Preliminary clinical application of domestically produced Chinese minimally invasive surgical robot system "Micro Hand S " in colon cancer

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Background: The Micro Hand S robot is the first domestically produced surgical robot that has entered clinical use in China, and this is the first report of its application in colon cancer.**Objective:** This study aimed to validate the safety and efficacy of the domestically produced Chinese minimally invasive Micro Hand S surgical robot system in complex surgery, such as robotic complete mesocolic excision (R-CME).**Methods:** From March 2018 to December 2018, 30 patients with right hemicolon cancer underwent R-CME with the Micro Hand S robot system. The operative findings, morbidities, oncological findings and unique characteristics were summarizedwere analyzed.**Result:** 12 patients with right hemicolon cancer and 18 patients with sigmoid colon cancer underwent RCME with the Micro Hand S robot system. During the study period, the median operative duration was 209 (range, 180-255) min, and the median estimated blood loss volume was 35 (range, 25-75) ml. The median number of lymph nodes harvested was 42 (21-77), and the median postoperative hospital stay was 5 (range, 4-7) days. According to the Clavien-Dindo classification, there were no severe complications except for 7 cases of grade I complications and 5 cases of grade II complications. The conversion rate for all operations was 0%. There were no cases of 30-day readmission or 30-day mortality.

Conclusion: Clinical application of domestically produced Chinese minimally invasive surgical robot system “Micro Hand S ” in selected colon cancer patients is technically feasible and safe.

Keywords: Micro Hand S surgical robot system, robot-assisted complete mesocolic excision, colon cancer, safety, feasibility

Introduction

To deliver more value to the Chinese health care system, Central South University in collaboration with Tianjin University developed a low cost and easy-to-operate minimally invasive surgical robot system, the Micro Hand S system, in 2013[7] (as shown in Figure 1). However, adoption of the domestic surgical robot was relatively limited to simple surgical procedures in previous clinical applications, and the safety and efficacy of the domestically produced Chinese surgical robot system in complex surgical procedures, such as radical resection for colon cancer, have not been determined. As one current mode of radical operation, complete mesocolic excision (CME) for colon cancer has been proven to significantly decrease the rate of recurrence[1,2]. Robotic systems offer technical advantages, such as improved vision and ergonomics and precise dissection, and these systems have revolutionized the CME procedure in colorectal surgery[3,4,5,6]. To verify the safety and feasibility of the use of domestic surgical robots in complex surgical applications, such as CME for colorectal cancer, we conducted a pilot application of the domestic surgical robot in CME for colon cancer beginning in December 2017. In this study, we report the initial experiences of robotic CME (R-CME) with the Micro Hand S system for colon cancer, as well as the histopathological and operative outcomes and unique characteristics of the domestic surgical robot.

Methods

Our study retrospectively summarized the data of 30 consecutive colon cancer patients who underwent R-CME using a domestically produced surgical robot in the Gastrointestinal Surgery Department, Xiangya Third Hospital, Central South University, from March 2018 to December 2018. This study was registered with "Clinicaltrials.gov" and was approved by the Association for the Accreditation of Human Research Protection Program (AAHRPP) (NCT02752698). All patients were informed of the advantages and disadvantages of the R-CME procedure, and written informed consent was obtained routinely. All patients underwent 12 months of follow-up.

Our criteria for selection were as follows: (i) endoscopic biopsy-proven primary colon cancer; (ii) patient age ranging from 18 to 75; (iii) American Society of Anesthesiology (ASA) class ≦3; (iv) no preoperative treatment, and (v) treatment with R-CME. The exclusion criteria included emergency surgery, synchronous or metachronous multiple primary colorectal cancer, preoperative neoadjuvant chemoradiotherapy, distant metastasis, extensive tumor invasion into adjacent organs, or other severe cardiopulmonary compromise.

Data such as patient demographics, clinical stage, operative duration, complications, length of hospital stay, histopathological results and the operation video were recorded, and the research data were processed in accordance with current data protection legislation.

Surgical technique

Here, we report on the treatment of one ileocecal tumor and one sigmoid tumor as examples. The tumors were 3 cm and 4 cm in diameter and were located by endoscopy; the preoperative histopathological diagnosis demonstrated adenocarcinoma. The operations were performed using the medial-to-lateral approach through three robotic ports and one assistant port.

