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Use of a Convex Pouching System in the Postoperative Period

A National Consensus

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ABSTRACT

Convex pouching systems have been available for ostomy patients for decades; however, controversy remains over the use of convexity in the postoperative period. A group of 10 nurses and physicians with expertise caring for patients with an ostomy completed a scoping review identifying research-based evidence and gaps in our knowledge of the safety and effectiveness related to the use of a convex pouching system following ostomy surgery. Results of this scoping review demonstrated the need for a structured consensus to define best practices when selecting a pouching system that provides a secure and reliable seal around the stoma, avoids undermining and leakage of effluent from the pouching system, and contributes to optimal health-related quality of life for patients following ostomy surgery. The expert panel reached consensus on 8 statements for the use of convex products immediately after surgery and throughout the first 6 months after stoma creation, as well as describing goals in choosing the best pouching system for the patient with an ostomy.

KEY WORDS: Colostomy, Convex pouching system, Convexity, Ileostomy, Mucocutaneous junction, Mucocutaneous separation, Ostomy, Peristomal skin complications, Postoperative, Urostomy.

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Disclosure: This work is financially supported by Coloplast A/S (Humlebaek, Denmark).

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (JWOCNOnline.com).

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DOI: 10.1097/WON.0000000000000874

INTRODUCTION

Approximately 1 million people in the United States live with an ostomy, and around 100,000 new ostomies are created each year in the United States.¹ The management of an ostomy includes the use of a pouching system to collect stoma effluent. The most basic goal of a pouching system is to provide reliable wear time from the time the system is applied to a planned removal time in a manner that maintains intact and healthy peristomal skin.^{2,3} A primary cause of ostomy-related complications is pouch leakage, erosion of the faceplate allowing urinary or fecal effluent to come into contact with the peristomal skin. Up to 80% of patients with an ostomy will experience peristomal skin complications.^{4,5} Peristomal skin injury is loss of the epidermis and in some cases the dermis underneath the adhesive borders of the pouching system. Multiple peristomal skin complications have been identified including peristomal moisture-associated skin damage (a form of irritant contact dermatitis), allergic contact dermatitis, medical adhesive-related skin injuries, and pressure injuries.⁶⁻¹⁰ The need for ongoing use of a pouching system creates challenges for managing peristomal skin damage. This challenge is particularly apparent when attempting to maintain an effective skin seal in the presence of injured, moist peristomal skin.¹¹ Selection of an effective pouching system that conforms around the stoma and to the peristomal body profile is essential when managing peristomal skin complications.

The adhesive barrier of an ostomy pouching system is available in multiple sizes and shapes. The opening (aperture) of the adhesive faceplate should match the size and shape of the stoma, and the contours of the faceplate should accommodate the



Figure 1. Flat ostomy barrier.

peristomal skin and abdominal contours. Skin barriers may be flat (Figure 1), convex (incorporating an outer curvature with respect to the aperture) (Figure 2), or concave (incorporating an inner curvature with respect to the aperture) (Figure 3). A flat skin barrier is appropriate for a person with a flat peristomal area and a well-budded stoma with the os in the center of the stoma.¹² In contrast, a convex barrier is used to flatten peristomal skin that has folds or creases and/or facilitates stoma protrusion above the skin, enabling discharge of effluent into the pouch. A concave barrier can be used to conform to an outward peristomal body profile, frequently seen in patients with a peristomal hernia.⁶

Convex pouching systems have been available for ostomy patients for decades; however, their use immediately after surgery is controversial.¹³⁻¹⁵ Concerns raised by clinicians about the possible complications from the use of convexity in the postoperative period include development of a mucocutaneous

