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250 Robotic Pancreatic Resections: Safety and Feasibility

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Abstract

Background and Objectives—Computer Assisted Robotic Surgery allows complex resections and anastomotic reconstructions to be performed with nearly identical standards to open surgery. We applied this technology to a variety of pancreatic resections to assess the safety, feasibility, versatility and reliability of this technology.

Methods—A retrospective review of a prospective database of robotic pancreatic resections at a single institution between August 2008 and November 2012 was performed. Peri-operative outcomes were analyzed.

Results—250 consecutive robotic pancreatic resections were analyzed; pancreaticoduodenectomy (PD =132), distal pancreatectomy (DP=83), central pancreatectomy (CP=13), pancreatic enucleation (10), total pancreatectomy (TP=5), Appleby resection (4), and Frey procedure (3). Thirty day and 90 day mortality was 0.8 % and 2.0%. Rate of Clavien 3 and 4 complications was 14 and 6 %. The ISGPF grade C fistula rate was 4%. Mean operative time for the two most common procedures was 529 ± 103 mins for PD, and 257 ± 93 mins for DP. Continuous improvement in operative times was observed over the course of the experience. Conversion to open procedure was required in 16 patients (6%);(11 PD, 2 DP, 2 CP, 1 TP) for failure to progress (14) and bleeding (2).

Conclusions—This represents to our knowledge the largest series of robotic pancreatic resections. Safety and feasibility metrics including the low incidence of conversion support the robustness of this platform and suggest no unanticipated risks inherent to this new technology. By defining these early outcome metrics this report begins to establish a framework for comparative effectiveness studies of this platform.

Keywords

Robotic; Pancreatic; minimally invasive surgery; pancreatic cancer

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Introduction

Despite dramatic improvements in mortality following pancreatic surgery, morbidity remains substantial. Consequently, the therapeutic window remains quite small for many pancreatic procedures. Minimally invasive surgery has reduced the morbidity of many operative procedures and appears to have a similar potential in pancreatic surgery (1–6). However, despite nearly 20 years since its first description, laparoscopic pancreatic surgery has failed to reach the technological tipping point, and still remains feasible only in the hands of a few early adopters (7, 8). It is quite likely that the inherent limitations of laparoscopic technology have impaired its widespread adoption (9).

Robotics has emerged as both an alternative and adjunct to laparoscopic surgery. For several operations including prostatectomy and gynecologic procedures, modest data exists suggesting significant improvements in outcomes with robotics over laparoscopy (10, 11). However, others have failed to see significant advantages to the more costly robotic platform, especially for relatively straightforward ablative procedures (12, 13). Given the limitations of current laparoscopic technology and the need for meticulous vascular control as well as complex reconstruction in pancreatic surgery, we hypothesized that the computer assisted robotic platform would be particularly well suited for these procedures. We previously reported the safety of our early experience of complex pancreatic resections (14–18). We now report our experience with 250 consecutive robotic-assisted pancreatic resections. We evaluate the safety, feasibility, versatility and reliability of this platform in the hands of dedicated, high volume pancreatic surgeons. We conclude that this platform poses no unanticipated risks inherent to the new technology; early outcomes are equivalent to open and laparoscopic platforms; and considerable improvement in several performance metrics can be expected with more experience. By defining these early outcome metrics this report establishes a framework for more in depth studies on comparative effectiveness of the currently available platforms of open, laparoscopic and robotic pancreatic surgery.

Methods

A retrospective review of a prospectively maintained database on all robotic pancreatic procedures at the University of Pittsburgh was performed. Study procedures were approved by the University of Pittsburgh Institutional Review Board (approval #10090200). We reviewed all perioperative events occurring within 90 days of surgery. Details of the pancreatic remnant and the pancreatic anastomosis were recorded and classified by the criteria of the International Study Group of Pancreatic Surgery. All pancreatic fistulae, regardless of their clinical significance, were identified and classified by the International Study Group on Pancreatic Fistula (ISGPF) criteria (19). All postoperative complications were graded according to the Clavien–Dindo classification (20).

Statistical analysis was performed using STATA-10 (College Station, TX). Distributional characteristics for each outcome variable were checked for normalcy. Data are represented as means ± standard deviation or median and interquartile range (IQR) as appropriate. P-values <0.05 were considered significant. Student's t-test was used to compare normally

distributed variables between groups, and the Wilcoxon rank-sum test was used for non-normally distributed variables. The chi-square or Fisher's exact test was used to compare categorical variables between groups, as appropriate. To test improvements over time, we used Spearman's rank correlation obtaining correlation coefficient (rho) and related p values.

