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Short-term outcomes of KangDuo surgical robot- versus Da Vinci surgical robot-assisted radical resection of colorectal cancer: a prospective cohort study

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Abstract

Background and purpose The KangDuo Surgical Robot-01 (KD-SR-01) system is a recently introduced robot-assisted endoscopic surgical device originally designed in China. The purpose of this prospective cohort study was to ascertain whether the KD-SR-01 system was substantially equivalent to a comparable robotic device in terms of safety, efficacy and treatment costs during colorectal cancer resection, and evaluate the learning curve of KangDuo robotic surgery.

Method From October 2022 to May 2023, 50 patients (aged 18–80 years) with colorectal cancer were enrolled and randomly assigned to either the KangDuo group (KD-SR group; 26 patients) or the Da Vinci group (DV group; 24 patients). The primary endpoints were surgical success and conversion rates. In addition, cumulative summation (CUSUM) was used to plot the learning curve of KangDuo robot-assisted colorectal surgery and identify turning point (TP) case.

Results The two cohorts both successfully completed the procedure without any conversion to open or laparoscopic surgery. Time to first flatus and incidence of perioperative adverse events were equivalent between the KD-SR and DV groups. Additionally, no disparities were observed in pathological outcomes. Duration of operation and console time of the KD-SR group were significantly longer than those of the DV group. However, DV group had higher total hospitalization costs. With CUSUM analysis, TP for docking time, console time and duration of operation of KD-SR group were seen at the 11th case.

Conclusion Considering the complexity of the procedure, KangDuo robot-assisted colorectal cancer surgery is safe and reproducible for the surgical management of colorectal cancer. In addition, 11 procedures seem to be the number required to reach the learning curve plateau in terms of operative time by the experienced surgeon.

Trial registration The study was registered at www.chictr.org.cn (Registration number: ChiCTR2200063172, Data of Registration: 2022-09-01).

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Highlights

The exploration and implementation of a novel robotic surgical platform is of great significance for the minimally invasive and precise surgical treatment of colorectal tumors.

This prospective study will evaluate the implementation of Kangduo robotic surgical system in colorectal cancer, which has demonstrated exceptional safety, efficacy, and economy.

The achievement is expected to accelerate the dissemination and implementation of new technologies, facilitate the rational allocation of medical resources, and close disparity gaps in the surgical treatment of colorectal cancer across economically unbalanced regions.

Keywords Colorectal cancer, KangDuo robotic surgery, DaVinci robot, Short-term outcomes, Learning curve

Introduction

Colorectal cancer, which has high morbidity and mortality, imposes a significant burden on global health [1]. Currently, the management of colorectal cancer necessitates a comprehensive approach centered on surgical intervention and the surgical concept for treatment is progressively shifting toward minimally invasive techniques that prioritize precision, functional preservation, and prompt recovery while adhering to standardized and radical principles to optimize both the quality of surgery and postoperative outcomes [2]. For colorectal cancer surgery, robot-assisted endoscopic surgery can effectively address the limitations of traditional laparoscopic procedures while preserving the benefits of minimally invasive techniques, thereby enhancing intraoperative precision [3]. Notably, a robotic system offers a more flexible manipulator that proves particularly advantageous especially for patients with low rectal cancer or complex pelvic anatomy [4, 5]. Studies indicate robotic rectal surgery reduces blood loss by approximately 10% (40 vs. 50 mL, $p < 0.0001$) and intraoperative complication rates (5.5 vs. 8.7%, $p = 0.030$) compared to laparoscopy [6]. Furthermore, the robotic system shows greater adaptability for obese patients, with tremor filtration reducing technical errors in fatty tissues (blood loss: weighted mean difference = -49.23 mL, $p < 0.001$), offering a safer minimally invasive option for complex cases [7]. For surgeons, robotic equipment with enhanced ergonomic design has facilitated a transition from "on-site surgery" to "off-platform surgery". In the revolution of robotic surgery, the Da Vinci Surgical System is undoubtedly a benchmarking product. However, the nature of technological development is to pursue innovation and diversity, and numerous countries are actively engaged in the research and development of robot equipment, with China's KangDuo Surgical Robot-01 (KD-SR-01) system serving as one of the prominent examples. The KD-SR-01 system consists of an open console, a three-arm patient cart, a vision cart, and surgical micro-instruments. The device has been successful in urological tumors [8–11]. Herein, we present the findings of a prospective cohort study evaluating the efficacy, safety, and treatment costs of radical resection of colorectal cancer using either the KangDuo robot or the Da Vinci robot. Additionally, we provide insights into the learning curve involved in performing colorectal cancer surgery using the KangDuo robot.

