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ORIGINAL ARTICLE

Performance of da Vinci Stapler during robotic-assisted right colectomy with intracorporeal anastomosis

Craig S. Johnson[1] · Andrew Kassir[2] · Daryl S. Marx[3] · Mark K. Soliman[4]

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Abstract

Applications for surgical staplers continue to grow, due to the increase in minimally invasive surgical approaches, and range from vessel ligation to tissue transection and anastomoses. Complications associated with stapled tissue, such as bleeding or leaks, continue to be a concern for surgeons, as both can be associated with prolonged operative times and can contribute to postoperative morbidity and mortality. The goal of this retrospective study was to evaluate the performance of the da Vinci® Xi EndoWrist® Stapler 45 with SmartClamp™ technology during robotic-assisted right colectomy with intracorporeal anastomosis. We reviewed 113 consecutive cases from four medical centers. Preclinical diagnoses were inflammatory bowel disease (IBD) ($n=5$), benign bowel disease ($n=77$), and malignant bowel disease ($n=31$). No anastomotic leaks occurred; one event of anastomotic bleeding (0.88%) resolved without surgical intervention. Overall, there were 643 clamp attempts (5.7 attempts per case), and 570 fires (5.0 fires per case). SmartClamp™ occurrences happened in approximately one out of three cases, with the highest proportion of occurrences in the IBD group (2.0 occurrences per case). The most commonly fired reload was blue (1.5 mm closed height) with 4.1 blue reloads fired per case overall. No incomplete fires occurred during the procedures. The study data demonstrate the performance of the da Vinci Xi EndoWrist® Stapler 45 as used in right colon resection with intracorporeal anastomosis. The collection and analysis of these data provide surgeons with information related to stapler firings, which were not previously available; as such, this analysis may lead to deductions that are useful for intraoperative decision-making and clinical outcomes.

Keywords Colectomy · Intracorporeal anastomosis · Colorectal disease · Bowel disease · Stapler · Robotic assisted

Introduction

The applications for surgical staplers continue to grow due to the increase in minimally invasive surgical approaches. Applications for such instruments range from vessel ligation to tissue transection and creation of anastomoses. Complications associated with stapled tissue, such as bleeding or leaks, continue to be a concern for surgeons, as both can be associated with prolonged operative times and can contribute to postoperative morbidity and mortality [1, 2]. As such, basic stapling principles still apply today: minimize tissue trauma/manipulation, ensure tissue perfusion while also maintaining hemostasis, and produce a tension-free anastomosis. Surgeons who perform minimally invasive procedures can be challenged by their reliance on visual and tactile cues as they assess tissue characteristics. This subjectivity may limit a surgeon's consistent success with stapling, as well as limit the surgeon's ability to draw conclusions across patient populations. Efforts have been made to standardize reload selections to three finished staple heights (1.0, 1.5, and 2.0 mm), each corresponding to a color (white, blue, and green, respectively) and to the desired finished "B" shape to minimize tissue and vessel crushing.

A recent addition to robotic-assisted instruments is the da Vinci® Xi EndoWrist Stapler 45 with SmartClamp™ technology (Intuitive Surgical, Inc., Sunnyvale, CA USA). SmartClamp™ technology, using a software-based algorithm, measures jaw closure and displays objective feedback

✉ Craig S. Johnson
cjohnson@satulsa.com

1 Department of Surgery, Oklahoma Surgical Hospital, 2408 E81st St Suite 300, Tulsa, OK 74137, USA

2 Colon and Rectal Clinic of Scottsdale, Scottsdale, AZ, USA

3 Department of Surgery, Monroe Surgical Hospital, Monroe, LA, USA

4 Colon and Rectal Clinic of Orlando, Orlando, FL, USA

prior to firing, to optimize staple line formation. The goal of this retrospective study is the evaluation of performance for the da Vinci Xi EndoWrist Stapler 45 with SmartClamp™ technology, during robotic-assisted right colectomy procedures with intracorporeal anastomosis. The performance was analyzed in terms of number of clamp attempts, SmartClamp™ occurrences (defined in "Materials and methods"), number of firings, and other outcomes of interest including anastomotic leakage and bleeding.

Materials and methods

Data sources and study sample

The performance outcomes from 113 consecutive cases from four medical centers for elective robotic-assisted right colectomy with intracorporeal anastomosis using the da Vinci Xi Surgical System and EndoWrist Stapler 45 with SmartClamp™ technology were included and retrospectively evaluated. Inclusion criteria were male and female patients of at least 18 years of age with a preclinical diagnosis of either inflammatory bowel disease or benign or malignant bowel neoplasm. Patient demographics, medical history, procedural details, pathology and tumor staging, clinical outcomes including complications, and stapler-specific details were documented on standardized case report forms.

