Systematic review of operative outcomes of robotic surgical procedures performed with endoscopic linear staplers or robotic staplers

Mario Gutierrez1 · Richard Ditto1 · Sanjoy Roy1

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Abstract
A comprehensive review of operative outcomes of robotic surgical procedures performed with the da Vinci robotic system using either endoscopic linear staplers (ELS) or robotic staplers is not available in the published literature. We conducted a literature search to identify publications of robotic surgical procedures in all specialties performed with either ELS or robotic staplers. Twenty-nine manuscripts and six abstracts with relevant information on operative outcomes published from January 2011 to September 2017 were identified. Given the relatively recent market release of robotic staplers in 2014, comparative perioperative clinical outcomes data on the performance of ELS vs. robotic staplers in robotic surgery is very sparse in the published literature. Only three comparative studies of surgeries with the da Vinci robotic system plus ELS vs. da Vinci plus robotic staplers were identified; two in robotic colorectal surgery and the other in robotic gastric bypass surgery. These comparative studies illustrate some nuances in device design and usability, which may impact outcomes and cost, and therefore may be important to consider when selecting the appropriate stapling technologies/technique for different robotic surgeries. Comparative perioperative data on the use of ELS vs. robotic staplers in robotic surgery is scarce (three studies), and current literature identifies both types of devices as safe and effective. Given the longer clinical history of ELS and its relatively more robust evidence base, there may be trade-offs to consider before switching to robotic staplers in certain robotic procedures. However, this literature review may serve as an initial reference for future research.

Keywords Robotic surgical procedures · Surgical staplers · Surgical stapling · Colorectal surgery · Gastric bypass

Introduction
Stapling is a critical step during many surgical procedures involving the transection of vessels as well as other types of tissue—irrespective of the surgical approach. Staple line integrity is critical to creating a functional anastomosis or a clean transection and has been the focus of continuing innovation by surgical stapler manufacturers [1]. Staple line failure resulting in postoperative leaks is one of the most serious and feared complications for any surgery. Technical aspects of stapling may vary and factors such as anatomical location, tissue viscosity, staple height, and other intrinsic properties of the stapling system itself may substantially influence appropriate staple line formation [2]. Many studies acknowledge that surgeon experience is critical in creating an anastomosis with sufficient staple line integrity to resist leakage and promote healing [3–5].

In most robotic surgical procedures performed in the last decade, the portion of the procedure requiring tissue stapling has been performed by a bedside surgeon/assistant using conventional endoscopic linear staplers (ELS). Starting from the initial mechanically actuated devices, innovation in endoscopic stapling technology has introduced powered devices (available since 2010), which utilize a motor for both staple firing and knife blade action.

In late 2014, Intuitive Surgical (Sunnyvale, CA, USA) received United States Food and Drug Administration (FDA) clearance for the EndoWrist Xi® stapler (referred to as the EndoWrist Stapling System-EWSS) compatible with the da Vinci Xi Surgical System, which offered the first integrated stapling option for the da Vinci robotic system. This newly integrated stapler allows for the entire procedure to be completed by the console surgeon. Since then, Intuitive Surgical
has implemented some voluntary recalls and product corrections [6]. Of the 26 Intuitive Surgical EndoWrist Class 2 product recalls documented in the FDA database, 16 (62%) involve the EWSS [6]. These device recalls suggest that transitioning from ELS to robot-integrated staplers may involve some trade-offs that should be considered before transitioning from ELS to totally robot-integrated staplers. We carried out a review of the literature to assess and summarize reports of operative outcomes of stapled robotic surgical procedures, so that it may serve as a reference for future outcome comparisons of procedures performed with these stapling devices.

Methods

A systematic literature search of Ovid Embase/Medline, PubMed, and QUOSA was conducted for reports on the topic of robotic surgical procedures performed using ELS published between January 1, 2004 and March 13, 2017. Search keywords included, but were not limited to: robot (and variations like robotic surgery, robot-assisted surgery, robotic surgery), da Vinci (with variations), laparoscopic (with variations), and Echelon, EndoPath, Endo GIA, EndoWrist, stapler (with variations), surgical stapling, endoscopic stapler, linear stapler, flex stapler, endocutter (with variations), endostapler, Ethicon, Covidien, Intuitive. Duplicate publications and preclinical (animal and bench testing) publications were removed. Two investigators reviewed and screened the abstracts of identified studies for relevance and potential inclusion in the review. Pertinent human studies, restricted to the English language were selected for full paper review. Studies were excluded if they did not use stapling during the robotic surgical procedure (e.g., suturing), used a circular stapler only, or if the stapler or robotic system used in the surgical procedure was not specified. Only reports on da Vinci robotic surgical procedures performed using Echelon Flex™ staplers (Ethicon, Johnson & Johnson, New Brunswick, NJ) or the Endo GIA™ staplers (Covidien, Mansfield, MA) and/or EndoWrist Xi® robotic staplers (Intuitive Surgical, Sunnyvale, CA, USA) were selected for inclusion in this review. The literature search was completed on March 21, 2017 and a weekly alert was set up on QUOSA for relevant key words to continue to identify reports throughout 2017 (referred to here as the manual search).