Method

Study participants

This is a prospective cohort study aimed to verify whether the KD-SR-01 surgical system is substantially equivalent to a comparable robotic surgical device, the Da Vinci Endoscopic Surgical System (Intuitive Surgical, Inc.), in terms of safety, efficacy, and treatment costs during laparoscopic colorectal cancer resection and to evaluate the learning curve of KangDuo robotic surgery. The study protocol has been approved by Medical Ethics Committee of the Second Affiliated Hospital of Harbin Medical University prior to the start of the study, and all patients provided written informed consent. This study has been registered on www.chictr.org.cn (Registration number: ChiCTR2200063172; Public title: To evaluate the efficacy and safety of endoscopic surgical system assisted laparoscopic colorectal cancer resection in clinical trials; Date of registration: September 1,2022).

1. Inclusion criteria were as follows:

1) Patients pathologically diagnosed with colorectal cancers requiring colorectal resection;
2) No infiltration into surrounding organs and tissues and no metastasis on imaging;
3) Age 18–80 years old, gender no issue;
4) Able to cooperate with complete follow-up and related examinations;
5) Voluntarily participate in this experiment and sign the informed consent.

2. Exclusion Criteria were as follows:

1) Exclude patients with familial adenomatous polyposis or ulcerative colitis cancer;
2) Patients involving surrounding organs requiring combined organ resection, CRM(+) for rectal cancer, or R0 resection is not expected;
3) Patients with cardiovascular and cerebrovascular diseases, blood system diseases, and diabetes that

cannot be controlled and cannot meet surgical standards;
4) Patients with immune system diseases that cannot be controlled and cannot meet surgical standards;
5) Severely obese people with BMI > 30 kg/m^2;
6) Patients with intestinal obstruction, bleeding, or perforation requiring emergency surgery;
7) Patients who cannot tolerate anesthesia and laparoscopic surgery;
8) Pregnant or breastfeeding women;
9) ASA score greater than grade II
10) Participants who have not completed clinical trials of other investigational drugs or devices.

Kangduo robot system

The KD-SR-01 system is a "master slave" platform consisting of a surgeon control console, a three-arm patient cart, and a high-definition vision cart (Fig. 1). The surgeon console is an open vision system with a foot clutch for switching systems. The patient cart is equipped with two surgical arms and a camera arm. For safety, the system automatically locks the robotic arms of the patient cart when the sensor on the console detects the surgeon's hands separation from the device. The vision cart is employed by the assistant physician to observe the surgical field. The three-arm patient cart was placed on the left side of the patient.

Surgical procedures

In the clinical study, all surgical interventions were conducted by a single experienced surgeon who had previously undergone over 200 standardized robotic surgeries and received comprehensive training in approved surgical methodologies. A comprehensive case report form was meticulously completed for each patient.

As detailed below, the surgical procedure was executed by utilizing the KD-SR-01 system (Supplementary Fig. 1). Prior to the attachment of the mechanical device, abdominal exploration was carried out to ascertain the absence of implants or metastatic nodules in the liver, gallbladder, small intestine, and pelvic cavity. During the anterior rectal resection, the lymph nodes at the root of the inferior mesenteric artery were dissected, the mesenteric vessels and their branches were meticulously dissected, the superior rectal artery and the inferior mesenteric vein were transected, and subsequently, standardized total mesorectal excision (TME) was performed. The clear visual field and stable operation during the procedure significantly mitigated the risk of pelvic vegetative nerve injury (Supplementary Fig. 2). The resection of the distal rectum of the tumor was conducted by utilizing an endoscopic linear cutter to achieve a minimum distal incision margin of 2 cm. Subsequently, disengagement of the robotic instrument and relocation of the cart away from the patient were performed. The specimen was extracted through a small incision. In vitro transection of the proximal bowel was executed, followed by in vivo anastomosis using a circular stapler. Depending on individual patient characteristics, either NOSES or ileostomy approach was selected for optimal outcomes (Supplementary Figs. 1 A–1 C).

