



Update on robotic surgery for rectal cancer treatment

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Abstract: Laparoscopic total mesorectal excision (TME) is technically demanding and has a steep learning curve. Moreover, two recent randomized controlled trials have questioned the oncological safety of laparoscopic treatment for rectal cancer. Robotic surgery, thanks to its technical advantages, could potentially overcome the intrinsic limitations of standard laparoscopy. In this paper we will describe the surgical technique of robotic TME and review the recent literature on robotic rectal surgery. Short term, functional and oncological outcomes will be taken into consideration, as well as learning curve and costs. Robotic rectal resection is reported to have lower conversion rates (CRs), better functional outcomes and shorter learning curve, with comparable oncological results. Robotic surgery remains more time consuming and affected by higher costs. The technological advantages provided by the robotic system could probably facilitate the widespread adoption of minimally-invasive TME, that still has a low penetration worldwide. The educational capabilities of the platform, together with structured training programs, could allow novice surgeons to safely approach colorectal surgery.

Keywords: Robotic rectal resection; total mesorectal excision (TME); rectal cancer; circumferential resection margin; low anterior resection; oncological outcomes

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Introduction

While laparoscopic treatment for colon cancer has showed several undisputed short term advantages over the traditional open approach, with equivalent long term oncologic outcomes (1,2), two recently published trials have questioned this assumption for rectal cancer (3,4).

Total mesorectal excision (TME), since it was first described by Heald in 1982 (5), is considered the gold standard treatment for rectal cancer, due to the significant reduction in local recurrence rate (6). The standard and rigid laparoscopic instrumentation, with the camera hold by the assistant surgeon, add complexity to the TME. The pelvis is a confined location, that becomes even more unfavorable in males, and when dealing with bulky

tumors or obese patients. Therefore, TME remains a challenging procedure, with high conversion rates (CRs) (7,8) and a steep learning curve (9). Robotic surgery, with its endowristed instruments with 7 degrees of freedom, 3D full HD vision with a stable optical platform, tremor filtering, and motion scaling could overcome some of the technical limitations of standard laparoscopy, reducing the degree of procedural complexity. This could potentially increase the diffusion of minimally-invasive TME, that still maintains a low penetration worldwide (10-12).

This paper aims to describe the surgical technique of robotic TME and to review the recent literature on robotic rectal surgery with a focus on short term results, functional and oncological outcomes, learning curve and costs.

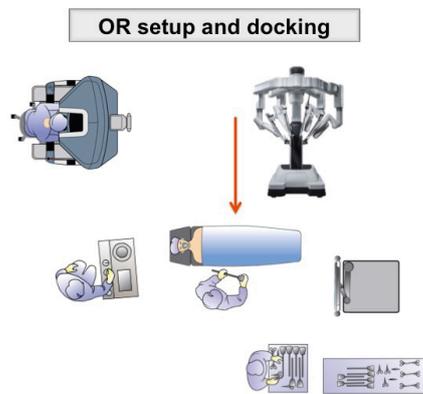


Figure 1 Operative room setup and docking.

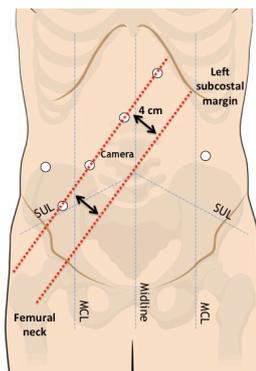


Figure 2 Trocar layout.

Robotic TME: surgical technique

Herein we describe the technique for full-robotic TME with the DaVinci Xi surgical platform (Intuitive Surgical Inc., Sunnyvale, CA, USA). This system allows for an easier setup and multiquadrant access thanks to a faster docking, simpler OR setup (boom-mounted rotating arms) and longer instruments, when compared to previous robotic systems.

Patient positioning

The patient is placed in lithotomy position with arms alongside the body and is carefully secured with dedicated patient positioning system (Pink Pad, Xodus Medical Inc., PA, USA) to prevent sliding.

First assistant stands on the patient's right side. The scrub nurse is at the lower right side of the table and the assistant's monitor is located at the patient's left shoulder.

The cart is placed at the patient's left side and is docked from the left lower quadrant (*Figure 1*).