Results

All procedures were performed in a purely minimally invasive fashion. All operations were initiated laparoscopically, with minimal laparoscopic dissection performed to allow exposure of the retorpertioneum,, and placement of laparoscopic retractors prior to docking the robot. For example, in a robotic pancreaticoduodenectomy (PD), laparoscopy is limited to the following steps: entry into the lesser sac, mobilization of the right colon, kocher maneuver, division of the antrum/or duodenum and division of the proximal jejunum. The remainder of the resection and all of the reconstruction is performed with the robotic platform. For the distal and central pancreatectomy (DP and CP) for example, the robot is docked immediately after laparoscopic exploration and entrance into the lesser sac. Accordingly, the term 'conversion' is used to describe a conversion to a laparotomy after the robot was docked

Types of procedures

We identified 250 consecutive robotic pancreatic resections performed between January 2008 and December of 2012. They included 132 pancreaticoduodenctomies (PD), 83 distal pancreatectomies (DP), 13 central pancreatectomies (CP), 10 enculeations, 5 total pancreatectomies (TP), 4 Appleby procedures, and 3 Frey procedures.

Demographics

The demographics of the cohort are reported in Table 1. Median age was 65 (18–90). Forty-nine percent were male and median BMI was 27.1 with 38 percent having BMI in the obese to super obese range. Fifty-two percent of the subjects had previous surgery. The median Charleston Co-morbidity Index (CCI) score was 4. A majority of the resections were performed for malignancy (71%): pancreatic ductal adenocarcinoma (PDA) 31%, pancreatic neuroendocrine (NET) 23% and duodenal/bile duct/ampullary cancers 17%. Twenty-one percent of the resections were for pre malignant lesions including IPMN and MCN. Eight percent were for benign lesions of the pancreas. For the PD group, 106 (80.3%) cases were performed for malignant pathology (PDA= 54, periampullary= 39, NET=39, metastatic renal cell ca= 1), 20 for premalignant lesions, and 6 for benign disease. In the DP cohort, 60 (72.3%) were performed for malignancy (PDA=22, NET= 34, metastatic lesions= 4), 17 for premalignant, and 6 for benign pathology.

Metrics of Safety

Overall 30 day and 90 day mortality was 0.8 and 2% (Table 2). Mortality was observed only in the cohort of patients undergoing pancreaticoduodenectomy, with two (1.5%) thirty-day mortalities and five (3.8%) ninety-day mortalities. Mortalities were evenly distributed throughout the experience and not clustered in the early cases. Causes of thirty day mortality

were: 1) Case 56: rapid onset of sepsis and multi-system organ failure in a fifty-five year old male with BMI 48; and 2) Case 85: post operative myocardial infarction leading to cardiac arrest in an eighty year old women whose procedure was converted to open early. Causes of 90 day mortality were: 1) Case 7: sepsis, multi-system organ failure from biliary and pancreatic leak in setting of postoperative small bowel obstruction and failure to thrive. 2) Case 87: respiratory failure in setting of leak from G-tube requiring re-operation in an 82 year old male. 3) Case 113: Respiratory failure, withdrawal of care in nursing facility in a patient status post successful repair of GDA pseudo aneurysm.

Post-operative complications classified by the Clavien-Dindo schema are presented in Table 2. Incidence of clinically significant complications (grade 3 and 4) was 21% for PD, 13% for DP, 23% for CP, 30% for enucleation, 20% for TP, 100% for Appleby and 33% for Frey procedure. Table 3 depicts the most common complications for the entire cohort 250 patients. In examining the PD cohort there was a statistical significant trend towards decreased major complications (Grade 3–5) in the last 40 cases 27/88 (30%) versus 6/44 (16 %) $p<0.05$ (Figure 1).

Median estimated blood loss ranged from 50–300 ml for all the procedures with the exception of total pancreatectomy (1000 ml) (Figure 2). Eleven percent of the patients required intraoperative transfusion.

There were 2 Clavien- Dindo grade 3–4 bleeding events as follows: DP #61: pancreatic staple line bleed, required take back to OR (Clavien 3-resolved), and PD #102: upper GI bleed secondary to esophagitis/coagulopathy (Clavien 4-resolved). There were 8 pseudoaneurysms (PSA) all of which occurred in the PD cohort (6%). Three of those manifested as post pancreatectomy hemorrhage (PPH): PD #1: GDA stump bleed, required take back to OR (Clavien 4-resolved), PD #75: GDA pseudoaneurysm, stented (Clavien 4-resolved), PD # 77: Hepatic artery bleed, stented (Clavien 4-resolved), In addition there were 5 events listed as pseudoaneurysm where the patient did not experience significant bleeding but aggressive use of arteriography revealed possible PSA.