Integral to the da Vinci surgical system is an internal data log that captures the reload selection (by color and length) used during each procedure as well as the number of clamp attempts and stapling fires. Definitions of terms specific to stapling with the EndoWrist Stapler follow:

Clamp: Upon depressing the surgical system's blue foot pedal, the stapler applies compression through the anvil and prepares the tissue for firing. Feedback is displayed to guide the user towards 100% clamp completion. ***100% Clamp completion***: At 100% clamp completion, the stapler jaws are adequately closed, and the firing function is enabled. At less than 100% clamp completion, the software detects inadequate jaw closure and the surgical system disables firing. ***SmartClamp™ Technology***: using a software-based algorithm, SmartClamp™ measures jaw closure and displays objective feedback prior to firing, to optimize staple line formation. During clamping, SmartClamp™ feedback displays the percentage of clamp completion that has been achieved based on the installed reload. This feedback enables the surgeon additional time for tissue compression or modification of workflow during the intraoperative use of the stapler to achieve 100% clamp completion (Fig. 1). ***SmartClamp™ Occurrence*** is a prompt which guides the surgeon to 100% clamp completion if clamping is not reached during the first clamp attempt. ***Clamp attempts***: the total count of all clamping attempts—whether 100% or less than 100%. The surgeon can decide not to fire the stapler even if 100% clamp has been achieved. For a single procedure, the number of clamp attempts is always equal to or greater than the number of fires. ***Fire***: The firing function is available once the stapler is at 100% clamp completion. The firing sequence results in simultaneous stapling and cutting of tissue. ***Incomplete fires***: Incomplete fires occur when the stapler stops the firing sequence due to a preset safety force limit being reached. The surgeon can then unclamp and remove the stapler.

All outcomes for data collected in this study were evaluated using descriptive statistics. Descriptive statistics were performed with SAS 9.4 (Cary, NC USA). Continuous data were expressed as mean ± standard deviation; categorical variables were summarized as frequencies and proportions.

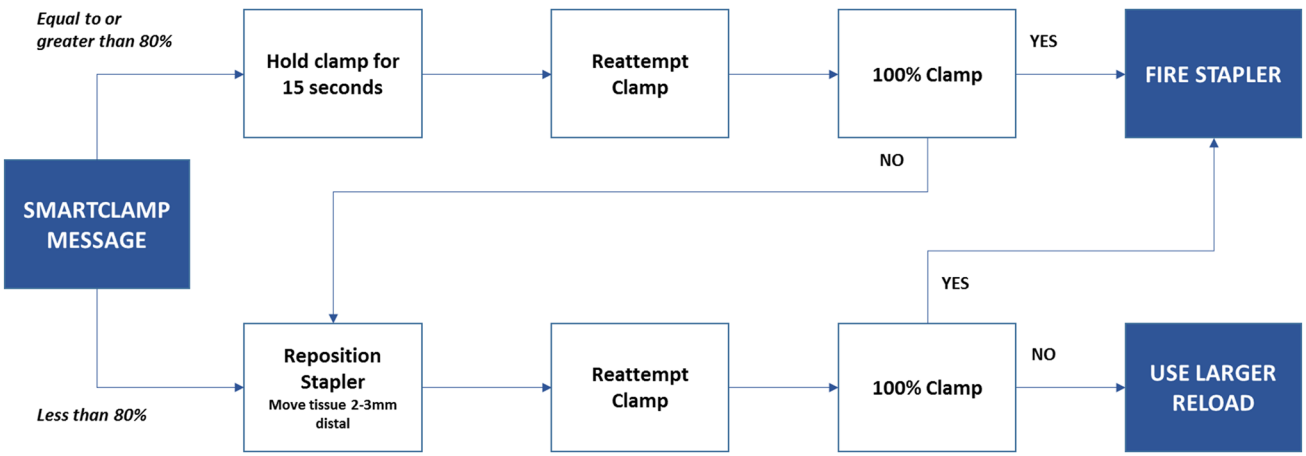

Fig. 1 Intraoperative workflow for stapler use (workflow diagram was provided courtesy of Intuitive Surgical, Inc.)

Results

One hundred thirteen patients underwent robotic-assisted right colectomy with intracorporeal anastomosis utilizing with EndoWrist Stapler 45 with SmartClamp™ technology. Four colorectal surgeons performed the procedures within a 17-month period (February 2015–June 2016) at their respective medical institutions. Preclinical diagnoses were inflammatory bowel disease (IBD) ($n=5$), benign bowel disease ($n=77$), and malignant bowel disease ($n=31$). Baseline demographics and medical histories are outlined in Table 1. Patients with inflammatory bowel disease were considerably younger than patients with benign or malignant disease (36.2-year-old versus 67.0 and 69.8-year-old, respectively). Also particular to the IBD group was the higher proportion of females; whereas in the other two groups, gender representation was comparable. The benign and malignant bowel disease patients had diminished physical status compared to the IBD group and had higher incidences of comorbidities at baseline. No patients, regardless of preclinical diagnosis, had undergone abdominopelvic surgery within 30 days prior to their index right colectomy.

