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ORIGINAL ARTICLE

Comparing rates of bowel injury for laparoscopic and robotic ventral hernia repair: a retrospective analysis of the abdominal core health quality collaborative

J. D. Thomas[1] · C. K. Gentle[2] · D. M. Krpata[2] · A. S. Prabhu[2] · A. Fafaj[2] · S. J. Zolin[2] · S. E. Phillips[3] · S. Rosenblatt[2] · M. J. Rosen[2] · C. C. Petro[2]

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Abstract

Purpose Bowel injury during laparoscopic and robotic ventral hernia repair is a rare but potentially serious complication. We sought to compare bowel injury rates during minimally invasive approaches to ventral hernia repair using a national hernia registry.

Methods Patients undergoing elective laparoscopic and robotic ventral hernia repair (including cases converted-to-open) between 2013 and 2021 were retrospectively identified in the Abdominal Core Health Quality Collaborative registry. The primary outcome was bowel injury, which included partial- and full-thickness injuries and re-operations for missed enterotomies. Statistical analysis was performed using multivariate logistic regression.

Results Overall, 10,660 patients were included (4116 laparoscopic, 6544 robotic). The laparoscopic group included more incisional hernias (68% vs 62%, $p < 0.001$) and similar rates of recurrent hernias (23% vs 22%, $p = 0.26$). A total of 109 bowel injuries were identified, with more occurring in the laparoscopic group (55 [1.3%] laparoscopic vs. 54 [0.8%] robotic; $p = 0.01$). Specifically, there were more full-thickness and missed enterotomies in the laparoscopic group (29 laparoscopic vs. 20 robotic; $p = 0.012$). Bowel injury resulted in higher rates of wound morbidity and major post-operative complications including sepsis, re-admission, and re-operation. Following adjustment for recurrent and incisional hernias, prior mesh, patient age, and hernia width, bowel injury during laparoscopic repair remained significantly more likely than bowel injury during robotic repair (OR 1.669 [95% C.I.: 1.141–2.440]; $p = 0.008$).

Conclusion In a large registry, laparoscopic ventral hernia repair is associated with an increased risk of bowel injury compared to repairs utilizing the robotic platform. Knowing the limitations of retrospective research, large national registries are well suited to explore rare outcomes which cannot be feasibly assessed with randomized controlled trials.

Keywords Enterotomy · Bowel Injury · Ventral Hernia · Minimally Invasive Hernia Repair · Laparoscopy · Robotic Surgery · Surgical Complications

Introduction

Minimally invasive ventral hernia repair has demonstrated benefits over open ventral hernia repair such as decreased risk of surgical-site infections, decreased post-operative pain and hospital stay, and a faster return to activity [1–6]. However, prospective trials and large systematic reviews have identified higher enterotomy rates during laparoscopic compared to open repairs [7–9]. Over the past decade, the utilization of robotic approaches for ventral hernia repair has dramatically increased [10, 11]. Use of the robot offers an alternative approach to traditional laparoscopy, potentially expanding the role of the minimally invasive platform to

✉ C. C. Petro
petroc@ccf.org

[1] Department of Surgery, Massachusetts General Hospital, Boston, MA, USA

[2] Cleveland Clinic Center for Abdominal Core Health, Digestive Disease and Surgery Institute, Cleveland Clinic Foundation, Cleveland, OH, USA

[3] Department of Biostatistics, Vanderbilt University Medical Center, Nashville, TN, USA

additional hernias that may have been previously offered either a laparoscopic or open repair. Despite this rapid evolution of minimally invasive hernia repairs, contemporary literature exploring the enterotomy rates between robotic and laparoscopic approach is sparse.

Recent clinical trial data have signaled a possible increased risk of enterotomy when performing robotic versus laparoscopic ventral hernia repair, despite many users touting the advantages of robotic adhesiolysis compared to its laparoscopic counterpart [12, 13]. However, the low incidence of bowel injuries during this procedure makes clinical trials an impractical tool to detect meaningful differences in this rare complication. Thus, we queried a large, prospectively maintained national registry to compare the rate of bowel injury between laparoscopic and robotic approach in patients who underwent minimally invasive ventral hernia repair. Additionally, we aim to use this study to explore the potential role for large registries to investigate underpowered secondary safety outcomes of clinical trials.

