Loop Ileostomy Reversal After Colon and Rectal Surgery

A Single Institutional 5-Year Experience in 944 Patients

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Background: Diverting loop ileostomy is used to mitigate the sequelae of anastomotic dehiscence.

Objective: To report the rate of complications after ileostomy reversal using standardized definitions to aid physicians who are deciding whether to divert anastomoses.

Methods: Patients who underwent diverting loop ileostomy closure from January 1, 2005, through February 28, 2010, were identified using a prospective database. Perioperative variables and 30-day outcomes were reviewed. Complications were graded according to the Clavien-Dindo Classification, in which grade III, IV, or V represents major complications. Univariate analysis assessed the relationship between operative variables and surgical outcomes.

Results: A total of 944 patients underwent reversal: 43.1% were women, the mean age was 47.2 years, the mean body mass index (calculated as weight in kilograms divided by height in meters squared) was 25.7, and 18.5% were American Society of Anesthesiologists class III or IV. Indications for the initial operation were ulcerative colitis (49.5%), rectal cancer (27.5%), diverticular disease (6.8%), and other (16.1%). Anastomotic technique for reversal was sutured fold-over in 466 patients (49.4%), stapled in 315 (33.4%), and handsewn end to end in 163 (17.3%). After reversal, the mean time to first bowel movement, tolerance of soft diet, and discharge from hospital was 2.6, 3.7, and 5.2 days, respectively. Handsewn cases had longer operative times and longer times to bowel movement, soft diet, and discharge. Overall, complications occurred in 203 patients (21.5%), including 45 patients (4.8%) who experienced a major complication; there were no deaths within 30 days.

Conclusion: Ileostomy closure is associated with a low rate of major grade III and IV complications and should be reserved for patients who have a predicted postoperative major complication rate of 5% or more without diversion.

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THE NEED FOR FECAL DIVERsion in colorectal surgery is highly variable and influenced not only by the site of the anastomosis but also by preoperative and intraoperative risk factors. For some procedures, such as ultralow anterior resection, coloanal anastomosis, or ileal pouch anal anastomosis, the risk of anastomotic leak is high enough

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(13% for ileal pouch anal anastomosis and 11% for coloanal anastomosis)[1,2] to warrant routine fecal diversion, whereas for others (eg, right, left, and sigmoid resections), the risk is sufficiently low (1%-7%) that fecal diversion is rarely indicated.[3-10] There are other procedures, such as anterior resection, in which surgeons must individualize the decision regarding fecal diversion because the leak rates are highly variable (3%-23%).[11-20] In such cases, risk adjustments often are made at the time of surgery. Telem and colleagues[21] describe a model of 5 intraoperative risk factors and propose that proximal diversion should be considered for patients with 3 or more intraoperative risk factors. Taken together, the current literature provides baseline leak rates for specific procedures and provides risk adjustment models that allow surgeons to estimate the anastomotic leak rate for a given procedure in a given patient. What is missing are more precise data on rates of serious and/or major long-term complications that can occur as a result of secondary stoma reversal procedures; that is, events that would counterbalance the benefits of diversion. We know that the cre-

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ation of stomas can cause transient problems with high stoma output and dehydration as well as local stoma complications, such as prolapse and hernias.[22,23] What we do not know are the rates of major complications from stoma reversal using standardized tools to quantitate the complication severity. We, therefore, studied a large prospective database to more precisely quantitate the risk of major (grades III-V) postoperative complications following loop ileostomy reversal using the Clavien-Dindo classification system.

METHODS

This study was approved by the Mayo Clinic Institutional Review Board. A prospective colorectal divisional database was used to identify all patients from January 1, 2005, through February 28, 2010, who underwent loop ileostomy reversal. Patients who underwent concurrent abdominal procedures at the time of ileostomy reversal were excluded. Baseline characteristics included age, sex, body mass index (calculated as weight in kilograms divided by height in meters squared), American Society of Anesthesiologists status, and the primary diagnosis. Operative data included operative time (in minutes), type of incision (local site or midline), presence of parastomal hernia, and ileostomy reversal technique as follows: sutured fold-over closure of the small bowel without resection (FO), resection with stapled closure with side-to-side anastomosis (ST), and resection with handsewn end-to-end anastomosis (EE). Operative data at the time of ileostomy construction included the mode of surgery (minimally invasive surgery or open laparotomy) and use of adhesion barrier material. Minimally invasive surgery techniques included laparoscopic-assisted surgery, hand-assisted laparoscopic surgery, and robotic-assisted laparoscopic surgery.