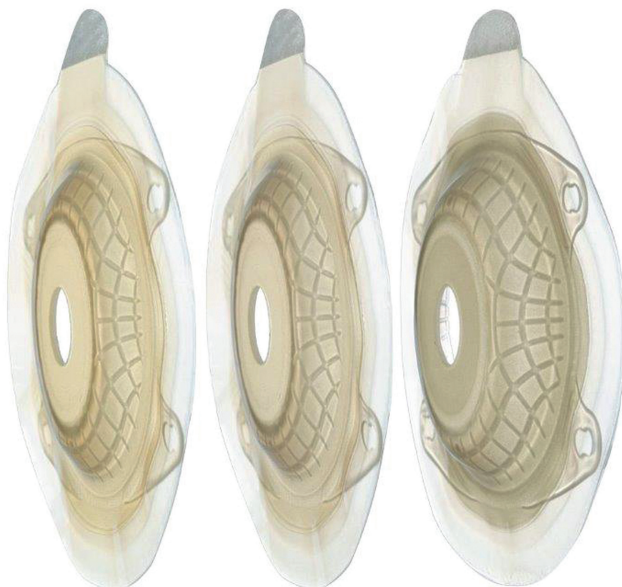


Figure 2. Convex ostomy barriers.



Figure 3. Concave barrier.

separation and pressure injuries. Nevertheless, some clinicians have asserted that convexity is needed in some instances to maintain the seal around a new ostomy, and pouching systems incorporating convexity can be safely used immediately following stoma surgery.¹⁴

The purpose of this article is to report on outcomes of a scoping review and development of consensus statements guiding the use of a convex pouching system following ostomy surgery. The panel also developed a detailed and comprehensive glossary of terms defining type of ostomies and pouching systems including convex pouching systems, and a pathway guiding the use of convexity during the postoperative period following ostomy creation.

STRATEGIES: SCOPING REVIEW AND DEVELOPMENT OF CONSENSUS STATEMENTS

A scoping review was conducted using PRISMA scoping review guidelines to identify current best evidence related to the use of convexity following ostomy surgery and to identify gaps in knowledge.¹⁶ Inclusion criteria included articles published between 1996 and 2021. We acknowledge that pouching systems with a convex faceplate emerged approximately 25 years ago around the time Rolstad and Boarini¹⁷ published their seminal article. Nevertheless, the date range for this scoping review was selected because it corresponds with the increasingly widespread use of convexity in practice. Exclusion criteria were articles that did not include the use of convex pouching systems and those written in a language other than English. An electronic database search included PubMed, EMBASE, and CINAHL. Search terms were as follows: convexity + peristomal skin complications, peristomal skin issues, peristomal skin conditions, convexity + risk factors, convexity + postoperative, convexity + post discharge, ostomy + quality of life + convexity, mucocutaneous separation + stoma + convexity, convex skin barrier. See Supplemental Digital Content Appendix A (available at: <http://links.lww.com/JWOCN/A70>) for comprehensive list of pre-defined search terms and Boolean combinations. Articles identified in that search were then evaluated for inclusion into the analysis via title and abstract review, followed by full-text

review (Figure 4). If an article was selected for inclusion, data extraction was performed that included type of article, sample size, methods and outcomes of original research reports, and outcomes and/or key points of review articles, clinical guidelines, or best practice documents.

Outcomes of the scoping review revealed a paucity of evidence related to the use of convexity following ostomy surgery, and a particular lack of evidence regarding its use for the first month following surgery. Therefore, consensus statements guiding best practice related to the use of convexity were generated using a modified Delphi process.^{18,19} This process is designed to enable a diverse group of experts to reach a collective accord concerning best practice when underlying evidence is lacking. The philosophy underlying the Delphi process is based on the belief that when people think together, they can make better decisions.²⁰ An expert panel was convened, comprising 10 health care providers with experience in managing patients with an ostomy in inpatient, outpatient, and home care settings. Due to the COVID-19 global pandemic, the consensus was conducted virtually using online meeting platforms and asynchronous online collaboration boards.

FINDINGS: SCOPING REVIEW

The initial search of electronic databases identified 2257 records. After removing duplicates, 1860 elements were retrieved. A title and abstract review yielded 93 elements that were read in full. Ultimately, 21 elements that met inclusion criteria were selected for data extraction (Figure 4). These elements were reviewed by a subcommittee of consensus panel members for the use of convexity in the postoperative period. Of the 21 elements included in the scoping review, 6 were original studies²¹⁻²⁶ and 3 were original survey reports.²⁷⁻²⁹ The other elements were protocols for the nursing management of patients with an ostomy, best practice documents, and consensus statements or reviews.^{13-15,30-38}

