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RESEARCH ARTICLE

# Trends in surgical outcomes for Ileal pouch–anal anastomosis construction using a large nationwide database

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## Abstract

**Aim:** Ulcerative colitis (UC) affects over 3 million (1.3%) US adults, approximately 20% of whom will require surgery. Since it was first described in 1978, restorative proctocolectomy with ileal pouch–anal anastomosis (IPAA) has become the gold standard for patients requiring surgery, as well as for patients with familial adenomatous polyposis (FAP). In 1991 the laparoscopic approach to IPAA was introduced. The aim of this study was to evaluate the advances made in IPAA as minimally invasive surgery (MIS) has become more prevalent.

**Method:** The American College of Surgeons NSQIP database from 2005 to 2019 was used. Laparoscopic (MIS) and open cases of IPAA construction for UC or FAP were used. These patients were subdivided into three time point cohorts: early (2005–2009), middle (2010–2014) and recent (2015–2019). Univariable and multivariable analyses were performed to evaluate morbidity, mortality and hospital length of stay.

**Results:** A total of 6184 patients were analysed, and 2555 underwent MIS while 3629 underwent open surgery. After multivariable analysis, the MIS approach was associated with a lower risk of morbidity compared with open procedures [relative risk (RR) = 0.86, $p < 0.0001$, 95% CI 0.78–0.94], both in the early and recent periods [early period = RR = 0.66 ($p < 0.0001$), recent period RR = 0.78 ($p = 0.0029$)]. Superficial surgical site infection (SSI) was consistently lower in the MIS cohort across all three time periods. After multivariable analysis, the overall RR of superficial SSI in the MIS cohort was 0.41 ($p < 0.0001$) [early period RR = 0.35 ($p < 0.0001$), middle period RR = 0.55 ($p = 0.0007$), recent period RR = 0.31 ($p < 0.0001$)]. The RR of deep space SSI was decreased overall (RR = 0.58, $p = 0.013$, 95% CI 0.62–0.93), with the most significant effect occurring during the early period (RR = 0.30, $p = 0.0260$, 95% CI 0.105–0.868). Sepsis related to any infective aetiology was also decreased in the MIS cohort (RR = 0.76, $p = 0.0093$, 95% CI 0.62–0.93), especially in the recent time period (RR = 0.63, $p = 0.0344$, 95% CI 0.41–0.97). Furthermore, hospital length of stay was decreased in the MIS cohort (−0.287 days, $p = 0.0170$), with a greater difference occurring in the more recent cohort (−0.375 days, $p = 0.0418$).

Alyssa Habermann and Hannah Gassie contributed equally to this work.

**Conclusion:** With increasing utilization of minimally invasive techniques in IPAA creation there have been significant decreases in the rates of morbidity including decreasing rates of superficial and deep space SSI, as well as decreased hospital length of stay.

**KEYWORDS**
ileal pouch-anal anastomosis, J pouch, minimally invasive surgery, ulcerative colitis

## INTRODUCTION

Ulcerative colitis (UC) is an autoimmune inflammatory bowel disease marked by continuous uniform mucosal and submucosal inflammation of the colon and rectum. First-line treatment for this chronic condition typically consists of medical management. With the advent of more advanced biological therapies there has been a significant decrease in rates of surgery in patients with UC; however, approximately 20%–25% of patients with UC will require surgery [1–3]. Until the 1950s, total proctocolectomy with end ileostomy was the standard surgical treatment for UC [4]. During the 1950s and 1960s, subtotal colectomy with ileorectal anastomosis became a popular option to avoid stoma in patients with minimal rectal disease, but of course this carried the risks involved with leaving behind the diseased rectum, including the risk of malignancy.

In 1978, an ileal pouch–anal anastomosis (IPAA) was first described by Parks and Nicholls [5]. This procedure, which involves a total proctocolectomy, creation of a pouch from a loop of terminal ileum and anastomosis between the ileal pouch and anus, affords the benefit of removing the entire rectum without the need for a permanent ostomy. Since its inception, restorative proctocolectomy with IPAA has become the gold standard for surgical management of UC as well as familial adenomatous polyposis (FAP), which also requires resection of the rectum to minimize the risk of developing malignancy [2].