Methods

Patient identification

Following Institutional Review Board approval, all adult patients who underwent an elective, minimally invasive (laparoscopic or robotic) ventral hernia repair between 2013 and 2021 were retrospectively identified within the Abdominal Core Health Quality Collaborative (ACHQC) registry. Minimally invasive ventral hernia repair cases that were converted-to-open were classified based on the initially attempted surgical approach. Robot-assisted and laparoscopic-assisted cases were excluded from the analysis, as complex adhesiolysis could have been performed open in these cases. A robot-assisted or laparoscopic-assisted case is defined within the ACHQC as an operative approach that meets all of the following criteria: (1) some component of the operation was performed through a laparotomy incision, (2) the laparotomy incision was closed to allow establishment of pneumoperitoneum, and (3) the mesh (if utilized) was placed robotically or laparoscopically.

Data source

De-identified patient data were queried from the ACHQC registry. The ACHQC is a hernia-specific, prospective national registry with the objective of continuous quality improvement and is unique from most large registries in that data are collected in real time by the surgeons themselves [14]. At the time of this study, the ACHQC included 452 surgeons practicing in academic, community, and academic-affiliated settings. The ACHQC collects demographic information, hernia-specific variables, and operative details, as well as patient-reported outcomes (PROs) and post-operative follow-up information at standardized patient encounter timepoints. It also has a validated method to ensure the accuracy of recorded data, which occurs at regular intervals.

Outcome of interest

The primary outcome of this study was bowel injury rate. A bowel injury is defined within the ACHQC as a partial-thickness bowel injury and/or a full-thickness enterotomy/colotomy. If the surgeon identified the occurrence of a bowel injury, but failed to indicate the injury depth, it was still considered for analysis. Surgeons prospectively indicate the presence of an intra-operatively recognized bowel injury at the time of their case entry within the QC. As such, we additionally included patients requiring re-operation for a primary indication of "missed enterotomy" in the primary outcome to capture enterotomies that were not initially recorded.

Statistical analysis

Data were described using median and interquartile ranges (IQR) for continuous variables and counts with percentages for categorical variables, as appropriate. For analysis, patients were divided into two groups based on surgical approach: laparoscopic versus robotic. Univariate analysis of variables was performed between these two groups. Statistical significance was achieved by examining p values generated by appropriate statistical testing (e.g., Wilcoxon test or Pearson test). To account for variability of operative details, three multivariate logistic regression models were run to determine the effect of minimally invasive ventral hernia repair approach on bowel injury. Regression model covariates were selected based on expert consensus. Covariates included surgical approach (laparoscopic versus robotic), operating on a recurrent hernia, incisional hernia repair (suggesting history of prior abdominal surgery and potential for intra-abdominal adhesions), presence of prior mesh, patient age, and hernia width. Patient age was considered as a categorical variable based on the following groupings: (1) less than 50 years old, (2) between 50 and 69 years old, and (3) older than 69 years old. Hernia width was categorized into three sizes using the European Hernia Society incisional hernia classification system (W1 < 4 cm; W2 ≥ 4–10 cm; W3 ≥ 10 cm) [15]. Odds ratios (OR) with 95% confidence intervals (95% C.I.) are provided for the logistic regression model results. p Value < 0.05 was considered significant. R 3.6.2 (2019-12-12) was used for all analyses.

Results

A total of 10,660 patients within the ACHQC met study inclusion criteria: 4116 patients underwent laparoscopic ventral hernia repair (152 converted-to-open) and 6544 patients underwent robotic ventral hernia repair (120 converted-to-open). Univariate analysis of baseline demographic data and operative details between the laparoscopic and robotic group revealed statistically significant differences in most variables (Table 1). Of note, the laparoscopic group included more patients with incisional hernias (68% vs. 62%; $p < 0.001$). There was no difference in rates of prior hernia repairs between laparoscopic and robotic approaches (23% vs. 22%; $p = 0.26$).

Overall, 109 bowel injuries (55 laparoscopic and 54 robotic) were identified (Table 2). Of note, there were 3 patients in the laparoscopic group with a reported full-thickness bowel injury as well as a re-operation for a missed enterotomy; these patients were only counted once. Before multivariate logistic regression modeling, the incidence of reported intra-operative bowel injury was significantly greater in the laparoscopic group than in the robotic group (1.3% vs. 0.8%; $p = 0.01$). There were more full-thickness enterotomies and re-operations for missed enterotomies in

Table 2 Bowel injury incidence by minimally invasive surgical approach

	Laparoscopic ($n = 4116$)	Robotic ($n = 6544$)	p Value
Bowel injury, n (%)	55 (1.3%)	54 (0.8%)	0.01
Partial-thickness injury	27	34	
Full-thickness injury	19	18	
Re-operation for missed enterotomy	10	2	
Thickness unknown	2	0	