No studies were retrieved that evaluated the efficacy or safety of the use of a convex pouching system during the postoperative period.²¹⁻²⁶ A single clinical practice guideline from the Multidisciplinary Italian Study Group for Stomas was identified that advised against the use of a convex pouching system during

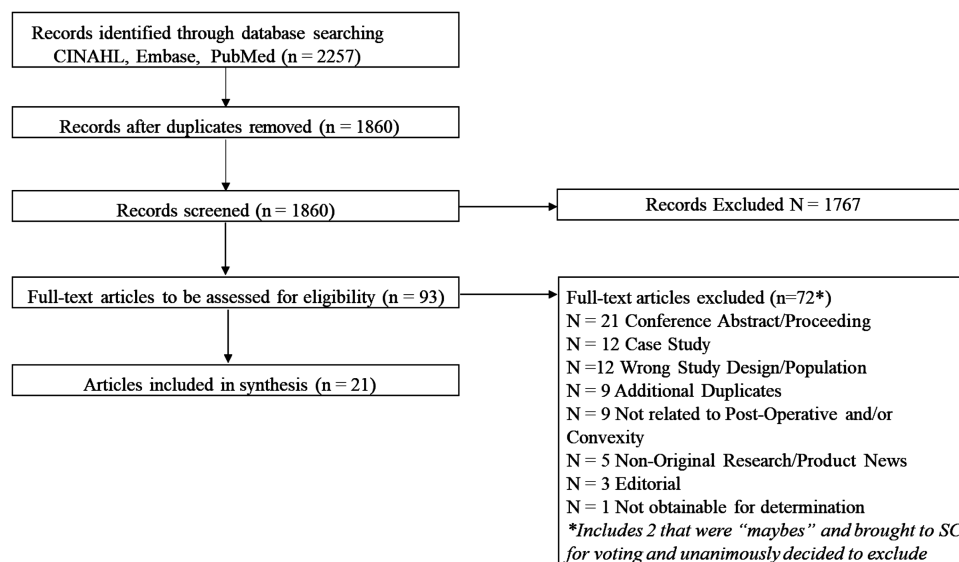


Figure 4. PRISMA diagram.

the “first postoperative days” due to concerns regarding the potential for mucocutaneous separation.¹⁵ This recommendation was based on expert opinion rather than supporting evidence and the time frame was not further identified. Based on these apparent gaps in evidence and paucity of best practice guidance, the panel moved forward with generation of best practice statements guiding the use of convexity during the postoperative period.

Consensus Statements

Because of a lack of standardization of care periods following ostomy surgery highlighted by the scoping review, the panelists reached consensus on 3 postoperative time periods: (1) immediate postoperative period, days 0 to 8; (2) postoperative period, days 9 to 30; and (3) transition phase, days 31 to 180 (Table 1). These periods were defined to conform with current care patterns for patients undergoing ostomy surgery and broad time frames suggested in the scoping review.

In addition, panelists reached consensus on 8 statements guiding best practice for the use of a convex pouching system in the postoperative period following ostomy surgery (Table 2). The first statement outlined the most important care priorities when caring for a patient with an ostomy. The panel determined that having a reliable pouching system that prevents leakage is the paramount goal. Wear time, the number of days that a person wears the pouching system, should be predictable; no leakage or undermining should occur between pouch application and removal. Wear time, which will vary between patients, is dependent upon multiple factors such as stoma abdominal location, os location, stoma effluent, and patient preference. We determined that all ostomy management decisions should consider the overall health and well-being of the patient and contribute to an optimal health-related quality of life for the patient.

Two statements focused on when a convex pouching system may be used. The panel agreed that a convex pouching system should be used regardless of when the ostomy was created and can be safely considered for use in the immediate postoperative period and other postoperative periods. Consensus was reached on the use of convexity during the postoperative period, with the primary goal of ensuring a secure and predictable seal for the pouching system. Panelists further concurred that in many cases convexity is needed to achieve this goal.

