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

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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] Surgeons 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.

The goal of this retrospective study was to evaluate the performance of the EndoWrist Stapler 45 for the da Vinci Xi® surgical system, during robotic-assisted right colectomy procedures with intracorporeal anastomosis.

The authors reviewed 113 consecutive cases performed between February 2015–June 2016 from four medical centers. Preclinical diagnoses were inflammatory bowel disease (IBD) (n = 5), benign bowel disease (n = 77), and malignant bowel disease (n = 31).

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.

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Results

Clinical outcomes (Table 1)

There were no intraoperative injuries reported in the 113 cases.

The incidence of clinical outcomes of interest was low: one anastomotic bleed (0.88%) and no anastomotic leaks postoperatively through discharge, despite 570 fires over the course of the study.[3-6] The sole event of anastomotic bleeding resolved without surgical intervention.

There were no conversions to open, and there was one case of blood transfusion in the malignant disease group.

Table 1. 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*, n (%)				
Anastomotic leak	0	0	0	0
Anastomotic bleed	1 (0.9)	0	1 (1.3)	0

*Postoperative through discharge
SD standard deviation of the mean

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Da Vinci® stapler performance (Table 2)

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.

SmartClamp™ occurrences happened in approximately one out of three cases overall. While the overall SmartClamp occurrence rate was 5.7%, SmartClamp rates in inflammatory bowel cases were much higher at 25%.

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.

Table 2. Stapler details

	Overall (n = 113)		Inflammatory bowel disease (n = 5)		Benign bowel disease (n = 77)		Malignant bowel disease (n = 31)	
Variable	Total	Average	Total	Average	Total	Average	Total	Average
Clamp attempts, n	643	5.7	40	8.0	432	5.6	171	5.5
SmartClamp™ occurences*, 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 fires	0	0.0	0	0.0	0	0.0	0	0.0

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

Key takeaways

This study is the first of its kind to provide technological and scientific evaluations of the EndoWrist Stapler 45 for the da Vinci Xi® surgical system, matched to clinical outcomes of interest. The results demonstrate the stapler's performance as used in right colon resections with intracorporeal anastomosis. The authors show that they were able to incorporate SmartClamp™ feedback into their intraoperative use of the stapler, ultimately achieving appropriate jaw closure on the diseased tissue and full firings with no anastomotic leaks. The analysis of these collected data provides surgeons with information related to stapler firings, which were not previously available; as such, this information may lead to deductions that are useful for intraoperative decision-making and clinical outcomes.

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Study limitation

This study was a retrospective analysis and thus 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.

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FINANCIAL DISCLOSURE

Dr. Johnson, Dr. Marx and Dr. Soliman have received compensation from Intuitive Surgical for consulting and/or educational services.

IMPORTANT SAFETY INFORMATION

Serious complications may occur in any surgery, including da Vinci® Surgery, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to, one or more of the following: injury to tissues/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain.

Risks specific to minimally invasive surgery, including da Vinci® Surgery, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning; a longer operative time, the need to convert to an open approach, or the need for additional or larger incision sites. Converting the procedure could result in a longer operative time, a longer time under anesthesia, and could lead to increased complications. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all da Vinci instruments.

For Important Safety Information, indications for use, risks, full cautions and warnings, please also refer to www.davincisurgery.com/safety and www.intuitivesurgical.com/safety.

Individual surgical results may vary.

DA VINCI XI® PRECAUTION STATEMENT

The demonstration of safety and effectiveness for the specific procedure(s) discussed in this material was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

The EndoWrist® Stapler, EndoWrist Stapler Reloads and other Stapler accessories for the da Vinci Xi System are intended to be used with the da Vinci Xi Surgical System (IS4000) for resection, transection, and/or creation of anastomoses in General, Thoracic, Gynecologic and Urologic surgery. The device can be used with staple-line or tissue-buttressing materials (natural or synthetic).

The EndoWrist Stapler 45 Instruments and Reloads for the da Vinci Xi System should not be used on tissue such as the liver or spleen, where tissue compressibility is such that clamping of the instrument would be destructive. Do not use the EndoWrist Stapler 45 Instrument or Reloads for the da Vinci Xi System on the aorta.

The EndoWrist Stapler 45 for the da Vinci Xi System (IS4000) is not compatible for use with the da Vinci, da Vinci S, or da Vinci Si Surgical System.

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