

# Transabdominal Redo Ileal Pouch Surgery for Failed Restorative Proctocolectomy

## Lessons Learned Over 500 Patients

Feza H. Remzi, MD, FACS, FASCRS, FTSS (Hon),\* Erman Aytac, MD, FTBS,\*† Jean Ashburn, MD, FACS,\* Jinyu Gu, MD,\* Tracy L. Hull, MD, FACS, FASCRS,\* David W. Dietz, MD, FACS, FASCRS,\* Luca Stocchi, MD, FACS, FASCRS,\* James M. Church, BSc, MBChB, MedSci, FACS, FRACS,\* and Bo Shen, MD, FACG, AGAF, FASGE‡

**Objectives:** The purpose of this study was to report our large, single-center experience of transabdominal ileal pouch-anal anastomoses (IPAA) redo surgery for a failed initial IPAA.

**Background:** IPAA fail from 3% to 15% of the times, mainly due to technical or inflammatory conditions. There is limited information about the surgical, functional, and quality-of-life (QOL) outcomes of redo surgery for failed IPAA, especially in large series of patients.

**Methods:** Patients undergoing transabdominal redo surgery for failed IPAA between 1983 and 2014 were evaluated. Primary endpoints were morbidity of the surgery, the proportion of patients with a functioning pouch, frequency of defecation and incidence of incontinence, and the patients' perception of QOL.

**Results:** There were 502 (43% males) patients with a median age of 38 years and median body mass index 24 kg/m<sup>2</sup> at the time of revision surgery. A new pouch was created in 41% of patients whereas 59% had their original pouch revised and retained. Postoperative mortality was 0% and morbidity was 53%. The short-term anastomotic leak rate was 8%. At a median follow-up of 7 years after redo surgery, 101 (n = 20%) patients had redo IPAA failure. Pelvic sepsis developing after redo ileal pouch surgery was the primary indicator of pouch failure (hazard ratio, 3.691; 95% confidence interval, 2.411–5.699; *P* < 0.0001). Overall functional outcomes and QOL scores were acceptable.

**Conclusions:** Patients with a failed ileoanal pouch may be offered redo pouch surgery with a high likelihood of success in terms of function and QOL.

**Keywords:** ileal pouch, ileal pouch–anal anastomosis, redo, repeat, transabdominal

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Complete removal of the colon and rectum is indicated for surgical treatment of ulcerative colitis and profuse familial

From the \*Department of Colorectal Surgery, Digestive Disease Institute, Cleveland Clinic, Cleveland, OH; †Acibadem University School of Medicine, Istanbul, Turkey; and ‡Department of Gastroenterology and Hepatology, Digestive Disease Institute, Cleveland Clinic, Cleveland, OH.

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Reprints: Feza H. Remzi, MD, FACS, FASCRS, FTSS (Hon), Department of Colorectal Surgery, Digestive Disease Institute, 9500 Euclid Ave, Cleveland, OH 44195. E-mail: remzif@ccf.org.

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adenomatous polyposis, indeterminate colitis, and a highly select subset of patients with Crohn disease (CD). As long as the anal sphincter complex is intact, ileal pouch–anal anastomosis (IPAA) restores intestinal continuity after proctocolectomy and allows per anal defecation with acceptable functional outcomes and good quality of life (QOL).<sup>1,2</sup>

Short-term postoperative morbidity after IPAA varies between 28% and 58% and up to 15% of pouches fail due to technical or inflammatory complications.<sup>1–5</sup> Pouch failure is a disaster for a patient who is highly motivated to avoid a permanent ileostomy. Some of these patients can be offered surgical revision of their failed pouch, which is usually their only option to avoid a permanent stoma. Because revision of an IPAA is a complex and difficult procedure, few centers have accumulated substantial experience, and information about its outcomes remains scant. In particular, there are few data regarding the durability of redo IPAA and its long-term outcomes including complications, function, and QOL.<sup>3,6</sup> Such data are important when counseling patients with a failed primary IPAA. We have accumulated a large experience with revisionary surgery of the failed IPAA, and in this study, we report this experience.

### MATERIALS AND METHODS

All patients undergoing transabdominal redo surgery for failed IPAA between 1983 and 2014 were evaluated. Data were obtained from an institutional review board–approved, prospectively maintained database. The Cleveland Clinic Institutional Review Board approved this database. The following data were abstracted from the database: patient demographics, primary diagnosis, technical details of the primary IPAA, indications for redo surgery, preoperative management, operative technique of the redo IPAA surgery, intraoperative blood loss, operating time, intraoperative and short-term complications, and long-term outcomes including morbidity, mortality, IPAA function, and QOL.

Primary endpoints of the analysis of these data were perioperative morbidity, the proportion of patients with a functioning pouch, frequency of defecation and incidence of incontinence, and the patients' perception of QOL. A secondary aim was to use logistic regression to determine the factors associated with failure of the redo pouch procedure.

### Preoperative Evaluation

Patients underwent a comprehensive clinical examination before redo IPAA surgery. Although perioperative evaluation has evolved through the years, in all cases, there was an accurate and detailed history of the presenting symptoms and the prior pouch surgery. For patients referred to us, this included both operative records and pathology reports and usually the pathology slides on

which the report was based. Then according to the clinical situation and presumptive diagnosis, we obtained some or all of the following: examination under anesthesia, flexible pouchoscopy, gastrografin enema, magnetic resonance imaging, computed tomography or computed tomography–enterography, and anal physiology testing. Since 2001, preoperative testing has usually been coordinated through our pouch center.

