

The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for Ostomy Surgery

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STATEMENT OF THE PROBLEM

Statistics regarding ostomy-related metrics remain elusive in the United States because of underreporting and coding limitations. The estimated number of ostomates in the United States is 750,000 to 1 million, with approximately 150,000 new ostomies created each year.¹ Stoma creation has a relatively high rate of associated morbidity, ranging from 20% to 80%; peristomal skin complications and parastomal hernia (PSH) are the most common associated morbidities.² A population-based study using the Michigan Surgical Quality Collaborative, which included 4250 patients, identified a 37% unadjusted surgical complication rate for elective cases involving an ostomy and 55% unadjusted surgical complication rate for emergency cases involving an ostomy.¹ In this study, risk-adjusted stoma-related morbidity rates varied significantly among hospitals, indicating a potential to improve outcomes in outlying institutions.

Beyond the typical short-term metrics captured in standard databases, the morbidity of ostomy surgery may also be measured in terms of the stoma-related negative effects on the quality of life and other long-term morbidities related to having an ostomy.^{3–8} Many patients have ostomies that are considered “problematic” and present with management problems like skin irritation and pouching difficulties that require prolonged and specialized care and result in increased utilization of health care resources and increased costs.^{9–15} The incidence and impact of short- and long-term stoma-related complications can be mitigated by perioperative education and marking, proper surgical technique, and attention to postoperative care pathways. The purpose of these clinical practice guidelines (CPG) is to guide surgeons and other health care providers to improve the quality of care and outcomes for patients undergoing ostomy surgery.

METHODOLOGY

This CPG focuses on the surgical care of patients requiring an ostomy and addresses issues like choosing an ostomy type, technical aspects of ostomy creation and closure, prevention and management of ostomy-related complications, and perioperative care. The guideline does not address whether an ostomy should be created in a given clinical scenario because this evidence base was reviewed in other American Society of Colon and Rectal Surgeons (ASCRS) CPG related to specific diseases (eg, diverticulitis, rectal cancer, and ulcerative colitis).¹⁶⁻¹⁸ Urostomies, continent ileostomies, stomas in the pediatric population, and a comprehensive review of nursing ostomy care (eg, skin care, use of different appliances, or other management systems) are beyond the scope of these guidelines.

These guidelines are based on the last ASCRS CPG for Ostomy Surgery published in 2015.¹⁹ Because of the changes in the strength or quality of the evidence (Table 1), this updated CPG contains 2 new statements, 9 modified statements, and omission of 1 statement from the 2015 CPG. The remaining statements were not changed, but the literature review and supporting statements were updated. A systematic search of MEDLINE, PubMed, Scopus EMBASE, and the Cochrane Database of Systematic Reviews was performed from January 1, 2014, to December 1, 2021. Individual literature searches

were conducted for each statement within the guidelines and were restricted to English language and adult patients (Fig. 1). Search strategies were based on the concepts of intestinal stomas, and the various relevant diagnostic procedures, surgical interventions, and care pathways related to these diagnoses using multiple subject headings, text words, and descriptors. The 4008 screened articles were evaluated for level of evidence, favoring randomized clinical trials, meta-analyses and systematic reviews, comparative studies, and large registry retrospective studies over single-institutional series, retrospective reviews, and observational studies. Additional references identified through embedded references and other resources as well as practice guidelines or consensus statements from relevant societies were also reviewed. A final list of 205 tabulated citations was evaluated for methodologic quality, the evidence base was evaluated, and a treatment guideline was formulated by the subcommittee for this guideline. The final grade of recommendation and level of evidence for each statement were determined using the Grades of Recommendation, Assessment, Development, and Evaluation system (Table 2).²⁰ When agreement was incomplete regarding the evidence base or treatment guideline, consensus from the committee chair, vice chair, and 2 assigned reviewers determined the outcome. Members of the ASCRS CPG Committee worked in joint production of these guidelines from inception to final

TABLE 1. What is new in the 2022 ASCRS Ostomy Surgery Clinical Practice Guidelines

| Topic | Recommendation |
|--------------------------------------|---|
| 2022 New recommendations | |
| Ostomy closure | 11. Routine water-soluble contrast studies in the absence of a clinical suspicion of anastomotic dehiscence or stricture may not be necessary before closure of a protective ostomy. Grade of recommendation: weak recommendation based on low-quality evidence, 2C |
| | 12. Early closure of protective ileostomies may be performed in select low-risk patients with a colorectal anastomosis without clinical evidence of anastomotic leak. Grade of recommendation: weak recommendation based on moderate quality evidence, 2B |
| 2022 Updated recommendations | |
| Perioperative management | 2. Appropriate potential ostomy sites should be marked preoperatively by a trained provider when possible. Grade of recommendation: strong recommendation based on moderate-quality evidence, 1B |
| Ostomy creation | 5. When indicated, a loop ileostomy or a loop colostomy is effective for fecal diversion. Grade of recommendation: strong recommendation based on moderate-quality evidence, 1B |
| | 7. In nonobese patients, the routine use of a support rod at the time of loop ileostomy construction is not necessary. Grade of recommendation: strong recommendation based on high-quality evidence, 1A |
| | 8. The routine use of prophylactic mesh to prevent parastomal hernia at the time of ostomy creation is not recommended. Grade of recommendation: weak recommendation based on high-quality evidence, 2A |
| | 9. Extraperitoneal tunneling of an end colostomy may decrease the risk of parastomal hernia. Grade of recommendation: weak recommendation based on moderate-quality evidence, 2B |
| | 10. Managing patients with a new ileostomy with a perioperative care pathway may decrease the risk of hospital readmission. Grade of recommendation: weak recommendation based on moderate-quality evidence, 2B |
| Ostomy closure | 13. Loop ileostomy closure can be performed using stapled or handsewn techniques. Grade of recommendation: strong recommendation based on high-quality evidence, 1A |
| | 14. Ostomy-site skin approximation should be performed when feasible, and purse string skin closure has advantages compared with other techniques. Grade of recommendation: strong recommendation based on high-quality evidence, 1A |
| | 15. Minimally invasive Hartmann's reversal is a safe alternative to open reversal. Grade of recommendation: strong recommendation based on moderate-quality evidence, 1B |
| 2015 Recommendations excluded | |
| Ostomy creation | Use of antiadhesion materials may be considered to decrease adhesions at temporary ostomy sites. Grade of recommendation: weak recommendation based on moderate-quality evidence, 2B |

ASCRS = American Society of Colon and Rectal Surgeons.