Pancreatic fistula occurred in 76 subjects (30%) (Table 4). Nearly half of these (47%) were type A leaks. Thirty (40%) were type B leaks requiring prolonged drainage. The overall incidence of type C leaks requiring major intervention was 13% (n=10). All grade C leaks (3.7%) occurred in the PD and DP cohorts, except one in the CP cohort. The clinically significant leak rate (Grades B and C) following pancreaticoduodenectomy was 7.4 %.

Metrics of Feasibility

Operative times, conversion rates and re-operations are listed for each of the procedures in Table 5. The longest operative times were noted for those procedures requiring reconstruction: pancreaticoduodenectomies took a median time of 527 minutes +/−103 and total pancreatectomies took a median time of 504 minutes +/− 113. The ablative procedures were markedly shorter with distal pancreatectomies exhibiting a median time of 256 +/− 93 min and enucleations being the shortest at 204 +/− 67 minutes. Significant improvement in operative times for the two most common procedures PD and DP was noted over the course of the experience (Figure 3).

Conversion to open procedure was required in sixteen cases (6%): PD (11) DP (2), CP (2) and TP (1) (Table 4). Fourteen conversions were due to failure to progress, while 2 were for bleeding. A majority of the conversions were in the first 30 cases of the experience. Conversion rates for the most complex procedure PD improved to 3.8% for the last 116 cases.

Re-operation was required in 4 PDs (gastroduodenal artery pseudoaneurysm, leak from gastric staple line, leak from gastric tube site, and small bowel obstruction). One patient with DP had postoperative bleeding from the pancreatic staple line requiring reoperation and one patient required tracheostomy for prolonged ventilator dependence following central pancreatecomy.

In the PD cohort, 80.3% cases were performed for malignancy; an R0 resection rate of 87.7 % was observed (93 out of 106) with a median lymph node harvest of 19 (range 4–61). In the DP cohort, 72 % of cases were performed for malignant pathology, 97% of which had margin negative resections (58 out of 60), with a median lymph node count of 14

Versatility and Reliability

We examined the utilization of the three available operative technologies (open, laparoscopic and robotic) at our institution over the study time period (Figure 4). We observed a consistent trend towards an increased utilization of the robotic platform, such that robotics surpassed laparoscopic procedures in 2009. In 2012 the robotic platform was used for more than 50% of all pancreatic resections at our institution.

Discussion

The adoption of new surgical technology is a complex and poorly characterized phenomenon (8). Randomized trials are rarely feasible due to the inability to blind observers and patients to the type of procedure and the lack of necessary equipoise for informed consent. As a result, the majority of new technologies are adopted based on results of large single and multi-institutional retrospective experiences. As a group of experienced pancreatic surgeons we began a dedicated prospective effort to evaluate the safety, feasibility, reliability and versatility of the computer assisted robotic platform in 2008. This effort was largely driven by early results suggesting that minimally invasive surgery could reduce the substantial morbidity associated with pancreatic resections, and our perception that shortcomings in the laparoscopic technology will prevent widespread adoption of this platform when applied to pancreatic surgery.

One of the most significant advances in pancreatic surgery over the last thirty years has been the dramatic improvement in mortality (21). The overall 30-day mortality in our series was 0.8 % for all 250 resections. Mortality was only observed in the cohort of subjects undergoing PD (30 day mortality: 1.5%). This incidence is well within the confidence limits of current published open and laparoscopic series of PD. More recent reports suggest that a more accurate reflection of the true stress of pancreatic resection is the 90-day mortality. The few reports that have documented 90-day mortality place it between 3 and 5% (22, 23). Our series compares favorably with a 90-day mortality of 3.8 %. This experience suggests that computer assisted minimally invasive technology, when applied by a team of proficient

pancreatic surgeons, does not demonstrate unforeseen risks that place subjects at greater risk of mortality.

Despite improvements in pancreatic surgery mortality, morbidity rates remain considerable even in the highest volume centers. We examined the morbidity associated with robotic assisted pancreatic resections by the rigorous Clavien-Dindo scoring system (20, 24, 25). The frequency and characteristics of the complications observed with the robotic platform did not dramatically differ from most large series of open and laparoscopic pancreatic resections (24–26). We did not identify any new or previously unrecognized complications directly as a result of the use of the robotic platform. Our initial concerns about lack of haptic feedback have been circumvented by its substitution with the enhanced visualization and magnification afforded by the robotic camera. Importantly the rate of clinically significant Grade 3 and 4 complications (10% and 11% respectively) in the cohort undergoing pancreaticoduodenectomy, was comparable to those reported in 633 open PD from several high volume centers (25). Encouragingly, we did observe over the course of the experience a statistically significant decline in these complications. Future studies will focus on this more mature experience with propensity ranked comparisons of robotic, laparoscopic and open technologies in order to ascertain if the minimally invasive approach can decrease the morbidity of these procedures.