Results of the literature search

There were 239 total publications (94 manuscripts and 146 abstracts) identified with potentially relevant information. From the systematic search, 27 manuscripts and 2 abstracts were identified with information directly relevant to this review. Three manuscripts and four abstracts, which were additionally identified from the manual search performed between March 21, 2017 and January 30, 2018, were also included in this review. Thus, the total number of studies included in this review was 36 [7–42]. Figure 1 shows the process of publication selection. The perioperative outcomes reported in the studies are presented in Table 1.
| Study | Surgical procedure and study population | Clinical outcomes |
|-------|----------------------------------------|------------------|
| da Vinci robotic surgical procedures performed with ELS vs. EWSS (studies: n=3) |  |  |
| Hagen et al. [7] Robotic gastric bypass performed with Echelon ELS (49 patients) vs. EWSS (49 patients); January 2015 to July 2016; U.S. | ELS Operative time: 194 min, (p = 0.104) Intraoperative complications: 0, (p = 0.495) Recharges needed to complete gastric pouch: 4.1, (p = 0.005) Stapling costs: $1787, (p < 0.001) | EWSS Operative time: 216 min Stapler clamping unsuccessful: 19% Intraoperative complications: 2, with 1 being stapling related Recharges needed to complete gastric pouch: 4.9 Stapling costs: $2212 |
| Holzmacher et al. [8] Colorectal robotic surgeries performed with ELS (58 patients) vs. EWSS (35 patients); 2012 to 2014; U.S. Note: The ELS used in robotic surgery were not further defined with the manufacturer | ELS Operative time: 264 min (p = 0.769) Hospital length of stay: 4.3 days (p = 0.895) All complications: 10 (p = 0.778) Bleeding: 1 (p = 0.554) Anastomotic leak: 6 (p = 0.705) Staple fires per patient: 2.7 (p = 0.001) Stapler cost: $631 per patient (p = 0.001) | EWSS Operative time median: 270 min Hospital length of stay: 4.4 days All complications: 5 Bleeding: 2 Anastomotic leak: 1 Staple fires per patient: 1.9 Stapler cost: $473 per patient |
| Atasoy et al. [9] Rectal transection in robotic surgery for cancer with ELS (62 patients) vs. EWSS (45 patients); December 2014 to April 2017; Turkey; The ELS used in robotic surgery was either the Ethicon Echelon Endopath or Covidien Endo GIA Roticator, but counts of each ELS utilization were not identified | ELS Staple fires per patient: 2 (p = 0.58) Overall complication rate: 24% (p = 0.32) Anastomotic leak rate: 3% (n = 2) (p = 1) | EWSS Staple fires per patient: 2 Overall complication rate: 31% Anastomotic leak rate: 5% (n = 2) |
| da Vinci robotic surgical procedures performed with echelon ELS (studies: n = 18) Abdominal surgical procedures (study n = 8) |  |  |
| Study                        | Surgical procedure and study population | Clinical outcomes |
|-----------------------------|-----------------------------------------|-------------------|
| Smeenk et al. [10]          | Robotic gastric bypass (RGB) with ELS (100 patients) vs. laparoscopic gastric bypass (LGB) with manual stapler device (100 patients); November 2011 to January 2013; Netherlands | RGB: Operative room time: 117 min, Median hospital stay: 2 days, Staple defect: 1%, Staple line bleeding: 2%, Surgery-related morbidity: 5%, Major morbidity: 3%, No mortality |
| Myers et al. [11]           | Robotic gastric bypass (RGB, 100 patients) vs. laparoscopic (LGB, 100 patients); October 2009 to September 2011; U.S. | RGB: Operative time: 144 min, Hospital length of stay: 37 h, Readmissions: 3 patients, No conversions, No mortality |
| Kosanovic et al. [12]       | Robotic sleeve gastrectomy (RSG, 134 patients) vs. robotic gastric bypass (RGB, 165 patients); 2009 to 2012; U.S. | RSG: Operative time: 107.1 min, Hospital length of stay: 2.3 days, Bleeding: 0.7%, No leaks, Perioperative complications: 2.2% |
| Ijah et al. [13]            | Robotic sleeve gastrectomy (RSG, 20 patients) vs. laparoscopic sleeve gastrectomy (LSG, 20 patients); October 2011 to October 2012; Nigeria & India | RSG: Operative time: 153 min, Hospital stay: 3.9 days, Significant complications: 5% |
| Vilallonga et al. [14]      | Robotic sleeve gastrectomy (RSG, 100 patients) vs. laparoscopic sleeve gastrectomy (LSG, 100 patients); September 2006 to November 2012; Spain | RSG: Operative time: 108 min, Hospital length of stay: 4 days, Bleeding: 2%, Leak rate: 3%, No perioperative complications, No conversions, No mortality |
| Diamantis et al. [15]       | Sleeve gastrectomy; case series of 19 patients; Greece | Single arm study, Operative time: 95.5 min, No hemorrhage or leakage from staple line, No perioperative morbidity, No mortality |
| Study                  | Surgical procedure and study population                                                                 | Clinical outcomes                                      |
|-----------------------|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| Vilallonga et al. [16] | Anastomosis duodenoileal bypass; case series of 3 patients; Spain                                       | Single arm study<br>Operative times: 124 min, 174 min, 138 min<br>Hospital length of stay: 2 days<br>No perioperative complications in 30 days<br>No conversions<br>No mortality |
| Dogra et al. [17]     | Laparoscopic augmentation ileocystoplasty; case report of 1 male patient; India                          | Case report<br>Operative time: 420 min<br>Estimated blood loss: 200 mL<br>Hospital length of stay: 6 days |
| Liver surgical procedures (study n = 2) |                                                                                                         |                                                        |
| Xu et al. [18]        | Resection for hilar cholangiocarcinoma, case series that compared 10 patients with robotic surgery to 32 patients with open surgery; May 2009 to October 2012; China | Robotic surgery<br>Operative time: 703 min<br>Blood loss: 1360 mL<br>Blood transfusion: 60%<br>Complications: 90%<br>Major morbidity: 30%<br>Hospital stay: 16 days<br>Mortality: 10%<br>Open surgery<br>Operative time: 475 min<br>Blood loss: 1014 mL<br>Blood transfusion: 53%<br>Complications: 50%<br>Major morbidity: 16%<br>Hospital stay: 14 days<br>Mortality: 6% |
| Calin et al. [19]     | Resection for liver metastasis; case report of 1 female patient; U.S.                                    | Case report<br>Operative time: 369 min<br>Estimated blood loss: 100 mL<br>Hospital stay: 4 days |
| Colorectal surgical procedures (study n = 5) |                                                                                                         |                                                        |
| Morelli et al. [20]   | Intersphincteric resection with (15 patients) and without double-stapling (15 patients); April 2010 to December 2014; Italy | Single arm study<br>Low postoperative complications for both procedures |
| Bae et al. [21]       | Anterior resection for colon cancer; case series of 11 patients; August 2014 to December 2014; Korea     | Single arm study<br>Operative time: 289 min<br>Mean proximal and distal resection margins were 7.8 and 4.7 cm<br>Hospital length of stay: 11.1 days<br>Postoperative complications: 36.4%<br>Surgical site infections: 2 patients<br>No anastomotic leakage<br>No conversions<br>No mortality |
| Study | Surgical procedure and study population | Clinical outcomes |
|-------|----------------------------------------|------------------|
| Morelli et al. [22] | Surgery for endometriosis with colorectal involvement; 10 patients; January 2011 to December 2013; Italy | Single arm study  
Operative time median: 280 min  
Hospital length of stay: 6 days  
Estimated blood loss: 200 mL  
No significant postoperative complications  
No conversions |
| Leong et al. [23] | Low anterior resection; case report of 1 female patient; Korea | Case report  
Operative time: 215 min  
Blood loss: <50 mL  
Hospital length of stay: 6 days  
No complications (i.e., uneventful postoperative course) |
| Trastulli et al. [24] | Surgery for colon cancer; case series of 20 patients; June 2011 to May 2012; Italy | Single arm study  
Operative time: 327.5 min  
Hospital length of stay: 4.5 days  
Blood loss: 55 mL  
No anastomotic leaks  
1 infection complication  
No conversions  
No mortality |
| Thoracic surgical procedures (study n = 1) | | |
| Rinieri et al. [25] | Robotic surgery with Echelon stapler or sutures (16 patients) vs. video-assisted thoracic surgery (VATS) with Endo GIA stapler (32 patients); April 2010 to June 2014; France | Robotic  
Operative time: 140 min  
Estimated blood loss: 50 mL  
Hospital stay: 4 days  
Major postoperative complications: 2 patients  
Conversions: 2 patients  
VATS  
Operative time: 150 min  
Estimated blood loss: 100 mL  
Hospital stay: 5 days  
Major postoperative complications: 7 patients  
Conversions: 5 patients |
| Kidney surgical procedures (study n = 1) | | |
| Giacomoni et al. [26] | Nephrectomy; 20 patients; November 2009 to November 2012; Italy | Single arm study  
Operative time: 311 min  
Hospital length of stay: 5 days  
Median bleeding 174 mL  
Intraoperative hemorrhage: 5%  
Complications: 2 patients  
No severe postoperative complications  
No conversions |
### Table 1 (continued)