Panelists also reached consensus on 2 statements concerning indications for the use of a convex pouching system and the use of a belt. Pouch seal leakage, which is associated with peristomal skin complications and possible failure for patient adjustment, is one indication for the use of a convex pouching system. The peristomal body profile should be assessed for uneven profiles such as the area pulling inward, concavity around the stoma, scars, creases, and whether the peristomal abdomen is soft or firm with gentle palpation. Another indication for the use of convexity is the location

TABLE 1.
Postoperative Period Definitions

Postoperative Period	Time Frame
Immediate postoperative period	Days 0-8
Postoperative period	Days 9-30
Transition period	Days 31-180

TABLE 2.
Convexity Consensus Statements

1	The primary goals when working with a patient to choose an ostomy pouching system are to: <ul style="list-style-type: none"> • Secure a reliable seal around the stoma to avoid leakage; • Provide a <i>predictable</i> wear time; and • Contribute to an optimal quality of life for the patient.
2	A convex ostomy pouching system can be safely used regardless of when the stoma was created.
3	Convexity should be considered in the immediate postoperative period to ensure a secure, consistent, predictable seal and reduce the risk of leakage. The type and characteristics of the convexity used should be based upon the ability to provide a secure seal and exert the least amount of pressure on the mucocutaneous junction.
4	A convex pouching system may be necessary if any of the clinical findings are present: <ul style="list-style-type: none"> • The patient is experiencing leakage. • Peristomal skin complications due to leakage are present. • 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.
5	A pouching system belt should be introduced when convexity alone does not provide a secure seal. The group acknowledged that using a belt in the immediate postoperative period may increase pressure on the mucocutaneous junction.
6	Follow-up by an ostomy nurse specialist should occur within the first 2 wk after hospital discharge following stoma creation or stoma revision.
7	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), and transition phase (day 31-6 months) and should include: <ul style="list-style-type: none"> • Type of ostomy; • Characteristics of the stoma; • Stoma effluent—type and volume; • Patient’s peristomal body profile; • Topography of area around the stoma assessed in the sitting, standing, and supine positions (may need to consider lying on back and on side); • Condition of peristomal skin; • The ability of the patient to self-manage pouching system; • Patient’s physical activity levels; and • Patient’s preferences.
8	If a change in the pouching system is made, reassessment should be conducted by an ostomy nurse specialist within 2-3 wk after the change to assess the seal, wear time, and patient acceptance of the new system.

of the stoma lumen or os. If the os is below or even with the skin, effluent may undermine the seal and can cause leakage; convexity may be selected to direct the stoma effluent into the pouch, preventing undermining or leakage. Panelists also agreed that a pouching system belt can be used to stabilize the pouch seal and convexity. Nevertheless, they also acknowledged that in some instances a belt can increase pressure on the newly sutured mucocutaneous junction. While acknowledging the need to be aware of pressure from a belt, panelists supported that prevention of leakage, peristomal skin injury, and impaired adaptation outweigh the possible injury to the mucocutaneous junction that can be managed with topical wound care.

The final 3 consensus statements focused on ostomy nurse care and follow-up. Panelists believed that follow-up should be ongoing for 6 months and whenever a pouching system change was made. Panelists reached consensus that follow-up should occur within the first 2 weeks following hospital discharge because of evolving stoma and peristomal body profile changes that occur as healing progresses. Further, panelists concurred that a full assessment should be conducted in each stage of the postoperative periods: immediate postoperative period (days 0-8), postoperative period (days 9-30), and transition phase (30 days-6 months) because of a more gradual evolution of changes to the ostomy and abdomen and to evaluate the patient's adaptation to a ostomy and mastery of self-management skills. The assessments include inspection of the ostomy for character or effluent, volume of output, size, location of os, along with the peristomal body profile including creases, folds, and skin integrity. Ideally, panelists concurred that inspection should be performed with the patient in a standing, sitting, and supine positions. Panelists further concurred that time should be spent evaluating the patient's ability to manage their pouching system including selection, wear time, and independence in pouch changes. This evaluation should also address whether the pouching system allows the patient to participate in daily activities, and their overall satisfaction with their pouching system.

In addition, the panel identified the need for consensus statements to be accessible for both ostomy specialists and nonspecialists. For this reason, a glossary of terms (see Supplemental Digital Content Appendix B, available at: <http://links.lww.com/JWOCN/A70>) was developed to accompany

the statements along with a visual pathway (Figure 5) to help health care providers determine when to choose a convex pouching system.