The principle morbidity in nearly all pancreatic resections is the development of a pancreatic fistula. Rates of pancreatic fistula are highest in the distal pancreatectomy with a recent randomized trial suggesting the incidence approaches 40% when critically evaluated prospectively by ISGPF guidelines (27). Indeed, in our series 43 % of DP had a pancreatic fistula, however the majority of these (61%) were clinically insignificant Grade A leaks. As has been reported (27), there did not appear to be a difference in PF rates between oversewing and stapling in our cohort of robotic DP (data not shown.) Fistula rates following open pancreaticoduoectomy when evaluated by ISGPF criteria have been reported to be between 10 and 20% (28–32). Rates of clinically significant Grade C leaks are reported to be between 1–5%. Our incidence of all Grade C fistulas is within the confidence intervals of these studies (28). This data suggests that use of computer assisted robotic surgery is not associated with any unanticipated rise in pancreatic fistula rates. We did observe a trend towards improvements in clinically significant fistula rates in the PD cohort with experience, however given the low incidence of leaks it will require an additional 200 cases to for this improvement to reach statistical significance.

Next, we examined several metrics of feasibility including operative time and conversion rate. Despite long operative times early in our experience, we observed significant improvement over the course of 4 years. Currently, the median time to complete a pancreaticoduodenctomy in the last 50 cases is 360 minutes (approximate breakdown: laparoscopic mobilization =60–90 mins, robot docking =5 mins, robotic resection =120 mins, robotic reconstruction =120 mins). This compares very favorably to published series of laparoscopic pancreaticoduodenectomy (2). Moreover these times are approaching those reported for open pancreaticoduodenectomy by several high volume centers over the last decade (33, 34). Similarly for distal pancreatectomies, the mean operative time has significantly improved, with OR times now equivalent to laparoscopic and open series (2). It

is likely that we have reached peak efficiency with regards to operative time. However, new refinements in the robotic platform including energy and stapling devices are expected in the coming years, raising the possibility of additional improvement in surgical times. Another metric of feasibility, conversion rate, was quite low for the entire series (6%). Most of the conversions were in the PD cohort (11%) and occurred more frequently in the first 20 patients. The rate of conversion in the last 112 PD cases is 4.5 percent. This conversion rate is equivalent or lower than the conversion rate for early series of laparoscopic PD (1,3,9,35). In addition, we have previously reported that one of the advantages of the robotic platform for distal pancreatectomy is the low conversion rate when compared to laparoscopic procedures (17). The current updated series of distal pancreatectomies continues to support this observation with an overall conversion rate of 2%, which is substantially lower than most major series of laparoscopic distal pancreatectomy (2). This emphasizes one of the advantages of the robotic platform; improved visualization and dexterity allows for more complex cases to be completed by minimally invasive approach. Future studies comparing robotic and laparoscopic approaches should be designed to further explore these differences.

As our experience with this technology has matured, we have observed several interesting points with regard to its utilization. First, we are able to apply the technology successfully to nearly every type of pancreatic resection that can be performed, including the technically challenging Appleby resection, PD and total pancreatectomy. Next, when examining utilization we observed that the robotic platform replaced laparoscopy as our preferred minimally invasive technique.

We have not endeavored in this initial experience to answer many critical questions regarding comparative effectiveness of computer assisted robotic surgery versus laparoscopic and open approaches. We certainly recognize the importance of these studies given the current economic pressures on the health care market. Our decision not to perform these correlative studies is supported by our findings demonstrating substantial refinement in multiple important metrics over the course of this experience including conversion rate, operating room times and complications. Meaningful comparison of two different surgical approaches mandates that each approach be at or near its plateau phase. Our work begins to establish the benchmark for computer assisted robotic assisted pancreatic surgery and lays the framework for important comparative effectiveness studies.

In conclusion, we report here our experience over the last four years with 250 robotic pancreatic resections. We conclude that this technology demonstrates similar safety and feasibility profiles to the laparoscopic and open platforms. Moreover the technology is robust allowing completion of a wide diversity of cases. Further research to evaluating comparative effectiveness of minimally invasive platforms and open surgery are now required.