Of the ten patients who had a re-operation for missed enterotomy in the laparoscopic group, three also had an intra-operative bowel injury recorded and thus appear in the table twice

Table 1 Baseline characteristics and operative details

	Laparoscopic ($n = 4116$)	Robotic ($n = 6544$)	p Value
Age (years, time of surgery), median [IQR]	57 [47–67]	57 [46–67]	0.13
Gender, n (%)			
Female	2170 (53%)	3148 (48%)	< 0.001
BMI (kg/m^2), median [IQR]	32 [28–37]	32 [28–36]	0.043
Co-morbidities, n (%)			
Diabetes	740 (18%)	1092 (17%)	0.085
COPD	233 (6%)	328 (5%)	0.14
Hypertension	1887 (46%)	3135 (48%)	0.038
Inflammatory bowel disease	83 (2%)	120 (2%)	0.5
Nicotine use within 1 month, n (%)	483 (12%)	840 (13%)	0.093
ASA Class, n (%)			< 0.001
1	283 (7%)	557 (9%)	
2	1864 (45%)	3131 (48%)	
3	1875 (46%)	2737 (42%)	
4	87 (2%)	113 (2%)	
None assigned	7 (0.2%)	6 (0.09%)	
History of abdominal wall SSI, n (%)	194 (5%)	415 (6%)	< 0.001
Hernia width (cm), median [IQR]	3 [2–5]	4 [2–6]	< 0.001
Recurrent hernia, n (%)	939 (23%)	1432 (22%)	0.26
Prior mesh, n (%)	608 (15%)	944 (14%)	0.62
Hernia type, n (%)			< 0.001
Umbilical	883 (21%)	1844 (28%)	
Incisional	2778 (68%)	4083 (62%)	
Other	455 (11%)	617 (9%)	
Mesh used, n (%)	3878 (94%)	6401 (98%)	< 0.001
Onlay	159 (4%)	163 (3%)	
Inlay	76 (2%)	116 (2%)	
Sublay	3643 (89%)	6122 (64%)	

the laparoscopic group (combined 29 laparoscopic vs. 20 robotic; $p=0.012$). Compared to the group without bowel injury, patients who had an identified bowel injury were more likely to have an incisional hernia (88% vs. 64%, $p<0.001$), a parastomal hernia (11.9% vs. 3.8%, $p<0.001$), a recurrent hernia (41% vs. 22%, $p<0.001$), and have had prior mesh use (29% vs 14%, $p<0.001$). Of the patients with an intra-operatively recognized bowel injury, 23 (48%) in the laparoscopic group and 14 (27%) in the robotic group were converted-to-open ($p=0.03$).

Out of the 109 patients with bowel injuries identified, 9 required small bowel resection. Patients who had a bowel injury were more likely to experience post-operative wound morbidity, including higher rates of surgical-site infections (SSI), surgical-site occurrences (SSO), and surgical-site occurrences requiring procedural intervention (SSOPI) than patients who did not have a bowel injury (Table 3). Of the 87 total SSIs in the study population, the bowel injury group was more likely to develop an organ space SSI (53.3% vs. 6.9%, $p<0.001$), whereas infections which developed in patients without bowel injury were more likely to be superficial (75% vs. 33%, $p=0.002$). Of the 727 reported SSOs, patients with a bowel injury were more likely to develop infected seromas (2/17 for bowel injury group, 10/710 for no bowel injury group, $p<0.001$). Two enterocutaneous fistulas developed in the bowel injury group (2/17 for bowel injury group, 2/710 for no bowel injury group, $p<0.001$). Despite these wound complications, there were no reported cases of infected synthetic mesh in the bowel injury group.

Patients who experienced a bowel injury were more likely to have re-admission (17.6% vs 3.1%, $p<0.001$) and re-operation (11.93% vs 0.86%, $p<0.001$) than those without a bowel injury. Further complications that occurred with greater frequency in the bowel injury group included post-operative septic shock (2.75% vs. 0.019%, $p<0.001$), myocardial infarction (0.92% vs. 0.057%, $p<0.001$), acute renal failure (2.75% vs. 0.11%, $p<0.001$), and respiratory failure requiring intubation (4.59% vs. 0.095%, $p<0.001$). Mortality was not statistically different between the two groups (Table 3).