DISCUSSION

The purpose of this scoping review and consensus was to explore evidence and reach consensus concerning use of a convex pouching system during the postoperative period. The statements described in this article provide best practice guidance for the use of convexity in the postoperative period; panelists reside in the United States, and consensus statements reflect practice experiences and practice patterns among this group. Statement 1 defines the primary goals when choosing a pouching system as ensuring a reliable seal, predictable wear time, and adaptation to life with an ostomy. This statement is consistent with published literature stating that pouch security and maintenance of peristomal skin are the most important factors in decision making when determining product choices.^{39,40} The panel also recognized that all decisions concerning ostomy management should consider the overall health and well-being of the patient.

When a patient undergoes ostomy creation, a process of psychological adaptation begins.^{1,12,39} To facilitate that adjustment during the postoperative period, a secure pouching system seal must be selected and introduced to the patient. If the pouch seal is not secure, leakage and peristomal skin injury may occur, negatively affecting peristomal skin health and adaptation to the ostomy.^{1,3,39} Panelists reached consensus that a convex pouching system can be used safely even during

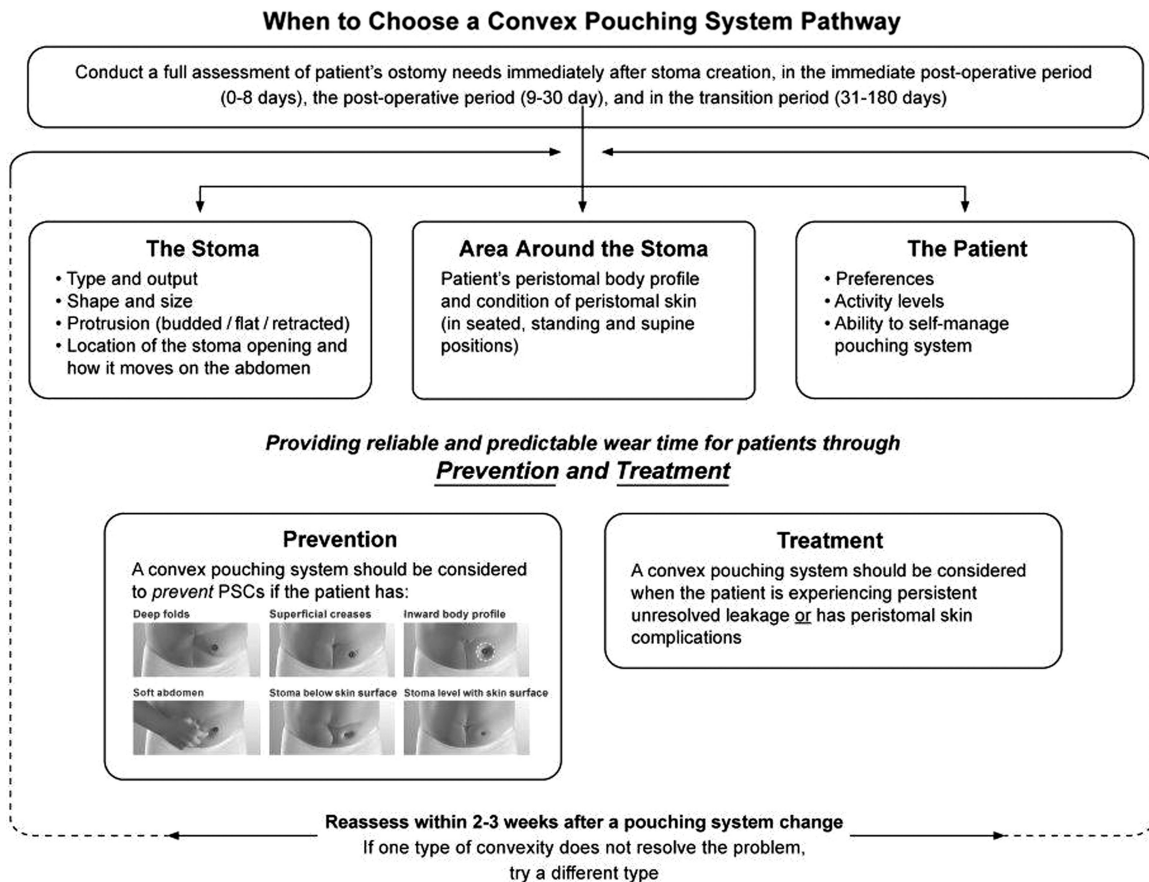


Figure 5. Postoperative convexity consensus pathway.

the postoperative period, and that convexity should be considered in the immediate postoperative period to ensure a secure, consistent, predictable seal and reduce risk of leakage. Statement 4 provides guidance to the clinician on the assessments used to determine when to use convexity to help prevent leakage (Table 2).