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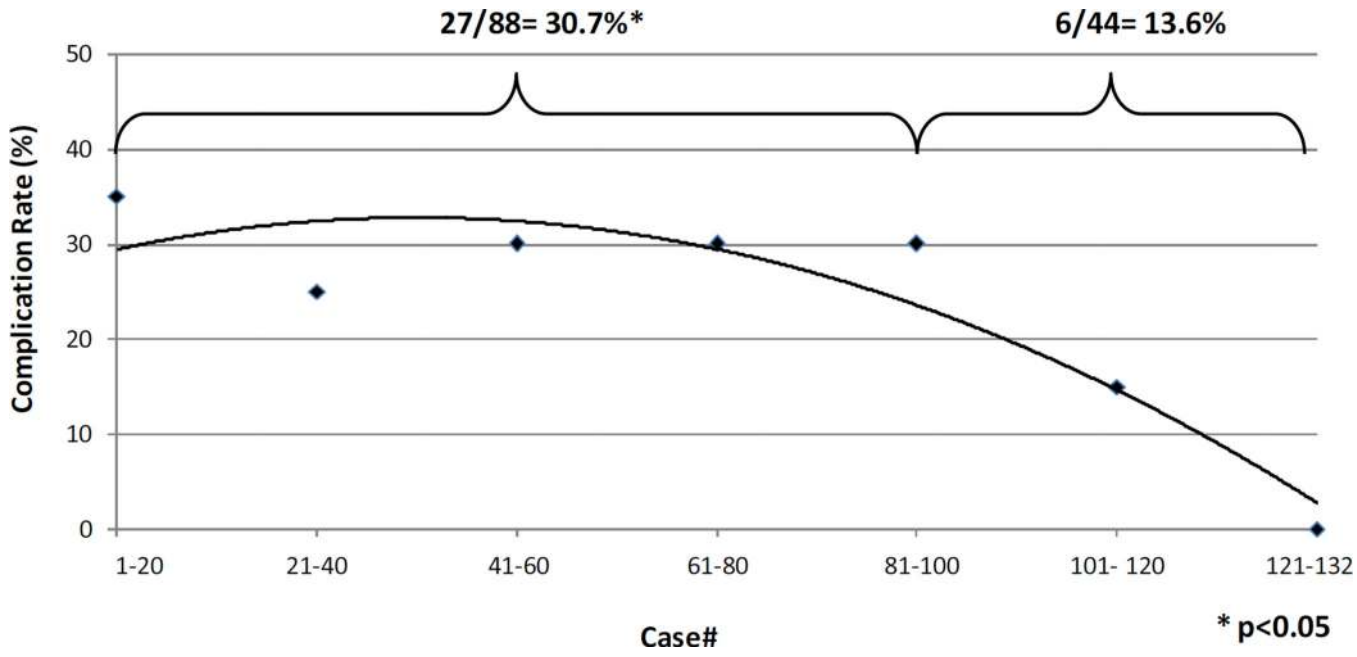

Figure 1.
Rate of Clavien-Dindo grade 3–5 complications following robotic pancreaticoduodenectomy improves with experience