The crude odds ratio (OR) for surgical approach (laparoscopic compared to robotic) and bowel injury is 1.628 (95% C.I.: 1.116–2.374; $p=0.011$). Based on unadjusted data from the ACHQC, patients have a 63% increased risk of having a bowel injury during ventral hernia repair when it is performed laparoscopically compared to robotically. The adjusted multivariate logistic regression model revealed that the OR for surgical approach is 1.669 (95% C.I.: 1.141–2.440; $p=0.008$), indicating that a patient undergoing a laparoscopic ventral hernia repair is approximately 1.7 times as likely to have a bowel injury, on average, compared to a patient undergoing robotic repair. When hernia width categories are considered, the odds of bowel injury increase with increasing hernia width (Table 4). Although patients with prior mesh are more likely to have a bowel injury, this is not statistically significant (OR 1.326 [95% C.I.: 0.744–2.360]; $p=0.338$).

Table 3 Post-operative complications between bowel injury and no bowel injury groups

	No bowel injury ($n=10{,}551$)	Bowel injury ($n=109$)	p Value
SSI, *n* (%)	72 (0.68%)	15 (13.8%)	<0.001
SSO, *n* (%)	710 (6.7%)	17 (15.6%)	<0.001
SSOPI, *n* (%)	128 (1.4%)	19 (18.6%)	<0.001
Re-admission, *n* (%)	285 (3.1%)	18 (17.6%)	<0.001
Re-operation, *n* (%)	91 (0.86%)	13 (11.9%)	<0.001
Septic shock, *n* (%)	2 (0.02%)	3 (2.75%)	<0.001
Myocardial infarction, *n* (%)	6 (0.06%)	1 (0.92%)	<0.001
Cardiac arrest, *n* (%)	2 (0.02%)	0	0.89
Urinary tract infection, *n* (%)	21 (0.2%)	2 (1.8%)	<0.001
Acute renal failure, *n* (%)	12 (0.11%)	3 (2.75%)	<0.001
Pneumonia, *n* (%)	14 (0.13%)	1 (0.92%)	0.03
Post-operative respiratory failure requiring intubation, *n* (%)	10 (0.09%)	5 (4.59%)	<0.001
Pulmonary embolism, *n* (%)	10 (0.09%)	1 (0.92%)	0.008
Stroke, *n* (%)	4 (0.04%)	0	0.84
Deep vein thrombosis, *n* (%)	16 (0.15%)	0	0.68
Mortality, *n* (%)	32 (0.3%)	1 (0.92%)	0.25

SSI surgical-site infection, *SSO* surgical-site occurrence, *SSOPI* surgical-site occurrence requiring procedural intervention

Re-admission and SSOPI data were available for 9144 no bowel injury patients and 102 bowel injury patients

Discussion

Our study investigates the impact of minimally invasive ventral hernia repair approach on bowel injury using a national registry. In this study of over 10,000 patients, we found that laparoscopic ventral hernia repair is associated with an increased risk of bowel injury compared to robotic repair; this relationship is maintained when confounding factors are

Table 4 Bowel injury odds ratios by hernia width comparing laparoscopic to robotic approach

Hernia width	Odds ratio (95% CI)	p Value
4–10 cm compared to < 4 cm	2.509 (1.526–4.124)	<0.01
> 10 cm compared to 4–10 cm	4.340 (2.181–8.633)	<0.01

adjusted for using multivariate logistic regression. Not surprisingly, bowel injury resulted in higher rates of post-operative wound morbidity and other major post-operative complications, including enterocutaneous fistula, re-operation, septic shock, myocardial infarction, acute renal failure, and intubation for respiratory failure. Beyond the results of this study, our findings help to emphasize the importance and role of national registries as adjuncts to prospective RCTs within surgical research to characterize these rare events.

Bowel injury is a rare but serious complication during ventral hernia repair that deserves investigation. Our findings are consistent with prior studies which have shown that rates of post-operative complications including surgical-site infection, re-operation, re-admission, enterocutaneous fistula, and sepsis are higher in patients who have an enterotomy during minimally invasive ventral hernia repair compared to those who do not [16–19]. This underscores the importance of minimizing bowel injuries to avoid higher rates of complications. The incidence of bowel injury during minimally invasive ventral hernia repair has been reported to be anywhere from 0 to 14%, but is commonly believed to be between 1 and 2% [19–21]. The rates of bowel injury identified within this study during laparoscopic and robotic ventral hernia repair were low, and on par with these previously published figures. This suggests that the ACHQC is accurately capturing this particularly rare intra-operative complication. Additionally, our methodology for identifying intra-operative bowel injury at the time of surgery and including re-operations for missed and unrecognized enterotomies is similar to other previously published prospective and retrospective studies [19]. Based on this, we feel that we have captured most of the clinically significant bowel injuries within our study.