Patient positioning and port placement for right hemicolectomy (Figure 2, A): After general anesthesia was induced, the patient was placed supine in the Trendelenburg position at 10-15° and rolled to the left 10-15 degrees with the legs in adjustable stirrups. Pressure points and bony prominences were padded. The body position was secured with a vacuum-mattress device, especially laterally on the left side. The patient was carefully secured to the table to avoid any shifting when rolling the table. The camera port A was placed on the left spinoumbilical line (SUL) 2-3 cm medial from the left midclavicular line (MCL); the distance to the symphysis pubis should be 16-18 cm. Port B was placed 7-8 cm below the left costal margin and on the left MCL; the distance to the camera port should be at least 8-10 cm. Port C was placed on the right SUL and 2-3 cm lateral to the intersection with the MCL; the distance to other instrument ports and the camera port should be at least 8-10 cm. The assistant port D was placed 8-10 cm caudal to the right instrument port, a minimum of 8 cm from the endoscope port and slightly lateral to the left MCL. This port was used for suction/irrigation, ligation and retraction. the patient cart was positioned over the patient's right side during this procedure.

Patient positioning and port placement for sigmoid colectomy (Figure 2,B): After general anesthesia was induced, the patient was placed supine in the Trendelenburg position at 10-15° and rolled to the left 10-15 degrees with the legs in adjustable stirrups. Pressure points and bony prominences were padded. The camera port A was placed 2-3 cm above the umbilicus on the midline; the distance to the symphysis pubis should be 16-18 cm. Port B was placed at the middle line of right clavicle intersects the lower edge of umbilical plane.port C was placed 3-5 cm below the costal margin of the left axillary anterior line of the right clavicle.The assistant port D should be placed at10 cm below the B point, right lateral clavicle median line. We located the cart over the patient's left side during this procedure.

Surgical procedures for right hemicolectomy (Figure 3): (i) Initial exposure: The surgeon flips the greater omentum over the transverse colon toward the diaphragm using laparoscopic instrumentation with the side assistant and then moves the small intestine toward the left side of the abdomen. (ii) Primary vascular control: Using an ultrasonic scalpel and bipolar forceps, primary vascular control is achieved by dividing the ileocolic artery and vein, the gastric colonic stem, and the right branch of the middle colic artery and vein (the right colic artery is not isolated). The extent of the necessary vascular control depends on the tumor location, planned anastomosis location and patient anatomy. In this example, the surgeon dissociates the ileocolic vessel, middle colic vessel and gastric colonic stem and then cuts off the ileocolic vessel. (iii) Inferior dissection and mobilization of the ascending colon: The inferior dissection starts at the retrocecal recess, working caudally over the duodenum to the head of the pancreas. Once complete, the lateral attachments of the ascending colon are taken down starting at the right paracolic gutter and moving caudally to the hepatic flexure until the ascending colon is completely mobilized. The hepatic flexure should be left in place until the vasculature is ligated and then later taken superiorly. (iv) Final mobilization: The transverse mesocolon is divided from the root to the colon. All extra tissue on the transverse colon is cleared at the location for final transection of the transverse colon. The omentum in the avascular plane is dissected toward the transverse colon. Finally, the lateral attachments are divided, and the hepatic flexure is fully mobilized. (v) Colon division and anastomosis: The procedure is performed via mini-laparotomy due to the application of a circular gastrointestinal stapler. Preparation for this is performed through the mini-laparotomy at the upper-right quadrant port location to remove the resected bowel.

Surgical procedures for sigmoidectomy (Figure 4): (i) Initial exposure: The greater omentum is flipped over the transverse colon toward the liver. Small bowel loops are retracted out of the pelvic area into the upper-right quadrant. In female patients, the uterus is suspended. (ii) Primary vascular control: Primary vascular control is achieved by dividing the inferior mesenteric artery (IMA) first, followed by the inferior mesenteric vein (IMV). (iii) Medial-to-lateral mobilization of the sigmoid and descending colon: The dissection extends from the superior to inferior border of the pancreas, laterally following Gerota's fascia and inferior to the psoas muscle where the ureter crosses the iliac vessels. (iv) Descending colon mobilization: To achieve tension-free anastomosis, the splenic flexure is mobilized via a medial approach. (v) Rectal dissection: Rectal dissection is performed using an elliptical dissection pattern moving from posterior laterally to the left side, then to the right and finally to the anterior side of the rectum down to the level 5 cm away from the colon tumor. (vi) Specimen extraction and anastomosis: Specimen extraction and anastomosis are performed via standard laparoscopy or with robotic assistance, with preparation through the mini-laparotomy at the lower-right quadrant port location.