### Operative Approach

Patients are placed in the Lloyd-Davies position and both abdomen and perineum are prepared for operation. Ureteral stents are placed in majority of patients. The previous incision is used for laparotomy or a midline incision is made for those previously operated by laparoscopic technique. The pouch is mobilized to the pelvic floor with sharp dissection. The decision on whether to resect the old pouch and create a new one or to repair/revise/reattach the old pouch is made by the operating surgeon and depends on the viability and integrity of the mobilized pouch, the reach of the proposed new pouch, and the cause of pouch failure. Although a handsewn IPAA with mucosectomy was usually performed, a stapled IPAA was done if there was a rectal stump long enough for a linear stapler to be applied below the current anastomosis.

For a handsewn anastomosis, the anus was distracted by a series of anal everting sutures and a mucosectomy performed to a level just above dentate line. The pouch was pulled through the pelvis and anastomosed with a series of interrupted 2/0 polyglycolic acid sutures. If access to the top of the anal canal was difficult, a minimum of 4 sutures were placed, 1 in each of the 4 quadrants, before the pouch was pulled through. As these were tied, the pouch was manipulated into place. The IPAA was sometimes then stented with a 22 F mushroom catheter that was sutured in place and kept until the patient's discharge from hospital or 4 to 6 weeks after the operation. All but 25 patients had fecal diversion, using either the preexisting ileostomy or a new diverting loop ileostomy. Ileostomy closure was usually scheduled 3 months after redo IPAA surgery. Preclosure contrast enema and intraoperative digital anal examination and pouchoscopy were used to confirm pouch and anastomotic integrity. If any complication was noticed, ileostomy reversal was delayed and the complication treated.

### Assessment of IPAA Function and QOL

Patients were asked to complete annual questionnaires designed to evaluate pouch function and QOL. These were usually administered at their annual clinic visit. If patients were followed up elsewhere, this information was obtained by mail or telephone contact. In this questionnaire, frequency of bowel movements, daytime/nighttime seepage, pad use, and restrictions are assessed. Anal seepage, pad usage, and restrictions were simply recorded as being present or not (0 = no, 1 = yes). QOL assessment is performed using the validated Cleveland Global Quality of Life score, which includes 3 items: current QOL, current health, and current level of energy, each measured on a scale of 0 to 10 (0, worst; 10, best). The scores are added and the final Cleveland Global Quality of Life utility score is obtained by dividing the resulting number by 30 [range (0–1); 0: worst, 1: best].<sup>7</sup>

### Definitions

Short-term follow-up time is defined as the first 30 days after redo IPAA creation and long-term follow-up as more than 30 days after IPAA creation. Overall short-term morbidity rate is calculated by dividing the number of patients who had at least 1 postoperative complication by the total number undergoing surgery. Pouch failure is defined as excision of the ileoanal pouch or permanent diversion with a proximal ileostomy.<sup>3</sup> Anastomotic leak is a break in the

integrity of the anastomosis documented by a combination of clinical, endoscopic, radiologic, and operative findings. Bowel obstruction is defined as the presence of at least 3 of the following 5 symptoms: nausea, abdominal pain, vomiting, abdominal distension, absence of flatus and/or stool within the last 24 hours, findings indicating obstruction upon plain radiographic or contrast studies, or a diagnosis of intestinal obstruction as confirmed by surgery.<sup>1</sup> Ileal pouch anal anastomotic stricture is diagnosed by digital examination in the outpatient clinic or operating room. A clinically significant anastomotic stricture is defined as one requiring treatment. Pouch-related fistula is defined as an abnormal passage or sinus from the pouch to another surface or organ. Pelvic sepsis is defined as the development of a pelvic or perianal infectious process detected by clinical, radiological, or operative means, and which occurred either within 3 months of loop ileostomy closure or within 3 months of restorative proctocolectomy, when stoma diversion is not performed.<sup>8</sup>

Patients who have pouch-related symptoms without evidence of an anatomical and clinically proven pathology are considered to have pouch dysfunction. Definition and treatment of pouchitis varied throughout the years of the study. We had initially been liberal in our use of metronidazole or ciprofloxacin, relying on symptoms to diagnose pouchitis including increased stool frequency, urgency, tenesmus, incontinence, nocturnal seepage, abdominal cramping, pelvic discomfort with high fever, dehydration, and malnutrition. Currently, we rely on symptoms and both endoscopic and histologic findings before administering medical therapy in symptomatic patients. Surgery for pouchitis is considered only in cases in which there is a total lack of response to medical therapy.<sup>2</sup>

### Statistics

Categorical variables were reported as frequency (%) and continuous variables were reported as median and range, except where otherwise noted. The significance of differences between groups with respect to categorical variables was tested using Fisher exact test or  $\chi^2$  test, and with respect to continuous variables using the Wilcoxon rank sum test for the assessment of perioperative and short-term outcomes. The impact of patients' characteristics and overall postoperative outcomes on pouch failure was assessed with log-rank tests. Cox proportional hazard regression was applied to assess the independent risk factors related to pouch failure by including the parameters that were significantly different in log-rank tests. A *P* value of 0.05 was considered statistically significant.