Port placement

A Veress needle is inserted in the left hypochondrium (Palmer's point) for the induction of a 12-mmHg pneumoperitoneum. A 12-mm optical port is inserted in the right flank. Four 8-mm robotic trocars are then inserted along a straight line that is parallel to and about 4 cm cranial to the costofemoral line, maintaining a 6–8 cm distance between each port. Ports are also located at least 2–3 cm away from bony prominences. An additional 8-mm robotic port is placed in the left flank and will be used for the pelvic phase of the procedure (*Figure 2*).

Robot positioning and docking

A complete exploration of the abdominal cavity is performed and an intraoperative liver ultrasonography is carried out with a laparoscopic dedicated probe to complete the intraoperative staging of the disease. The patient is then placed in a 20–25° Trendelenburg position with a 20–25° right tilt: the greater omentum and the small bowel loops are retracted out of the pelvic area into the right upper quadrant laparoscopically.

The robotic cart is then approximated and deployed for docking from the patient's left side. A green laser, emitted from the overhead boom, is used to define the correct cart position. The optical port is then docked and the endoscope is inserted to complete the automated targeting process towards the left iliac fossa. The other robotic arms are then docked and robotic instruments are inserted under visual control.

Step-by-step review of critical elements of the procedure

Full-robotic TME is essentially based on 3 steps:

- ❖ Splenic flexure mobilization;
- ❖ Vascular control;
- ❖ TME.

Splenic flexure mobilization

The transverse mesocolon is lifted up with the grasper in R1 (*Figure 3*). The lesser sac is entered through the incision of transverse mesocolic root at the level of the anterior pancreatic border. Splenic flexure mobilization is carried out with a medial-to-lateral approach along the pancreatic body. A sponge is placed underneath the transverse mesocolon and the splenic flexure is

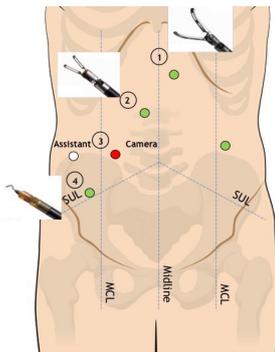


Figure 3 Splenic flexure mobilization and vascular control, instruments setup.

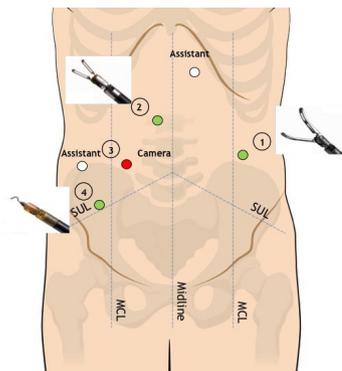


Figure 4 Total mesorectal excision, instruments setup.

retracted medially by the assistant. Splenic flexure mobilization is completed in a lateral-to-medial fashion along the white line of Toldt up to the inferior splenic pole and the plane previously developed is easily reached. Coloepiploic detachment is then carried out.

Vascular control

During this step of the procedure R2 and R4 are the operative arms, whereas R1 is used for stable retraction. A 30°-down robotic camera is mounted on robotic arm R3. The assistant trocar in the right flank is used for suction/irrigator, clip applier, swab introduction or additional retraction if needed.

The assistant grasper and the robotic grasper in R1 lift anteriorly and laterally the sigmoid colon and upper rectum to expose the root of the sigmoid mesocolon and the upper mesorectum. The peritoneum is then incised at the level of the sacral promontory to obtain the avascular presacral plane and the hypogastric nerves are identified. The robotic

monopolar hook on R4 and bipolar grasper on R2 work synergically for the dissection of the IMA, which is freed by the surrounding lymphatic tissue, providing a wide locoregional lymphadenectomy and preserving the main trunks of the hypogastric plexus at the IMA origin.

Before IMA division, the Toldt's fascia is identified underneath the inferior mesenteric vein (IMV) in a medial-to-lateral fashion and left gonadal vessels and left ureter are identified and preserved. The IMA is then dissected free and a high-tie is performed by the application of Hem-o-lok® (Teleflex, Weck, USA) clips. The dissection along the Toldt's fascia, that has been previously identified cranially and caudally to the IMA origin, is completed in a medial-to-lateral fashion and the retroperitoneal structures are preserved. The IMV is isolated and dissected at its root between clips at the inferior border of the pancreas.