For left hemicolectomy, the sigmoid artery was transected, and the lymph nodes at the root of the inferior mesenteric artery were excised. The tumor had an incisal margin distance of 5 cm distally and 10 cm proximally. Subsequently, disengagement of robotic instruments occurred, which was followed by retraction of the cart away from the patient. The remaining steps proceeded as previously described. The selection of different intestinal anastomosis methods was contingent upon tumor location (Supplementary Figs. 1D–1 F).

For right hemicolectomy, a central approach was often preferred, necessitating precise dissection along the anatomical plane and separation of Toldt's fascia from the

Fig. 1 The KD-SR surgical robotic system: (**A**) the vision cart; (**B**) the surgeon console; (**C**) the patient cart

retroperitoneum while preserving the intact tumor envelope and its primary lymphatic drainage. The sequential removal of ileocolic vessels, right colonic vessels, middle colonic vessels, or branches was performed with meticulous cleaning of the lymphatic adipose tissue at the vascular root. Complete mesocolic excision (CME) was conducted, and an appropriate anastomotic method was selected based on intraoperative conditions (Supplementary Figs. 1G–1I).

Successful surgery was defined as being able to complete the surgery according to the established protocol without conversion to other surgical methods (including ordinary laparoscopic surgery and open surgery). All surgeries required unedited video recordings, which were saved on CD-ROM.

Outcomes

The primary endpoints were surgical success and conversion rates and secondary endpoints were surgical efficacy (time to first flatus, National Aeronautics and Space Administration task load index[NASA-TLX] rating scale, and intraoperative operating sensation score), safety (robotic docking time, console time, duration of operation, intraoperative blood loss, intraoperative blood transfusion, and Clavien–Dindo grade, perioperative adverse events, serious adverse events, postoperative hospital stay, number of harvested lymph nodes, negative margins, laboratory and imaging tests), and treatment costs (anesthesia, surgery, nursing, the total cost of hospital stay).

Docking time was defined as the interval from the movement of the robotic cart toward the operating table to the docking of the last cannula to the corresponding arm. Console time was defined as the time from robot docking to robot undocking. The modified NASA-TLX rating scale was used for the subjective evaluation of surgeons.

Laboratory examinations, including hemoglobin (Hb), white blood cell (WBC), neutrophil count (NEUT), alanine aminotransferase (ALT), and aspartate aminotransferase (AST), were assessed at various time points, including pre-surgery, postoperative 1st day, postoperative 3rd day, and 4th week after surgery. An imaging examination, namely B-ultrasound, was performed 4th week after the operation to observe postoperative recovery and whether there was fluid accumulation.

Statistical analysis

Data from eligible patients with colorectal cancer were collected from the Second Affiliated Hospital of Harbin Medical University. For categorical variables, the two-sided either Pearson $\chi 2$ test or Fisher's exact test (expected frequency < 5) was used, as appropriate. For continuous variables, the Student's *t*-test (normal distribution, reported with mean and SD) or the Mann–Whitney U test (non-normal distribution, reported with median and IQR) were used, as appropriate, to compare data between groups. SPSS version 22.0 was used for statistical analysis. All P-values were two-sided and were considered statistically significant when less than 0.05.

The cumulative sum (CUSUM) method was used to quantitatively evaluate the time-based learning curve, including docking time, operating time, and duration of operation. CUSUM values were calculated according to the order of operation dates for all cases. Operation time CUSUM was defined as $\sum_{i=1}^{n}(x_i - \mu)$, where x_i is operation time of each case and μ is the mean operation time of the cohort. Learning curve fitting: The ordinal number of the operation was utilized as the abscissa, while the CUSUM value of the operation time served as the ordinate for plotting and fitting a curve. R^2 was used to determine the goodness of fit. The vertex of the CUSUM fitting curve, which represents the turning point (TP), was utilized as the minimum cumulative number of operations required to surpass the learning stage. The patients were divided into two groups: the pre-TP group (learning phase) and the post-TP group (post-learning phase). MATLAB R2021a (9.10.0.1602886) was used for data analysis and plotting.