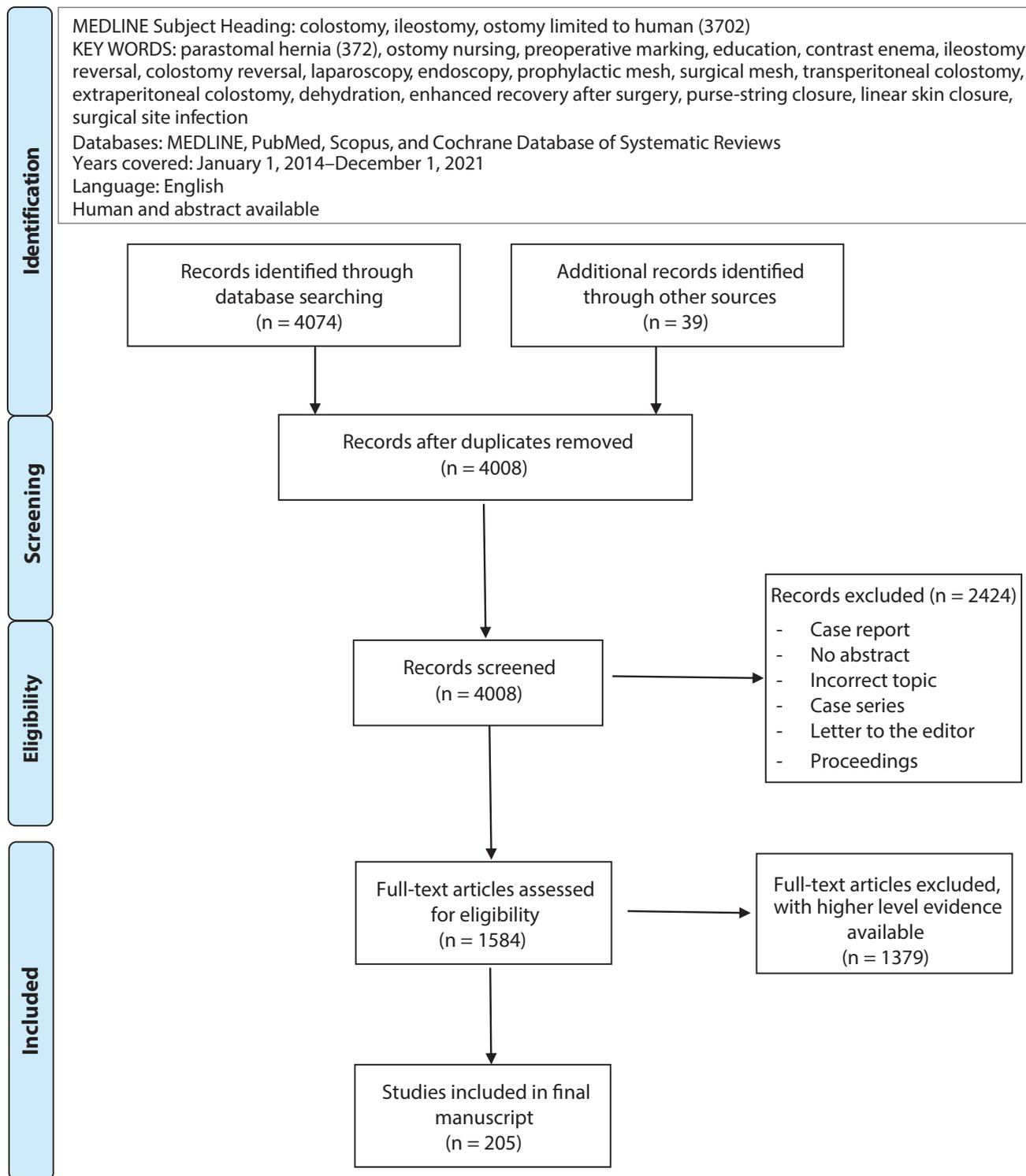


FIGURE 1. PRISMA literature search flow sheet. PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analysis.

publication. Recommendations formulated by the subcommittee were reviewed by the entire CPG Committee. Final recommendations were approved by the ASCRS Executive Council and peer-reviewed in *Diseases of the Colon and Rectum*. In general, each ASCRS CPG is

updated every 5 years. No funding was received for preparing this guideline, and the authors have declared no competing interests related to this material. This guideline conforms to the Appraisal of Guidelines for Research and Evaluation checklist.

TABLE 2. The GRADE system—grading recommendations

| Description | Benefits vs risks and burdens | Methodologic quality of supporting evidence | Implications |
|---|--|--|--|
| 1A Strong recommendation: high-quality evidence | Benefits clearly outweigh risks and burdens or vice versa | RCTs without important limitations or overwhelming evidence from observational studies | Strong recommendation: can apply to most patients in most circumstances without reservation |
| 1B Strong recommendation: moderate-quality evidence | Benefits clearly outweigh risks and burdens or vice versa | RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies | Strong recommendation: can apply to most patients in most circumstances without reservation |
| 1C Strong recommendation: low- or very low-quality evidence | Benefits clearly outweigh risks and burdens or vice versa | Observational studies or case series | Strong recommendation: may change when higher quality evidence becomes available |
| 2A Weak recommendation: high-quality evidence | Benefits closely balanced with risks and burdens | RCTs without important limitations or overwhelming evidence from observational studies | Weak recommendation: best action may differ depending on circumstances or patients' or societal values |
| 2B Weak recommendation: moderate-quality evidence | Benefits closely balanced with risks and burdens | RCTs with important limitations (inconsistent results and methodologic flaws, indirect or imprecise) or exceptionally strong evidence from observational studies | Weak recommendation: best action may differ depending on circumstances or patients' or societal values |
| 2C Weak recommendation: low- or very low-quality evidence | Uncertainty in the estimates of benefits, risks, and burdens; benefits, risks, and burdens may be closely balanced | Observational studies or case series | Very weak recommendation: other alternatives may be equally reasonable |

GRADE = Grades of Recommendation, Assessment, Development, and Evaluation; RCTs = randomized controlled trials.