Previous studies, both retrospective and prospective, present conflicting data that suggest one minimally invasive ventral hernia repair approach is more favorable from the perspective of lowering the risk of bowel injury [13, 22–24]. In August 2017, our group published a registry-based comparative analysis of surgical outcomes following laparoscopic and robotic intraperitoneal onlay mesh (IPOM) repair [22]. That study revealed four bowel injuries in the laparoscopic group compared to zero in the robotic group, a statistically significant difference. The present study corroborates those findings, with more detail regarding thickness of injury and missed enterotomies owing to the vast increase in study patient sample.

To our knowledge, this is one of the first studies to demonstrate an increase in re-operations for missed enterotomies during laparoscopic compared to robotic ventral hernia repair. It is difficult to postulate as to the reason for this based on our retrospective series but could be that the result of unmeasured variables which indicate intra-operative complexity, or that more partial-thickness injuries were found intra-operatively in the robotic group avoiding re-operation. We believe that it deserves further expert discussion which may point toward differences in surgical decision-making when a bowel injury is suspected. A review of literature across other specialties including gynecology [25–28], urology [29], and colorectal surgery [30–32] revealed a lack of studies directly comparing the effect of minimally invasive surgical approach on the incidence of bowel injury; however, the rare nature of bowel injuries during laparoscopic and robotic procedures is consistently referenced.

Two RCTs investigating clinical outcomes of laparoscopic versus robotic IPOM repair for ventral hernia were recently published. In the study by Olavarria et al. [13], patient enrollment was powered ($n = 120$) to identify a 1-day difference in hospital length of stay following laparoscopic and robotic ventral hernia repair. The authors reported three enterotomies (2 during robotic versus 1 during laparoscopic repair) within their study and identified this as a potential complication that could not be adequately addressed due to a lack of statistical power. Instead, the authors suggest that this signal needs to be further investigated using a large multi-institutional RCT to better assess the safety, efficacy, and effectiveness of robotic versus laparoscopic ventral hernia repair. Similarly, in the PROVE-IT Trial [23], our group published the outcomes of laparoscopic versus robotic IPOM repairs. In this study which included 75 patients, there were two partial-thickness bowel injuries in the laparoscopic group and one in the robotic group (authors reported a non-significant p value > 0.99), none of which required conversion to open. Once again, this highlights the rarity of the event, as well as the inability to assess all clinically relevant secondary outcomes in prospective trials despite robust design. Both aforementioned trials were carefully designed and conducted to study the intended primary outcomes. However, they also shed light upon interesting secondary outcomes that may warrant further investigation.

This study explores those underpowered RCT signals and suggests that robotic ventral hernia repair is less likely than laparoscopic ventral hernia repair to result in a bowel injury. This slight decrease in a rare but detrimental complication adds data to an increasingly complex value equation regarding the robotic platform. However, how are the findings of a retrospective analysis to be weighted in this value equation? Conventionally, RCTs are cited as influencing surgical practice and considered the gold standard. Assuming the rates discovered in this study, to appropriately power an RCT investigating the rate of bowel injury during laparoscopic versus robotic ventral hernia repair would require a sample size of 13,022 subjects ($\alpha = 0.05$, $\beta = 80\%$). This is not practical. Based on the size of our study, we are confident that the rates we have identified are close to the true rate of bowel injury in each surgical approach. As such, a 0.5% difference in bowel injury incidence means that a laparoscopic surgeon

would have to complete 200 robotic ventral hernia repairs to prevent one bowel injury. On the other hand, robotic ventral hernia repair is associated with increased hospital costs and operative times, in the context of similar surgical outcomes compared to laparoscopic repair [13, 23, 33]. However, our findings suggest that performing a laparoscopic ventral hernia repair adds risk of bowel injury for the patient which can lead to serious complications. The debate between laparoscopic versus robotic repair remains complex and surgeons should use all available evidence to inform individual surgical practice.