Laparoscopy was first described for colon resection in 1991 by Jacobs et al. [6]. Shortly thereafter, Wexner and colleagues were the first to describe laparoscopic ileoanal pouch surgery [7–9]. Subsequently, throughout the 1990s, surgeons began to perform laparoscopic IPAA [10]. Early studies showed a significantly longer length of surgery, higher complication rates and higher costs in patients who underwent laparoscopic IPAA compared with open IPAA [11–13]. However, as time went on outcomes began to improve. A 2009 Cochrane review of 11 trials ($n$ = 607) found no significant difference in mortality, morbidity, reoperation or readmission rates between open and laparoscopic IPAA [14]. A 2013 National Surgical Quality Improvement Program (NSQIP) database analysis went on to report a lower complication rate and overall lower mortality rate in patients who underwent laparoscopic compared with open IPAA [15]. Accordingly, there has been an increase in the use of laparoscopy in IPAA over the past several decades [16].

In this paper, we sought to evaluate the ongoing advances made in IPAA construction as minimally invasive surgery (MIS) has become more prevalent. We conducted a retrospective review of the NSQIP database to compare outcomes between open and laparoscopic IPAA over several time periods. Our intention was to assess how outcomes have changed over time as MIS technologies have improved and surgeons have developed expertise in the surgical method.

**What does this paper add to the literature?**

This paper provides an overview of changes over time in postoperative outcomes of ileal pouch-anal anastomosis as minimally invasive surgery has become more prevalent.

## METHOD

The ACS NSQIP database from 2005 to 2019 was used to identify minimally invasive and open cases of IPAA construction for UC or FAP. The CPT code 44211 was used to identify cases of minimally invasive IPAA. The NSQIP database does not report separate CPT codes for laparoscopic and robotic IPAA. The CPT codes 45113, 44157 and 44168 were used to identify cases of open IPAA. All CPT codes are for diversion procedures. The ICD9/10 codes used for UC, family history of colonic polyps and benign neoplasm of the colon were 556/K51, V18.51/Z83.71 and 211.3/D12.6, respectively. Exclusion criteria were age <18 years, American Society of Anesthesiologists class 5 and emergency cases. Additionally, only patients with complete data sets were analysed.

The data were divided into three cohorts based on year of surgery: early (2005–2009), middle (2010–2014) and recent (2015–2019). The cohorts were divided evenly over the number of years that NSQIP data have been available. Preoperative demographics, comorbidities and relevant lab values were collected as were postoperative morbidity, mortality, hospital length of stay and complications. Complications were grouped by haematological, surgical site, cardiac, respiratory, infectious, neurological and renal. Chi-square/Fisher's exact test or the Wilcoxon test were used to compare between groups. Relative risks (RRs) were estimated via Poisson regression with robust standard errors (via sandwich estimators) for all outcomes except hospital length of stay. The open group was used as the reference. A linear regression model was used for hospital length of stay. A multivariable model was constructed using backwards selection via the Akaike information criterion. All analyses were performed in R v.4.1.1.

## RESULTS

A total of 6184 patients were analysed, of whom 2555 underwent MIS while 3629 had open surgery. A combined total of 1318 patients underwent restorative proctocolectomy in the early time period, 2461 patients in the middle time period and 2405 in the recent time period. The only preoperative variables with a statistically significant difference between the MIS and open groups were a higher rate of chronic steroid use in the MIS group (44.31% vs. 25.52%, $p < 0.0001$) and a higher percentage of patients with white blood cell count (WBC) <4 in the open group (11.66% vs. 12.32%, $p < 0.0001$) (Table 1).

**TABLE 1** Breakdown of preoperative variables between minimally invasive surgery (MIS) and open ileal pouch–anal anastomosis groups between 2005 and 2019.