TME

During this step, R1 is moved and connected to the left flank 8-mm trocar to achieve optimal access to the mesorectum, whereas R2 and R4 remain in their original position (Figure 4). An additional 8-mm epigastric trocar is now available in order to maximize the assistance with cranial retraction on the sigmoid colon and simultaneous suction/irrigation or additional gentle pelvic sidewall retraction.

Robotic R2 and R4 are the operative arms, whereas R1 is used to expose the pelvic area with lateral traction on pelvic sidewalls or anterior/upward traction on the Douglas peritoneal reflection, vaginal wall or seminal vesicles/Denonvilliers fascia. Frequent repositioning of R1 is fundamental to maintain the adequate countertraction that will allow the dissection plane to be continued up to the level of the pelvic floor.

TME is carried out according to Heald's principles through the so-called "holy plane". This step is fundamental to avoid the transection of the hypogastric nerve plexus and sacral venous plexus located deep in the parietal layer within the presacral space. Dissection starts on the posterior aspect of the mesorectal envelope: the right lateral and the anterior plane are then subsequently dissected up to the seminal vesicles in a counterclockwise fashion. The left lateral pelvic fascia is then dissected up to its lower portion to allow for the identification of the pelvic nerve plexus and to gain access to the "bare rectum area" (Figure 5). Dissection is then completed anteriorly on the lower portion of the Denonvilliers fascia and circumferentially below the reflection of the mesorectal fascia to gain access

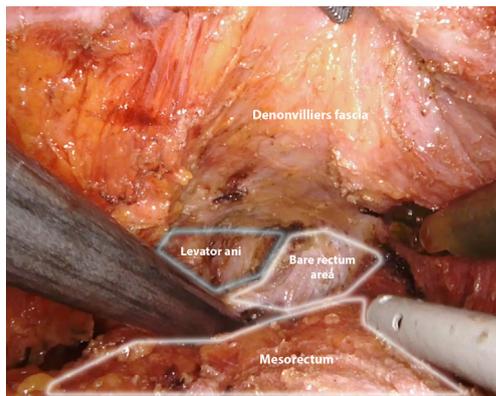


Figure 5 Intraoperative view after completion of total mesorectal excision.

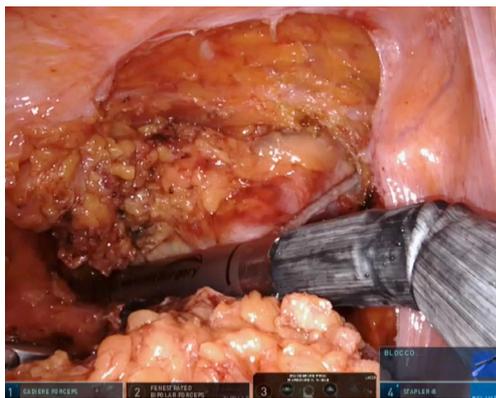


Figure 6 Ultralow rectal transection with endowristed robotic stapler.

to the levator ani plane. During the dissection of the lower mesorectum, it may be helpful to shift to a 0° camera in order to achieve better visualization.

According to tumor distance from the anal verge, rectal transection is performed with 45-mm robotic staplers (Figure 6) after evaluation of rectal stump perfusion with the integrated fluorescence imaging system (Figure 7).

Short-term postoperative outcomes

To date, few studies with low level of evidence comparing robotic versus laparoscopic rectal resection are available. No multicentre randomized controlled trial has been published yet. Nevertheless, several meta-analysis have been published as the interest in robotic surgery is growing.

Several studies reported longer operative time for

the robotic approach compared to laparoscopy (13-15), the available meta-analysis showed no significant differences between the two procedures (16-19). Only one study reported a shorter operative time for robotic rectal resection (20).

Laparoscopic rectal resection is a demanding procedure with still high CRs (21); the CLASICC trial reported a CR of 34% (7), while in the COLOR II trial CR to open surgery decreased to 17% (8). Recently, two randomized trials (3,4) found a CR of 9% and 11.3% respectively. To date, the majority of the studies showed lower CRs to open surgery for robotic rectal approach when compared to laparoscopy (22-24) and, probably, this is the most frequently reported finding in favour of robotic rectal surgery in the literature. Trastulli *et al.* (18) reported a CR of 2% for robotic rectal resections, and Xiong *et al.* (17) in a recent meta-analysis comparing robotic and laparoscopic TME, found a significantly lower CR for the robotic group.