As presented in Table 2, the mean overall operating time was 149.4 ± 42.4 min, and operating times among the three disease groups were similar. There were no conversions to open, and there was one case of blood transfusion in the malignant disease group. Most surgeons (96.2%) performed extractions through a Pfannenstiel incision.

Postoperative pathological staging indicated that, of the benign and malignant bowel disease patients, 37% (40/108) had malignant pathology, with tumor location in the ascending colon (26/50, 52%) and cecum (20/50, 40%) for most of the cases. The mean size of the malignant tumors ranged from 3.6 to 6.5 cm.

Table 1 Patient demographics and medical history

Variable	Overall ($n=113$)	Inflammatory bowel disease ($n=5$)	Benign bowel disease ($n=77$)	Malignant bowel disease ($n=31$)
Mean age ± SD, year	66.4 ± 11.9	36.2 ± 10.4	67.0 ± 8.9	69.8 ± 12.2
Gender, *n* (%)				
Female	61 (54.0)	4 (80.0)	42 (54.5)	15 (48.4)
Male	52 (46.0)	1 (20.0)	35 (45.5)	16 (51.6)
Mean BMI ± SD, kg/m^2	29.3 ± 6.4	27.8 ± 9.2	29.8 ± 6.2	28.4 ± 6.3
ASA physical status classification, *n* (%)				
1, 2	49 (44.1)	4 (80.0)	34 (44.7)	11 (36.4)
3–6	62 (55.9)	1 (20.0)	42 (55.3)	19 (63.3)
Unknown	2	0	1	1
≥ 1 comorbidity, *n* (%)	85 (75.2)	1 (20.0)	60 (77.9)	24 (77.4)
Prior abdominopelvic surgery, *n* (%)				
Within 30 days prior to index colectomy	0	0	0	0

SD standard deviation of the mean, *BMI* body mass index, *ASA* American Society of Anesthesiologists

Table 2 Procedural details

Variable	Overall ($n=113$)	Inflammatory bowel disease ($n=5$)	Benign bowel disease ($n=77$)	Malignant bowel disease ($n=31$)
Mean operating/procedure time ± SD, min[a]	149.4 ± 42.4	164.8 ± 34.1	146.6 ± 44.0	153.8 ± 39.7
Conversion to open, *n*	0	0	0	0
Mean blood loss ± SD, mL	54.0 ± 75.6	140.0 ± 174.6	44.0 ± 19.4	64.7 ± 120.6
Transfusion, *n* (%)	1 (0.9)	0	0	1 (3.2)
Extraction site, *n* (%)				
Pfannenstiel	102 /106 (96.2)	4 (80.0)	71/73 (97.2)	27/28 (96.4)
Trocar site	3/106 (2.8)	1 (20.0)	1/73 (1.4)	1/28 (3.6)
McBurney's	1/106 (0.9)	0	1/73 (1.4)	0

SD standard deviation of the mean

[a]Skin-to-skin (first incision to close)

Clinical outcomes, of interest, are reported in Table 3. There were no intraoperative injuries reported in the 113 cases. Noteworthy was the absence of an anastomotic leak postoperatively through discharge. There was one event of anastomotic bleeding, which occurred within the benign bowel disease group. The anastomotic bleed resolved postoperatively and did not require intervention.

Overall, there were 643 clamp attempts for an average of 5.7 attempts per case, and 570 fires with an average of 5.0 fires per case (Table 4). SmartClamp™ occurrences happened in approximately one out of three cases overall, with the highest proportion of occurrences in the IBD group (2.0 occurrences per case on average). The most commonly fired reload was blue (1.5 mm) with an average of 4.1 blue reloads fired per case overall. No incomplete fires occurred in any of the procedures.

Discussion

This study is the first of its kind to provide technological and scientific evaluation of the da Vinci Xi EndoWrist Stapler 45 usage. Controlled by the surgeon from the surgeon console, the da Vinci Xi EndoWrist Stapler 45 can be articulated a total of 108° left and right and 54° up and down. Coupled with SmartClamp™ technology, the da Vinci Xi EndoWrist Stapler 45 measures jaw closure prior to firing and provides objective feedback, as demonstrated by the clamp completion indicator. Once the system indicates 100% clamp completion, the firing sequence is enabled. Jaw closure and clamp completion are critical to preparing the tissue for optimal "B" formed staples. Laparoscopic staplers differ in this regard, as feedback is limited to subjective measures, such as tactile or audible feedback and there are no preprogrammed limits to prevent excessive jaw separation. In