| Total | MIS, *n* (%) | Open, *n* (%) | *p*-value |
|---|---|---|---|
| Female | 1124 (44.03) | 1476 (40.67) | **0.0085** |
| Age (years) | | | |
| 18–30 | 847 (33.15) | 1091 (30.06) | 0.1500 |
| 31–40 | 572 (22.39) | 846 (23.31) | |
| 41–50 | 501 (19.61) | 708 (19.51) | |
| 51–60 | 394 (15.42) | 611 (16.84) | |
| 61–70 | 209 (8.18) | 326 (8.98) | |
| 71–90 | 32 (1.25) | 47 (1.30) | |
| ASA class | | | |
| 1–2 | 1886 (73.90) | 2575 (71.03) | **0.0132** |
| 3–4 | 666 (26.10) | 1050 (28.97) | |
| BMI (kg/m$^2$) | | | |
| <30 | 2048 (80.16) | 2797 (77.07) | **0.0038** |
| >30 | 507 (19.84) | 832 (22.93) | |
| Impaired functional status | 14 (0.55) | 14 (0.39) | 0.6064 |
| Current smoker | 234 (9.16) | 308 (8.49) | 0.3580 |
| Dialysis | 0 (0.00) | 2 (0.06) | 0.5150 |
| Hypertension | 324 (12.68) | 548 (15.10) | **0.0071** |
| Insulin use | 97 (3.80) | 198 (5.46) | **0.0026** |
| COPD | 15 (0.59) | 30 (0.83) | 0.2750 |
| CHF | 1 (0.04) | 1 (0.03) | 0.9999 |
| Chronic steroid use | 1132 (44.31) | 926 (25.52) | <**0.0001** |
| Bleeding disorder | 48 (1.88) | 69 (1.90) | 0.9486 |
| Hct (%) | | | |
| <31 | 384 (15.03) | 541 (14.91) | 0.9519 |
| 31–45 | 1918 (75.07) | 2736 (75.39) | |
| >45 | 253 (9.90) | 352 (9.70) | |
| Cr (mg/dL) | | | |
| <1.19 | 2426 (94.95) | 3392 (93.47) | **0.0150** |
| >1.19 | 129 (5.05) | 237 (6.53) | |
| WBC (10$^3$/μL) | | | |
| <4 | 298 (11.66) | 447 (12.32) | **<0.0001** |
| 4–11 | 1873 (73.31) | 2826 (77.87) | |
| >11 | 384 (15.03) | 356 (9.81) | |
| Albumin (g/dL) | | | |
| >3.5 | 1237 (48.41) | 1794 (49.44) | 0.4294 |
| <3.5 | 1318 (51.59) | 1835 (50.56) | |

*Note*: Values in bold are statistically significant.

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; Cr, creatinine; Hct, haematocrit; MIS, minimally invasive surgery; WBC, white blood cell count.