Results

Thirty patients underwent RCME with the Micro Hand S system between March 2018 and December 2018, including 8 cases of ileocecal cancer, 4 cases of ascending colon cancer and 18 cases of sigmoid colon cancer. The patient demographics and operative outcomes are summarized in Table 1. There were 12 females (40%) and 18 males (60%), with a median age of 64 (range, 46-75) years. The median body mass index (BMI) was 27.71 (range, 26-31) kg/m^2. The median tumor diameter was 4.5(range, 3-6) cm. The median operative duration was 209 (range, 180-255) min, and the estimated blood loss volume was 35 (range, 25-75) ml ml. The overall operative conversion rate was 0%; no patients required conversion to conventional laparoscopic abdominal surgery or open surgery. The mean time to the return of bowel sounds and the resumption of an oral diet was 3 and 4 days, respectively. The median length of hospital stay after the operation was 5 (range, 4-7) days. There were no cases of mortality within 30 days. According to the Clavien-Dindo classification (as summarized in Table 1), seven patients experienced grade I complications (28%), including wound complications in two patients, hypokalemia in two patients and hypertension in three patients. Furthermore, five patients suffered from grade II complications (20%), including hypoproteinemia in three patients, intraabdominal hemorrhage in one patient and ileus in one patient. All patients with complications were discharged after conservative treatment, and no patients underwent reoperation.On pathological examination (Table 2), the median area of the mesentery (AM) in right side colon cancer group was 12,852.4 (range, 11,294.1-15,371.5) mm^2, the median distance from the vascular tie (DVT) to the tumor was 128.59 (range, 127.54-133.03) mm, and the median excisional large bowel length (LBL) was 214.32 (range, 172.16-239.53) mm. The median AM in the sigmoid colon cancer group was 10,165.4 (range, 8,039.5-12,026.3) mm^2, the median DVT to the tumor was 140.7 (range, 139.5-141.3) mm, and the median excisional LBL was 213.5 (range, 208.5-239.7) mm. The median number of lymph nodes (LNs) harvested was 42 (range,21-77). The distal resection margin from the tumor was 14.5 (range, 12-17) cm. At a follow-up time of 12 months, there were no cases of recurrence or disease-related mortality.

Discussion

An increasing number of studies have indicated that robot-assisted surgery might have similar safety and efficiency for colon cancer patients as laparoscopic-assisted surgery and open surgery. Presently, the da Vinci robotic system offers technical advantages, such as improved vision, better ergonomics and precise dissection, leading to notably superior results in harvesting LNs and performing more precise mesenteric dissection in R-CME[8]. Several previous studies found that R-CME reduced the estimated blood loss volume, allowed comparable LN retrieval, and resulted in similar postoperative recovery compared with traditional techniques[9.10]. It has been demonstrated that robotic surgery could be an alternative option for colon cancer patients[11].

In our series, the domestically produced surgical robot exhibited the same characteristics as a similar imported surgical robot in R-CME, including terminal instrument dexterity and a stable 3D high-definition endoscope. Using this domestically produced robot system, the surgeon performed CME with little bleeding (the estimated blood loss volume was 35 (range 25-75) ml) as well as a low conversion rate (the conversion rate was 0%). Formisano and Cleary have also presented similar findings[12.13]. In their series, although the authors presented limited information on clinical outcomes and no histopathological data, they reported a reduction in the conversion rate and blood loss volume with the robotic approach. Additionally, according to the Clavien-Dindo classification, there were no severe complications except for 7 (28%) cases of grade I complications and 5 (20%) cases of grade II complications. All patients with complications were discharged after conservative treatment without surgical, endoscopic or radiological intervention. The present outcomes demonstrate that R-CME using the Micro Hand S robot is feasible and safe for the treatment of colon cancer in terms of reduced trauma and a lower incidence and severity of complications.

The number of harvested LNs is crucial for the prognosis and is regarded as a measure of quality in colon cancer care. In our study, the median number of harvested LNs was 42 (range, 21-77), higher than that in the majority of studies reporting on open, laparoscopic[16.17] and R-CME techniques[18]. Furthermore, the distal resection margin from the tumor, the median AM and the median DVT to the tumor showed that the pathological characteristics and morphological measurements of R-CME with the Micro Hand S system are acceptable compared with those reported in other studies[19]. Previous studies have shown that CME is associated with better surgical specimen quality, which includes an adequate harvested LN number, DVT to the tumor and AM[20.21]. At the 12-month follow-up, there were no cases of recurrence or disease-related mortality.R-CME using the Micro Hand S system has the potential to improve long-term local recurrence-free survival for colorectal cancer patients.