PERIOPERATIVE MANAGEMENT

1. Patients undergoing elective stoma creation should receive preoperative and postoperative ostomy education by a specialized provider such as a wound ostomy and continence nurse. Grade of recommendation: strong recommendation based on moderate-quality evidence, 1B

Stoma education in the perioperative setting has been shown to reduce length of hospital stay, patient anxiety, and the rate of peristomal complications while increasing patients' self-reported quality of life.^{21–28} A trial that randomized 42 patients to an intensive preoperative educational program before ostomy surgery or postoperative teaching found that preoperative education decreased length of stay (8 versus 10 d; $p = 0.02$), decreased need for unplanned health care interventions postdischarge, decreased time to ostomy care proficiency (5.5 versus 9 d; $p < 0.001$), and resulted in significant cost savings.²¹ Some of these findings were replicated in a more recent retrospective study that incorporated preoperative stoma education into an enhanced recovery care pathway, and, in this setting, preoperative education was still associated with a length of stay benefit (8 versus 9 d; $p = 0.02$).²⁹ A meta-analysis of 68 studies reported that lack of preoperative stoma site marking and wound ostomy nurse specialist consultation before stoma surgery was 1 of 6 risk factors associated with an increased likelihood of stoma-related complications; other risk factors included age more than 65 years, female sex, BMI more than 25 kg/m², diabetes mellitus, and abdominal malignancy as the underlying reason for ostomy surgery.³⁰ Another retrospective study

evaluated the impact of a 2-hour preoperative stoma education class led by a certified Wound Ostomy and Continence Nurse (WOCN) for patients undergoing colorectal surgery in which a stoma was anticipated and found that educated patients ($n = 124$) experienced significantly fewer stoma complications than uneducated patients ($n = 94$). In this study, the study group had less leakage from the ostomy pouching system and less peristomal skin damage (20% versus 45%; $p = 0.002$) but had no improvement in the length of stay or in the 30-day readmission rate.³¹

A meta-analysis evaluating ostomy patients included 38 studies and reported that several modifiable factors were associated with improved quality of life, including having had preoperative stoma site marking and education (exercise, family support, maintenance of social networks, spirituality, and financial stability were also related factors).³² In a multicenter prospective trial of 402 patients evaluating the impact of specialized ostomy nursing on the health-related quality of life of patients with new ostomies, patients treated in hospitals with specialized ostomy nurses were less concerned with appearance and were more comfortable with cleaning, changing, and disposing of ostomy appliances. In addition, study patients reported less fearfulness, improvements in sleep, and better overall health.³³

2. Appropriate potential ostomy sites should be marked preoperatively by a trained provider, when possible. Grade of recommendation: strong recommendation based on moderate-quality evidence, 1B

Preoperative ostomy-site marking is associated with reduced postoperative stoma and peristomal complications and

improved patient self-care and health care quality of life. In a systematic review of 10 studies including 2109 patients, preoperative stoma site marking was associated with reduced stoma and peristomal complications (both early and late) including prolapse, retraction, necrosis, skin complications (OR, 0.52; 95% CI, 0.42–0.64), and hernias (OR, 0.25; 95% CI, 0.09–0.71).³⁴ Another systematic review of 20 studies found that preoperative stoma site marking was associated with a reduction in complication rates (OR, 0.47; 95% CI, 0.36–0.62), improvement in self-care deficits (OR, 0.34; 95% CI, 0.18–0.64), and increased health-related quality of life (standardized mean difference, 1.05; 95% CI, 0.70–1.40).³⁵

Although site marking by a certified ostomy nurse is considered ideal, other trained providers may site stomas and counsel patients preoperatively, especially in emergency situations. When surgeons and surgical trainees were evaluated after choosing ostomy sites, investigators found that the sites chosen by surgeons were a median 2 cm away from the sites chosen by ostomy nurses. In this study, most “badly sited” stomas were placed too low on the abdominal wall.³⁶ In this study, “seniority” had no impact on the results as trainees and attending surgeons had similar outcomes and colorectal surgeons sited locations more concordantly with the ostomy nurse specialists than general surgeons. A survey of surgical trainees showed that their training in ostomy-site selection was haphazard and infrequently involved an ostomy nurse specialist.³⁶

In 2015, the ASCRS and the WOCNs Society published a Joint Position Statement of the value of preoperative stoma marking for patients undergoing fecal ostomy surgery and subsequently expanded these recommendations in 2021.^{37,38} Surgeons who choose ostomy sites should be familiar with the principles of proper ostomy site selection, including evaluating patients in multiple positions to identify adequate sites, avoiding folds and scars, considering the beltline, and siting the ostomy within the rectus abdominus muscle. Although preoperative site marking is strongly recommended, it is acknowledged that intraoperative circumstances may not allow for the optimal skin site to be used in all situations. Given the cumulative evidence and, in particular, the 2 large systematic reviews published in 2020 and 2021, the grade of this recommendation was changed from 1C in 2015 to 1B.

3. Patients benefit from follow-up for ostomy teaching, care, and support. Grade of recommendation: strong recommendation based on low-quality evidence, 1C

Patients living with an ostomy may experience negative effects on their quality of life, sexual difficulties, depression, dissatisfaction with their appearance, and challenges with self-image and travel.^{4,13,15,39–44} Stoma creation can also result in feelings of embarrassment or shame; patient concern about disclosing their stoma status to others can lead to self-imposed limits and isolation.⁴⁵

One randomized trial and several observational studies support the value of postdischarge ostomy nursing care, which can be provided in the home, outpatient, or telephone setting.^{46–50} Follow-up stoma care is associated with increased ability of patients to care for themselves independently, fewer ostomy-related problems, improved ostomy adjustment, increased satisfaction with care, and improved quality of life.^{46,47,51,52}

Over time, patients with permanent ostomies may continue to have untreated ostomy-related complications and challenges.^{12,53–57} A multicenter noncomparative study of 743 long-term ostomy patients revealed that 61% of patients had objective evidence of peristomal skin problems, 28% experienced frequent leakage, and 87% used various accessories to facilitate pouching their ostomy; meanwhile, 55% had not seen a WOCN in more than 12 months. After 2 visits with a WOCN, participants experienced significant decreases in the frequency of pouch leakage ($p < 0.001$) and accessory use, improvement in skin condition, and a small improvement in the mean overall quality-of-life scores (Stoma-QOL: 56.8 versus 58.9; $p < 0.001$). The greatest change in the Stoma-QOL scores was observed in patients who were in the lowest QOL at baseline; their mean QOL scores rose from 43.8 at visit 1 to 50.1 at visit 2 ($p < 0.001$).⁵³ These data suggest that even long-term ostomy patients have difficulty with ostomy care and may benefit from expert counseling. Trained ostomy nurses provide an essential service to patients with ostomies beyond the immediate perioperative period.^{58,59}

OSTOMY CREATION

4. When feasible, laparoscopic ostomy formation is preferred to ostomy formation via laparotomy. Grade of recommendation: strong recommendation based on low-quality evidence, 1C