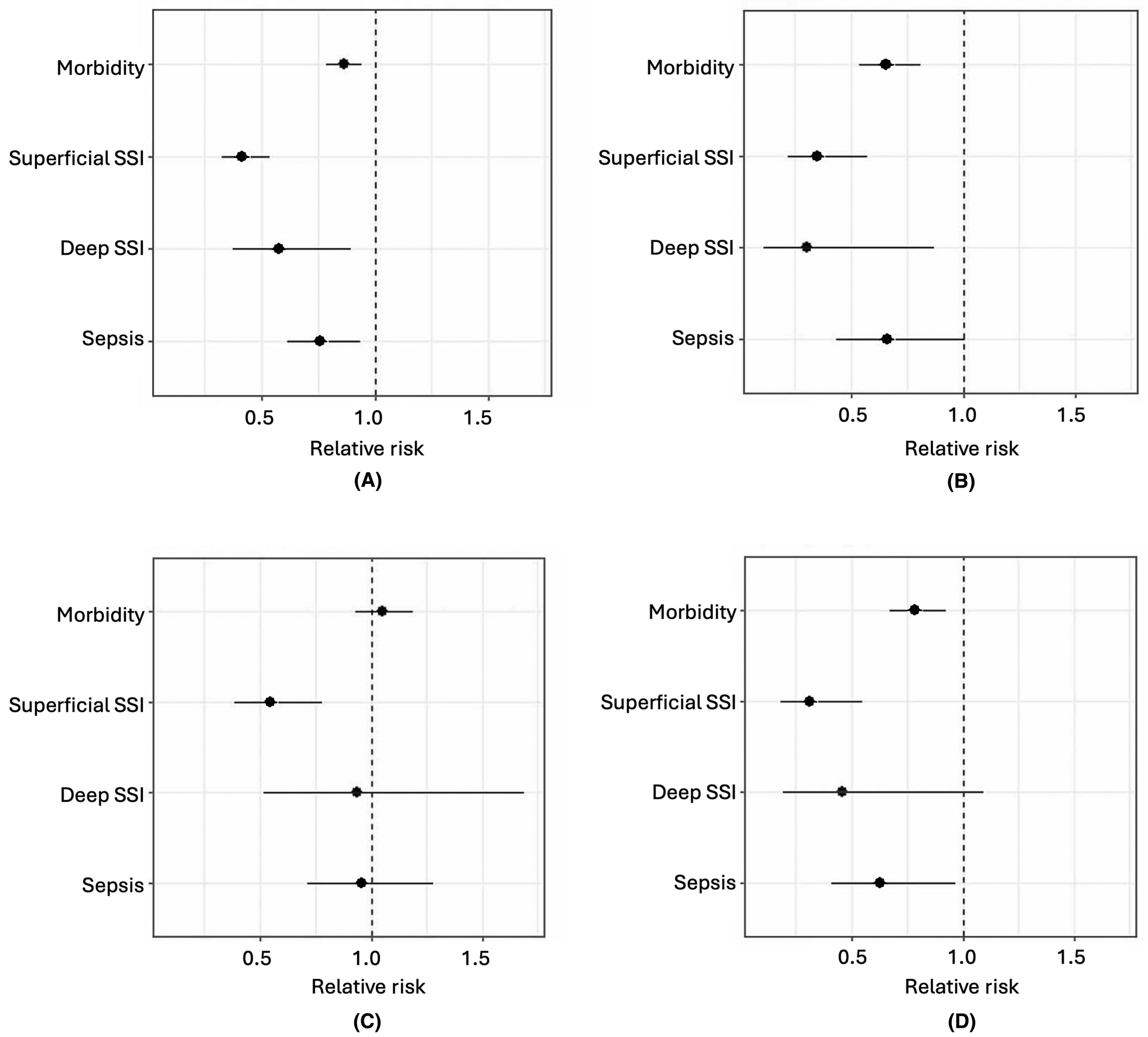


**FIGURE 1** Multivariable analysis of surgical outcomes in minimally invasive surgery compared with open ileal pouch–anal anastomosis creation: (A) overall, (B) early time period (2005–2009), (C) middle time period (2010–2014) and (D) recent time period (years 2015–2019) (SSI, surgical site infection).

After univariate and multiviariate analysis, the MIS approach was associated with lower risk of morbidity compared with open procedures (RR = 0.86, $p < 0.0001$, 95% CI 0.78–0.94), both in the early and recent periods [early period RR = 0.66 ($p < 0.0001$), recent period RR = 0.78 ($p = 0.0029$)] (Figure 1, Tables 2 and 3). Superficial surgical site infection (SSI) was consistently lower in the MIS cohort across all three time periods. After multivariable analysis, the overall RR of superficial SSI in the MIS cohort was 0.41 ($p < 0.0001$) [early period RR = 0.35 ($p < 0.0001$), middle period RR = 0.55 ($p = 0.0007$), recent period RR = 0.31 ($p < 0.0001$)]. The RR of deep space SSI was decreased overall (RR = 0.58, $p = 0.013$, 95% CI 0.62–0.93), with the most significant effect occurring during the early period (RR = 0.30, $p = 0.0260$, 95% CI 0.105–0.868). Sepsis related to any infective aetiology was also decreased in the MIS cohort (RR = 0.76, $p = 0.0093$, 95% CI 0.62–0.93), especially in the recent time period (RR = 0.63, $p = 0.0344$, 95% CI 0.41–0.97). Furthermore, hospital length of stay was decreased in the MIS cohort (−0.287 days, $p = 0.0170$), with a greater difference occurring in the more recent cohort (−0.375 days, $p = 0.0418$). Haematological, cardiac, respiratory, infective (listed separately from SSI), neurological and renal complications did not differ significantly between the MIS and open groups.

## DISCUSSION

The results of this study demonstrate that with increasing utilization of minimally invasive techniques in IPAA creation there have been significant decreases in the rates of morbidity, including decreasing

**TABLE 2** Univariate analysis comparing outcomes of minimally invasive surgery (MIS) versus open ileal pouch–anal anastomosis between 2005 and 2019.