Additionally, in our study, the median operative duration was 209 (range, 180-235) min, and this parameter in recent studies on using the da Vinci robot for standard right hemicolectomy ranged from 159 to 287 min [14.15]. As a trade-off for the optical magnification and finer instrument movements, the application of the da Vinci Si for robotic hemicolectomy in our center results in a confined active work area. However, the CME procedure for colon cancer spans a large operative field across multiple quadrants. The drawback causes a more time-consuming endeavor for surgeons who are equally competent in laparoscopy. However, for the Micro Hand S robot, the slave manipulator is based on the folding principle of the laminated double parallelogram mechanism[15]. By optimizing the joint layout, the Micro Hand S robot can achieve miniaturization and has a more compact design overall, while the robot manipulator is capable of a wide range of movements in space and is highly foldable. Moreover, the range of rotation of the R1 and R2 joints of the robotic slave manipulator is (-120°, 120°) and (-30°, 140°), respectively (Figure 5). The folding mechanism and novel design of the slave manipulator reduce the requirements of the operating room environment and allow the slave manipulator to span a large operative field across multiple quadrants using a single dock on the robot patient cart, which can help reduce assistant fatigue and shorten the operative duration and anesthesia time for CME.

Secondly,the degree of freedom (DOF) arrangement of the instrument in the Micro Hand S is in the roll-pitch-roll form (the open and close motion is not included), which differs from the roll-pitch-yaw form of the da Vinci surgical robot instrument (shown in Figure 6). The ranges of motion are pitch deflections (-70~70 degrees) and end rotation (-360~360 degrees).The design integrates the degree of freedom of rotation directly at the end, which makes the most complex stitching operation under the endoscope easier, simplifies the complexity of the control system, and enhances the adaptability to complex surgery. Furthermore, the master manipulator of the surgical robot adopts a series of three rotary joint structures (as shown in Figure 7) and is used to realize the locations of surgical input from the doctor. This layout method has the advantages of a large movement space, a simple structure and a small volume. Because the axes of the first two joints are perpendicular to the earth, the motion is less affected by gravity, and the operation is easy and flexible. Above-mentioned unique characteristics help to facilitate the R-CME procedure,and shorten the operation time.

There are still some limitations to the present study. First, it was a retrospective case series study that was noncomparative in nature and lacked long-term data. Second, this study was performed by the author who is one of the few surgeons with two different kind of robotic operation experiences. Considering R-CME using one new surgical robot in the present study, the unique experiences could affect the results of study. Thus, the findings may not be generalizable to surgeons in other settings with different levels of experience in minimally invasive surgery. Third, this study is limited by the lack of long-term data on overall survival (OS), recurrence-free survival (RFS), and local RFS. Certainly, future research should include prospective, large-scale, randomized controlled studies with longer follow-up times.

In conclusion, our outcomes suggest that R-CME using Micro Hand S surgical robot is a safe and feasible surgical procedure with acceptable morbidity and provides excellent specimen quality. The technical superiority of this domestic surgical robotic system seems to overcome the shortcoming of time consuming in robotic surgery. Certainly, future research should include prospective, randomized trials with long-term follow-up.

Ethical review committee: Association for the Accreditation of Human Research Protection Program (AAHRPP)- D14002.

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Figure legends

Fig. 1: The domestically produced Chinese minimally invasive surgical robot system Micro Hand S

Fig. 2: Patient positioning and port placement for R-CME

Fig. 3:Surgical procedures for right hemicolectomy.

Fig. 4: Surgical procedures for sigmoid hemicolectomy.

Fig.5: Folding principle of the laminated double parallelogram mechanism in Micro Hand S system.

Fig. 6: A. In the da Vinci Si surgical robot, the degrees of freedom (DOF) arrangement of the instrument is in the roll-pitch-yaw form. B. In the Micro Hand S surgical robot, the DOF arrangement of the instrument is in the roll-pitch-roll form.

Fig. 7: Details of the master manipulator design.