| Study | Surgical procedure and study population | Clinical outcomes |
|-------|----------------------------------------|-------------------|
| **Pancreas surgical procedures (study \( n = 1 \))** | | |
| Liu et al. [27] | Distal pancreatectomy with robotic (102 patients) vs. laparoscopic (102 patients), January 2011 to December 2015, China | Both approaches used ELS |
| | Robotic | Laparoscopic |
| | Operative time: 207 min | Operative time: 200 min |
| | Hospital stay: 7.7 days | Hospital stay: 8.6 days |
| | Blood loss: 100 mL | Blood loss: 100 mL |
| | Transfusion rate: 2.9% | Transfusion rate: 3.9% |
| | Overall morbidity: 40.2% | Overall morbidity: 44.1% |
| | Pancreatic fistula: 30.4% | Pancreatic fistula: 35.3% |
| | Conversion rate: 2.9% | Conversion rate: 9.8% |
| **da Vinci robotic surgical procedures performed with endo GIA ELS (studies: \( n = 9 \))** | | |
| **Abdominal surgical procedures (study \( n = 2 \))** | | |
| Reche et al. [28] | Reversal of gastric bypass, case report; 1 female patient; France | Case report |
| | | Operative time: 232 min |
| | | Hospital length of stay: 8 days |
| | | No complications (i.e., uneventful postoperative course) |
| Vasilescu et al. [29] | Surgery for gastric cancer; case series of 2 patients; Romania | No postoperative complications |
| **Liver surgical procedures (study \( n = 2 \))** | | |
| Montalti et al. [30] | Robotic (36 patients) vs. laparoscopic (72 patients) liver resections; June 2008 to February 2014; Italy | Robotic |
| | | Hospital length of stay: 6 days |
| | | Complications: 19.4% |
| | | Blood loss: 415 mL |
| | | Bleeding: 5.5% |
| | | Conversions: 13.9% |
| | | Mortality: 2.8% |
| | Laparoscopic | Hospital length of stay: 4.9 days |
| | | Complications: 19.4% |
| | | Blood loss: 437 mL |
| | | Bleeding: 2.8% |
| | | Conversions: 9.7% |
| | | Mortality: 0% |
| Salloum et al. [31] | Laparoscopic hepatectomy; case series of 24 patients; March 2011 to June 2013 | Single arm study |
| | | Operative time: 164 min |
| | | Hospital length of stay: 6 days |
| | | Blood loss: 170 mL |
| | | Postoperative complications: 8% |
| | | 1 open conversion |
| | | All patients had R0 resection with a mean margin of 13 mm |
| | | No mortality |
| Study | Surgical procedure and study population | Clinical outcomes |
|-------|-----------------------------------------|-------------------|
| **Colorectal surgical procedures (study \( n = 3 \))** | | |
| Ahmed et al. [32] | Rectal surgery; case series of 100 patients; May 2013 to April 2015; U.K. | Single arm study<br>Operative time median: 240 min<br>Blood loss median: 10 mL<br>Hospital length of stay median: 7 days<br>No intraoperative complications<br>Anastomotic leakage: 2%<br>No anastomotic bleeding<br>No conversions<br>Readmission rate: 12%<br>No mortality |
| Rovielli et al. [33] | Colectomy; case series of 4 patients; Italy | Single arm study<br>Operative time: 235 min<br>Blood loss: 100 cc<br>Hospital length of stay median: 6 days<br>Morbidity: 75%<br>Major complications: 25%<br>No mortality |
| Liu et al. [34] | Surgery for urostomy and colostomy; case report of 1 female patient | Case report<br>Operative time: 6 h<br>Blood loss: < 50 mL<br>No complications (i.e., uneventful postoperative course) |
| **Kidney surgical procedures (study \( n = 1 \))** | | |
| Patel et al. [35] | Laparoscopic nephroureterectomy; case series of transition from da Vinci Si to Xi of 55 patients; U.S. | Single arm study<br>Operative time: 154 min<br>Estimated blood loss: 120 mL<br>Hospital length of stay: 2 days<br>Positive surgical margin: 7.3%<br>1 patient with intraoperative complication<br>3 patients with postoperative complications |
| **Prostate surgical procedures (study \( n = 1 \))** | | |
| Wit et al. [36] | Radical prostatectomy with stapling (55 patients) vs. another method (i.e. clips, electrocautery, 100 patients); July 2011 to December 2012; Netherlands | Robotic<br>Operative time median: 58 min<br>Estimated blood loss: 162 ml<br>Hospital length of stay median: 1 day<br>Positive surgical margins: 33%<br>Intraoperative complications: 11.7%<br>Other method<br>Operative time median: 74 min<br>Estimated blood loss: 134 ml<br>Hospital length of stay median: 1 day<br>Positive surgical margins: 42%<br>Intraoperative complications: 11% |
Table 1 (continued)