## RESULTS

Of the 502 patients, 215 (43%) were male and 287 (57%) were female. The number of patients accrued over the 3 decades of the study is shown in Figure 1 and reflects the growing number of patients with pouch in the country as a whole and in our own institutional practice. The median age of patients at the time of redo surgery was 38 (range: 13–82) years and their median body mass index was 24 (15–35) kg/m<sup>2</sup>. The median time to redo ileal pouch surgery after index IPAA creation was 3 (range: 0.4–29) years. The median follow-up after redo IPAA surgery was 7 (range: 0.1–31) years. The diagnoses of patients at the time of redo ileal pouch surgery, the referral patterns of patients with failed pouches, the configurations of pouches, and the types of anastomosis are all shown in Table 1. Gastroenterologists referred many of the outside patients. Among the patients who had index IPAA surgery at our institution, 269 patients had IPAA failure and we performed 108 (40%) trans-abdominal redo IPAA operations. A total of 161 patients did not undergo a redo IPAA surgery. Pouch complications causing failure in those who did not undergo a redo surgery were leak/fistula (46%), IPAA dysfunction (17%), pouchitis (14%), stricture (7%),

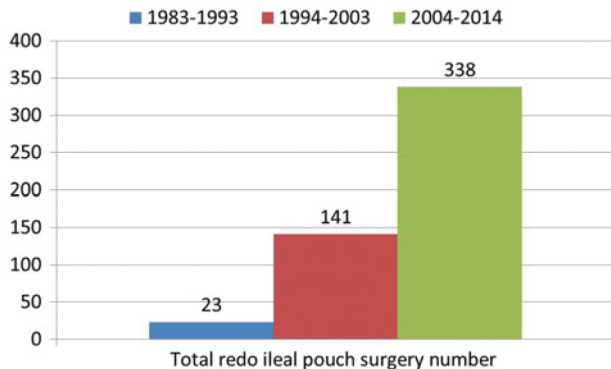


FIGURE 1. Distribution of patients in different time periods.

incontinence (5%), neoplasm (5%), and bowel obstruction (6%). Their primary diagnoses were ulcerative colitis/indeterminate colitis (54%), CD (37%), familial adenomatous polyposis (4%), and neoplasm (5%). Among the 108 attempted redo IPAA only 1 patient had to have an end ileostomy because the redo pouch would not reach the anus, and 21 patients had a continent ileostomy. Table 2 shows the causes of index failure in primary pouches. Anastomotic leak and fistula were the most common. Patients who underwent index IPAA surgery laparoscopically had more complications related to a residual length of rectum (>2 cm from the dentate line) requiring redo ileal pouch surgery than patients who underwent open index IPAA [n = 34/277 (12%) vs n = 12/35 (29%),  $P = 0.02$ ]. Rates of tumor necrosis factor  $\alpha$  inhibitors (n = 45) and steroid (n = 44) use before redo ileal pouch surgery were 9% in each group.

Table 3 shows the technical details of the redo pouch procedures. Distributions of the new pouch configurations (n = 207)

TABLE 1. Patient Characteristics Before Redo Ileal Pouch Surgery, n (%)

Primary diagnosis at the time of redo IPAA*	
Ulcerative colitis/indeterminate colitis†	419 (84)
Familial adenomatous polyposis	41 (8)
Crohn disease	32 (6)
Neoplastic	10 (2)
Referrals*	
Outside institution	394 (79)
Cleveland Clinic	108 (22)
Surgeon	220 (44)
Nonsurgeon	282 (56)
Pouch configuration*	
J-Pouch	425 (85)
S-Pouch	55 (11)
Others (straight ileoanal anastomosis, W-pouch)	22 (4)
Type of anastomosis (n = 314)	
Stapled	249 (79)
Handsewn with mucosectomy	65 (21)
Laparoscopic	35 (11)
Robotic	2 (0.3)
n = 314	
Index IPAA creation without diverting ileostomy (n = 314)	24 (8)
Prior IPAA revision attempt*	
Transanal revision	126 (25)
Transabdominal	20 (4)
Diverting ileostomy before redo ileal pouch surgery*	383 (76)

\*n = 502. Decimals are rounded.

†Twenty patients were diagnosed with Crohn disease after redo ileal pouch surgery.

TABLE 2. Operative Indications, n (%)

Leak/fistula	263 (52)
Pouch vaginal fistula*	85 (17)
Obstruction	116 (23)
Dysfunction	45 (10)
Pelvic perianal abscess	43 (9)
Pouchitis	14 (3)
Prolapse	11 (2)
Neoplastic	10 (2)

\*Patients with pouch vaginal fistula were evaluated in the leak/fistula group.

were J-pouch (n = 177), S-pouch (n = 27), W-pouch (n = 2), and H-pouch (n = 1). The primary pouch was preserved in 59 % of patients. The list of pouches in Table 3 includes both the new pouches and the old (primary) pouches. It can be seen that most patients underwent takedown of the existing IPAA and of these cases, the majority had a handsewn neo IPAA.

### Morbidity and Mortality

The median American Society of Anesthesiologists score was 2 (1–4). Median operating time was 246 minutes (range: 29–720 minutes). Median intraoperative blood loss was 300 mL (range: 20–2000 mL). Intraoperative ureteral injury occurred in 3 patients. Postoperative complications occurred in 53% (n = 270) of patients (Table 4), with pelvic sepsis the most common. There were no deaths related to surgery. Six patients experienced stoma complications including retraction (n = 3) and obstruction due to edema (n = 3). Early reoperation was required in 7 patients because of wound dehiscence (n = 2), bowel perforation (n = 2), bleeding (n = 2) and abdominopelvic abscess (n = 1). Four patients had urinary retention. Median length of stay after surgery was 7 days (range: 3–57 days) and readmission rate was 13% (n = 63).