| Outcome | MIS ($n = 2555$) | Open ($n = 3629$) | $p$-value |
|---|---|---|---|
| Overall a, $n$ (%) | **599 (23.44)** | **958 (26.40)** | **0.0084** |
| Overall mortality, $n$ (%) | 6 (0.23) | 3 (0.08) | 0.1750 |
| Median hospital length of stay (days) (IQR) | **5.00 (4.00, 8.00)** | **6.00 (4.00, 8.00)** | **<0.0001** |
| Specific complications, $n$ (%) | | | |
| Haematological | | | |
| Transfusion | 153 (5.99) | 218 (6.01) | 0.7761 |
| Deep-vein thrombosis | 80 (3.13) | 94 (2.59) | 0.2053 |
| Pulmonary embolism | 20 (0.78) | 20 (0.55) | 0.2631 |
| Surgical site | | | |
| Superficial SSI | **76 (2.97)** | **265 (7.30)** | **<0.0001** |
| Organ space SSI | 210 (8.22) | 300 (8.27) | 0.9466 |
| Deep SSI | **29 (1.14)** | **71 (1.96)** | **0.0117** |
| Cardiac | | | |
| Myocardial infarction | 2 (0.08) | 2 (0.06) | 0.7242 |
| Cardiac arrest | 5 (0.20) | 1 (0.03) | 0.0881 |
| Respiratory | | | |
| Pneumonia | 20 (0.78) | 33 (0.91) | 0.5950 |
| Reintubation | 9 (0.35) | 19 (0.52) | 0.3231 |
| Prolonged vent > 48 h | 10 (0.39) | 9 (0.25) | 0.3158 |
| Infectious | | | |
| Urinary tract infection | 94 (3.68) | 142 (3.91) | 0.6365 |
| Sepsis | 132 (5.17) | 225 (6.20) | 0.0861 |
| Septic shock | 14 (0.55) | 21 (0.58) | 0.8740 |
| Neurological | | | |
| Stroke | 2 (0.08) | 0 (0.00) | 0.1707 |
| Renal | | | |
| ARF | 6 (0.23) | 13 (0.36) | 0.3880 |

*Note*: Values in bold are statistically significant.

Abbreviations: ARF, acute renal failure; IQR, interquartile range; SSI, surgical site infection.

rates of superficial and deep space SSI as well as decreased hospital length of stay. Interestingly, not all these results held true across all time periods. While there was a lower risk of morbidity associated with the MIS approach in the early and recent periods, the risk of morbidity actually increased in the middle time period compared with the open approach. While rates of SSI and sepsis were decreased with the MIS approach across all time periods, this effect was more substantial in the early and recent time periods than in the middle time period.

The reason for the more pronounced risk reduction in the early and recent time periods compared with the middle time period is unknown. We suspect it may be related to the substantial increase in the number of patients who underwent restorative proctocolectomy between the early and middle time periods (1318 and 2461, respectively). With a greater number of laparoscopic IPAAs being performed, it is possible that a significant portion of these were performed by surgeons who were relatively new to the technique. Of course, with any technique, the experience of the surgeon can affect surgical outcomes. The NSQIP database deidentifies both surgeon and institution, so there was no way to control for individual surgeon or institutional experience with laparoscopy in this study. It is possible that the diminished risk reduction in the middle time period could be explained by an increase in the number of surgeons novice to the technique who performed laparoscopic IPAA during this period, but this theory cannot be proven with certainty based on the data available in this study. Additionally, the more widespread implementation of Enhanced Recovery After Surgery (ERAS) protocols for perioperative patient optimization in colorectal surgery in the recent time period may offer an explanation for the greater risk reduction compared with the middle time period [17]. Furthermore, as medical therapy for UC has improved, most notably in the area of biologicals, patients requiring surgery have become sicker on average (these are often patients with refractory disease requiring steroids), which may account for some of the differences in outcomes across time periods, especially from the early to middle time periods. The benefit for deep

**TABLE 3** Multivariate analysis comparing outcomes of minimally invasive surgery (MIS) versus open ileal pouch–anal anastomosis between 2005 and 2019.