| Study                  | Surgical procedure and study population                                                                 | Clinical outcomes                                                                 |
|------------------------|-----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| da Vinci robotic surgical procedures performed with EWSS (studies: \( n = 6 \)) |
| Abdominal surgical procedures (study \( n = 1 \)) |
| Alper et al. [37]      | Bariatric surgery with robotic (40 patients) vs. laparoscopic (57 patients) staplers; 2015 to 2016; U.S. | Robotic stapler                                                                   |
|                        | Study Surgical procedure and study population                                                                 | In primary group: 0/218 staple loads misfired                                     |
|                        |                                                                                                           | In revision group: 2/60 staple (3.3%) loads misfired, both patients developed staple line leak |
|                        |                                                                                                           | Misfire rate: 0.72%                                                              |
|                        | Laparoscopic stapler                                                                                  | No report of outcomes in abstract                                                |
| Colorectal surgical procedures (study \( n = 2 \)) |
| Bae et al. [38]        | Mesocolic excision and intra-corporeal anastomosis; case report of 1 female patient; Korea               | Case report                                                                       |
|                        | Study Surgical procedure and study population                                                                 | Operative time: 280 min                                                           |
|                        |                                                                                                           | Proximal and distal resection margins were 31 and 50 cm, respectively             |
|                        |                                                                                                           | Surgery was uneventful with no conversion                                         |
| Guadagni et al. [39]   | 1 male patient with adenocarcinoma of rectum, Italy                                                     | Case report                                                                       |
|                        | Study Surgical procedure and study population                                                                 | Operative time: 245 min                                                           |
|                        |                                                                                                           | Hospital stay: 8 days                                                             |
|                        |                                                                                                           | No surgical complications                                                         |
|                        |                                                                                                           | No conversion                                                                     |
| Bladder surgical procedures (study \( n = 2 \)) |
| Mass et al. [40]       | Radical cystectomy with ileal conduit; number of patients not provided; U.S.                           | Single arm study                                                                  |
|                        | Study Surgical procedure and study population                                                                 | Use of the robotic staplers can facilitate performance of intracorporeal diversions by allowing for safe division and anastomosis of bowel with minimal bedside assistance |
| Simone et al. [41]     | Radical cystectomy, 22 patients; March 2016 to October 2016; Italy                                     | Single arm study                                                                  |
|                        | Study Surgical procedure and study population                                                                 | Operative time median: 270 min                                                    |
|                        |                                                                                                           | Hospital stay median: 9 days                                                      |
|                        |                                                                                                           | 1 patient had wound infection                                                     |
|                        |                                                                                                           | 3 patients had grade 2 complications                                              |
|                        |                                                                                                           | Overall complication rate: 40%                                                    |
|                        |                                                                                                           | Overall severe complication rate: 18%                                             |
|                        |                                                                                                           | All surgeries successfully completed                                              |
|                        |                                                                                                           | No conversions                                                                   |
| Gynecologic surgical procedures (study \( n = 1 \)) |
| Benton et al. [42]     | Coincidental appendectomy; 10 patients; November 2013 to December 2013; U.S.                           | Single arm study                                                                  |
|                        | Study Surgical procedure and study population                                                                 | Intraoperative and postoperative complications: none                             |
|                        |                                                                                                           | No conversions                                                                   |
Comparative assessments of da Vinci robotic surgical procedures performed with ELS vs. EWSS