Short-term (30-day) postoperative outcomes included days to bowel movement, days to tolerate soft diet, and postoperative length of hospital stay. Overall morbidity, reoperation, and readmission rates were identified. Overall morbidity included both surgical and medical complications, which were retrospectively graded using the Clavien-Dindo staging system.[24,25] The overall morbidity is reflective of the number of patients who had at least 1 complication; that is, patients who had at least 1 complication were counted only once, and only their highest-grade complication was counted. In the present study, major complications were defined as those of grade III or higher (ie, grade III, IV, or V—those requiring at least endoscopic, radiographic, or surgical intervention).

In addition to the standard Clavien-Dindo classification, the following surgical complications were described: ileus/partial small-bowel obstruction (defined as the inability to tolerate oral feedings after eating a regular diet and/or 5 or more days of nothing to eat or drink or radiologic evidence of dilated small bowel, not requiring reoperation), small-bowel obstruction requiring reoperation, volvulus requiring reoperation, anastomotic leak (confirmed at abdominal exploration or abdominal imaging), abdominal abscess (confirmed at abdominal exploration or abdominal imaging without any signs of anastomotic leak), and wound complications (infection/breakdown); all other causes of reoperation were reported. Medical complications were defined as the presence of at least 1 of the following complications: electrolyte abnormalities, anemia requiring blood transfusion, new-onset atrial fibrillation, cardiac heart failure, myocardial infarction, and renal failure.

For analysis and reporting, patients were stratified according to the surgical technique of ileostomy reversal (FO, ST, or EE). The primary end point was the rate of major complications (grade III, IV, or V) after ileostomy reversal. The secondary end point was an evaluation of the differences in short-term outcomes between the various ileostomy reversal techniques using univariate analysis. The software JMP 8.0 (SAS Institute Inc, Cary, North Carolina) was used for all descriptive and comparative statistical analyses.

Our practice approach is, in general, to reverse diverting ileostomy no less than 12 weeks after the primary operation. General surgery residents and colorectal surgery fellows operated under the guidance of attending physicians during all procedures.

Three main closure techniques were used. The FO technique was performed leaving the mesenteric side of the small bowel intact and closing the small bowel enterotomy in a transverse fashion, using a double-layer technique with absorbable or slowly absorbable suture material.

The ST technique, which is typically used after a limited small-bowel resection, used a linear stapler (75 or 100 mm), approximating the antimesenteric border of the ileum, followed by a reload of the stapler, according to surgeon preference. The EE technique was performed when a small-bowel resection was considered necessary, and handsewn EE was constructed in a standard double-layer fashion using absorbable or slowly absorbable suture material. These techniques were performed either by local site incision—that is, when only an elliptical or circular incision was made around the stoma to perform the closure—or by a midline incision as needed, either before or during attempted reversal via the local site.

RESULTS

During the 5-year study period, 944 patients who underwent reversal of loop ileostomy were included: 466 (49.4%) by FO technique, 315 (33.4%) by ST technique, and 163 (17.3%) by EE technique. Patient demographic characteristics are shown in **Table 1**. The mean age and body mass index were 47.2 years and 25.7, respectively. Age and body mass index were slightly lower in the FO subgroup, but the 3 subgroups had similar preoperative American Society of Anesthesiologists physical status. The most common primary diagnoses were ulcerative colitis (49.5%), rectal cancer (27.5%), and diverticular disease (6.8%); primary diagnoses were significantly different among the subgroups.