None of the following factors were related to the 30-day complication rate: age, sex, body mass index, American Society of Anesthesiologists score, blood loss, operating time, CD, presence of a pouch vaginal fistula, creation of a new pouch, and sepsis as a cause of primary pouch failure. Postoperative complications were associated with an increased length of stay (Table 5).

### Long-term Pouch Survival

Pelvic sepsis (n = 66), anastomotic stricture (n = 51), bowel obstruction (n = 33), persistent wound infection (n = 20), anal

TABLE 3. Redo Ileal Pouch Surgery, n (%)

Pouch configuration	
J-Pouch	438 (87)
S-Pouch	61 (12)
W-Pouch	2 (0.3)
H-Pouch	1 (0.1)
Type of anastomosis	
Handsewn with mucosectomy	411 (82)
Stapled	22 (4)
Pouch revision with no ileoanal anastomotic intervention	69 (14)
Redo ileal pouch surgery without diverting ileostomy	25 (5)
New ileal pouch creation	207 (41)
Redo surgery on the de novo pouch*	295 (59)
Pouch repair/repair	160 (32)
Partial ileal pouch resection	80 (16)
Pouch augmentation	38 (8)
Pouch mobilization	17 (3)

\*Patients might have undergone more than 1 revision at the same time number and percentage represents key premier surgery.

**TABLE 4.** Short-term Complications After Redo Ileal Pouch Surgery, n (%)

Complications	
Pelvic sepsis	50 (10)
Ileus/bowel obstruction	81 (16)
Anastomotic leak	38 (8)
Wound infection	41 (8)
Urinary	25 (5)
Cardiopulmonary	21 (4)
Hemorrhage	13 (3)
Anastomotic stricture	13 (3)
Fistula	13 (3)
Venous thromboembolism	12 (2)
Pouchitis	8 (2)
Stoma complications	6 (1)
Bowel perforation	2 (0.4)
Wound dehiscence	2 (0.4)

incontinence (n = 14), pouchitis (n = 4), pouch prolapse (n = 5), and abdominal wall hernia (n = 5) were the ileal pouch-related surgical complications.

A total of 101 (20%) patients had redo IPAA failure. A transabdominal re-redo IPAA was performed in 16 patients after redo IPAA surgery and the pouch was salvaged in 13 patients. A total of 414 (83%) patients had a functional IPAA at most recent follow-up. Based on Kaplan-Meier estimations, 5-year pouch survival and 10-year pouch survival after redo surgery were 90% and 82%, respectively (Table 6).

In log-rank test, comparison of patient characteristics, operative and postoperative outcomes based on ileal pouch failure after redo surgery, CD, pouch vaginal fistula (as an operative indication for redo ileal pouch surgery), pelvic sepsis, and having a 30-day postoperative complication were associated with pouch failure (Table 7). Most recent diagnoses were considered for evaluating redo IPAA survival.

A multivariate Cox proportional hazard regression model revealed that having a postoperative complication in short term and pelvic sepsis (Table 8) were the independent risk factors for pouch failure after redo ileal pouch surgery.

**QOL and Functional Outcomes**

QOL and functional outcome results were analyzed in 261 (52%) patients (Table 9). Functional assessment was determined according to the number of patients who answered the questionnaires. Rates of daytime and nighttime stool frequencies were 6 (1–15) and 2 (0–9), respectively, and approximately 50% of patients had seepage and used pads by day and night. About one-third of patients had dietary restrictions, 18% of patients had social restrictions, 18% of patients had work, and 22% of patients had sexual restrictions. More than 90% of patients recommended surgery to others and declared that they would undergo surgery again if needed.

**DISCUSSION**

Restorative proctocolectomy is one of the most important advances in colorectal surgical technique of the last 50 years. It has allowed thousands of patients to avoid a permanent ileostomy and to live relatively normal lives free of the chronic medications and cancer risk of colitis and polyposis. Poor outcomes may lead to pouch failure, where the ileal pouch cannot be used because it does not work or because it is diseased. In this study, we have shown that failed pouches can be salvaged or reconstructed, and although the surgery is demanding and complicated, the ultimate long-term pouch function and QOL of the patients are good.

Since its initial description in 1978, restorative proctocolectomy with IPAA has had good results.<sup>1,9</sup> Initially, the procedure was limited to specialist centers and the early experience of those centers encouraged its more widespread use. The Cleveland Clinic began performing restorative proctocolectomy in 1983 on the background of a solid reputation in the surgery of inflammatory bowel disease. Since then, approximately 150 restorative proctocolectomies have been done annually, and the Clinic has become a referral center for the failed pouch. This experience has been augmented by the pouch center, which opened in 2001, where a gastroenterologist (B.S.) who specializes in the treatment of diseased or dysfunctional pouches joined the team. Cleveland Clinic experience with redo pouch surgery has already been published in 3 different studies but we report it again because since 2009, we have doubled our experience.<sup>3,10,11</sup>

The causes of pouch failure in patients presenting for redo are instructive in themselves. Three-quarters of pouches failed because of sepsis or obstruction, events that are potentially preventable.