Only three recently conducted studies compared operative outcomes of robotic surgery with ELS vs. EWSS [7–9]. Hagen et al. compared 49 Roux-en-Y Gastric Bypass (RGB) surgeries performed with Echelon ELS with 60 mm reloads against 49 RGB surgeries performed with the 45 mm EWSS (matching criteria: age, gender, body mass index) at the University Hospital Geneva [7]. Hagen also described technique details on the stapling job during gastric pouch formation and compared the costs associated with both stapling techniques.

Both groups were demographically similar and the authors reported unsuccessful clampings in 19% of all the recorded stapling attempts in the EWSS group (n = 211), requiring a wait time for staple firing and sometimes repositioning of the EWSS, which likely contributed to the 22-min difference of operative time between groups, in favor of Echelon ELS, although not statistically significant (216 min vs. 194 min, p = 0.104). No unsuccessful clampings were reported within the ELS group. The difference in stapler cartridge length (45 mm EWSS, 60 mm Echelon ELS) may have contributed to the significant difference in reloads used to create the gastric pouch, in favor of Echelon ELS (4.1 ± 1.1 vs. 4.9 ± 1.6, p = 0.0048). Hence, there was a higher overall cost of stapling ($2212 vs. $1787 USD, p < 0.001) in the EWSS group, not including the cost associated with longer operative time.

In a second study, Holzmacher et al. compared operative outcomes and stapler cost of robotic colorectal surgery (left, sigmoid, subtotal, and total colectomy; low anterior resection for malignancy, diverticular disease, or inflammatory bowel disease) performed using ELS with 45 mm reloads (manufacturer not specified) in 35 cases and EWSS with 45 mm reloads in 58 cases [8].

The groups were demographically similar, and the authors reported no significant differences in blood loss, operating times, hospital length of stay, or complication rates. There were more staple firings in the ELS group (2.7 vs. 1.9 per patient), and the authors reported that the cost per patient for the ELS group was higher compared to the EWSS group ($631 vs. $473 per patient, p = 0.001). No patients in the ELS group required reoperations within 30 days, but three patients required reoperations in EWSS group (p = 0.05). On multivariate analysis, there was no statistically significant difference in the number of anastomotic leaks or overall complications between groups and the investigators of this study concluded that colorectal surgery performed with either EWSS or ELS are comparable in safety and effectiveness, but that EWSS may be more cost-effective than the 45 mm ELS in colorectal surgery.

In a third study, Atasoy et al. retrospectively compared operative outcomes and stapler utilization during robotic surgery for cancer performed with ELS with 60 mm reloads (Echelon Endopath, Ethicon; or Endo GIA Roticulator, Covidien) in 62 cases and with EWSS with 45 mm reloads in 45 cases [9]. The groups were demographically similar with the only exception being a greater percentage of male patients in the EWSS group (76 versus 55%, P = 0.03). The number of cartridges used were similar for both groups regardless of the type of stapler used in the procedure (ELS-2 vs. EWSS-2, P = 0.58), and the overall complication rate was similar between the groups (ELS-24% versus EWSS-31%, P = 0.32). Leak rates were also similar in both groups, 5 and 3% in the EWSS and ELS stapler groups, respectively (p = 1).

Non-comparative assessments

Operative outcomes of da Vinci robotic surgical procedures performed with ELS

Twenty-seven non-comparative studies reported on outcomes from da Vinci robotic surgeries performed with ELS; of these, 18 were with the Echelon ELS and 9 with the Endo GIA ELS. Robotic surgery performed with ELS is generally referred to as an advanced surgical technique for multiple types of procedures, including gastric bypass [10–12, 28], sleeve gastrectomy [12–15], liver resection [18, 19, 30, 31], colorectal surgery [20–24, 32–34], thoracic surgery [25], nephrectomy [26, 35], pancreatectomy [27], bladder surgery [34], and prostate surgery [36]. These procedures typically take longer than laparoscopic or open surgery [10, 11, 13, 14, 18], but have comparable or lower complication rates and/or more favorable perioperative outcomes [11–14, 25, 27, 36]. In these studies, stapling was typically performed by an assistant laparoscopic surgeon, and it was generally reported that although technically demanding, surgical procedures performed with the da Vinci robotic system or ELS are practical and safe.