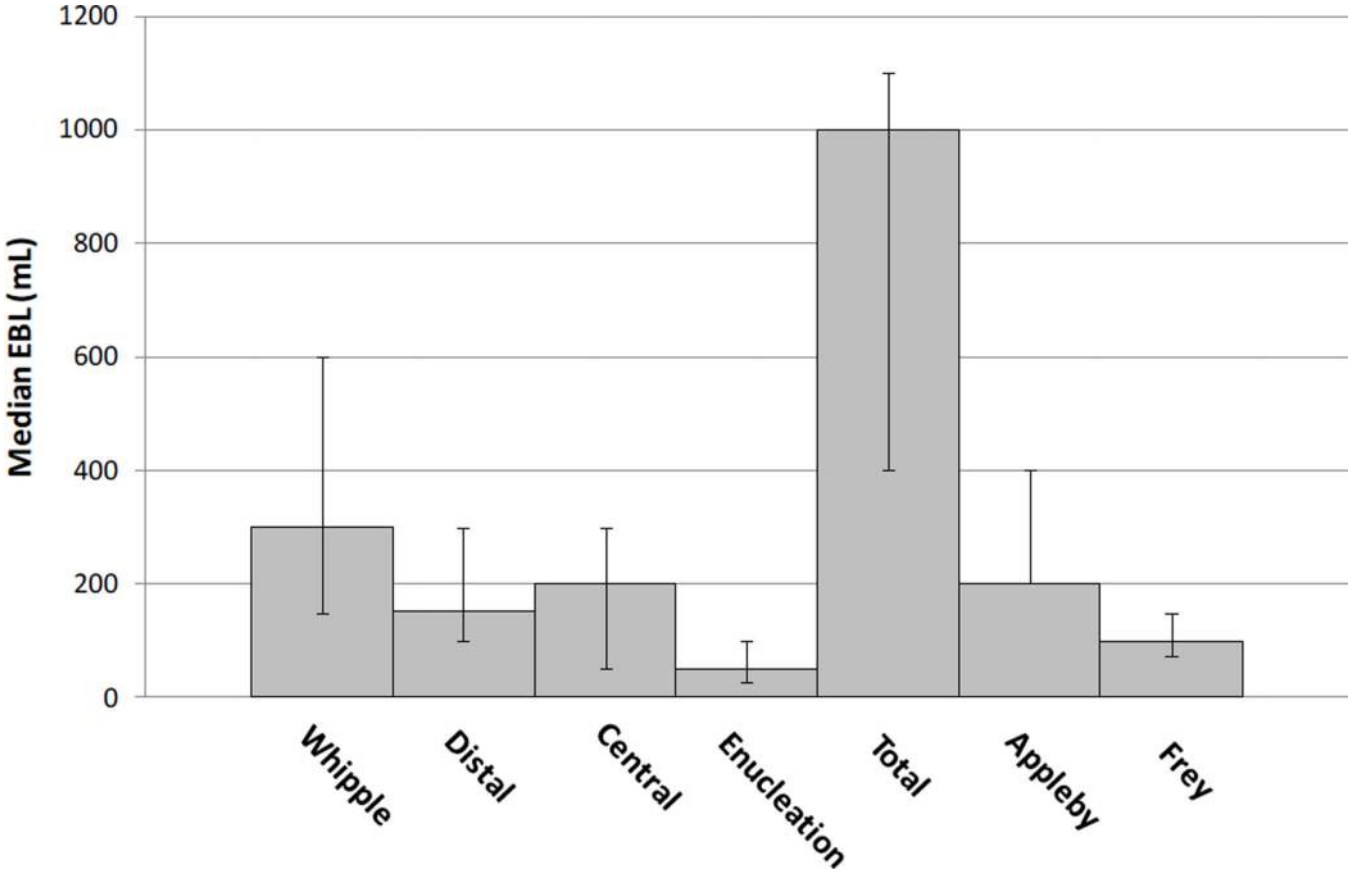

Figure 2.
Median estimated blood loss over 250 robotic pancreatic resections. Error bars represent interquartile range.