Table 1 Demographic characteristics and operative outcomes

Characteristic	Value (n = 30)
Median age (range)	64 (46-75)
Sex (female/male)	2:3 (12:18)
Median BMI, kg/m^2 (range)	27.71 (26-31)
Median blood loss volume, ml (range)	35 (25-75)
Median operative duration, min (range)	209 (180-255)
Median robot docking time, min (range)	30 (25-35)
Median time to first flatus, days (range)	3 (2-4)
Median time to diet, days (range)	4 (3-5)
Median postoperative hospital stay, days (range)	5 (4-7)
Conversion rate, %	0
30-day mortality	0
90-day morbidity classified according to the Clavien-Dindo classification	
Grade I	7(28%)
Grade II	5(20%)
Grade IIIa	0
Grade IIIb	0
Grade IVa	0
Wound complication	2
Hypokalemia	2
Hypertension	3
Hypoproteinemia	3
Ileus	1
Intraabdominal hemorrhage	1

Reoperation, n(%)	0
30-day readmission，n(%)	0
30-day mortality，n(%)	0
recurrence (12 months follow up)	0

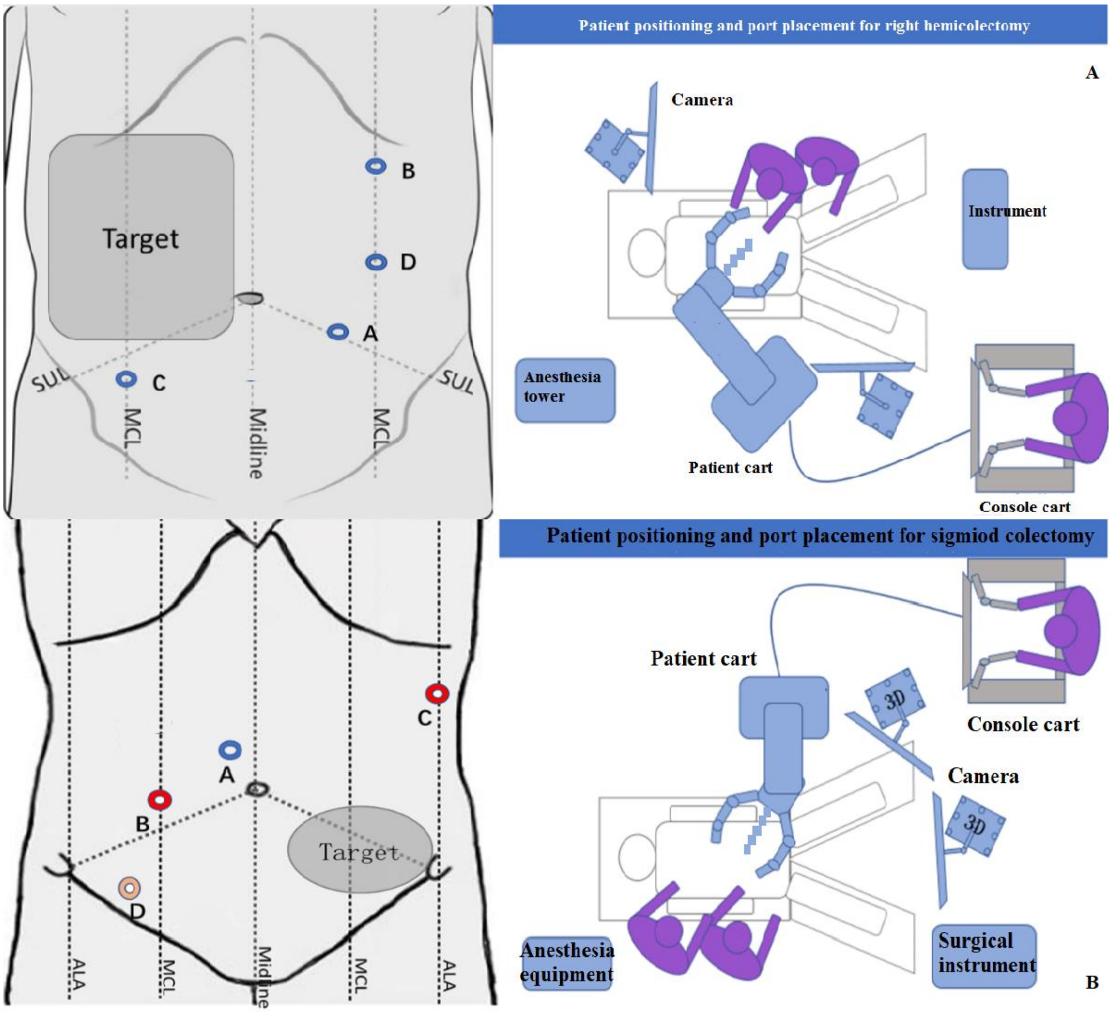
Table 1 Demographics and operative outcomes of patients who underwent RCME with the Chinese minimally invasive “Micro Hand S” surgical robot system