There are no randomized trials comparing ostomy creation utilizing a conventional open surgical approach versus minimally invasive approach (MIS). However, multiple observational studies have documented safety and favorable short-term outcomes of laparoscopic ostomy creation compared with open ostomy creation. Reported advantages of a laparoscopic approach include reduced pain and narcotic requirements, shorter hospitalization, earlier return of bowel function, and fewer overall complications than open surgery.^{60–62} A propensity-matched cohort of 358 patients who underwent elective open or laparoscopic colostomy formation reported decreased length of stay (5 versus 7 d; $p < 0.05$) and wound complications (13% versus 27%; $p < 0.05$) in the laparoscopic cohort.⁶¹ A case-matched analysis of 196 patients (63 laparoscopic and 133 open) indicated that open surgery was associated with increased estimated blood loss ($p = 0.01$), longer hospital stay ($p < 0.001$), and higher postoperative ileus ($p = 0.03$) and readmission rates

($p = 0.002$).⁶² Conversion to open surgery during stoma creation is uncommon, ranging from 0% to 16%, with more recent series reporting rates in the single digits.^{60,63}

Although data are limited, laparoscopically created ostomies may also be easier to reverse. In a retrospective study, patients who underwent loop ileostomy closure were evaluated based on whether the index procedure had been laparoscopic ($n = 145$) or open ($n = 206$).⁶⁴ Patients in the laparoscopic group had a significantly shorter mean operative time (60.9 versus 82.6 min; $p < 0.001$), shorter hospital stay (4.9 versus 5.8 d; $p = 0.04$), and a lower overall complication rate (14.5% versus 24%; $p = 0.02$).

5. When indicated, a loop ileostomy or loop colostomy is effective for fecal diversion. Grade of recommendation: strong recommendation based on moderate-quality evidence, 1B

Although proximal diversion of the fecal stream can be accomplished with an ileostomy or colostomy, loop stomas are often preferred for temporary fecal diversion because of their relative ease of closure. The choice of loop ileostomy (LI) versus loop colostomy (usually transverse loop colostomy [LC]) has been evaluated in 5 randomized controlled trials (RCTs) and several observational studies in an effort to determine whether 1 approach is superior.⁶⁵⁻⁷¹ Several meta-analyses have also been performed but report conflicting results in large part because of the heterogeneity among studies.⁷²⁻⁷⁸ Both LI and transverse LC effectively divert the fecal stream⁷⁹ and minimize the consequences of anastomotic dehiscence.⁷²

The main difference in an LI versus LC is the rate of complications at the time of creation and subsequent closure. A meta-analysis that evaluated temporary diverting LI ($n = 821$) and LC ($n = 630$) found that an LI was associated with significantly lower incidence of stoma prolapse or retraction (OR, 0.26; 95% CI, 0.11-0.60) and rate of PSH (OR, 0.52; 95% CI, 0.30-0.88) but was associated with a significantly higher incidence of dehydration (OR, 2.67; 95% CI, 1.18-6.06) compared with an LC.⁷⁷ The incidence of stomal dermatitis, parastomal infection, stoma bleeding, and morbidity related to stoma reversal was the same in the 2 groups. Postoperative ileus was significantly more common following LI closure (OR, 2.23; 95% CI, 1.12-4.43), whereas LC reversal was significantly more likely to have a surgical site infection (SSI; OR, 0.24; 95% CI, 0.11-0.49) or incisional hernia (OR, 0.39; 95% CI, 0.19-0.83).

Loop ileostomy patients may have a better quality of life relative to colostomy patients because of decreased odor, less need to adjust clothing secondary to prolapse, and greater ease of ostomy care.^{65,67,80,81} However, 1 small randomized trial did not show a difference in “social restriction” between the patients randomly assigned to a diverting colostomy ($n = 39$) versus ileostomy ($n = 37$).⁸²

This recommendation was changed from the 2015 CPG in which a loop ileostomy was preferred to a loop colostomy.

Given the aggregate of the literature, both an LI and an LC are effective means of diversion, and each approach has an associated risk-benefit profile; therefore, a recommendation strongly in favor of 1 operation over another cannot be made.

6. When possible, both ileostomies and colostomies should be fashioned to protrude above the skin surface. Grade of recommendation: strong recommendation based on low-quality evidence, 1C

Surgical technique influences the incidence of stoma-related morbidity, and stoma height, in particular, has been reported as a modifiable risk factor for complications.^{9,10,83,84} In a report of 192 stoma patients, 52 (27.1%) were identified with problematic stoma; significant risk factors for having a problematic stoma were having a colostomy, a short stoma height, a higher BMI, emergency surgery, and lack of preoperative site marking. In this study, patients with problematic stomas were associated with having a significantly longer hospital stay and requiring increased outpatient care.¹⁰ Another retrospective study of 279 patients who underwent loop ileostomy formation found that surgical technique affected the incidence of parastomal dermatitis, mucocutaneous separation, stoma retraction, and stoma prolapse.⁸⁵ In this study, it was the height of the efferent stoma limb that was associated with stomal dermatitis and not the height of the proximal limb, whereas most other studies have demonstrated a near-linear inverse relationship between stoma protrusion height and the likelihood of having a problematic ostomy.^{9,57}

In general, ileostomies should protrude at least 2 cm over the skin surface, whereas colostomies should protrude at least 1 cm.⁸⁶ However, it is acknowledged that this degree of protrusion is not possible in all clinical circumstances. In patients with a thicker abdominal wall, a foreshortened mesentery, obesity, Crohn's disease, or neuroendocrine or desmoid tumors, it may be difficult to mature an ostomy with an ideal stoma height. Nevertheless, surgeons should avoid creating ostomies flush with the skin when technically possible. Techniques that may be used to gain length for an ostomy include selective mesenteric vessel ligation, “end-loop” ostomies, and choosing an upper abdominal site in obese patients.

7. In nonobese patients, the routine use of a support rod at the time of loop ileostomy construction is not necessary. Grade of recommendation: strong recommendation based on high-quality evidence, 1A

In 2006, a small RCT compared ileostomies fashioned with a rigid bridge versus no bridge and demonstrated no significant difference in stoma retraction rates.⁸⁷ Since then, there have been 3 additional RCTs and 2 cohort studies evaluating the use of support rods for both loop ileostomies⁸⁸⁻⁹⁰ and colostomies.^{91,92} A meta-analysis of these studies included 1131 patients with a loop stoma (569 patients had

a support rod) and found no difference in stoma retraction rates (OR, 0.65; 95% CI, 0.32–1.32); however, patients with a support rod had significantly higher rates of stoma necrosis, peristomal dermatitis, and mucocutaneous separation. Importantly, no studies have specifically evaluated the utility of support rods in obese patients, and the average BMI in the aforementioned studies ranged from 19.5 to 26.2 kg/m². If a support rod is used, small observational studies have shown that flexible versions, such as a red rubber catheter, may permit easier fitting and changing of stoma appliances.^{93–95} Considering the evidence currently available, this recommendation has been revised since the 2015 CPG, which focused on the physical properties of a support rod.