Operative variables are presented in **Table 2**. The overall mean (SD) operative time for ileostomy reversal was 98 (35) minutes, and the EE technique took longer than the others. The local site was used as the sole incision in 96.5% of the patients, and a significantly higher proportion of the FO operations were performed through the local site. Parastomal hernia was identified during ileostomy closure in 4.2% of the patients. At the time of ileostomy construction, a minimally invasive surgery technique was used in 51.9% of patients. The FO technique was performed in 54.6% of the patients who underwent minimally invasive surgery during ileostomy construction compared with 44.9% of the patients who underwent open surgery during ileostomy construction ($P = .003$).

Short-term variables are shown in **Table 3**. The mean (SD) time to first bowel movement, soft diet, and discharge from hospital was 2.6 (1.8) days, 3.7 (3.3) days, and 5.2 (4.3) days, respectively. With regard to postoperative recovery, the EE subgroup had a significantly lon-

Table 1. Baseline Characteristics[a]

Characteristic	Overall (N = 944)	FO (n = 466)	ST (n = 315)	EE (n = 163)	*P* Value
Age, mean (SD), y	47.2 (16.8)	44.7 (16.6)	49.2 (17.0)	50.5 (16.1)	<.001
Female sex	**407** (43.1)	209 (44.8)	130 (41.3)	68 (41.7)	.57
BMI, mean (SD)	25.7 (5.2)	25 (4.8)	26.3 (5.3)	26.4 (6.0)	<.001
Primary diagnosis					
Ulcerative colitis	**467** (49.5)	262 (56.2)	144 (45.7)	61 (37.4)	
Rectal cancer	**260** (27.5)	101 (21.7)	96 (30.5)	63 (38.7)	
Diverticular disease	**64** (6.8)	27 (5.8)	26 (8.3)	11 (6.7)	
Crohn disease	**40** (4.2)	19 (4.1)	15 (4.8)	6 (3.7)	.002
FAP	**29** (3.1)	16 (3.4)	6 (1.9)	7 (4.3)	
Colon cancer	**19** (2.0)	6 (1.3)	8 (2.5)	5 (3.1)	
Other[b]	**65** (6.9)	35 (7.5)	20 (6.3)	10 (6.1)	
ASA physical status					
Class 1	**56** (5.9)	32 (6.9)	19 (6.0)	5 (3.1)	
Class 2	**713** (75.5)	353 (75.8)	237 (75.2)	123 (75.5)	.51
Class 3	**174** (18.4)	80 (17.2)	59 (18.7)	35 (21.5)	
Class 4	**1** (0.1)	1 (0.2)	NA	NA	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); EE, end-to-end anastomosis; FAP, familial adenomatous polyposis; FO, fold-over closure; NA, not applicable; ST, side-to-side anastomosis.
[a]Data are given as number (percentage) unless otherwise indicated.
[b]Urogynecological disorders, rectovaginal fistula, hereditary nonpolyposis colon cancer, slow transit constipation, or Paget disease.

Table 2. Operative Data

Characteristic	Overall (N = 944)	FO (n = 466)	ST (n = 315)	EE (n = 163)	*P* Value
Operative time, mean (SD), min	98/944 (35)	91/466 (30)	96/315 (37)	122/163 (36)	<.001
Surgical approach, local site, No. (%)	**911**/944 (96.5)	461/466(98.9)	297/315 (94.3)	153/163 (93.9)	<.001
MIS at ileostomy construction, No. (%)[a]	**480**/925 (51.9)	262/462 (56.7)	142/305 (46.6)	76/158 (48.1)	.01
Presence of parastomal hernia, No. (%)	**40**/944 (4.2)	15/466 (3.2)	17/315 (5.4)	8/163 (4.9)	.30

Abbreviations: EE, end-to-end anastomosis; FO, fold-over closure; MIS, minimally invasive surgery; ST, side-to-side anastomosis.
[a]There were 925 patients who had their primary surgery (ileostomy construction) at our institution.