Operative outcomes of da Vinci robotic surgical procedures performed with EndoWrist robotic staplers

Six non-comparative studies (two manuscripts, four abstracts) reported on the use of the EWSS with the da Vinci robotic system. These initial experience reports generally suggested that totally robotic procedures, in bariatric [37], colorectal [38, 39], bladder [40, 41], and gynecological surgical procedures [42] may be safe and have the advantage of console surgeon autonomy and precise stapler control.

One of these non-comparative papers by Bae et al. described a single-case study of right-sided colon cancer where EWSS was used to create an intracorporeal...
anastomosis [38]. The reported case was successful and the surgeon performed stapling from the console. However, the authors cautioned against possible increased risk of inadvertent strictures caused by posterior bowel wall involvement during the intracorporeal stapling procedure, as well as increased operative time associated with intracorporeal anastomosis creation.

In another study, Benton et al. reported no intraoperative or postoperative complications in a case series of ten gynecologic surgeries where EWSS was used to complete coincidental appendectomies. However, the authors noted larger series of patients will be needed to evaluate safety and efficiency [42].

Discussion

A wide array of surgical procedures has been accomplished with the advanced technology of the da Vinci robotic system performed with either ELS or EWSS. Most studies in this systematic review are non-comparative reports of perioperative outcomes of robotic surgical procedures that used ELS for stapling jobs in robotic procedures; which is not surprising given the relatively recent (2014) launch of the EWSS. Although totally robotic surgical procedures may allow for the entire procedure to be completed by the console surgeon and no stapling-specific outcomes (e.g., staple line integrity, intraoperative misfires, and/or postoperative leakage) have not yet been described in the literature, some studies in this systematic review suggest that there may be trade-offs to be considered when transitioning from using ELS for stapling jobs. A bariatric surgery, non-comparative series by Alper et al. reported that the EWSS staple load misfired in 3.3% of patients who had revision bariatric surgeries [37]. This possible failure may align with issues mentioned in the FDA product recall database [6].

The study by Hagen et al. compared the 60 mm Echelon ELS (which is the most used reload size in bariatric procedures) vs. the only size (45 mm) reload offered with EWSS which explains, at least in part, the larger number of firings needed, and therefore cost, with the EWSS [7]. Hagen et al. also reported unsuccessful stapler clamping in nearly 20% of all recorded attempts with EWSS in bariatric surgery. The investigators suggest that the same design features, which confer the EWSS higher amounts of articulation, may also limit the clamping force of EWSS. The two other studies by Holzmacher et al. and Atasoy et al. did not report on stapler clamping failures in colorectal procedures [8, 9].

The study by Atasoy et al. compared the 45 mm EWSS vs. 60 mm ELS in rectal cancer surgery and found that the number of cartridges used were similar in both groups (costs were not compared in this study) [9]. Holzmacher et al., on the other hand, compared 45 mm EWSS vs. 45 mm ELS; which may not be reflective of the real-life preference for 60 mm ELS in many laparoscopic colorectal procedures [8]. Although the authors did not explain why fewer firings were needed with EWSS (if both groups used the same size reloads), this may explain, at least in part, the lower stapler cost in the EWSS group [8]. It is also difficult to assess if the difference in cost would have been the same with a different ELS brand, as there was no mention of the ELS brand used in their study.

Both the number of stapler firings required and tissue re-clamp rate, may impact a third criteria for consideration—operative time. Hagen et al. reported fewer stapler firings and a lower tissue re-clamp rate with Echelon ELS vs. EWSS, as well as shorter operative time with Echelon ELS vs. EWSS; however, given that the difference in operative time was not statistically significant [7], only studies with larger sample size may be able to corroborate this possible difference. Holzmacher et al. reported fewer firings with the 45 mm EWSS vs. 45 mm ELS, but the operative time was similar between groups (270 vs. 264 min, \( p = 0.769 \)) [8].

When evaluating the cost of ELS and EWSS, Hagen et al. found EWSS stapling costs to be significantly higher than Echelon ELS for bariatric procedures (2212 vs. 1787 USD, \( p = 0.0001 \)) [7]. On the other hand, Holzmacher et al. found ELS (manufacturer not reported) stapling costs to be significantly higher than EWSS for colorectal procedures (631 vs. 473 USD, \( p = 0.001 \)) [8]. Atasoy et al. did not report stapler costs [9]. The cost structures for ELS and EWSS are different and must be carefully considered when evaluating device value. For the cost assessment of EWSS, the cost per fire can be determined by adding the cost of the stapling device, which is reusable up to 50 uses, with the stapler reloads [7]. The cost calculation for EWSS should also consider the use of trocar reducers, cannula seals, and stapler sheaths that are necessary to operate the device. For ELS, on the other hand, the cost per fire should be calculated with consideration for the acquisition of only the stapling device and reloads.

Conclusions

Systematic reviews like this one are at best able to offer insights, formulate new hypotheses to test, and ascertain the status of a subject or procedure. They are not able to draw firm conclusions or make clear recommendations because of the limited number of comparative reports, coupled with the small sample sizes, and the heterogeneity of the surgical procedures involved in the studies evaluated. The key finding in this literature review is that there is very little comparative perioperative data between the use of ELS and EWSS in robotic surgery (three studies). Given that ELS has a longer clinical history and relatively more robust evidence base (ELS-27 studies; EWSS-6 studies), surgeons and medical
device purchasers should consider possible trade-offs before switching their entire clinical utilization to EWSS.