Table 2 Pathological characteristics and morphological measurements

Characteristic or Measurement	Value (n = 30)
Tumor diameter, cm, median (range)	4.5 (3-6)
Location of the tumor	
Ileocecum	8
Ascending colon	4
Sigmoid colon	18
pT stage	
T1N0M0	0
T2N0M0	4
T2N1M0	17
T3N1M0	9
T3N2M0	0
T4N1-2M0	0
Ileocecal and ascending colon cancer	
Area of mesentery, mm^2, median (range)	12,852.4 (11,294.1-15,371.5)
Distance from the vascular tie to the tumor, mm, mean (range)	128.59 (127.54-133.03)
Excisional large bowel length, mm, median (range)	214.32 (172.16-239.53)
Sigmoid colon cancer	
Area of mesentery, mm^2, median (range)	10,165.4 (8,039.5-12,026.3)
Distance from the vascular tie to the tumor, mm, mean (range)	140.7 (139.5-141.3)
Excisional large bowel length, mm, median (range)	213.5 (208.5-239.7)
Number of dissected lymph nodes (range)	42 (21-77)
Number of positive lymph nodes, median (range)	5(0-7)
Distal resection margin, cm, median (range)	14.5 (12-17)

Table 2 Pathological characteristics and morphological measurements

Fig. 1: The domestically produced Chinese minimally invasive surgical robot system Micro Hand S