8. The routine use of prophylactic mesh to prevent parastomal hernia at the time of ostomy creation is not recommended. Grade of recommendation: weak recommendation based on high-quality evidence, 2A

The high rate of PSH has led many surgeons to place a mesh reinforcement at the time of stoma creation as a potential prophylaxis. Previous systematic reviews demonstrated a reduction in PSH rates with prophylactic mesh, and this approach was shown to be cost-effective.^{96–105} A meta-analysis published in 2017 of 7 RCTs including 432 patients found that implantation of mesh at the time of stoma creation reduced the incidence of clinically detected PSHs (10.8% versus 32.4%; $p = 0.001$) and radiologically detected PSHs (34.6% versus 55.3%; $p = 0.01$) without increasing the incidence stoma-related complications.¹⁰⁰ However, a 2019 study randomized 240 patients to a lightweight polypropylene sublay mesh versus no mesh at the time of permanent end colostomy creation and found no statistically significant difference between the 2 groups in the rates of clinically diagnosed PSH or PSH diagnosed by CT scan at 1-year follow-up.¹⁰⁶ In this study, there was no significant difference in perioperative complications between the groups. A 2020 trial randomized 200 patients to end colostomy creation with or without a synthetic lightweight monofilament mesh in the retromuscular space and found no significant difference in the rates of PSH (28% versus 31%) at 24 months.¹⁰⁷ Again, there was no difference in stoma-related complications in this study. A 2021 trial randomized 209 patients undergoing end colostomy creation to utilizing a cruciate incision (standard practice, $n = 74$), a circular fascial incision made with diathermy and targeting a diameter that was 50% of the width of the bowel ($n = 72$), or a prophylactic synthetic partially absorbable mesh in the sublay position ($n = 63$). In this study, there were no statistically significant differences between the groups regarding the PSH rate. However, increasing age and BMI were associated with a PSH.¹⁰⁸

A meta-analysis of 7 studies evaluating the use of a mesh at the time of colostomy formation to prevent PSH¹⁰⁹ found no statistically significant benefit to mesh implantation at 1-year follow-up. In a meta-analysis of 11 studies,

prophylactic mesh reduced the rate of both clinical (OR, 0.27; 95% CI, 0.12–0.61) and radiological (OR, 0.39; 95% CI, 0.24–0.65) PSHs in patients with a minimum of 12-month follow-up. However, a sensitivity analysis that included only studies with a low risk of bias showed no significant benefit of prophylactic mesh in preventing PSH.¹¹⁰

A 2015 randomized trial of 70 patients who underwent end colostomy creation with or without an intraperitoneal dual-component onlay mesh showed that mesh did not significantly reduce the risk of radiologically detected PSH, but mesh repair was associated with a significantly lower risk of clinically detected PSH (14.3% versus 32.3%; $p = 0.04$).¹¹¹ The long-term follow-up of this trial, published in 2020, included 20 of the 35 patients in the original mesh group and 15 of the 35 patients in the original control group with a median follow-up of 65 months. The rates of radiologically detected PSH (45% versus 58.3%, $p = 0.72$) and clinically detectable PSH (20% versus 33.3%, $p = 0.45$) were the same in both groups. Interestingly, only 1 of 35 patients (2.7%) in the mesh group and 6 of 35 patients (17.1%) in the control group underwent a PSH repair during the long-term follow-up period ($p = 0.03$).¹¹² Considering the evidence currently available, which included 2 additional RCTs, this recommendation has been changed from the 2015 CPG. The heterogeneous nature of the interventions, materials, and surgical methods used was considered with respect to the weak recommendation.

9. Extraperitoneal tunneling of an end colostomy may decrease the risk of parastomal hernia. Grade of recommendation: weak recommendation based on moderate-quality evidence, 2B

Extraperitoneal tunneling of an end colostomy has been proposed as a technique to decrease the risk of PSH.^{113–116} In a meta-analysis of 10 studies (2 RCTs and 8 retrospective studies) including 347 patients with an extraperitoneal colostomy and 701 patients with a conventional colostomy, Kroese et al¹¹⁷ reported that extraperitoneal tunneling was associated with significantly lower PSH rates (6.3% versus 17.8%; $p < 0.001$) and significantly lower stoma prolapse rates (1.1% versus 7.3%; $p = 0.01$). In this study, there was no difference in complication rates between the groups.¹¹⁷ Given the evidence, this recommendation was upgraded from a 2C in the 2015 CPG to a 2B.

10. Managing patients with a new ileostomy with a perioperative clinical care pathway may decrease the risk of hospital readmission. Grade of recommendation: weak recommendation based on moderate-quality evidence, 2B

Complications after ileostomy creation are common, with morbidity rates reaching as high as 30%. In patients with a new ileostomy, dehydration is the most common cause of morbidity occurring in up to 40% of patients and often resulting in hospital readmission.^{118–122} In an effort to

mitigate the risks of dehydration and readmission, various perioperative care pathways have been implemented, including a variety of interventions like educating and empowering patients, standardizing discharge criteria, tracking fluid input and output after hospital discharge, engaging visiting nurse services, monitoring postoperative serum electrolytes, administering intravenous or oral hydration, and utilizing telemedicine visits and early follow-up after hospital discharge. Managing patients with a perioperative clinical care pathway has been shown to significantly decrease rates of readmission due to dehydration.^{123–130} A retrospective review comparing 232 patients treated with an ileostomy pathway and 161 patients treated without a pathway reported significantly decreased rates of 30-day readmission (25.9% versus 35.4%; $p = 0.04$) and of readmissions due to high output and/or dehydration (3.9% versus 15.5%; $p < 0.001$) in patients treated on a clinical pathway. The key components in this pathway included preoperative education with teaching materials, inhospital patient engagement with an emphasis on patient self-management, observing patients managing their own ostomy, and tracking postdischarge intake and output with assistance from a visiting nurse. An RCT of 79 patients who were treated with or without 1 L of isotonic oral solution daily for 40 days postoperatively found that the readmission rate was significantly higher in the control group (29% versus 10%; $p = 0.001$).¹²⁶

Meanwhile, other studies have reported that ileostomy pathways do not decrease readmission rates.^{122,131,132} In an RCT of 100 patients who either received an ileostomy education and monitoring program or received routine postoperative care, intervention patients were more likely to require outpatient intravenous fluids (25% versus 6%; $p = 0.008$), and there were no differences between the 2 groups in overall hospital readmissions (20.4% versus 19.6%; $p = 1.0$), readmissions for dehydration (8.2% versus 5.9%; $p = 0.71$), and patients developing acute renal failure (10.2% versus 3.9%; $p = 0.26$). Multivariable analysis found that week-end discharges to home were significantly associated with readmission (OR, 4.5; 95% CI, 1.2–16.9).¹³³ Considering the heterogeneous outcomes with respect to care pathways, this recommendation was downgraded from strong to weak based on moderate-quality evidence from the previous CPG.