Maintaining a seal around the stoma was deemed key to prevention of leakage of effluent between the adhesive faceplate and underlying peristomal skin. Leakage is the undermining of the adhesive seal by stool or urine and can cause peristomal skin injury such as peristomal moisture-associated skin damage,⁷ as well as necessitate frequent changes with resultant medical adhesive-related skin injuries resulting in peristomal skin damage and difficulties achieving a reliable seal.⁴¹ A study in 2006 found that 45% of the patients examined had peristomal skin complications and that 77% were related to leakage.³ Addressing the pouching system seal is key to prevention of leakage, which in some cases may mean using a convex pouching system.

Historically, there has been concern about causing a mucocutaneous separation from the pressure of convexity; however, this has not been supported through research. Risk factors for mucocutaneous separation are infection, diabetes mellitus, corticosteroids, malnutrition, excessive tension on the stoma, and stoma necrosis.^{42,43} While panelists acknowledged that mucocutaneous separations occur in some patients with the use of a convex product, they further observed that this complication occurs in patients fitted with flat pouching systems and they questioned the link of an increased risk to use of convex systems, given the paucity of evidence in this area of care versus their collective clinical experience.

The reported incidence of mucocutaneous separation varies across the literature. Nastro and colleagues⁴⁴ reported an incidence of 4% to 24%. However, a smaller study by Salvadalena⁴⁵ found an incidence of less than 3%. Italian Guidelines for the Nursing Management of Enteral and Urinary Stomas in Adults¹⁵ advised against the use of convexity during the first postoperative days. However, the panel strongly supported that finding a pouching system that can achieve predictable wear time was the overriding goal and determined that the risk of mucocutaneous separation that can be managed with effective wound care did not outweigh this fundamental goal of care.^{43,46,47} Weighing the balance of risk of mucocutaneous separation and the importance of peristomal skin integrity, the panel recommended ostomy clinicians consider the type and characteristics of convexity based on its ability to provide a secure seal, prevent leakage, and maintain/restore optimal peristomal skin health, while taking steps to exert the least amount of pressure possible on the mucocutaneous junction.

Statements 6 to 8 focused on ongoing assessment by an ostomy nurse following ostomy surgery. Specifically, panelists achieved consensus that follow-up by an ostomy nurse specialist within the first 2 weeks after hospital discharge following stoma creation or revision is necessary. In their discussion, multiple panelists recommended follow-up by an ostomy nurse specialist within 2 weeks of hospital discharge should be a standard of care for managing all patients with fecal or urinary ostomies. This recognition arose from knowledge of and experiences with changes in the ostomy, peristomal skin, and abdominal contour adjacent to the ostomy. These changes need to be assessed by an ostomy nurse specialist to determine if a different pouching system size and shape is required. This recommendation is consistent with the latest guidelines from

the WOCN Society for the management of fecal and urinary ostomies, as well as guidelines published in the *British Journal of Nursing* in 2019.^{2,39}

CONCLUSIONS

Questions over the use of convexity in the postoperative period have been a discussion in the ostomy community for more than a decade. A panel of nurse and physicians practicing in the United States with experience and expertise in ostomy care reached consensus that convexity can be used any time after surgery. Discussion among panelists was based on the identification that achieving a secure pouch seal with no leakage is a fundamental goal of ostomy management and essential to reduce or eliminate leakage and peristomal injury and help the patient adapt to life with a stoma. Panelists also reached consensus concerning the need for a routine follow-up visit with an ostomy nurse 2 weeks following hospital discharge and additional visits when pouching system changes are made.

ACKNOWLEDGMENT

Development of the postoperative convexity consensus was facilitated by Bain Group Consulting.

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