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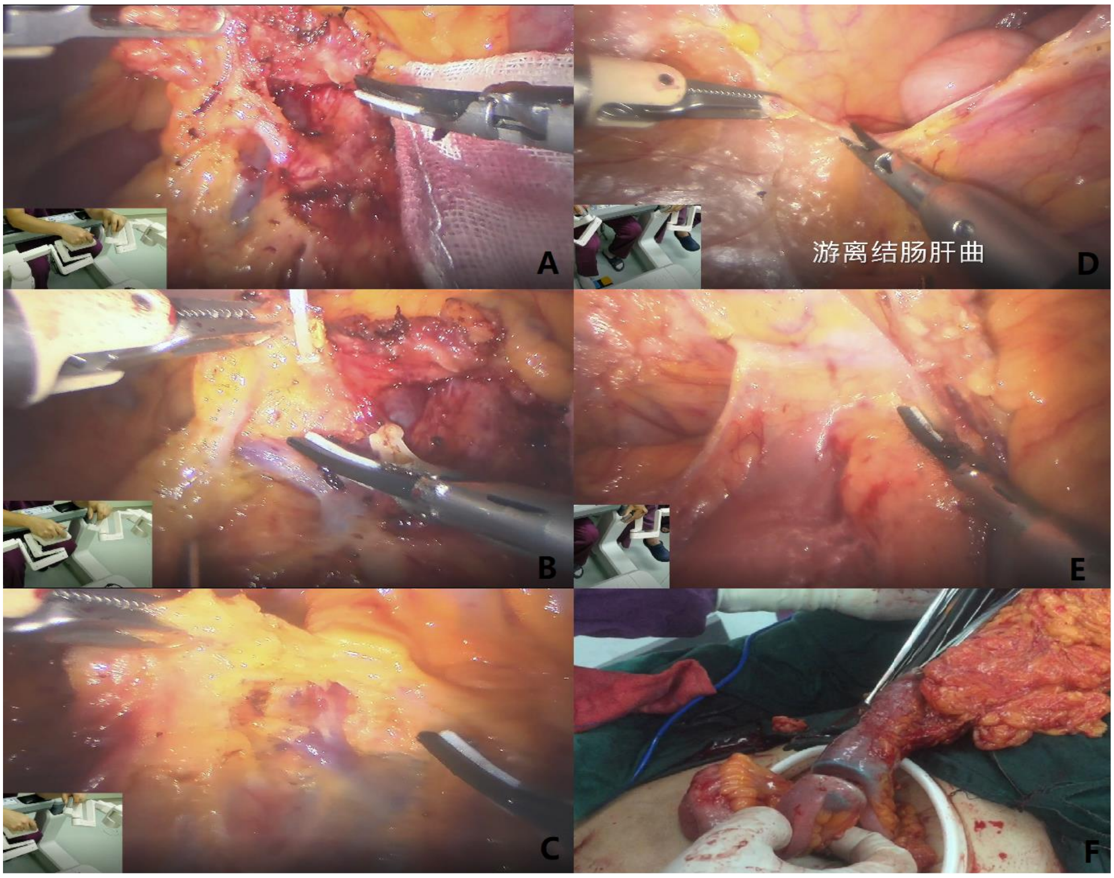
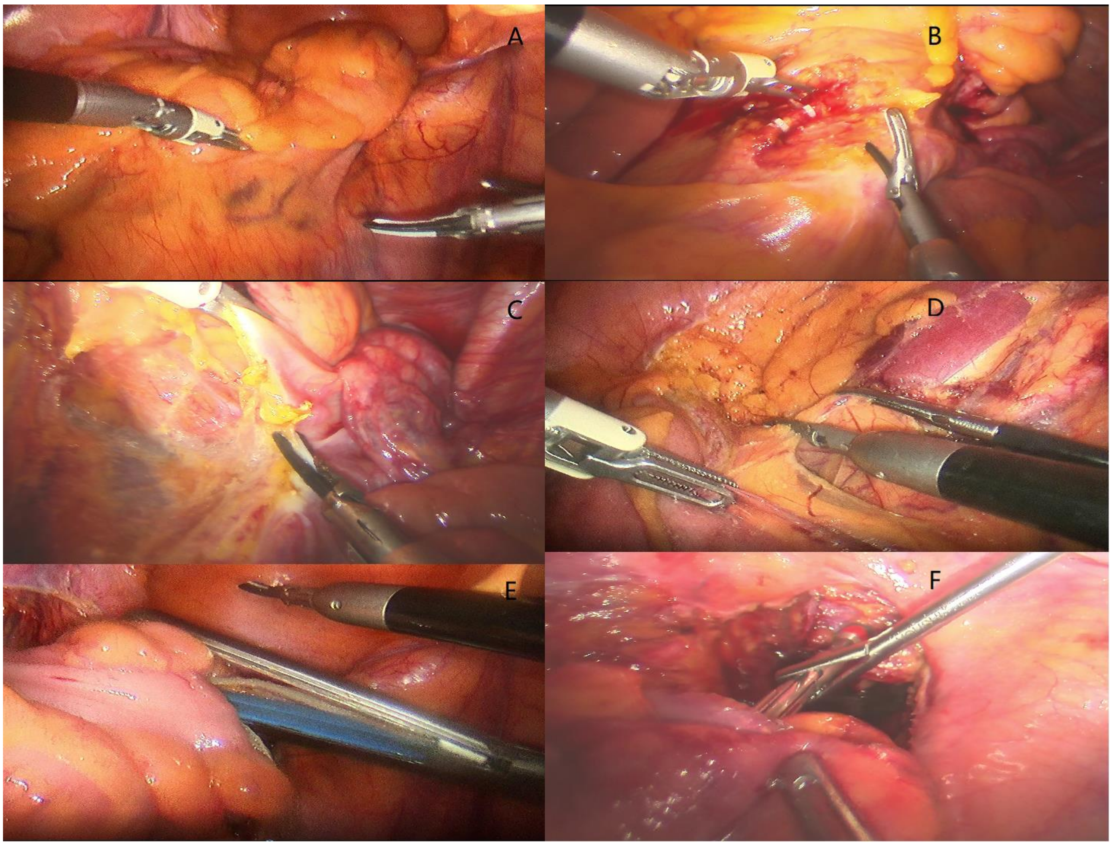


Fig. 3:Surgical procedures for right hemicolectomy.



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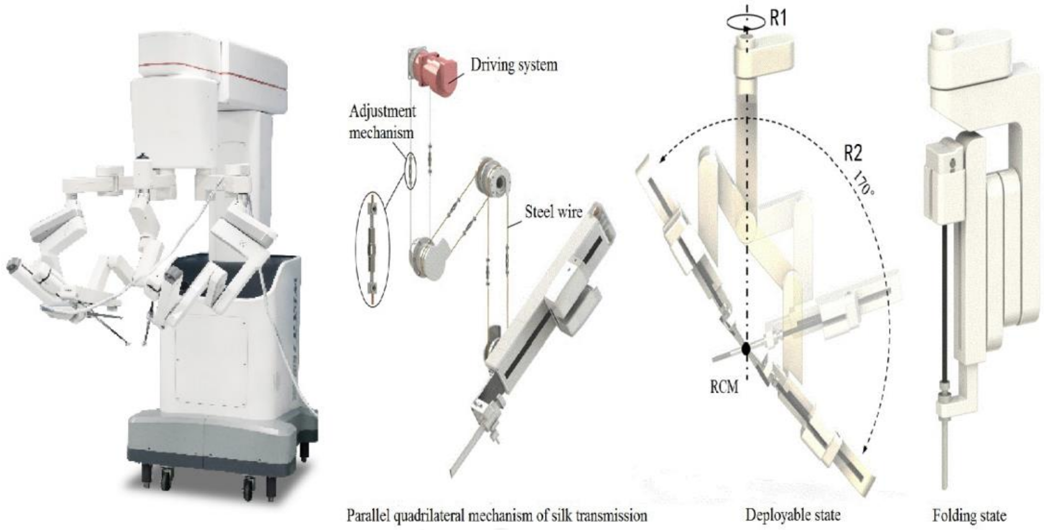

