li> <li>With a soft peristomal region, firm convexity can be a better option than soft convexity</li> <li>People with peristomal skin disorders can require convexity</li> <li>In the immediate postoperative period, convexity can be considered</li> <li>The stoma care nurse is best prepared to advise patients and health care providers on the appropriate use of convexity</li> <li>Loop stomas with the distal opening at skin level can be an indicator for convexity</li> <li>Stoma opening that is off-center can be an indicator for convexity</li> <li>A stoma opening below the level of the skin can be an indicator for convexity</li> <li>Convexity can be used to manage enterocutaneous fistulae</li> </ul>
<p><b>Outcomes</b></p> <ul style="list-style-type: none"> <li>Use of convexity can extend wear time</li> </ul>

belt: “A belt can be used to enhance the effect of convexity.” Ostomy belts are used to provide support to the pouching system, either by stabilizing the system or by enhancing the pressure exerted by the system to achieve a good seal.<sup>1,2</sup> Panelists agreed on one final statement about characteristics pertaining to placement of a product with a convex feature at the base of the stoma: “The effect of convexity can be enhanced if placed close to the base of the stoma.” There is no uniformity in the construction for convex barriers, with some barriers delivering their pressure to the periphery of the barrier and others closer to the inner aperture.<sup>25</sup>

### Patient Assessment

Nine statements achieved consensus that addressed issues related to assessment. The panel reached agreement that in order to assess for the need for convexity, the pouching system should be removed. They further reached consensus that the best position for assessment for convexity is sitting. Additional statements related to patient assessment prior to the application of convexity focused on type of output from the stoma, location of the stoma opening, stoma height, whether the stoma telescopes, location of the distal lumen in the loop or double-barrel stoma, abdominal tone, contour of the peristomal region, and the presence of peristomal skin disorders.

Panelists unanimously agreed that assessment occurs after the pouching system has been removed from the abdomen, enabling the clinician to evaluate the abdominal skin and contours. Removal of the system is also recommended because it allows for a focused assessment of the peristomal skin, includ-

ing the presence of any moisture associated or other forms of peristomal skin damage.<sup>23,25</sup> The peristomal plane should also be assessed with the system removed, identifying any contours such as creases, folds, bulges, or gullies that may contribute to a compromised seal.<sup>1,2,23,26</sup> The panel agreed that the position of the patient during assessment is important; the sitting position was recommended because it allows optimal assessment of abdominal contours and the position of the stoma within the abdomen. Panelists acknowledge that several authors suggest that assessment in multiple positions (lying, sitting, standing, and bending) may be considered when assessing the patient for use of a pouching system with convexity.<sup>6,23,26,27</sup> A comprehensive peristomal assessment that includes abdominal tone, contours of peristomal region, and the presence of peristomal skin disorders was deemed important by all panel members. Convex pouching system selection is described as “matching” the relative rigidity (tone) of the abdomen and the peristomal plane with the depth and rigidity of the available products.<sup>2</sup> Alterations to the peristomal plane such as skin creases, folds, wrinkles, or gullies are frequently described as benefitting from use of products with a convexity feature, as the barrier protrusion can “stabilize” the plane and prevent leakage.<sup>22</sup>

Three additional statements were discussed that focused on the ongoing evaluation of patients using convexity within a pouching system. All panel members concurred that assessment for convex products was not a singular event and required regular reassessment to ensure that the overarching goals of a secure and predictable seal and intact peristomal skin are maintained. Given the absence of research providing

a timeline for reevaluation, panelists agreed that the timing of reassessment must be based on individual patient needs and clinician judgment. Panel members also reached consensus that assessment of adverse effects of application such as ulceration or pain when using convex products is needed with each pouching system change.

The panel also reached unanimous consensus that a nurse with expertise on ostomy care is best prepared to advise patients and health care providers on the appropriate use of convexity. The involvement of an ostomy nurse in patient management positively impacts quality of life.<sup>28,29</sup> Preoperative stoma site selection by a trained specialist has been identified as essential to prevent complications and to prepare the patient for ostomy surgery.<sup>30,31,32</sup> The appropriate use of convexity may be a contributing factor in the outcomes experienced by patients postoperatively. Equal emphasis needs to be given to researching the impact of ostomy nurses' selection of convex barriers on patient outcomes.

### Indications for Convexity

Twelve statements focused on clinical indications for convexity. The first statement indicated that products incorporating convexity may be used in persons living with a colostomy, ileostomy, or urostomy. Panelists also agreed that liquid output can be a reason to use convexity when seeking to prevent or manage leakage. Discussion occurred about the importance of the position of the stoma with respect to surrounding abdominal contours. Consensus statements identified the influence of a protruding stoma, stoma opening below the level of the skin, ostomy opening that is off-center, and loop stomas with a distal opening at the skin level.

One statement about stoma protrusion generated the most discussion. The original statement read, "A stoma protruding more than 20 mm may not indicate need for convexity." More than half of panelists disagreed with this statement when presented. Some suggested that inclusion of such a precise measurement as 20 mm lacked adequate support. Others argued that the location of the opening of the stoma was more important than the magnitude of stomal protrusion. They stated that they consider stoma movement (telescoping) or intermittent protrusion and retraction of the stoma an indication for convexity. After 2 rounds of discussion, the original statement was simplified. The revised statement, "A protruding stoma can require convexity," reached consensus with 90% agreement on the third round of voting. All other characteristics reached consensus with less discussion, and all have been identified as indications for convexity in prior publications.<sup>6,22,23,25</sup>

Panelists recognized the need to more fully identify clinical indications for pouching systems or accessories with soft versus firm convexity. Two statements reached consensus; these statements noted that soft convexity options may be better option than firm convexity in patients with firm peristomal region, while firm convexity products may be a better option for persons with a soft peristomal region. Panelists identified examples illustrating the relationship of patient assessment and selection of soft versus firm convex options and agreed with the conclusions of other experts, noting that soft convexity may bend and move with the body better than firm options when there are creases on a soft abdomen that might cause a rigid convex product to lift off the skin.<sup>1-5,7</sup> Panelists also opined that support provided by firm convex options may provide better support for soft folds and creases. They consistently emphasized the importance of individualized patient assessment and product selection.