OSTOMY CLOSURE

11. Routine water-soluble contrast studies in the absence of a clinical suspicion of anastomotic dehiscence or stricture may not be necessary before closure of a protective ostomy. Grade of recommendation: Weak recommendation based on low-quality evidence, 2C

There are no randomized trials evaluating the use of water-soluble contrast enemas (WSCE) or any other preoperative evaluation of anastomotic integrity before reversal of

a protective ostomy. Although the literature supports the sensitivity and positive predictive value of WSCE in detecting anastomotic leaks, several studies have questioned the utility of WSCE in routine clinical practice.^{134–145} Dimitriou et al¹³⁴ performed a WSCE on 339 patients after low pelvic anastomosis before ostomy reversal and identified 24 patients (7.1%) with an anastomotic leak. Of these patients, only 29% had an uncomplicated postoperative course from their index procedure, indicating that, in most cases, the surgeon could have a clinical suspicion of which patients were at highest risk of poorly healed anastomosis.¹³⁴ A systematic review of 1142 contrast enemas (CE) across 11 studies found that CE had high specificity (95.4; 95% CI, 92.0–97.4), negative predictive value (98.4; 95% CI, 97.4–99.1), moderate sensitivity (79.9; 95% CI, 63.9–89.9), and positive predictive value (64.6; 95% CI, 55.5–72.9) for the detection of clinically significant anastomotic complications including leaks and strictures. The authors also demonstrated a high degree of correlation between CE and clinical examination findings (96.7%). Methods used for clinical assessment in this study included digital rectal examination, proctoscopy, flexible sigmoidoscopy, and examination under anesthesia (EUA). Across the studies, 754 pairs of examinations were compared, and clinical assessment and CE were concordant in 731 patients (96.7%). Occult radiologic leaks were seen in 5.7% of CE.¹³⁷

Another meta-analysis compared CE with endoscopic procedures and digital rectal examination in rectal cancer patients before closure of a diverting ostomy and included data from 2 prospective and 11 retrospective studies comprising 1903 patients. The analysis demonstrated equal or better results for sensitivity and specificity of both endoscopic procedures and digital rectal examination compared to contrast. No patient had an anastomotic leak that was described by a CE but not by digital rectal examination or an endoscopic procedure.¹⁴³ Similarly, in a retrospective study that compared 91 patients with low pelvic anastomoses who underwent flexible endoscopy (FE) before ileostomy closure versus 100 patients who underwent both FE and contrast evaluation (CE) before reversal, there were no significant differences in the detection of pelvic anastomotic leak (2.2% versus 1%), anastomotic stricture (1.1% versus 6%), or postoperative anastomotic complications (4.4% versus 9%) between the groups.¹⁴⁶

Similar findings published in the setting of IPAA call into question the routine use of preoperative pouchogram. A retrospective study of 52 pouch patients without immediate postoperative complications evaluated patients with a contrast study performed at a median of 14 weeks (range, 7–71 weeks) after IPAA and by an EUA on the day of the ileostomy closure. In this study, 1 asymptomatic patient (2%) had an anastomotic leak demonstrated on contrast study, which was subsequently confirmed at EUA, and 2 patients (3%) with a normal pouchogram, 1 symptomatic and 1 asymptomatic,

subsequently had an anastomotic leak demonstrated at EUA.¹⁴⁷ Another study evaluated 61 patients following IPAA before ileostomy closure¹⁴⁸ with a pouchogram and pouchoscopy. Preoperatively, both pouchogram and pouchoscopy were negative for leakage in all 61 patients, and subsequently, the ileostomies were reversed. Fourteen months after ileostomy closure, a single patient presented with a pouch vaginal fistula. The negative predictive value of the double assessment was 98.4%. Their combination did not alter the diagnostic accuracy or have any effect in further management.

12. Early closure of protective ileostomies may be performed in select low-risk patients with a colorectal anastomosis without clinical evidence of anastomotic leak. Grade of recommendation: weak recommendation based on moderate-quality evidence, 2B

A temporary ileostomy is effective in reducing the severity of anastomotic complications in a variety of clinical conditions. Long-term stomas can manifest stoma-related complications such as prolapse, hernia, dehydration, and skin-related problems. Three adequately powered RCTs have evaluated the outcomes of early versus late ileostomy closure in patients with a low rectal anastomosis. It is important to recognize that the data are new and emerging regarding early closure (EC), and this recommendation could subsequently change pending new clinical data.

In 1 study, 186 patients were randomized to EC on day 8 or late closure (LC) on day 60 if there was no radiographic sign of anastomotic leak by postoperative day 7. A total of 39% of the EC group and 41% of the LC group received preoperative radiation. There were no deaths within 90 days, and overall morbidity rates were the same in the EC and LC groups (31% versus 38%; $p = 0.254$). Overall surgical complications (15% in both groups) and need for reoperation (8% in both groups) were similar, but wound complications were more frequent after EC (19% versus 5%; $p = 0.007$), whereas small-bowel obstruction (3% versus 16%; $p = 0.002$) and medical complications (5% versus 15%; $p = 0.02$) were more common with LC. Functional outcomes at 90 days were the same in both groups. Of note, 5 patients in the EC group developed enterocutaneous fistula versus 1 patient in the LC group, but no p value was reported, and all of these were managed conservatively.¹⁴⁹

A more recent multicenter RCT evaluated EC (closure 8–13 days after index procedure, $n = 55$) versus LC (closure >12 weeks after index procedure, $n = 57$) in 112 patients with a low rectal anastomosis without clinical signs of postoperative complications and a normal CT scan or FE or both. The median time from index surgery to closure was 11 days in the EC group and 148 days in the LC group. The mean number of complications within 12 months of the index procedure was significantly lower in the EC group than that in the control group ($p < 0.001$).¹⁵⁰ A follow-up survey of these patients indicated

no clinically significant differences in health-related quality-of-life questionnaire scores between the groups at 3, 6, or 12 months.¹⁵¹ Using a sensitivity analysis and considering protocol-mandated examinations, the investigators demonstrated an overall difference in the mean cost per patient of \$3608 (US dollars) in favor of EC ($p = 0.02$). In this analysis, the predominant cost factors were reoperations, readmissions, and endoscopic examinations.¹⁵²