Table 3. Recovery Parameters and Short-term Outcomes After Ileostomy Closure[a]

Characteristic	Overall (N = 944)	FO (n = 466)	ST (n = 315)	EE (n = 163)	*P* Value
Time to bowel movement, mean (SD), days	2.6 (1.8)	2.6 (2.0)	2.2 (1.3)	3.2 (2.0)	<.001
Time to soft diet, mean (SD), days	3.7 (3.3)	3.7 (3.1)	3.4 (3.1)	4.6 (3.6)	<.001
Time to hospital discharge, mean (SD), days	5.2 (4.3)	5.1 (4.5)	4.7 (3.5)	6.2 (4.7)	<.001
Overall morbidity	**203** (21.5)	101 (21.7)	51 (16.2)	51 (31.3)	.001[b]
Reoperation rate	**37** (3.9)	16 (3.4)	11 (3.5)	10 (6.1)	.28
Readmission rate	**31** (3.3)	14 (3.0)	10 (3.2)	7 (4.3)	.72
Rate of ICU admission	**23** (2.4)	12 (2.6)	7 (2.2)	4 (2.5)	.95

Abbreviations: EE, end-to-end anastomosis; FO, fold-over closure; ICU, intensive care unit; ST, side-to-side anastomosis.
[a]Data are given as number (percentage) of patients unless otherwise indicated. No patients died.
[b]The Bonferroni correction was applied.

ger recovery in terms of days to first bowel movement, soft diet, and discharge from hospital. With regard to overall morbidity, the EE subgroup had a higher postoperative complication rate. Rates of reoperation, admission to the intensive care unit, and readmission were not significantly different among the 3 subgroups.

The most common causes for reoperation were abdominal septic conditions (18 [1.9%]) and small-bowel obstruction (10 [1.1%]). The causes of reoperation for small-bowel obstruction were adhesions (n=5), anastomotic strictures (n=2), hematoma (n=1), midjejunum ischemia (n=1), and pelvic small-bowel hernia (n=1). Other causes for reoperation included volvulus (n=4), bleeding (n=2), incisional hernia (n=1), recurrent rectovaginal fistula (n=1), and infected abdominal wound mesh (n=1).

The postoperative complications were graded according to the Clavien-Dindo classification (**Table 4**). The overall morbidity, including both surgical and medical complications, was 21.5%; major complications (grades III and IV) occurred in 45 patients (4.8%).

Table 4. Clavien-Dindo Classification of 30-Day Surgical Complications

Classification	Definition	% of Patients
Grade 1	Any deviation from the normal postoperative course without the need for pharmacologic treatment or surgical, endoscopic, and radiologic interventions. Allowed therapeutic regimens are drugs as antiemetics, antipyretics, analgetics, and diuretics, and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.	5.4
Grade 2	Requiring pharmacologic treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.	11.2
Grade 3	Requiring surgical, endoscopic, or radiologic intervention	4.2
3a	Intervention not under general anesthesia	
3b	Intervention under general anesthesia	
Grade 4	Life-threatening complication (including CNS complications) requiring IC/ICU management[a]	0.6
4a	Single organ dysfunction (including dialysis)	
4b	Multiple organ dysfunction	
Grade 5	Death as a result of complications	. . .
Overall		21.5

Abbreviations: CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.

[a] Brain hemorrhage, ischemic stroke, or subarachnoidal bleeding but excluding transient ischemic attacks.

Most of the major morbidity (grades III and IV) was due to complications requiring reoperation (grade III) (37 [3.9%]), which was not significantly different among the 3 subgroups. A comparative analysis of 30-day specific complications in the subgroups is shown in **Table 5**. The ST group had a significantly lower rate of postoperative ileus/partial small-bowel obstruction. The rates of wound complications, small-bowel obstruction requiring reoperation, volvulus, anastomotic leak, intra-abdominal abscess, and medical complications were not significantly different among the 3 subgroups in the 30-day postoperative period.

COMMENT

This large, single-institution study of outcomes after ileostomy reversal surgery demonstrated that, despite an overall complication rate of 21.5%, grades III and IV complications with ileostomy reversal surgery were observed relatively infrequently (<5%). These findings support our practice of diverting loop ileostomy construction when the perceived risk of anastomotic leak at the primary operation is estimated to be 5% or more. The risk is assessed on the basis of the anastomotic location, local conditions, and patient comorbidities. These results suggest that a minimum risk of 5% of anastomotic leak at the time of ileostomy construction should be considered a cutoff value for surgeons who are deciding whether to divert an anastomosis in an individual patient.