**TABLE 5.** Assessment of the Relation Between Patients' Characteristics and Operative Outcomes With Short-term Postoperative Morbidity

	Postoperative Morbidity (–), n = 232	Postoperative Morbidity (+), n = 270	P
Age, yr	37 (13–76)	39 (16–82)	0.699
Body mass index, kg/m <sup>2</sup>	24 (15–35)	24 (15–35)	0.747
ASA score	2 (1–4)	2 (1–4)	0.950
Sex (male), n (%)	93 (40)	122 (45)	0.250
Diagnosis, n (%)	21 (9)	31 (12)	0.373
Crohn disease			
Septic indications, n (%)	136 (59)	170 (63)	0.320
Laparoscopic creation of the index ileal pouch, n (%)	19 (13)	18 (11)	0.556
Prior revision attempt, n (%)	63 (27)	83 (31)	0.378
Diverting ileostomy before redo ileal pouch surgery, (%)	175 (75)	208 (77)	0.673
New ileal pouch creation during redo surgery, n (%)	90 (39)	117 (43)	0.303
Pouch revision with no ileoanal anastomotic intervention, n (%)	35 (15)	34 (13)	0.419
Redo ileal pouch surgery without diverting ileostomy, n (%)	12 (5)	13 (5)	0.854
Operating time, min	244 (57–720)	249 (29–720)	0.800
Estimated blood loss during surgery, mL	315 (20–1800)	300 (100–2000)	0.997
Postoperative length of hospital stay, d	6 (3–43)	7 (4–61)	<0.001

ASA indicates American Society of Anesthesiologists.

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**TABLE 6.** Kaplan-Meier Estimates of Pouch Survival After Redo Surgery

Year	%	CI (95% Lower, 95% Upper)
1	98.3	97.3–99.3
5	90.2	87.6–92.4
10	82.4	78.8–85.6

CI indicates confidence interval.

Twists in the pouch mesentery can happen easily, especially during laparoscopic pouches, and laparoscopically performed pouches tend to have longer rectal stumps than those performed open. A long rectal stump predisposes to kinking and obstruction and can be avoided by checking the position of the stapler by digital rectal examination before the stapler is fired. The likelihood of a mesenteric twist can be minimized by making sure that the cut edge of the small bowel mesentery is straight and passes up and to the right toward the stump of the ileocolic artery. In addition, the staple line constituting the pouch should be straight and anterior, right down to the anastomosis. Anastomotic leaks and fistulas can be minimized by sound technique. Anastomoses are checked by air insufflation and the integrity of the donuts, and routine loop ileostomy is worthwhile. This minimizes the effects of a leak and may save the pouch. If sepsis happens after an ileoanal pouch, early and adequate treatment may prevent chronic sepsis and pouch failure. The decision to perform ileoanal pouches in patients with CD is a crucial one as this is a factor in failure of the redo pouch. However, our data, where CD is not an independent factor predicting pouch failure, may reflect the better options now available for medical treatment available for this disease and more accurate selection of patients with CD who will do well. Some of the cases whose index pouches failed because of severe pouchitis may have had CD or ischemia, but this was a very small group (n = 14, 3%). These patients all did well and none has developed recurrent severe pouchitis after a follow-up of 5 years. The group of patients with pouch failure from neoplasia was even smaller (n = 10, 2%) and made up of anal transition zone (n = 6) and pouch neoplasia (n = 4). Five of the 10 patients had familial adenomatous polyposis. The size of this group may increase as pouches and their anastomoses mature.

**TABLE 7.** Evaluation of Patients' Characteristic and Operative and Postoperative Outcomes Based on Ileal Pouch Failure After Redo Surgery

	Intact Redo IPAA (–) (n = 401)	Failed Redo (+) (n = 101)	P*
CD vs non-CD, n (%)	35 (9)	17 (17)	<b>0.054</b>
Septic indications, n (%)	237 (59)	69 (68)	0.091
Pouch vaginal fistula, n (%)	60 (15)	25 (25)	<b>0.048</b>
Laparoscopic creation of the index ileal pouch, (%)	33 (13)	4 (6)	0.404
Index IPAA at CCF	82 (21)	26 (26)	0.745
Prior revision attempt, n (%)	113 (28)	33 (33)	0.861
Diverting ileostomy before redo ileal pouch surgery, n (%)	310 (77)	73 (72)	0.227
New ileal pouch creation during redo surgery, n (%)	160 (40)	47 (47)	0.425
Pouch revision with no ileoanal anastomotic intervention, n (%)	57 (14)	12 (12)	0.589
Redo ileal pouch surgery without diverting ileostomy, n (%)	23 (6)	2 (2)	0.087
Short-term postoperative morbidity, n (%)	197 (49)	73 (72)	<b>&lt;0.001</b>
Pelvic sepsis, n (%)†	57 (14)	54 (54)	<b>&lt;0.001</b>
Small bowel obstruction/ileus, n (%)†	65 (16)	16 (16)	0.404
Anal stricture, n (%)†	51 (13)	11 (11)	0.295
Fecal incontinence, n (%)†	7 (2)	7 (7)	0.537

\*Log-rank P value.

†Based on overall number of events after redo ileal pouch surgery.

CCF indicates Cleveland Clinic Foundation. CD indicates Crohn's disease.