In the most recent randomized trial, Elsner et al¹⁵³ reported EC in patients who underwent an open low anterior resection with colorectal anastomosis. The study included 37 patients in the EC group (2 weeks) and 34 patients in the LC group (12 weeks), and all patients underwent preoperative CE studies and digital rectal examination. The study was closed early because of safety concerns, with 10 of 37 EC patients having failed stoma closure. Of note, 86% of the EC patients had a transverse coloplasty of the colonic conduit to improve their postoperative function, and the average distance of the anastomosis was 3 cm from the anal verge. All patients in the EC group who had an anastomotic dehiscence noted before ileostomy closure (4/37) were assigned to the EC group in this intention-to-treat analysis. Of the remaining 6 patients who failed EC, 3 had a leak of the colorectal anastomosis, 2 had a leak from the ileostomy closure, and 1 had a wound infection of the ostomy closure site.¹⁵³ In a meta-analysis of 6 studies comparing EC (defined as closure within 6 weeks, $n = 269$) versus LC (defined closure after 6 weeks, $n = 259$), the rates of major complications (5.2% versus 3.6%) and anastomotic leak (3.3% versus 3.5%) were similar in the 2 groups.¹⁵⁴ These results confirmed the findings of an earlier meta-analysis of 4 studies including 142 patients.¹⁵⁵

A multicenter randomized trial of early (7–12 days) versus late (8 weeks or more) ileostomy closure following proctectomy with IPAA was closed early after interim analysis because of increased complications in the EC group. The median Comprehensive Complication Index was 14.8 in the EC group versus 0 in the LC group ($p = 0.02$).¹⁵⁶

In total, the data on early protective ostomy closure are new and emerging. Early ileostomy closure appears to be contraindicated in high-risk cases such as coloanal anastomosis with transverse coloplasty or IPAA. This recommendation is subject to change as new clinical evidence becomes available.

13. Loop ileostomy closure can be performed using stapled or handsewn techniques. Grade of recommendation: strong recommendation based on high-quality evidence, 1A

Four RCTs compare stapled versus handsewn techniques for the closure of a loop ileostomy.^{157–160} In general, the results across the trials are the same with a trend toward a higher risk of postoperative bowel obstruction and longer operative time in the handsewn groups.¹⁶¹ In 1 of the RCTs, the HASTA trial, which enrolled 337 patients across 27

centers, 10.3% of the stapled patients and 16.6% of hand-sewn patients developed postoperative bowel obstruction ($p = 0.10$), and 3% of stapled patients and 1.8% of hand-sewn patients developed anastomotic leak ($p = 0.46$).¹⁵⁷ In this trial, operative time was significantly shorter in the stapled group by 15 minutes ($p < 0.001$).¹⁵⁷ Several observational studies have suggested an association between stapled stoma reversal and shorter hospital length of stay; however, the possibility of selection bias in these studies must be considered.¹⁶²⁻¹⁶⁴ A meta-analysis of 4917 patients across 15 studies (3406 handsewn and 1511 stapled stoma reversals) reported similar anastomotic leak rates in 2 groups of patients (2.9% versus 2.0%) and a higher rate of small-bowel obstruction in the handsewn group compared to the stapled group (7% versus 5.5%; $p = 0.01$).¹⁶⁵ The addition of the large meta-analysis led to an upgrade to a 1A recommendation. In patients undergoing ileostomy closure after an ileoanal anastomosis, some surgeons recommend a handsewn ileostomy closure, as this avoids the wider lumen and staple line caused by a stapled anastomosis in case a redo ileoanal anastomosis is ever required.

14. Ostomy-site skin approximation should be performed when feasible, and purse-string skin closure has advantages compared with other techniques. Grade of recommendation: strong recommendation based on high-quality evidence, 1A

Traditionally, ostomy closure wounds were left open and allowed to heal by secondary intention because of the risk of SSI, which has been reported to be as high as 41%.¹⁶⁶⁻¹⁷⁰ Nonetheless, many surgeons close the skin, either partially or completely, to avoid the need for prolonged wound care. Closure techniques include primary closure, delayed primary closure, secondary closure, negative pressure wound therapy, closure incorporating a drain, and purse-string closure.

In a meta-analysis of 20 studies (6 RCT and 14 observational), including 1812 patients (826 purse-string closure versus 986 primary closure) undergoing ostomy reversal, rates of SSI were significantly lower in patients with a purse-string closure (3.1%) versus primary closure (20.2%; OR, 0.14; 95% CI, 0.09–0.21). Length of hospital stay, hernia rates, and operative times were similar between the 2 groups.¹⁷⁰ Subgroup analysis, including only the 6 RCTs, confirmed these results. In another systematic review of 319 patients from 4 RCTs that compared purse-string closure versus primary closure,¹⁷¹ there were no significant differences in the rates of incisional hernia, length of hospital stay, or operative times between the study groups. However, patients with a purse-string closure had higher satisfaction with their cosmetic outcomes (standard mean difference, 0.7; 95% CI, 0.13–1.27) and a significantly lower rate of SSI (risk difference, -0.25 ; 95% CI, -0.36 to -0.15).¹⁷²⁻¹⁷⁵ Given the aggregate of the literature, this recommendation was upgraded from a 1B recommendation in the 2015 CPG to a 1A recommendation.

15. Minimally invasive Hartmann reversal is a safe alternative to open reversal. Grade of recommendation: strong recommendation based on moderate-quality evidence, 1B

Although Hartmann reversal with a colorectal anastomosis¹⁷⁶ carries a high-risk profile, a variety of minimally invasive options have been described for this procedure, including robot-assisted closure and single and multiport laparoscopies.¹⁷⁷⁻¹⁸⁰ Although no randomized trials have compared open Hartmann reversal (OHR) versus laparoscopic Hartmann reversal (LHR), observational studies have documented the safety of a laparoscopic technique in this setting.^{181,182} An National Surgical Quality Improvement Program study evaluating patients who underwent either OHR or LHR between 2005 and 2014 demonstrated a 2.8% annual increase in the use of the laparoscopic approach with a concomitant decrease in open surgery from 100% to 74.2%.¹⁸³ In this study, laparoscopic colostomy reversal patients had fewer complications than those who had open surgery (OR, 0.56; 95% CI, 0.50–0.63; $p < 0.001$) and shorter length of stay (mean change, -1.77 d; $p < 0.001$). A meta-analysis of 13,740 patients from 26 studies compared the MIS ($n = 3170$) with OHR (10,570 patients).¹⁸⁴ Although the overall conversion rate was 17%, postoperative morbidity was significantly lower in the LHR (18.5% versus 29.3%; OR, 0.43; $p < 0.001$). In addition, patients undergoing LHR had fewer anastomotic leaks (2.6% versus 4.6%; OR, 0.58; $p < 0.001$) and significantly shorter postoperative hospitalization (-3.72 mean days; $p < 0.001$). These results have been replicated in other reviews, which demonstrate that LHR has less short-term complications than OHR in terms of overall morbidity, wound infection, postoperative ileus, and length of hospital stay.¹⁸⁵ Although these data support the safety and utility of the laparoscopic approach in centers with surgeons experienced in this technique, it is important to note the potential for selection bias in these observational studies. Given the additional evidence available since the 2015 CPG (the large meta-analysis and the National Surgical Quality Improvement Program study), this recommendation was upgraded from a 1C to a 1B recommendation.