A systematic review[26] of 48 studies, including 6107 patients, showed a mean morbidity of 17.3% following ileostomy reversal surgery. These results led to several concerns regarding the clinical utility of fecal diversion, emphasizing the need for better selection criteria in identifying patients who might gain an advantage from a diverting ileostomy. The limitation in interpretation of results from these studies was lack of a standardized system to classify and to grade surgical complications. Indeed, the purpose of a diverting ileostomy is to mitigate the effects of an anastomotic leak (a grade III complication) and severe complications that can lead even to death (grades IV and V). We believe the evaluation of the clinical effectiveness of a diverting ileostomy should be particularly focused on its role in avoiding major, intervention-requiring, and potentially life-threatening complications. To address this issue, we used the Clavien-Dindo classification of surgical complications that has been recognized and validated as a standardized and reliable tool for assessment of postoperative complications.[24,25] Using this system, we quantified the rate of overall complications after ileostomy reversal to be less than 25% and the rate of major complications after ileostomy reversal to be less than 5%, attesting to its relative safety.

We also investigated whether surgical techniques played a role in determining outcomes, because there is disagreement about the optimal closure technique. The FO technique was performed more often in patients who were operated on with minimally invasive surgery at the time of ileostomy construction. Minimally invasive surgery is associated with fewer adhesion formations and thus did not require bowel resection and favored FO closure. In terms of the preferred technique for ileostomy reversal, our results confirm and extend the findings in the literature by directly comparing the 3 techniques (FO, ST, and EE). Although one must bear in mind differences in surgeon preference and selection, our data suggest that FO is associated with better outcomes than EE, with shorter operative time, shorter hospital stay, faster postoperative recovery, and lower overall morbidity. On the other hand, ST was associated with a lower rate of postoperative ileus compared with that of FO but no advantages in terms of length of hospital stay, overall morbidity, or operative time compared with those of FO. We recommend that when small-bowel resection at the ileostomy site is necessary, physicians choose the ST technique. The cost associated with the stapler in choosing ST over EE can be equated with the benefits, such as shorter operative duration, lower morbidity, and shorter length of stay. The better results from ST are probably due to the larger anastomosis lumen achieved with ST. However, when a resection is not necessary, FO favors faster anastomotic healing because of the intact mesenteric side of the bowel wall with its blood supply. Nevertheless, it should be emphasized again that we did not find any significant differences in terms of severe complications (anastomotic leak and small-bowel obstruction requiring reoperation) among the 3 groups.

Table 5. Thirty-Day Specific Complications After Ileostomy Closure

Variable	No. (%) Overall (N = 944)	FO (n = 466)	ST (n = 315)	EE (n = 163)	*P* Value
Ileus/PSBO	**120** (12.7)	65 (13.9)	21 (6.7)	34 (20.9)	<.001[a]
Any infectious complication	**76** (8.1)	35 (7.5)	25 (7.9)	16 (9.8)	.65
Wound complication[b]	**44** (4.7)	17 (3.6)	17 (5.4)	10 (6.1)	.32
Any medical complication	**30** (3.2)	15 (3.2)	9 (2.9)	6 (3.7)	.89
Anastomotic leak	**12** (1.3)	8 (1.7)	2 (0.6)	2 (1.2)	.38
Intra-abdominal abscess	**10** (1.1)	5 (1.1)	2 (0.6)	3 (1.8)	.47
Small-bowel obstruction requiring reoperation	**10** (1.1)	4 (0.9)	2 (0.6)	4 (2.5)	.15
Volvulus	**4** (0.4)	2 (0.4)	2 (0.6)	. . .	.43
Bleeding	**2** (0.2)	. . .	1 (0.3)	1 (0.6)	.23
Incisional hernia	**1** (0.1)	. . .	. . .	1 (0.6)	.33
Rectovaginal fistula	**1** (0.1)	. . .	1 (0.3)	. . .	.17
Infected wound mesh	**1** (0.1)	1 (0.2)	. . .	. . .	.49

Abbreviations: EE, end-to-end anastomosis; FO, fold-over closure; PSBO, partial small-bowel obstruction; ST, side-to-side anastomosis.
[a]The Bonferroni correction was applied.
[b]Infection or breakdown.