Table 3 Clinical outcomes

Variable	Overall ($n=113$)	Inflammatory bowel disease ($n=5$)	Benign bowel disease ($n=77$)	Malignant bowel disease ($n=31$)
Mean time to first bowel movement ± SD, days	2.0 ± 1.0	1.4 ± 1.0	1.9 ± 0.9	2.3 ± 1.1
Length of stay, days				
Mean ± SD	3.0 ± 1.3	2.6 ± 0.5	2.8 ± 1.2	3.5 ± 1.5
Median (range)	3 (1–10)	3 (2–3)	3 (1–8)	3 (1–10)
Stapler-related intraoperative complications, *n* (%)	0	0	0	0
Stapler-associated postoperative complications of interest[a], *n* (%)				
Anastomotic leak	0	0	0	0
Anastomotic bleed	1 (0.9)	0	1 (1.3)	0

SD standard deviation of the mean

[a]Postoperative through discharge

Table 4 Stapler details

Variable	Overall ($n=113$)		Inflammatory bowel disease ($n=5$)		Benign bowel disease ($n=77$)		Malignant bowel disease ($n=31$)	
	Total	Average	Total	Average	Total	Average	Total	Average
Clamp attempts, *n*	643	5.7	40	8.0	432	5.6	171	5.5
SmartClamp™ occurrences[a], *n*	36	0.3	10	2.0	21	0.3	5	0.2
Fires, *n*	570	5.0	30	6.0	382	5.0	158	5.1
White reloads	17	0.2	2	0.4	8	0.1	7	0.2
Blue reloads	461	4.1	28	5.6	295	3.8	138	4.5
Green reloads	92	0.8	0	0.0	79	1.0	13	0.4
Incomplete	0	0.0	0	0.0	0	0.0	0	0.0

[a]*SmartClamp*™ occurrence is a prompt which guides the surgeon to 100% clamp completion if the clamping is not reached during the first clamp attempt

the event 100% clamp completion is not achieved and tissue is not adequately prepared, the surgeon can allow more time for tissue to compress further, reposition the stapler on the tissue, or consider changing reload selections. Optimal stapling of any tissue requires adequate tissue compression time to decrease the fluid in the tissue and to allow elongation of the tissue being compressed, smooth firing of the instrument, and consistent staple line formation; this need must be balanced against the risk of increased tissue tearing and excessive tensile strength [3]. The manufacturer's retrospective review of 10,000 EndoWrist stapling fires from system log data indicated that, when a user reaches at least 80% clamp completion on the first attempt, there is a > 90% probability of 100% clamp completion on the second attempt when the surgeon holds the clamp state for 15 s.

There are a number of variables that ultimately determine optimal staple formation, including but not limited to the evident device–tissue interactions. In the absence of objective feedback with laparoscopic stapling devices, the aim of SmartClamp™ technology is to reduce the guesswork associated with laparoscopic stapling devices and provide user feedback by means of a software-based algorithm.

Upon review of the stapler data, inferences with disease process and stapler dynamics can be made. The overall SmartClamp™ occurrence rate was 5.7%. SmartClamp™ rates in inflammatory bowel cases were much higher at 25%. We were able to incorporate SmartClamp™ feedback into our intraoperative use of the stapler, ultimately achieving appropriate jaw closure on the diseased tissue and full firings with no anastomotic leaks. Having this feedback can enable the surgeon to modify and improve intraoperative workflow in relation to stapling in these specific disease states.

The incidence of clinical outcomes of interest was low: one anastomotic bleed ($n = 1$; 0.88%) and no anastomotic leaks, despite 570 fires over the course of the study [3–6].

Our study was a retrospective analysis and, as such, lacked the robustness of a prospective randomized controlled trial; however, the patients were consecutive with different clinical presentations, and availability of the da Vinci log data from each case was an important factor for comprehensive analysis.

Conclusion

The study data demonstrate the performance of the da Vinci Xi EndoWrist Stapler 45 as used in right colon resections with intracorporeal anastomosis. The collection and analysis of these data provide surgeons with information related to stapler firings, which were not previously available; as such, this analysis may lead to deductions that are useful for intraoperative decision-making and clinical outcomes.

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Compliance with ethical standards

Conflict of interest Dr. Johnson receives consulting and education fees from Intuitive Surgical; Dr. Marx receives fees from Intuitive for education and case observation research; and Dr. Soliman is a consultant and lecturer for Intuitive and is on the medical advisory board for C-SATS. Dr. Kassir reports no conflicts of interest or disclosures.

Ethics approval All procedures, which were carried out and described in this study, were in accordance with the ethical standards of each institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Due to the retrospective nature of this study, formal consent was not required.

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