**TABLE 8.** Cox Proportional Hazard Regression Model Evaluating Possible Factors Associated With Ileal Pouch Failure After Redo Ileal Pouch Surgery

	Hazard Ratio (95% CI)	P
Pouch vaginal fistula (yes vs no)	1.642 (0.954–2.716)	0.072
Final diagnosis (Crohn disease vs others)	1.413 (0.836–2.518)	0.203
Pelvic sepsis (yes vs no)	3.691 (2.411–5.699)	<0.0001
Short-term postoperative morbidity (yes vs no)	1.7 00 (1.038–2.896)	0.035

Others have reported on redo pelvic pouch surgery, and a recent systematic review and meta-analysis by Theodoropoulos et al<sup>6</sup> summarized results from 31 studies chosen from the 127 that were potentially relevant. The largest number of patients undergoing abdominal pouch salvage came from our institution and totaled 241 patients.<sup>3</sup> The fact that only 3 prior studies (including our previous report) reported more than 100 patients and altogether there were only 170 redo operations (new pouch) and 675 revisional (old pouch revised) procedures puts our current study with 502 patients into perspective.<sup>3,12,13</sup> Average length of follow-up in the meta-analysis was also relatively limited at 39 months, with the longest mean follow-up of 65 months. The average morbidity reported by 7 of the studies was 41.4%, ranging from 19.5% to 65%. Reoperations were required in 27.1% of patients overall (range: 10%–72.7%) and the redo pouch failed an average of 19% of the time (range: 7.1%–30%).<sup>6</sup>

Our morbidity rate is in line with the literature, although with such a large proportion of outside referrals our patients have a high level of acuity. Our reoperation rate is considerably less than that in the meta-analysis and our pouch survival is good, considering the relatively high proportion of patients with CD and the length of our follow-up. Pouch failure rates increase with length of follow-up and so outcomes analysis is dynamic. Our results also suggest that select patients with a failed redo pouch can be candidates for a further redo, with a good expectation of success.

Theodoropoulos et al<sup>6</sup> analyzed functional results after revisional or redo pouch surgery and the results are similar to ours, with acceptable function and good QOL. It is surprising, however, what

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**TABLE 9.** Quality of Life and Redo Pouch Functions

	n = 261
CQOL	0.7 (0–1)
Bowel movements (n)	
Daytime	6 (1–15)
Nighttime	2 (0–9)
Seepage	
Daytime	48%
Nighttime	54%
Pad usage	
Daytime	49%
Nighttime	57%
Restrictions	
Dietary	34%
Social	18%
Work	18%
Sexual	22%
Would undergo surgery again	92%
Recommend surgery to others	93%

CGQL indicates Cleveland Global Quality of Life.

patients with an IPAA find acceptable. There are high rates of incontinence and seepage, and high rates of pad use, that mean irritated painful perianal skin and constant attention to anal cleanliness. Despite this, patients report an almost universal willingness to have the surgery again if it were necessary and to recommend the surgery to others. This is likely to reflect more their dread of a permanent ileostomy than their happiness with their continence and bowel habit. The meta-analysis results are heavily weighted by studies from the leading pouch centers around the world. This reinforces the notion that revisional surgery in patients with a failed ileoanal pouch is highly specialized and that the results are critically dependent on experience and technical proficiency.<sup>3,6,13–15</sup>

One of the most important decisions faced during pouch revision is whether to excise the old pouch and make a new one. This depends on the viability of the existing pouch after complete mobilization, and the ability of the new pouch to reach the anus without excess tension. An S pouch will reach further into the pelvis than a J, although our data show that a redo J is usually possible. A new pouch need not be made purely for functional reasons, however, as Fonkalsrud and Bustorff-Silva<sup>12</sup> found that the long-term functional results were similar, irrelevant of whether old pouches were reused or excised. MacLean et al showed a slight advantage for a new pouch in less complications (40% vs 51%), whereas Baixauli et al found that 86% (18/21) of the patients who underwent a new pouch and 81% (52/64) of those whose old pouch was reused still had a functioning pouch after a median 32.3-month follow-up.<sup>10,16</sup> Repair of the old pouch generally requires mobilization and disconnection from the anus, with a redo anastomosis. The most compelling reason for retaining the old pouch if possible is preservation of small intestine, especially the critical last 2 feet.

Our study also contributes significantly to the literature in showing the predictive factors for failure after redo pouch surgery. Pelvic sepsis produces an almost 4-fold increase in the risk of redo pouch failure, focusing us on the importance of technique in dissecting the old pouch anal anastomosis and in constructing the new. Even if a redo pouch fails, there is the opportunity for a further attempt to salvage the situation. The subset of patients in this study is strongly motivated to avoid a permanent ileostomy.

We are limited in our overall perspective because we have no information currently on the patients in whom an attempted redo pouch had to be abandoned, or on those who were referred for a redo

pouch but were not selected for surgery, and the reasons why. This was not the primary aim of the study as we wanted to focus on the success rate and outcomes on patients in whom a pouch redo was actually performed. However, we realize that patient selection plays a critical role in the success of a procedure and so lack of these data is an important limitation. We have tried to supply some of the missing data by reporting our experience with redo surgery on our own pouch patients. This gives some insight into the denominator of the overall study although we would expect our own redo rate to be less than the overall redo rate, because the incidence of technical issues causing the problem is likely to be lower. Technical issues such as kinks or twists are more easily repaired than sepsis or CD.