This measure of surgical outcome has also been chosen as primary endpoint of the ROLARR Trial, whose results have been recently presented. In the study design (superiority trial), it was hypothesized that the CR could be reduced by 50% (from 25% to 12.5%) in the robotic group. Though the study failed to meet the criterion for statistical superiority, an a priori defined subgroup analysis showed a possible advantage in the most challenging cases, namely male patients, low anterior resections and obese patients.

Regarding blood loss, some reports demonstrated a lower mean operative blood loss in robotic procedures compared to either open or laparoscopic ones (23,25).

Two studies (26,27) found a significant reduction in length of hospital stay in the robotic group, probably due to the lower overall surgical trauma of the robotic technique and to lower CRs. To date, however, there is no high level of evidence that robotic surgery could reduce length of stay when compared to standard laparoscopy (17,18,28).

Post-operative complications rates are similar and particularly the anastomotic leak rate is not different between the two approaches (17,18,24,28,29). Only one recent meta-analysis by Sun and coworkers (19) demonstrated a lower overall post-operative complications rate for the robotic group compared to the laparoscopic one.

Functional outcomes

Whether or not laparoscopic surgery could have an advantage over open surgery in preserving urogenital function is still controversial, later studies suggest better



Figure 7 Evaluation of bowel perfusion with integrated indocyanine green fluorescence imaging system.

outcomes with laparoscopy, but earlier reports stated the opposite (30). Undoubtedly, in this scenery the robotic system could find its place, combining the advantages of minimally invasive surgery with a more precise dissection.

Kim *et al.* (31), in their series of 69 patients, demonstrated that robotic TME is associated with earlier recovery of normal voiding (3 months versus 6 months) and erectile function (6 months versus 12 months) when compared to its laparoscopic counterpart. Recently, Panteleimonitis *et al.* (32) found that Robotic TME has better postoperative urogenital outcomes in men and urological outcomes in women. For female sexual function there was no difference between the two groups, but the sample was very small (9 laparoscopic, 4 robotic). Another series of 74 patients submitted to robotic TME, showed that robotic surgery allows for preservation of urinary and sexual function, with values at 1-year comparable to those measured before surgery (33). A similar trend for urogenital function has been observed in other studies (34,35).

Oncological outcomes

Studies comparing oncological outcomes of robotic and laparoscopic resections for rectal cancer have small number of cases, and for the most part are nonrandomized controlled trials with a short follow up (17,21).

A specimen with an adequate and complete mesorectum directly correlates with recurrence rates (36), but few studies on minimally invasive TME specify the macroscopic assessment of mesorectal excision according to the criteria initially described by Quirke (37). Baik *et al.* (38) reported statistical significance in the quality of the mesorectum in favor of the robotic group, ascribing this result to the technical advantages of the robotic platform. In a recent

review that considered 11 studies assessing the quality of the mesorectum, complete excision ranged from 100% to 60% in the robotic series, and from 100% to 40% in the laparoscopic group (21).

Preliminary results of the ROLARR trial seem to show no statistical difference between laparoscopic and robotic resection in terms of CRM positivity, thus confirming the results of several others series (13,24,26,39,40).

Kang *et al.* (15) in their case matched study reported a significant decrease in CRM involvement in the robotic group compared to the open group in mid to low rectal cancer resections. 165 patients had robotic resection with a CRM positivity rate of 4.2%, while the open group (165 patients) presented with a CRM positivity rate of 10.3%. No significant difference was found between the robotic and the laparoscopic group (CRM+ 6.7%).

Ghezzi *et al.* (41) reported a significant higher number of retrieved lymph nodes in the robotic group, this finding was confirmed also by other authors (13,27,42), but the majority of the studies reports similar numbers of harvested nodes between laparoscopic and robotic rectal resection (17,21).

Survival data from the ROLARR trial are still unavailable and reports of long-term oncologic outcomes for robotic rectal surgery remain limited (*Table 1*). No significant difference has been reported in overall and disease free survival (DSF) or local recurrence rates (LR) (53). Park *et al.* (26) found no differences in the 5-year overall survival (OS), DSF and local recurrence rates. Similar results were reported by Cho *et al.* in a case matched series of 278 patients (40), with a 5-year OS of 92.2% and a DSF of 81.8% in the robotic group. More recently, Kim *et al.* (45) showed that robotic surgery was a significant good prognostic factor for OS and cancer specific survival in multivariate analysis.