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Compliance with ethical standards

Conflict of interest Mario Gutierrez is an employee of Ethicon, a Johnson & Johnson company. Sanjoy Roy is an employee of Ethicon, a Johnson & Johnson company. Melissa Smith (Novosys Health) for medical writing assistance. All

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References

1. Chekan E, Whelan R (2014). Surgical stapling device-tissue interactions: what surgeons need to know to improve patient outcomes. Med Dev Evid Res. https://doi.org/10.2147/mder.s67338
2. Griffith PS, Birch D, Sharma A, Karmali S (2012) Managing complications associated with laparoscopic Roux-en-Y gastric bypass for morbid obesity. Can J Surg 55(5):329–336. https://doi.org/10.1503/cjs.002011
3. El-Kadre L, Tinoco AC, Tinoco RC, Aguilar L, Santos T (2013) Overcoming the learning curve of laparoscopic Roux-en-Y gastric bypass: a 12-year experience. Surg Obes Relat Dis 9(6):867–872. https://doi.org/10.1016/j.soard.2013.01.020
4. Thuler FR, Freitas WR, Iliaz EJ, Kassab P, Malheiros CA (2014). Laparoscopic bariatric surgery training program model: gastric bypass. BMC Surg. https://doi.org/10.1186/1471-2482-14-101
5. Lublin M, Lyass S, Lahmann B, Cunneen SA, Khalili TM, Elashoff JD, Phillips EH (2005) Leveling the learning curve for laparoscopic bariatric surgery. Surg Endosc 19(6):845–848. https://doi.org/10.1007/s00464-004-8201-x
6. U.S. Food & Drug Administration. Medical Device Recalls. Updated 7/29/2017. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=&productdevicecomplainttxt=EndoWrist&productcode=&IVDPrompts=&rootC aseText=&casestatus=&enterclassificationtype=text&recal Nunber=&postdatefrom=&postdateto=&productshortreason r=text&firmedglnam=&PMA_510K_Number=&pnnumber=&knun ber=&epagenumber=10&sortcolumn=cdcd. Accessed 15 Sept 2017
7. Hagen ME, Jung MK, Fahkho J, Buchs NC, Buehler L, Mendoza JM, Morel P (2017). Robotic versus laparoscopic stapling during robotic Roux-en-Y gastric bypass surgery: a case-matched analysis of costs and clinical outcomes. Surg Endosc. https://doi.org/10.1007/s00464-017-5707-6
8. Holzmacher JL, Luka S, Aziz M, Amdur RL, Agarwal S, Obias V (2017) The use of robotic and laparoscopic surgical stapling devices during minimally invasive colon and rectal surgery: a comparison. J Laparoendosc Adv Surg Techn 27:151–155
9. Atasoy D, Aytac E, Ozben V, Bayraktar O, Bayraktar IE, Aghayeava A et al (2018) Robotic versus laparoscopic stapler use for rectal transection in robotic surgery for cancer. J Laparoendosc Adv Surg Tech 28(5):501–505
10. Smeenk RM, van’t Hof G, Elsten E, Feskens PGBM (2016) The results of 100 robotic versus 100 laparoscopic gastric bypass procedures: a single high volume centre experience. Obes Surg 26:1266–1273
11. Myers SR, McGuirl J, Wang J (2013) Robot-assisted versus laparoscopic gastric bypass: comparison of short-term outcomes. Obes Surg 23:467–473
12. Kosanovic R, Romero RJ, Donkor C (2015) A comparative retrospective study of robotic sleeve gastrectomy vs robotic gastric bypass. Int J Med Robot 11:275–283
13. Ijah RF, Bhatia P, Kalman S, Khetan M, John S, Bindal V, Ali A (2014) Sleeve gastrectomy for morbid obesity: robotic vs standard laparoscopic sleeve gastrectomy methods. World J Laparosc Surg 7:1–6
14. Vilallonga R, Fort JM, Caubet E (2015). Robotically assisted single anastomosis duodenoeileal bypass after previous sleeve gastrectomy implementing high valuable technology for complex procedures. J Obes 2015:586419
15. Dogra PN, Regmi SK, Singh P, Bora G, Saini AK, Aggarwal S (2014) Robot-assisted laparoscopic augmentation ileocystoplasty in a tubercular bladder. Urol Ann 6:152–155
16. Xu Y, Wang H, Ji W, Tang M, Li H, Leng J, Meng X, Dong J (2016) Robotic radical resection for hiliar cholangiocarcinoma: perioperative and long-term outcomes of an initial series. Surg Endosc 30:3060–3070
17. Calin ML, Sadiq A, Arevalo G, Fuentes R, Flanders VL, Gupta N, Nasri B, Singh K (2016) The first case report of robotic multivisceral resection for synchronous liver metastasis from pancreatic neuroendocrine tumor: a case report and literature review. J Laparoendosc Adv Surg Tech A 26:816–824
18. Morelli L, Guadagni S, Di Franco G, Palmeri M, Caprilli G, D’isidoro C, Pisano R, Marciano E, Moglia A, Di Candio G, Mosca F (2016) Short-term clinical outcomes of robot-assisted intersphincteric resection and low rectal resection with double-stapling technique for cancer: a case-matched study. Int J Colorectal Dis 31:737–739
19. Bae SU, Jeong WK, Baes OS, Baeck SK (2016) Reduced-port robotic anterior resection for left-sided colon cancer using the Da Vinci single-site platform. Int J Med Robot 12:517–523
20. Morelli L, Perutelli A, Palmeri M (2016) Robot-assisted surgery for the radical treatment of deep infiltrating endometriosis with colorectal involvement: short- and mid-term surgical and functional outcomes. Int J Colorectal Dis 31:643–652
21. Leong QM, Son DN, Cho JS, Amar AH, Kim SH (2012) Robot-assisted low anterior resection for situs inversus totalis: a novel technical approach for an uncommon condition. Surg Laparosc Endosc Percutan Tech 22:e87-e90
22. Trastulli S, Desiderio J, Farinacci F, Ricci F, Listorti C, Cirocchi R, Boselli C, Noya G, Parisi A (2013) Robotic right colectomy for cancer with intracorporeal anastomosis: short-term outcomes from a single institution. Int J Colorectal Dis 28:807–814
25. Rinieri P, Peillon C, Salaün M, Mahieu J, Bubenheim M, Baste JM (2016) Perioperative outcomes of video- and robot-assisted segmentectomies. Asian Cardiovasc Thorac Ann 24:145–151