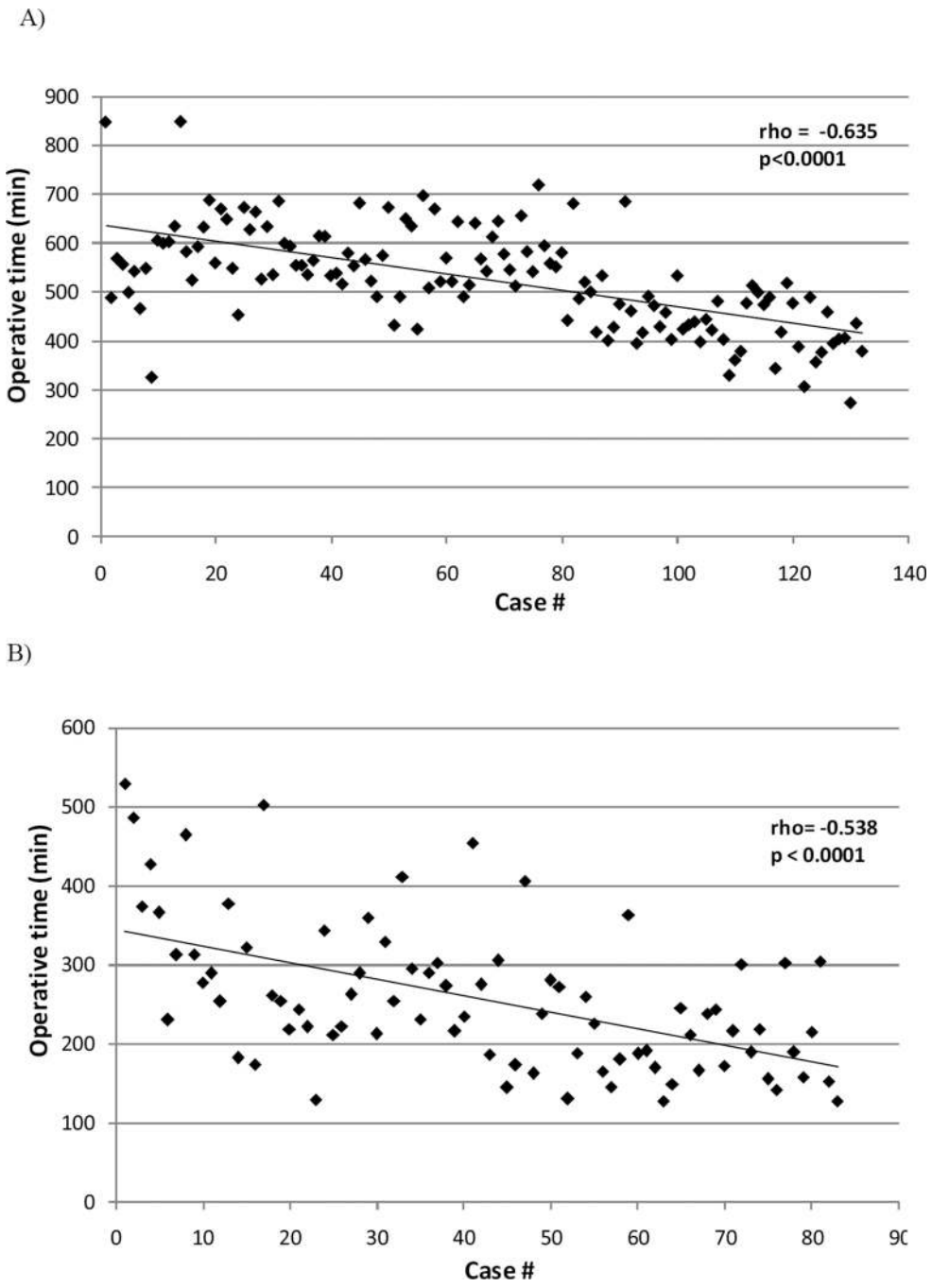

Figure 3.
Operative times over course of experience for robotic a) PD and b) DP.

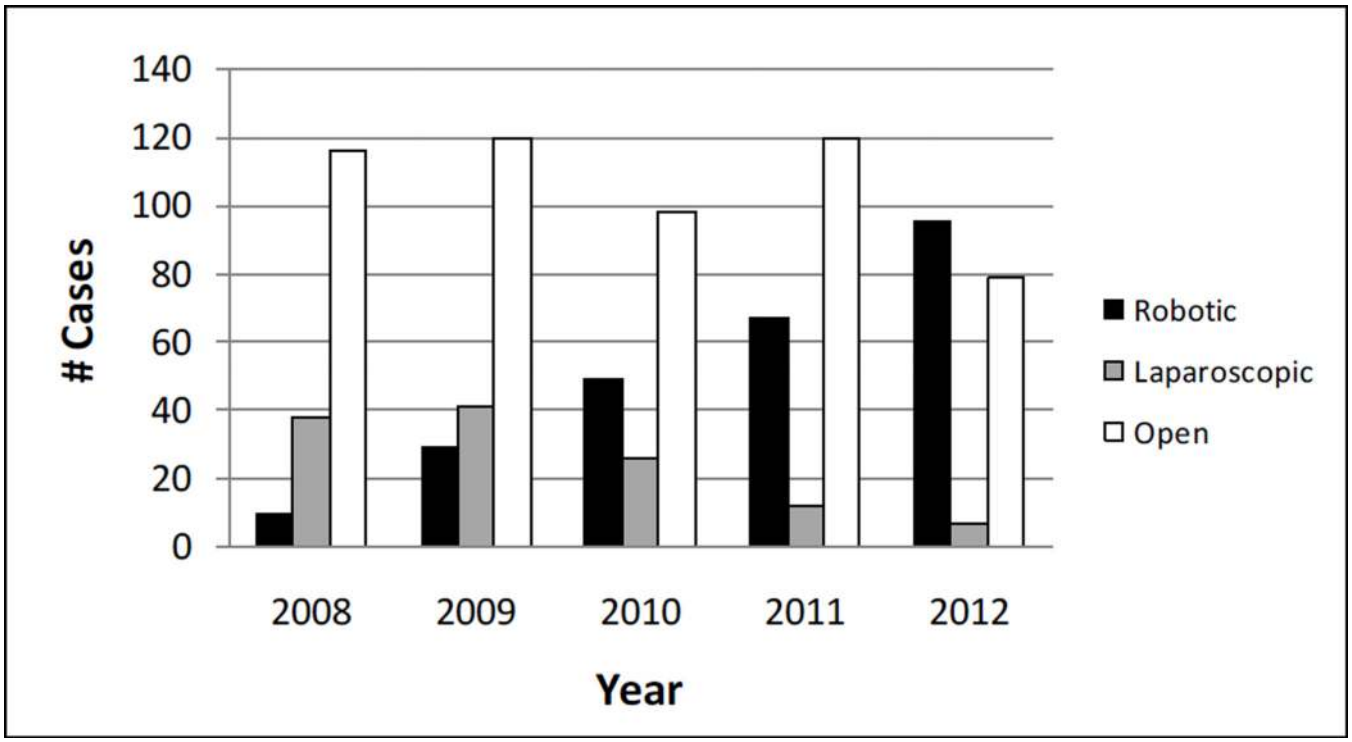

Figure 4.
Utilization of robotic technology for pancreatic resections at UPMC from 2008–2012