Table 1 Oncological mid- and long-term outcomes

Ref	Year	Country	Technique	Pts.	Harvested nodes (mean)	CRM + (%)	Distal margin (mm, mean)	Median FU months	LR %	DSF %	OS %
Lim <i>et al.</i> (43)	2017	South Korea	ROB	74	11.6	4	17	56.1	2.7	76.8 (5 y)	90 (5 y)
Tang <i>et al.</i> (44)	2017	China	LAP	64	14.7	1.6	22		6.3	76 (5 y)	93.3 (5 y)
Kim <i>et al.</i> (45)	2017	South Korea	ROB	392	14.6	2.5	35	24*	5.1	74.3 (3 y)	86.4 (3 y)
Law <i>et al.</i> (13)	2016	Hong Kong	ROB	192	20.2	4	23	40.3	-	72.6 (5 y)	90.5 (5 y)
Sammour <i>et al.</i> (46)	2016	USA	LAP	192	21	4.9	24		-	68 (5 y)	78 (5 y)
Feroci <i>et al.</i> (27)	2016	Italy	ROB	220	14**	4.1	30	31.4	-	81.9** (5 y)	71.8 (5 y)
Pai <i>et al.</i> (47)	2016	USA	LAP	171	12***	8.2	30		-	80** (5 y)	74.3 (5 y)
Park <i>et al.</i> (26)	2015	South Korea	ROB	276	22***	2.5	-	23.8	2.4# (5 y)	82# (5 y)	87# (5 y)
Cho <i>et al.</i> (40)	2015	South Korea	ROB	53	18	0	25	37.4	1.9	79.2 (3 y)	90.2 (3 y)
Ghezzi <i>et al.</i> (41)	2014	Brazil	LAP	58	11 [3-27]	1.7	15		5.2	83.4 (3 y)	90 (3 y)
Yoo <i>et al.</i> (48)	2014	South Korea	ROB	101	15	5	35	33	4	79.2 (3 y)	90.1 (3 y)
Hara <i>et al.</i> (49)	2014	South Korea	ROB	133	16.34	6.8	27.5	58	2.3	81.9 (5 y)	92.8 (5 y)
Baik <i>et al.</i> (50)	2013	South Korea	LAP	84	16.63	7.1	28.5		1.2	78.7 (5 y)	93.5 (5 y)
Baek <i>et al.</i> (51)	2010	USA	ROB	278	15	5	20	51.8*	5.9	81.8 (5 y)	92.2 (5 y)
Bianchi <i>et al.</i> (24)	2010	Italy	LAP	278	16.2	4.7	22		3.9	79.6 (5 y)	93.1 (5 y)
Pigazzi <i>et al.</i> (52)	2010	Multicentric (USA/Italy)	ROB	65	20.1	0	27	46.7*	3.2	73.2 (5 y)	85 (5 y)
Patrì <i>et al.</i> (20)	2009	Italy	OPEN	109	14.1	1.8	22	55.1*	16.1	69.5 (5 y)	76 (5 y)
	2014	South Korea	ROB	43	13.93	9.1 §	13.3	33.9	12.8	76.7 (3 y)	95.2 (3 y)
	2014	South Korea	LAP	26	21.42	19.2 §	16.7	36.5	8.3	75 (3 y)	88.5 (3 y)
	2014	South Korea	ROB	200	17***	2.5	18***	29.8	4.5	81.7 (5 y)	92 (5 y)
	2013	South Korea	ROB	370	15.6	5.7	25	24	3.6	79.2 (3 y)	93.1 (3 y)
	2010	USA	ROB	64	14.5	0	34	20.2	3.1	73.7 (3 y)	96.2 (3 y)
	2010	Italy	ROB	25	18	0	20	-	-	-	-
	2010	Italy	LAP	25	17	4	20		-	-	-
	2010	Multicentric (USA/Italy)	ROB	143	14.1	0.7	29	17.4	1.5	77.6 (3 y)	97 (3 y)
	2009	Italy	ROB	29	10.3	0	21	29.2*	0	100	96.6
			LAP	37	11.2	0	45	18.7*	5.4	83.7	97.2

ROB, robotic; LAP, laparoscopic; LR, local recurrence; DFS, disease free survival; OS, overall survival. *, mean; **, cancer specific survival; ***, cancer specific survival; #, 83 patients followed up for a minimum of 3 years; §, CRM ≤2 mm.