One statement that reached consensus focused on peristomal moisture-associated skin damage (PMASD) as an indication for selection of a product with convexity. The panelists discussed the strong relationship between skin irritation and leakage beneath the ostomy skin barrier. They emphasized the importance of correcting product fit when PMASD is present as well as its use for preventing further leakage and skin damage. Skin irritation is recognized as the most common complication for individuals with stomas; the most common contributor is exposure of the peristomal area to stoma effluent.<sup>34</sup>

A statement focusing on incorporating convexity in the period immediately following ostomy surgery generated considerable discussion among panelists. The initial statement posed to the panel read, "In the immediate postoperative period (first 3 days) soft convexity is preferred rather than firm convexity." This statement failed to gain consensus when first presented to the panel; subsequent discussion revealed multiple trigger points that led to this outcome. Some panelists raised concerns that convexity in the immediate postoperative period might increase the risk for mucocutaneous separation (MCS) by increasing pressure and mechanical forces at the base of the newly formed stoma, while others opined that MCS during the early postoperative period is more likely influenced by other patient-specific factors such as perioperative nutrition, immunologic compromise, the presence of postoperative abdominal distention, and surgical technique. They also commented on experiences with multiple patients who developed MCS but have never used convexity. Multiple panelists indicated that using convexity to achieve a secure and predictable seal is more important in the immediate postoperative period than the possible risk of MSC. Discussion also focused on the skill and knowledge required to safely select and apply a pouching system with convexity during the immediate postoperative period. Some panelists suggested that this task should be limited to ostomy nurse specialists, but others argued that such restriction might hinder access to convex products in patients cared for in facilities with no ostomy nurse specialists. This discussion also revealed the absence of consensus concerning the optimal timing of convexity use during the immediate postoperative period or selection of a product that provides soft versus firm convexity. Ultimately, the panel reached consensus on a simplified statement that read "In the immediate postoperative period, convexity can be considered."

In addition to prepared statements, panelists were given an opportunity to add additional statements for review and voting. Overwhelmingly, the members felt that enterocutaneous fistulae (ECFs) needed to be included as an indication for convexity. Ostomy care nurses are often tasked with the responsibility of managing ECFs, and they must often borrow skills and products from ostomy management to facilitate the care of these complex and challenging patients. The goals of ECF management are similar to those of ostomy care, with protection of the peristomal skin and containment of the effluent.<sup>35,36</sup> Panelists concurred that ostomy products are often used to support the management of ECFs and to achieve these goals. As a result of this discussion, a statement was added that explicitly acknowledged that pouching systems or accessory products with a convex feature may be used to manage ECFs. Panelists further concurred that additional research is needed to determine the optimal use of pouching products with a convexity for management of ECFs.

## Outcome Measures

Panelists discussed and reached consensus on a single statement that focused on the desired outcome when using products that incorporated convexity. This relatively simple statement indicated “Use of convexity can extend wear time.” Panelists acknowledged that multiple other outcomes may be used to measure the effectiveness of use of products with convexity. Nevertheless, extension of pouching system wear time was recognized as the central goal, whether this extension was directly attributable to prevention of leakage from the pouch or indirectly for alleviation and prevention of peristomal skin damage caused by exposure to effluent undermining the skin barrier.

## Statements That Did Not Achieve Consensus

Consensus was not achieved on all statements originally posed to the panel. Panelists were unable to reach consensus on a statement that read “Convexity can be used in pediatric patients with ostomies.” They uniformly agreed that there was insufficient pediatric experience amongst the members to discuss or include this statement in their final recommendations. Two other statements that were proposed by the panelists did not achieve consensus. They were (1) 1-piece flat systems may be an option to 2-piece convex systems, and (2) 1-piece flat/flexible systems may be an alternative to convex systems. The panelists discussed the merits of using a flat pouching system in the management of ostomies but emphasized that the focus of the consensus statements was to clarify the use of convex products rather than their alternatives.

## LIMITATIONS

The collaborative process of this international meeting provided a unique opportunity for discussion of a topic that, although central to ostomy care, lacks robust evidence. The panelists were able to focus on the topic, review the available literature, and discuss with colleagues their experiences with convex products. The consensus process, however, has inherent limitations. It does not generate new knowledge but reflects the opinions of the experts who served as panelists at the time the meeting was conducted. Current knowledge and opinions were discussed and agreed in the form of consensus statements; the outcomes of the meeting may have been different in larger or more diverse groups. In addition, the literature search, was limited to the English language. Additionally, the panel did not attempt to address the broad variations in convex barrier product descriptions and terminology that are used in the marketplace and clinical practice.

## CONCLUSIONS

Convex barrier products have been available for some time. They are broadly used, but supporting research is lacking. This international consensus meeting provided a unique opportunity for experts in the field of ostomy care to discuss the state of the available science and agree on key elements of the topic including patient assessment for convexity, product characteristics, and patient selection considerations. The resulting 26 consensus statements provide clarity for the use of convexity in ostomy practice that was not previously available. These statements have direct application in international settings and for specialty and generalist nursing practice settings.

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