PARASTOMAL HERNIA

16. Parastomal hernia repair should typically utilize mesh reinforcement. Grade of recommendation: strong recommendation based on low-quality evidence, 1C

Although there has been a significant increase in the annual number of PSH repairs performed in the United States, from 4150 in 1998 to 7623 in 2011,¹⁸⁶ there are no RCTs comparing methods of PSH repair. The routine use of mesh in the setting of PSH repair is based on the multiple retrospective observational studies that demonstrate high rates of hernia recurrence (46%–78%) with primary suture repair.¹⁸⁷ A systematic review of 30 observational

studies concluded that primary suture repair of a PSH was associated with a 69.4% risk of recurrent hernia.¹⁸⁷

In a study by the American Hernias Society Quality Collaborative, 94% of PSH repairs used mesh, and the most common mesh used was a permanent synthetic mesh. Overall, only 21% of the repairs were performed using an MIS approach.¹⁸⁸ Another retrospective study of 235 PSH repairs across 9 Finnish hospitals reported that mesh was used in 90% of cases.¹⁸⁹ The safety of a permanent synthetic mesh was evaluated in a meta-analysis of 469 patients who underwent elective mesh repair of their PSH. In this study, the overall postoperative morbidity rate was 24.9%, and the most common complication was SSI, which was seen in 3.8% of patients (95% CI, 2.3–5.7). Mesh infection was observed in 1.7% of patients (95% CI, 0.7–3.1), and obstruction requiring reoperation occurred in 1.7% of patients as well (95% CI, 0.7–3.0).¹⁹⁰

Biologic mesh has been evaluated in the setting of PSH repair, but no study has compared synthetic and biologic mesh in a randomized fashion. In a systematic review of 4 retrospective studies with a combined 57 PSH repair patients that utilized biologic mesh, 15.7% of patients developed recurrent hernias, and 26.2% developed wound-related complications.¹⁹¹ A retrospective study evaluating 58 patients who underwent PSH repair with biologic mesh demonstrated a comparable recurrence rate of 18% at a median of 3.8 years of follow-up.¹⁹² In general, biologic mesh should not be considered a superior alternative to synthetic mesh for elective PSH repair.¹⁹³

There is no consensus as to when a stoma should be relocated, and there is no literature to guide this decision. Relocation typically occurs as a joint decision between the patient and the physician when it becomes clear that keeping the ostomy at its current location is problematic. For example, in setting a large hernia sac, the overlying skin may not be healthy enough or may have stretched to the point that adherence of the ostomy appliance may be problematic; thus, stoma relocation may be necessary. A patient's body habitus may have changed over time with weight gain or loss, making relocation the preferred option. Whatever the reason, relocating a stoma is associated with the same high risk of hernia formation, and patients need to be counseled regarding the expected outcomes.^{194–196}

17. Minimally invasive parastomal hernia repair may be performed in selected patients. Grade of recommendation: strong recommendation based on low-quality evidence, 1C

There are no RCTs comparing the MIS approach to open PSH repair. However, a number of observational studies have established the feasibility of laparoscopic mesh PSH repair procedures and reported similar recurrence rates between the 2 approaches.^{190,197–201} The choice of techniques is influenced by a number of factors. Open surgery is favored in patients with a larger hernia defect and in

patients whose ostomies are taken down, rematured, or resited. A surgeon's experience and increasing case volume favor an MIS approach.¹⁸⁸ The use of MIS techniques appears to be increasing over time, with 1 retrospective multicenter study showing a 75% utilization rate in elective PSH repairs.¹⁸⁹ In a retrospective study of 62 patients that compared open (n = 31) with laparoscopic (n = 31) approaches, hernia repairs with mesh, operative times ($p < 0.001$), and median length of stay were shorter after laparoscopy (3 versus 7 days; $p < 0.001$). In this study, overall wound complications, other complications, and need for reoperation or readmission were similar between the 2 groups. However, long-term follow-up of patients in the laparoscopic cohort showed a significantly longer time to hernia recurrence.²⁰²

The most common MIS techniques for PSH repair are the modified Sugarbaker technique and the keyhole technique, which can be done with either 1 or 2 pieces of mesh (sandwich technique). In Sugarbaker-type repairs, an intact sheet of mesh is placed as an underlay, with the stoma limb exiting from under the mesh lateral to the abdominal wall defect. The keyhole or slit mesh technique uses 1 or 2 pieces (sandwich—a piece of mesh above and below the fascia) of mesh with an aperture cut for the stoma limb to pass through because it enters the abdominal wall. In 1 prospective randomized study, the recurrence rate after the laparoscopic keyhole was 35.9%, Sugarbaker was 21.5%, and sandwich technique was 13.5%.¹⁸⁹ Issues related to recurrence have been demonstrated in several retrospective studies that show significantly higher rates of hernia recurrence after a keyhole technique (58%–72.7%) compared with a Sugarbaker technique (0%–15.4%).^{203,204} However, the average duration of follow-up for patients in the slit mesh group was greater than twice that of the Sugarbaker group.²⁰³ A meta-analysis examining pooled data from 15 studies with a total of 469 patients demonstrated a PSH recurrence rate of 10.2% (95% CI, 3.9–19.0) after a laparoscopic Sugarbaker approach compared with a 27.9% recurrence (95% CI, 12.3–46.9) for the keyhole approach.¹⁹⁰ In a more recent retrospective study evaluating the long-term results of a keyhole technique (74 patients, using a 2-layer mesh of polypropylene and polytetrafluoroethylene with a self-cut slit) or the Sugarbaker technique (61 patients, using a coated polypropylene mesh) demonstrated 5 recurrences in the keyhole group (7%) and 6 recurrences (10%) in the Sugarbaker group. Late mesh-related morbidity occurred in 6 patients after keyhole (8%) and in 6 patients after Sugarbaker repair (10%).²⁰⁵

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