| | MIS versus open |
|---|---|
| All time periods | |
| Overall morbidity | |
| Relative risk | 0.860 |
| *p*-value | **<0.0001** |
| 95% CI | (0.787, 0.941) |
| Superficial SSI | |
| Relative risk | 0.416 |
| *p*-value | **<0.0001** |
| 95% CI | (0.324, 0.534) |
| Deep SSI | |
| Relative risk | 0.579 |
| *p*-value | **0.0130** |
| 95% CI | (0.376, 0.891) |
| Sepsis | |
| Relative risk | 0.759 |
| *p*-value | **0.0093** |
| 95% CI | (0.617, 0.934) |
| Hospital length of stay | |
| Estimate | −0.287 |
| *p*-value | **0.0170** |
| 95% CI | (−0.523, −0.051) |
| Early (2005–2009) (*n* = 1318) | |
| Overall morbidity | |
| Relative risk | 0.657 |
| *p*-value | **<0.0001** |
| 95% CI | (0.534, 0.807) |
| Superficial SSI | |
| Relative risk | 0.351 |
| *p*-value | **<0.0001** |
| 95% CI | (0.215, 0.574) |
| Deep SSI | |
| Relative risk | 0.303 |
| *p*-value | **0.0260** |
| 95% CI | (0.106, 0.868) |
| Sepsis | |
| Relative risk | 0.661 |
| *p*-value | 0.0559 |
| 95% CI | (0.432, 1.010) |
| Hospital length of stay | |
| Estimate | −0.069 |
| *p*-value | 0.7886 |
| 95% CI | (−0.571, 0.433) |
| Middle (2010–2014) (*n* = 2461) | |
| Overall morbidity | |
| Relative risk | 1.050 |
| *p*-value | 0.4266 |
| 95% CI | (0.928, 1.190) |
| Superficial SSI | |
| Relative risk | 0.549 |
| *p*-value | **0.0007** |
| 95% CI | (0.388, 0.776) |
| Deep SSI | |
| Relative risk | 0.935 |
| *p*-value | 0.8260 |
| 95% CI | (0.516, 1.690) |
| Sepsis | |
| Relative risk | 0.958 |
| *p*-value | 0.7740 |
| 95% CI | (0.714, 1.280) |
| Hospital length of stay | |
| Estimate | −0.122 |
| *p*-value | 0.5267 |
| 95% CI | (−0.502, 0.257) |
| Recent (2015–2019) (*n* = 2405) | |
| Overall morbidity | |
| Relative risk | 0.784 |
| *p*-value | **0.0029** |
| 95% CI | (0.669, 0.920) |
| Superficial SSI | |
| Relative risk | 0.314 |
| *p*-value | **<0.0001** |
| 95% CI | (0.181, 0.546) |
| Deep SSI | |
| Relative risk | 0.461 |
| *p*-value | 0.0760 |
| 95% CI | (0.195, 1.090) |
| Sepsis | |
| Relative risk | 0.630 |
| *p*-value | **0.0344** |
| 95% CI | (0.410, 0.967) |
| Hospital length of stay | |
| Estimate | −0.375 |
| *p*-value | **0.0418** |
| 95% CI | (−0.736, −0.014) |

*Note*: Values in bold are statistically significant.
Abbreviation: SSI, surgical site infection.

space infections seems to be lost after the first time period, which may be due to the increased proportion of more challenging cases being performed using minimally invasive techniques. Differences in SSI across time periods may also be explained by changes in preoperative bowel preparation practices, the use of different immunosuppressive agents and the use of different surgical approaches. Regarding the latter theory, the NSQIP database does not specify the type of incision. The general evolution across practices from larger incisions with extracorporeal vascular ligation to smaller incisions with intracorporeal vascular ligation may also have played a role in the trends seen across time periods.

While our study demonstrates improvement in short-term laparoscopic outcomes over time, there have been multiple recent studies that show no difference in long-term outcomes of laparoscopic restorative proctocolectomy. A 2015 retrospective cohort study by Benlice et al. revealed that open and laparoscopic IPAAs were associated with similar incidences of incisional hernia, small bowel obstruction (SBO) requiring hospital admission and SBO requiring surgery [18]. Mean follow-up was 8.1 and 9.6 years for the laparoscopic and open groups, respectively. In 2017, Baek et al. [19] published a retrospective case-matched cohort study which showed equivalent outcomes between laparoscopic and open groups for pouchitis, SBO, pouch–anal stricture and pelvic abscess or fistula at both 5 and 10 years. There was a significantly decreased rate of pouch excision or permanent ileostomy as well as decreased daytime and nighttime stool frequency in the laparoscopic group compared with the open group Nozawa et al. designed a similar study in 2022 which showed that the incidence of pouchitis and pouch failure did not differ between laparoscopic and open groups at 63.5 months [20]. Finally, a 2019 survey by Gorgun et al. [21] of 890 female patients who previously underwent IPAA reported a significantly shorter median time to pregnancy in the laparoscopic compared with the open group. Overall, long-term functional outcomes are largely equivalent between laparoscopic and open restorative proctocolectomy approaches despite improvement in the laparoscopic method over time.