Limitations

This study does have limitations which deserve mention. Due to the retrospective nature of this study, patient factors and surgeon preferences likely played a role, and despite controlling for variables such as recurrent hernia and hernia width, some selection bias likely exists in our sample. Surgeons electively enter their cases into the ACHQC database, and thus, the issues of surgeon-level variation and incomplete data entry also play a role. Factors not recorded in the AHSQC could also affect the outcome, such as trainee involvement in the surgical case, patient prior surgical history, and contents of the ventral hernia, and thus could not be controlled. We recognize that level of surgeon experience can also play a significant role in their comfort and skill in both laparoscopic and robotic hernia repair, which we were unable to account for in this study. Additionally, our definition of bowel injury includes partial-thickness injuries. There are inconsistent practices when intra-operatively handling a partial-thickness bowel injury due to various factors, such as method of injury (e.g., thermal injury versus sharp injury) or perceived depth. It is our assumption that clinically significant partial-thickness bowel injuries are being captured by the ACHQC. Generally, surgeons will repair concerning partial-thickness injuries by oversewing the bowel to prevent complications such as fistulization or perforation [34]. Due to a lack of granularity, we do not know if the recorded injury is a serosal abrasion versus a seromuscular injury without mucosal violation, nor do we know how the bowel injuries were repaired. Along similar lines, it is possible that the registry did not capture all bowel injuries. Although a common limitation of all retrospective studies that query national databases, the ACHQC has a robust quality assurance protocol that has reported data accuracy greater than 98% [14].

The role of registries to supplement prospective trials

Prospective trials sometimes generate signals that can only be considered hypothesis generating as they occur within underpowered secondary outcomes [35]. At this point, academic surgeons must determine the value of further investigation—we propose the use of large registries to guide this decision, as we demonstrate in this study. It is well accepted that RCTs are the highest level of evidence for establishing intervention benefit, safety, and efficacy guidelines within surgery. However, it is also known that the resource requirements, specialized skill set, and high associated costs are often a limitation for centers to perform RCTs and reason for discontinuation [36, 37]. Based on the results of this registry-based study, designing and powering an RCT to explore enterotomy after minimally invasive ventral hernia repair would not be worthwhile. Through our retrospective analysis of a hernia-specific registry which included over 10,000 patients, the odds of a bowel injury are 1.7 times greater when the ventral hernia is repaired laparoscopically instead of robotically. By carrying out a carefully designed retrospective study using surgeon entered point of care data, we have answered the question of bowel injury risk as efficiently and thoroughly as possible. This supports our belief that registry-based investigations should be utilized to explore underpowered signals generated by RCTs to provide justification for pursuing larger, and labor-intensive, prospective trial design efforts. Moving forward, we should emphasize the use of registry-based retrospective studies as adjuncts to prospective RCTs within surgical research, because each study design offers complimentary advantages. While RCTs isolate effects of interventions and minimize internal bias, registry-based trials offer population-based insight into real-world patterns that would otherwise be unfeasible without significant research infrastructure and support.

Conclusion

In a registry-based analysis of over 10,000 patients, robotic ventral hernia repair is associated with a decreased risk of bowel injury when compared to a laparoscopic approach. This suggests a potential role for the robotic platform in patients that may require extensive adhesiolysis and prefer a minimally invasive approach. Rates of rare events, such as bowel injury during minimally invasive ventral hernia repair, should be evaluated in large sample size registries to help interpret underpowered signals identified during prospective trials. The utilization of RCTs, and national

registries as adjuncts, is likely the ideal balance in surgical research.

Author contributions All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by JDT and SEP. The first draft of the manuscript was written by JDT and all authors commented on previous versions of the manuscript. Final manuscript was edited and prepared by CKG. All authors read and approved the final manuscript.

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Declarations

Conflict of interest Ajita S. Prabhu: intuitive research support and speaking honoraria, CMR surgical consulting fees, verb surgical consulting fees. Michael J. Rosen: receives salary support for his role as the medical director of the Americas Hernia Society Quality Collaborative; board member of Ariste Medical Inc. and has stocks from Ariste Medical; ongoing research grants from Pacira Pharmaceuticals and Intuitive Inc. David M. Krpata: received an educational grant from W.L. Gore. Aldo Fafaj: resident research grant from the Americas Hernia Society Quality Collaborative. None of these conflicts of interest are related to the submitted work. All other authors report no conflicts of interest.

Ethics approval This study received Institutional Review Board approval at our institution.

Human and animal rights and Informed consent Additionally, no animals were involved in any way in the conduct of the research.

Informed consent Since this is a retrospective study with minimal risk, the requirement for informed consent was waived as is standard for this kind of research.

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