Results

From October 2022 to May 2023, a total of 50 CRC patients from the Experimental Center of the Second Affiliated Hospital of Harbin Medical University were enrolled. Of these, 26 patients were randomly assigned to the KD-SR group and 24 to the DV group. Baseline clinical features were similar in the two groups (Table 1), and both groups were operated by the same surgeon.

Evaluation of surgical efficacy

The operation success rates of both groups were 100%, without statistical difference observed. Time to first flatus in the KD-SR group was comparable to the DV group (median 29.5 h [IQR 21.8 to 43.0] vs. median 30.5 h [IQR 23.5 to 44.5]; $P = 0.754$). In terms of the task load evaluation (NASA-TLX rating scale), the mental demand score of the KD-SR group was higher than that of DV group (mean 1.7 [SD 1.0] vs. mean 1.2 [SD 0.5]; $P = 0.047$). No significant difference was noted between the two groups in the intraoperative operating sensation score (Table 2).

Evaluation of surgical safety

Overall, a significant difference existed in the console time between the KD-SR and DV groups (median 68.3 min [IQR 56.4 to 79.7] vs. 50.8 min [IQR 40.1 to 67.6]; $P = 0.022$), as well as in the duration of operation (median 192.5 min [IQR 170.0 to 221.3] vs. median 155.0 min [IQR 141.3 to 168.8]; $P < 0.001$). However, the

Table 1 Clinical characteristics of the patients at baseline

	KD-SR Group($n=26$)	DV Group($n=24$)	*P*-value
Baseline characteristics			
Sex, n			0.423
Male	18(69.2%)	14(58.3%)	
female	8(30.8%)	10(41.7%)	
Age at operation			0.491
Mean(SD), years	61.0(10.3)	59.1(9.0)	
BMI			0.661
Mean(SD), Kg/m^2	23.4(3.0)	23.0(3.3)	
ASA, n			1.000
I	1(3.8%)	0(0.0%)	
II	25(96.2%)	24(100.0%)	
Comorbidity, n			
Hypertension	8(30.8%)	9(37.5%)	0.616
Cardiovascular disease	3(11.5%)	6(25.0%)	0.281
Diabetes	7(26.9%)	3(12.5%)	0.358
Previous abdominal surgery, n	4(15.4%)	5(20.8%)	0.721
Tumor location, n			0.928
Right colon	4(15.4%)	3(12.5%)	
Left colon	13(50.0%)	11(45.8%)	
Rectum	9(34.6%)	10(41.7%)	
Pathological characteristics			
Tumor differentiation, n			0.325
Well	0(0.0%)	2(8.3%)	
Moderate	21(80.8%)	17(70.8%)	
Poor	3(11.5%)	1(4.2%)	
Missing	2(7.7%)	4(16.7%)	
Histologic type, n			0.547
Adenocarcinoma	22(84.6%)	19(79.2%)	
Mucinous adenocarcinoma	2(7.7%)	1(4.2%)	
Missing	2(7.7%)	4(16.7%)	
Gross type, n			0.458
Ulcerative type	14(53.8%)	10(41.7%)	
Protrude type	9(34.6%)	8(33.3%)	
Missing	3(11.5%)	6(25.0%)	
Pathological T stage, n			0.177
Tis	0(0.0%)	1(4.2%)	
T1	4(15.4%)	7(29.2%)	
T2	6(23.1%)	1(4.2%)	
T3	7(26.9%)	9(37.5%)	
T4	9(34.6%)	6(25.0%)	
Pathological N stage, n			1.000
N0	17(65.4%)	15(62.5%)	
N1	5(19.2%)	5(20.8%)	
N2	4(15.4%)	4(16.7%)	
TNM stage, n			0.769
0	0(0.0%)	1(4.2%)	
I	9(34.6%)	6(25.0%)	
II	8(30.8%)	8(33.3%)	
III	9(34.6%)	9(37.5%)	
Perineural invasion, n	14(53.8%)	13(54.2%)	0.909
Lymphatic invasion, n	10(38.5%)	3(12.5%)	0.086
Vascular invasion, n	3(11.5%)	2(8.3%)	0.867
Maximum tumor diameter			0.112
Median(Q1, Q3), cm	4.0(2.8, 4.0)	4.0(3.3, 5.0)	