Learning curve

Rectal cancer surgery with TME is complex and demanding and the number of cases required to achieve the learning curve in laparoscopic rectal resection is estimated to be between 60 and 80 (9,54). The majority of the studies published so far suggest a shorter learning curve for robotic rectal cancer surgery, ranging from 15 to 30 cases (9,55,56). Yamaguchi *et al.* (57) found a learning curve of 25 cases before reaching the plateau. Robotic assistance could probably facilitate the adoption of minimally invasive rectal surgery (58), that still maintains a low penetration worldwide (10-12), by overcoming the technical constraints of standard laparoscopy and by shortening the learning curve.

The robotic technology represents a unique tool for training with the aid of the dual console and of the virtual simulator, but competence assessment is mandatory. Recently, a structured training protocol has been proposed (59), in an attempt to standardize and objectively evaluate the learning process.

The robotic system has the potential of shortening the learning curve for complex procedures not only for experienced surgeons (56), but also for novice surgeons that may learn a procedure approaching it directly with the robot. Foo *et al.* (60) evaluated the learning curve for robotic assisted rectal resection in a surgeon that had previously performed less than 5 open or laparoscopic rectal cancer resections. On a series of 39 consecutive TME they found the learning curve to be 25 cases. At our Institution, we recently introduced a structured training program in robotic colorectal surgery in order to assess its safety and efficacy for young surgeons without prior experience in both open and laparoscopic colorectal surgery. Robotic right colectomy with intracorporeal anastomosis has been chosen as a model and two junior attending surgeons were trained through sequential steps that included: virtual simulator, dry lab, wet lab hands-on courses, at least 20 procedures as table assistant and proctored clinical practice with the dual console. They were then privileged to perform right colectomy without mentoring. Preliminary results showed neither conversions nor intra- or postoperative complication. Mean operative time was 200 minutes and mean length of hospital stay was 6 days. The program will then involve novice surgeons in left-sided resections and, finally, in most complex procedures such as TME in a stepwise approach.

Costs

One of the biggest reasons for skepticism about robotic surgery is often related to high costs.

When focusing on robotic rectal cancer surgery, Kim *et al.* (61) and Park *et al.* (26) failed to prove the cost-effectiveness of robotic versus laparoscopic rectal resection based on short-term and long-term oncological outcomes, respectively. Baek *et al.* (62) in their case-matched study reported higher total hospitalization costs for the robotic group compared to the laparoscopic one, but without reaching a statistical significance. Besides, Byrn *et al.* (63) found that direct costs of robotic rectal resection decreased with time, showing that later procedures were actually less expensive. A recent Italian study (64) reported a similar finding: although overall mean costs of laparoscopic TME were significantly lower than those of robotic TME, costs gradually decreased in the robotic group as the surgeon advanced in his learning curve, thus suggesting a significant optimization of instruments and OR time use with experience.

Recently, Daskalaki *et al.* (65) reported that robotic and open liver resections were financially comparable. Though direct costs (purchase, maintenance and use of the system) were higher in the robotic group, they were balanced by shorter length of stay and better postoperative outcomes (lower rates of major complications and shorter ICU stay).

Conclusions

Robotic surgery is often considered to be associated with longer operative times because of the docking and system setup. However, these steps can be quickly performed with practice and are not among the main reasons for this finding. Robotic surgery represents a new concept of surgery, where precise dissection and careful visualization of even the smallest anatomical structure play a crucial role. This aspect could probably explain a trend towards better functional outcomes of robotic surgery versus the laparoscopic approach that should be further investigated.

The technological advantages provided by the robotic system translates into a shorter learning curve and lower CRs when compared to standard laparoscopy, and these aspects could probably facilitate the widespread adoption of minimally-invasive TME that still has a low penetration worldwide. Moreover, the educational capabilities of the platform, together with structured training programs, could

allow novice surgeons to safely approach colorectal surgery directly with the robot, defining the “robotic surgeon” as a new paradigm.

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