A randomized controlled trial by Hasegawa et al[27] compared outcomes after ST and EE and found that bowel obstruction is less frequent after ST (14% vs 3%), but there were no differences in terms of hospital stay, reoperation rate, or readmission rate. Previously, Hull et al[28] stated that the cost-effectiveness of ST was due to shortening the operative time by 15 minutes. Wong et al[29] reported an overall morbidity of 11.4% during 19 years' experience at a tertiary care hospital with loop ileostomy closure after ileal pouch anal anastomosis, but this cannot be generalized because of the young patient population (mean age, 37 years). However, no differences in complication rate and length of hospital stay between techniques were identified.[29] A recent meta-analysis of 7 studies[27-33] did not identify significant differences between ST and EE technique for loop ileostomy closure, although there is a clear trend in favor of ST in terms of shorter operative time and lower small-bowel obstruction rate.

The main limitation of this study lies in its retrospective nature and lack of control for selection and confounding. These limitations do not affect the primary analysis, but certainly the comparison between the various surgical techniques must be viewed in light of the selection bias. The recovery parameters were partly influenced by the "fast track" and "enhanced recovery" clinical pathways practiced by some of our surgeons.[10,34] One other issue that was not addressed in this study was the evaluation of stoma-related complications. Morbidity due to ileostomy is related not only to the reversal operation but also to the complications that can occur after the primary surgery (eg, peristomal dermatitis, prolapse, peristomal hernia, or small-bowel obstruction). Further research may clarify whether these complications significantly affect major morbidity and whether they should be considered in decision making during ileostomy construction at the time of primary surgery. Despite these limitations, this study provides unique insights into the expected outcomes after loop ileostomy reversal in a large heterogeneous, series of patients.

In conclusion, our experience with reversal loop ileostomy demonstrated a relatively low rate of major morbidity (4.8%). A diverting loop ileostomy should be considered for patients who anticipate an anastomotic complication rate of 5% or more without diversion. An FO could be preferred when a small-bowel resection is not necessary, whereas if a resection is mandatory, an ST might offer some clinical advantage.

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INVITED CRITIQUE

Diverting Ileostomies

Primum Minus Nocere (First, Do Less Harm)

Every surgeon has faced the intraoperative dilemma of whether to divert. In some cases, the decision appears obvious: an ultralow anastomosis, questionable tension, heavy pretreatment with corticosteroids or chemotherapy, or nutritional compromise.

However, most of the time it is a "judgment call" with real, but not overwhelming, risk at the anastomosis. Such judgment is often heavily influenced by a surgeon's recent experience (eg, the anastomosis that looked perfect, was tension free and well vascularized, and had no air leak on insufflation testing but leaked anyway). This type of experience might lead us to use the "safe" option of ileostomy more often.

However, the study by Luglio et al[1] demonstrates that it may not be that simple. They retrospectively reviewed a large tertiary referral center experience with ileostomy reversal and found a 21% morbidity, with 4.8% of patients experiencing major complications. The authors conclude that loop ileostomies should be reserved for patients with a predicted complication rate at the initial anastomosis of 5% or more.

However, their actual principle appears to be use of diversion in patients whose risk at the primary anastomosis exceeds the risk of the ileostomy. We would agree that this principle is sound but wonder about the application. Complication rates for ileostomy closure vary considerably among series. For example, as reviewed by Chow et al,[2] overall morbidity ranges from 3% to 38.5%, and laparotomy for bowel obstruction ranges from 0% to 15%. The 5% rule proposed here may not be appropriate for all centers or surgeons. Also, the introduction of modern systemic and regional treatments, such as combinations of oxaliplatin, bevacizumab, and radiation, may affect the risk of complications at the primary anastomosis, perhaps more than at the ileostomy.