26. Giacomoni A, Di Sandro S, Lauterio A (2013) Initial experience with robot-assisted nephrectomy for living-donor kidney transplantation: feasibility and technical notes. Transpl Proc 45:2627–2631

27. Liu R, Liu Q, Zhao Z, Tan XL, Gao YX, Zhao GD (2017) Robotic vs. laparoscopic distal pancreatectomy: a propensity score-match study. J Surg Oncol 116:461–469

28. Reche F, Mancini A, Borel AL, Faucheron JL (2016) Totally robotic reversal of omega-loop gastric bypass to normal anatomy. Obes Surg 26:1994–1995

29. Vasilescu C, Procopiuc L (2012) Robotic surgery of locally advanced gastric cancer: a single-surgeon experience of 41 cases. Chirurgia (Bucur) 107:510–517

30. Montalti R, Scuderi V, Patriti A, Vivarelli M, Troisi RI (2016) Robotic versus laparoscopic resections of posterosuperior segments of the liver: a propensity score-matched comparison. Surg Endosc 30:1004–1013

31. Salloum C, Tayar C, Laurent A, Malek A, Compagnon P, Memeo R, De Angelis N, Pascal G, Azoulay D (2014) Robot-assisted laparoscopic hepatectomy: the henri-mondor experience. In: 11th world congress of the International Hepato-Pancreato-Biliary association. Seoul South Korea (abstract)

32. Ahmed J, Nasir M, Flashman K, Khan J, Parvaiz A (2016) Totally robotic rectal resection: an experience of the first 100 consecutive cases. Int J Colorectal Dis 31:869–876

33. Roviello F, Piagnerelli R, Ferrara F, Scheiterle M, De Franco L, Marrelli D (2015) Robotic single docking total colectomy for ulcerative colitis: first experience with a novel technique. Int J Surg 21:63–67

34. Liu N, Risk M, George V, Robb B, Gardner T (2012) Incisionless dual diversions: creation of urostomy and colostomy using the da Vinci robot. Annual meeting of the American Urological Association, AUA. Atlanta, GA United States. J Urol 4(Suppl 1):e356 (abstract)

35. Patel MN, Aboumohamed A, Hemal A (2015) Does transition from the da Vinci Si to Xi robotic platform impact single-docking technique for robot-assisted laparoscopic nephroureterectomy? BJU Int 116:990–994

36. Wit EMK, De Jong J, Acar C, VAN Muilekom E, Tillier C, De Blok W, Poel VANDER. H (2016) Stapling for prostate pedicle management during robot-assisted radical prostatectomy. Minerva Urol Nefrol 68:429–436

37. Alper N, Bassiri-Tehrani B, Marks Y, Taggart J, Teixeira MD (2017) The safety and efficacy of the Da Vinci robotic stapler in robotic-assisted bariatric surgery. Surg Endosc 31:S190–S259 (abstract)

38. Bae SU, Jeong WK, Back SK (2016) Single-port plus an additional port robotic complete mesocolic excision and intracorporeal anastomosis using a robotic stapler for right-sided colon cancer. Ann Surg Treat Res 91:212–217

39. Guadagni S, di Franco G, Palmeri M, Furbetta N, Bianchini M, Gianardi D, Lucchesi M, Stefanini G, Caprili G, d’Isodore C, Melli F, di Candi G, Mosca F, Morelli L (2017) New technologies in robotic rectal resection: da Vinci Xi, Integrated Table Motion, Endowrist Robotic Stapler and indocyanine green fluorescence. Surg Endosc 31:S190–S259 (abstract)

40. Mass AY, Zhao LC, Huang WC (2014) Robotic intracorporeal ileal conduit using the intuitive Endowrist one robotic stapler. J Endourol 28(suppl 1):A314 (abstract)

41. Simone G, Guaglianone S, Minisola F, Ferriero M, Misuraca L, Tuderti G, Romeo G, Gallucci M (2017) Intracorporeal partly stapled Padua ileal bladder using robotic staplers: surgical technique, perioperative and early functional outcomes of a prospective single center series. J Urol 197(suppl):e681 (abstract)

42. Benton SA, Riley KA, Harkins GJ (2015) The use of a robotic stapling device for coincidental appendectomy. J Gynecol Surg 31:148–150