It is likely that as experience accumulated and the team approach exemplified by the pouch center concept became established, more challenging cases may have been attempted. However, this is to some extent balanced by the thorough workup and the range of medical options offered by the Pouch Center. In addition, there is always pressure from patients to try and improve their QOL while preserving per anal defecation. A second limitation of our study is the relatively low number of patients (261) who completed the functional and QOL questionnaire in full. We intentionally excluded incomplete questionnaires to have a consistent denominator to analyze patient complaints and IPAA functional outcome. Forty-seven percent of patients had most of their care elsewhere after surgery. However, the numbers responding are high enough to provide meaningful data that can be applied to the cohort as a whole. All of the Cleveland Clinic patients have supplied data, and the most recent follow-up is within 24 months in more than 80%.

When confronted with a patient who has a failed IPAA, the first step is to make a diagnosis of the reason for the pouch failure. The basis of this is a multidisciplinary evaluation using all the diagnostic tools available and the experience of those who see such patients regularly. Having made a diagnosis, nonsurgical treatment must be tried and exhausted before surgery is considered. Then a decision whether pouch redo is appropriate and reasonable is made. The options are outlined to the patient and recommendations are made on the basis of the usual consideration of advantages and disadvantages, benefits, and costs. If the diagnosis is structural, then redo is likely to be effective. We offer a re-exploration with a possibility of a pouch redo. We always emphasize that an end ileostomy may be the only option once the original pouch is mobilized or resected, because the remaining small bowel may not reach to form a new pouch. We always warn that if a new pouch is made, the function may be worse. Patients who are clearly not candidates for redo pouch surgery are those with active anal CD, those with loss of a critical amount to terminal ileum, and those with dysfunctional anal sphincters.

## CONCLUSIONS

Good outcomes are possible in most patients after redo ileal pouch surgery, although those who developed pelvic sepsis after redo ileal pouch surgery are at risk for failure of their revised pouch. Functional results, although imperfect, are acceptable to the highly motivated patients.

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## DISCUSSANTS

### D. Rothenberger (Minneapolis, MN):

I have no disclosures.

You and your colleagues from the Cleveland Clinic just updated your previous publication from 2009 in *Diseases of the Colon and Rectum*, and have more than doubled that series now. Your large experience is an opportunity for those of us who get involved in redos for failed ileal pouch procedures to understand what you have been through and to use some of the knowledge you've acquired to benefit our patients. A new pouch was created in 41% of your patients whereas 59% had their original pouch revised and retained.

In this series of redo operations, I think that it is perfectly understandable that morbidity occurred in 53% of your patients, but it is quite impressive that you did all of these without any operative deaths. I assume that reflects both your expertise in ileal pouch surgery and probably your wise selection of patients appropriate for reoperation.

It is important for the readers of the article to understand that this is a retrospective review of data that were abstracted from a prospectively maintained database that includes an annual questionnaire to update pouch function and quality of life.

I have 3 questions for you.

My first question relates to the denominator, that is, to your patient selection for salvage. I know that you said in your manuscript that you don't have specific information on how patients were selected, but I wonder whether you can at least give us some insight as to who is offered a salvage procedure and who is not? For instance, in my more limited experience, I learned to avoid salvage redo procedures in heavily muscled or obese males with a deep, narrow pelvis whose original ileal pouch failure resulted in a chronic

infection that resulted in a stiff, noncompliant anal canal despite months of diversion. I doubt very much that that's a salvageable situation but maybe you disagree. How many of your patients do you recall who fit this general description and how many of them were salvaged with good function?

Although a number isn't specifically available. I wonder how many times you recall starting out on a redo but ending up with an ileostomy? As I understand it, they would not have been included in the denominator.

How can you conclude that salvage surgery has a high likelihood of success without knowing this number? The denominator, I think, is very important. It seems that you would need to have done an intention-to-treat analysis to draw the conclusion you have suggested.

The second question relates to counseling of patients in obtaining informed consent. Your primary conclusion is that patients with a failed ileoanal pouch may be offered redo pouch surgery with a "high likelihood of success in terms of function and quality of life." But in the discussion in your manuscript, you also state

"it's surprising, however, what patients with an IPAA find acceptable. There are high rates of incontinence and seepage, high rates of pad use that means irritated, painful perianal skin, and constant attention to anal cleanliness. Despite this, patients report an almost universal willingness to have the surgery again if it were necessary and to recommend the surgery to others."

You subsequently noted, the subset of patients in this study is strongly motivated to avoid a permanent ileostomy.

Can you tell me how the "likelihood of success" in terms of function equates to the function you described in your manuscript? How do you go about obtaining informed consent, and, more importantly, having your patients understand the kind of life they may have in light of the poor function you described and the significant failure rate of 20% that you report for the redos?

The final question relates to the perceived quality of life data, which are dependent on the annual questionnaire that is part of your process. As I read the manuscript, in Table 9, you had 261 patients of the 502 in the series who had completed a questionnaire. It was unclear whether that was a one-time completion or the most recent completion of the questionnaire?

### Response From F.H. Remzi:

I thank you for your questions. Let me start by saying that this procedure is a patient-driven procedure. If somebody, after suffering long period of time, can accept and live with a permanent ileostomy, these are the patients we tell them it is time for them to move on with an ileostomy. Once again, this is a patient-driven procedure. It's amazing, as what we articulated, what the patients might go through and find the fact that after these redo procedures, their quality of life is still better than what it used to be with an ileostomy, and they still would undergo redo procedure again if needed to be.

We take our time for a very vigorous consenting in the preoperative evaluation and also going through all the intra- and postoperative possibilities. We give as much as information that we presented in our paper at the time of the preoperative visit. We also discuss the possibilities of sexual dysfunction. All these possibilities are explained to them preoperatively.