Table 1

Demographics of patients undergoing robotic assisted pancreatic resection

Patient Demographics	
Age	
Median (Range)	65 (18–90)
Gender, n(%)	
Male	122 (49%)
Female	128 (51%)
BMI, Median (Range)	27.5 (16–56)
< 20	13 (5%)
20–30	75 (30%)
31–40	84 (34%)
> 40	10 (4%)
Prior Surgery, n (%)	129 (52%)
ASA score, n (%)	
2	79 (32%)
3	161 (64%)
4	10 (4%)
Age Adjusted CCI, median (range)	4 (0–13)
0	51 (20%)
1–3	55 (22%)
4–6	105 (42%)
≥7	39 (16%)

Table 2

Morbidity and Mortality following robot assisted pancreatic resection

	Entire Cohort	Whipple	Distal	Central	Enucleation	Total	Appleby	Frey
	n=250	n=132	n=83	n=13	n=10	n=5	n=4	n=3
Mortality, 30-day, n(%)	2 (0.8%)	2 (1.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Mortality, 90-day, n(%)	5 (2.0%)	5 (3.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Morbidity, n(%)								
Grade I	39 (15%)	15 (11%)	14 (17%)	5 (38%)	1 (10%)	3 (60%)	0 (0%)	1 (33%)
Grade II	85 (34%)	40 (30%)	35 (42%)	5 (38%)	1 (10%)	1 (20%)	0 (0%)	1 (33%)
Grade III	34 (14%)	13 (10%)	11 (13%)	3 (23%)	3 (30%)	1 (20%)	2 (50%)	1 (33%)
Grade IV	15 (6%)	15 (11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (50%)	0 (0%)

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Table 3

Clavien-Dindo Grad 3–5 complications following robotic assisted pancreatic resections. n=54

Major Complications (Grade 3–5)	
Anastamotic leak	
Biliary	1 (2%)
Gastric	3 (6%)
Bleeding*	2 (3.7%)
Delayed gastric emptying	3 (6%)
Fascial dehiscence	1 (2%)
Fluid collection**	20 (38%)
Gastric ischemia	2 (4%)
Myocardial infarction	1 (2%)
Multi-system organ failure	6 (11%)
ERCP/stent for pancreatic leak	1 (2%)
Pleural effusion	1 (2%)
Pulmonary embolism	2 (4%)
Pseudoaneurysm¥	8 (14.8%)
Respiratory failure	1 (2%)
Small bowel obstruction	2 (4%)

* DP #61: pancreatic staple line bleed, required take back to OR. Clavien 3. Resolved. PD # 102: Upper GI bleed due to esophagitis/coagulopathy. Clavien 4. Resolved

** Needing percutaneous drainage: 10 amylase rich (already included as panc leaks in table 4), 8 non amylase rich abscesses, 2 hematomas

¥ All pseudoaneurysms occurred in the PD group (8/132 = 6%): 3 of which manifested as post pancreatectomy hemorrhage (PPH)

PD (pancreaticoduodenctomy), DP (distal pancreatectomy),

Table 4

Incidence of pancreatic leak following robotic assisted pancreatic resection

	Entire Cohort n=250	Whipple n=132	Distal n=83	Central n=13	Enucleation n=10	Total n=5	Appleby n=4	Frey n=3
Pancreatic Leak, n (%)	76 (30%)	22 (17%)	36 (43%)	12 (92%)	3 (30%)	0 (0%)	3 (75%)	1 (33%)
Grade A	36 (14%)	12 (9%)	22 (27%)	2 (15%)	1 (10%)	0 (0%)	0(0%)	0 (0%)
Grade B	30 (12%)	5 (3.7%)	10 (12%)	9 (69%)	2 (20%)	0 (0%)	3 (75%)	1 (33%)
Grade C	10 (4%)	5 (3.7%)	4 (4.8%)	1 (8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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Table 5

Operative outcomes following robotic assisted pancreatic resections

	Entire Cohort n=250	Whipple n=132	Distal n=83	Central n=13	Enucleation n=10	Total n=5	Appleby n=4	Frey n=3
Operative time (min)								
Mean ± SD	413 ± 164	527 ± 103	256 ± 93	394 ± 92	206 ± 67	503 ± 114	371 ± 62	441 ± 227
Conversion, n (%)	16 (6%)	11 (8%)	2 (2%)	2 (15%)	0 (0%)	1 (20%)	0 (0%)	0 (0%)
Reoperation, n(%)	6 (2%)	4 (3%)	1 (1%)	1 (8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
LOS*, d (range)	8 (3–87)	10 (4–87)	6 (4–12)	8 (6–19)	5 (3–12)	10 (7–18)	9 (6–14)	6 (5–9)
Readmission, n(%)	79 (32%)	38 (28%)	26 (31%)	6 (46%)	3 (30%)	1 (20%)	4 (100%)	1 (33%)

* LOS (Length of stay, days)