As MIS continues to advance, robotic surgery has made its way to the forefront of the field. Accordingly, it is pertinent to discuss utilization and outcomes of robots for restorative proctectomy, as this technique represents an increasingly relevant branch of MIS. The first report of robot-assisted laparoscopic surgery (RALS) for restorative proctocolectomy was a 2011 case series by Pedraza et al. [22]. The series described five patients who underwent RALS restorative proctocolectomy with a J pouch for refractory ulcerative colitis. The paper demonstrated both the feasibility and safety of the procedure. Soon after, a case-matched review of robotic versus laparoscopic proctectomy by Miller et al. showed comparable perioperative outcomes, complications and short-term functional results between the two cohorts [23]. In recent years, the use of robots for restorative proctocolectomy has become increasingly popular [24]. A 2021 systematic review by Flynn et al. [25] included a total of 640 patients who underwent robotic proctocolectomy in nine studies. Meta-analysis revealed a significantly increased operating time in the robotic group; the paper does note the learning curve associated with robotic surgery. There was no statistically significant difference in leak rates. Some of the papers included also reported significantly lower estimated blood loss and shorter hospital length of stay in the robotic group; however, this was not consistent across studies. Overall, the review concluded that while robotic proctocolectomy was safe with no significant adverse short-term outcomes more data were required on short- and long-term clinical outcomes. As surgeons continue to gain experience with robotic proctocolectomy and as the technique matures it will be interesting to see how surgical outcomes change over time. We anticipate an evolution similar to that which has been described in this paper, with progressive improvement in surgical outcomes.

There are several limitations to this paper that should be addressed. First, we are only able to assess association, not causation. Second, CPT codes for IPAA do not currently differentiate between laparoscopic and robotic procedures, so there was no way of identifying which patients in the MIS cohort underwent laparoscopic versus robotic surgery. Furthermore, NSQIP only reports the final CPT code, so it cannot be known if procedures were converted from MIS to open. Next, NSQIP deidentifies the institution where the data originated, therefore it is not possible to identify either individual or outlier hospitals. In addition, NSQIP tends to overrepresent tertiary care centres and may not be applicable to all hospitals. Finally, a significant amount of critical information is not available through NSQIP, such as intraoperative blood loss, anastomotic type (stapled versus handsewn), performance of mucosectomy, anastomotic leak test status and pouch function assessment.

## CONCLUSION

Since the introduction of minimally invasive restorative proctocolectomy, outcomes in the United States have improved over time. Specifically, there has been a decrease in the relative risk of superficial SSI and hospital length of stay that is more pronounced in the recent time period compared with the early and middle time periods. Additionally, there was an overall decreased relative risk of morbidity, deep SSI and sepsis in the MIS group compared with the open group. As robotic surgery becomes a more substantial part of the MIS landscape it will be interesting to see if outcomes of robotic IPAA change over time in a similar manner to laparoscopic outcomes. Based on the results of this study, we conclude that minimally invasive restorative proctocolectomy should be the technique of choice whenever it is deemed clinically appropriate by the surgeon.

### AUTHOR CONTRIBUTIONS

**Alyssa Habermann:** Writing – original draft; writing – review and editing. **Hannah Gassie:** Data curation; writing – review and editing; methodology. **Salem Rustom:** Formal analysis; software. **Nicole E. Wieghard:** Conceptualization; writing – review and editing; investigation. **Steven D. Wexner:** Conceptualization; investigation; writing – review and editing. **Stephen P. Sharp:** Conceptualization; investigation; writing – review and editing; supervision.

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## CONFLICT OF INTEREST STATEMENT

Dr Wexner is a consultant for ARC/Corvus, Baxter, Becton, Dickinson and Co, GI Supply, Glaxo Smith Kline, ICON Clinical Research Ltd., Intuitive Surgical, Leading Biosciences/PalisadeBio, Livsmed, Medtronic, Olympus, OstomyCure, Stryker, Takeda, Virtual Ports, is a member of the Data Safety Monitoring Board of JSR/WCG/ACI (Chair), Polypoid (Chair) and Boomerang and receives royalties from Intuitive Surgical Karl Storz Endoscopy America Inc., Medtronic and Unique Surgical Solutions, LLC.

The other authors do not have any disclosures to report.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

## ETHICS STATEMENT

The authors of this study have complied with the Best Practice Guidelines on Publishing Ethics.

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