We also tell them the potential failure rates that they need to understand and need to accept at the time of the surgery. Otherwise, we do not do the surgery. Again, it needs to be a patient-driven issue.

When they can avoid the ileostomy, the patients are most of the time very much okay with it and they also understand after undergoing through a redo procedure whether things don't work out, they can always go to an ileostomy.



Regarding the first question, we have emphasized the limitation of the study. We don't have the definitive denominator exactly how many patients came to see us for redo procedure during the study period and out of these how many we could not do it. However, there has been evolution and variation of the procedure. I can point out that in the last 7 years from my personal experience over 240 redo procedures, there may be very few that we could not do a redo. You are correct the weight, body mass impacts the decision making, these are very important factors. If somebody is significantly overweight, they have 2 options, either to lose the weight, or they may consider bariatric surgery if they want to push it, and then do redo afterward. Of course, they can also live with a permanent ileostomy; they have that right.

Regarding the last point, the quality of life data, we used the most recent one in analysis. One may have multiple quality of life evaluations. We decided to eliminate the patients who have not filled out the forms completely. We wanted to make sure that we have given clear and complete data in our results, that every single question was answered. That's the reason the response rate may be low; we did not want to change the denominator to each question.

#### J. Fleshman (Dallas, TX):

I have a few questions that will help us understand some of the details that you were talking about.

How many of these patients had undergone a transanal approach to the repair before you went to an abdominal redo approach?

What, in your opinion, was the reason that reoperation actually was able to treat the problem of chronic pouchitis? Is this something that we may be able to translate to treatment of other patients with chronic pouchitis?

Do you think there might actually be a role of combined Endo-Sponge Vacuum Assisted Closure (VAC therapy) with redo operation? Where might you have applied that in this large series, especially when you had a significant number of people who actually ended up failing as you went forward?

Finally, can you give us some details of the patients with neoplasia and how you are able to save a pouch in those individuals?

#### Response From F.H. Remzi:

I think the point that you are making about the transanal attempt is very critical. When we looked into our results, 25% of the patients had multiple transanal attempts before the surgery. That's something, in my opinion, not to do. The more the transanal procedures are done, the less likely for our patients to be fixed later with transabdominal redo procedure. That is a message that I like to give. It is also especially true for the pouch vaginal fistulas. Doing many transanal repairs in these patients takes away the opportunity for us to be able to fix these later with a transabdominal approach. If one had a failure, just redoing with a transabdominoperineal approach from the beginning increases the chance of success.

Pouchitis, it depends on what we define as pouchitis. This definition evolved through the decades. A true pouchitis with no associated other pathology and trying to do a redo pouch will not have good outcome. These patients don't do well. However, if the pouchitis is related to secondary causes such as leak abscess and others, then the results are good. We need to be very careful what exactly patients are being diagnosed as a true pouchitis.

The Endo-Sponge, is something that we were very eager to use once the company brought it to this side of the Atlantic. I think it has a huge potential to promote healing, get things to heal quicker, and potentially avoid these failures. People were not really using it, so the company took it off the market. So, we don't have it on this side of the Atlantic anymore to be able to use the sponge to help our patients. That is a concern.

To answer your question related to neoplasia, these are the patients who had the dysplasia at the ATZ or the mucosectomy site, so they had to go through a redo pouch procedure.

#### N. Hyman (Chicago, IL):

I have 2 specific questions for you.

One is, in your redos, when you have to make a new pouch, are you doing S pouches? Your own published experience has reported better outcomes with S pouches in patients with mucosectomies. I find it much easier in a redo to do an S pouch than another J.

Second, how do you deal with the fibrous rind in the pelvis with the patients who have chronic sepsis, because dealing with that is where you can get a lot of bleeding. Do you think we need to be aggressive about excising it, should we curette it, or selectively debride?

#### Response From F.H. Remzi:

The number one thing regarding the sepsis, that's something that I learned from my mentor Vic Fazio, you need to excise it. If you don't excise it, I think the results will not be good, so we push the limit on this and excise the phlegmon and sepsis-related fibrosis. We need to be careful, because we may get into severe bleeding. When I am excising this rind of tissue, I usually put a couple of clamps on it and excise around it. It is very critical to excise this tissue to get better results. Without doing this, doing a redo will be futile, things are going to fail because the pouch is going to get ischemic due to surrounding on going septic process. So, excising this infection is very critical.

Regarding the S pouch or J pouch, we have to take what the patient will give us. Most of the time J will work; if it does not, then I would do an S pouch. Throughout the years, I learned the fact that these patients are better served with initial diversion. So, I divert these patients first for 6 months. It detoxifies the patient, it reconditions them. Some of them may want to live with an ileostomy. That's quite all right. It actually gets them engaged and reconditions everyone in the family and allow us to push the limit because they are better conditioned for the complex redo procedure. I think it's a very important strategy to do 3-stage procedure in these patients.

It also helps them and us to overcome the reach issues by elongating the mesentery within this 6-month reconditioning period. It is also critical that you have to pick the right side for this ileostomy. We usually pick an area minimally 20 cm proximal from the tip of the existing pouch, so this part that is picked as an ileostomy site can come down as a new pouch anal anastomosis site if I cannot use the old pouch.

The S pouch in these cases had to be used for the reach issues, but still I don't do an intentional S pouch if I have a concern that I may be losing more bowel if something happens to these patients. If the J pouch gives me what we need I take that.