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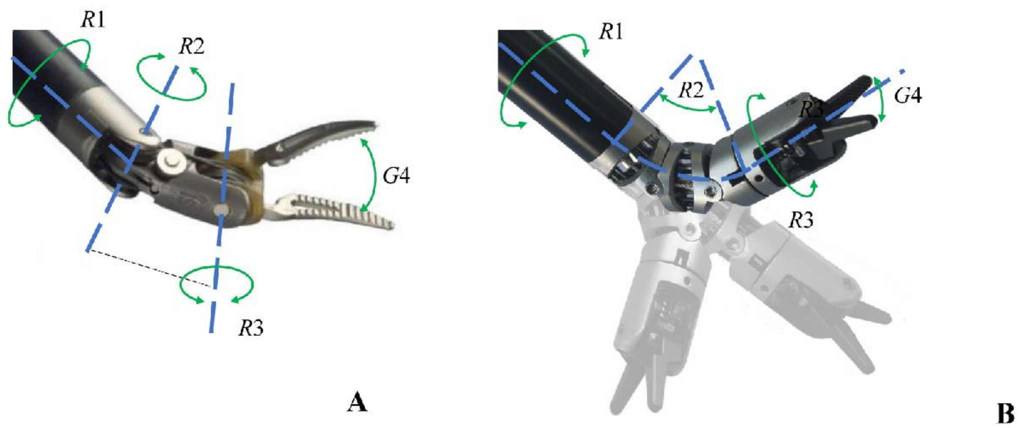

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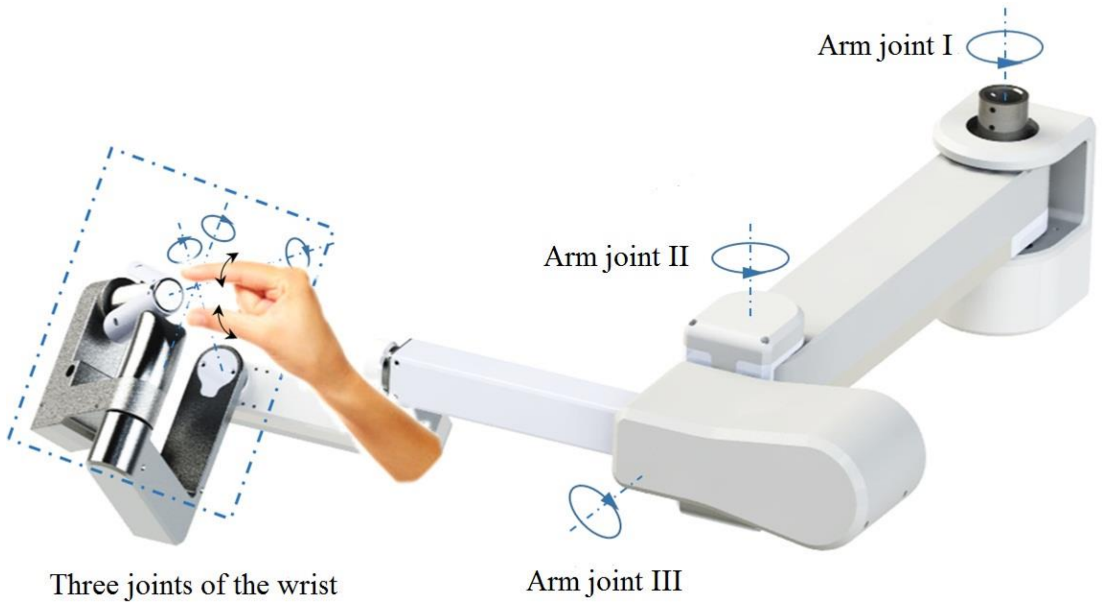

Fig. 7: Details of the master manipulator design.