Table 2 Comparative analysis of efficacy indexes of robotic surgery

	KD-SR Group($n=26$)	DV Group($n=24$)	*P*-value
Success, n	26(100.0%)	24(100.0%)	-
Conversions, n	0(0.0%)	0(0.0%)	-
Time to first flatus			0.754
Median(Q1, Q3), h	29.5(21.8, 43.0)	30.5(23.5, 44.5)	
NASA-TLX			
Mental demand			0.047
Mean(SD)	1.7(1.0)	1.2(0.5)	
Median(Q1, Q3)	1(1, 2)	1(1, 1)	
Max, Min	5, 1	3, 1	
Physical demand			0.382
Mean(SD)	1.6(1.1)	1.7(0.7)	
Median(Q1, Q3)	1(1, 2)	1(1, 2)	
Max, Min	5, 0	3, 1	
Temporal demand			0.893
Mean(SD)	1.5(1.0)	1.5(0.9)	
Median(Q1, Q3)	1(1, 2)	1(1, 1.8)	
Max, Min	4, 1	4, 1	
Performance			0.738
Mean(SD)	1.2(0.4)	1.3(0.4)	
Median(Q1, Q3)	1(1, 1)	1(1, 1.8)	
Max, Min	2, 1	2, 1	
Effort			0.795
Mean(SD)	1.4(0.6)	1.42(0.7)	
Median(Q1, Q3)	1(1, 2)	1(1, 2)	
Max, Min	3, 1	3, 1	
Frustration			0.625
Mean(SD)	1.4(0.6)	1.4(0.8)	
Median(Q1, Q3)	1(1, 2)	1(1, 1.8)	
Max, Min	3, 1	4, 1	
Operation Feeling Score, n			1.000
Moderate	26(100%)	24(100%)	

Table 3 Comparative analysis of safety indexes of robotic surgery

	KD-SR Group($n=26$)	DV Group($n=24$)	*P*-value
Duration of operation			<0.001
Median(Q1, Q3), min	192.5(170.0, 221.3)	155.0(141.3, 168.8)	
Docking time			0.140
Median(Q1, Q3), min	5.3(4.2, 7.4)	5.1(4.1, 5.9)	
Console time			0.022
Median(Q1, Q3), min	68.3(56.4, 79.7)	50.8(40.1, 67.6)	
Blood loss			0.297
Median(Q1, Q3), ml	50.0(30.0, 50.0)	50.0(50.0, 95.0)	
Intraoperative transfusion, n	0(0.0%)	0(0.0%)	-
Clavien-Dindo grade II or higher grade, n	1(3.9%)	2(8.3%)	1.000
Adverse events, n	7(26.9%)	4(16.7%)	0.382
Serious adverse events, n	1(3.9%)	2(8.3%)	0.943
Postoperative hospital study, days			0.684
Median(Q1, Q3), n	8.0(7.0, 9.0)	7.0 (7.0, 9.75)	
Number of harvested lymph nodes			0.835
Median(Q1, Q3), n	13.5(12.0, 16.3)	15.0(11.3, 16.8)	
Negative margins, n	51(98.08%)	48(100%)	1.000

docking time of robot equipment between the two groups (median 5.3 min [IQR 4.2 to 7.4] vs. median 5.1 min [IQR 4.1 to 5.9]; $P=0.140$) did not exhibit a statistically significant difference. There was no significant difference in the blood loss between the KD-SR and DV groups (median 50.0 mL [IQR 30.0 to 50.0] vs. median 50.0mL [IQR 50.0 to 95.0]; $P=0.297$). No intraoperative complications were observed in either group (Table 3).

Table 3 specifies the incidence of adverse events and postoperative Clavien–Dindo grade II or higher complications during the study. Eleven cases of operation-related adverse events were reported, including two cases of contact dermatitis, one case of an allergic reaction, fever or dyspepsia, two cases of abnormal liver function, one case of renal insufficiency, one case of incision bleeding, one case of delayed anastomotic blood release, one case of intractable hiccup, one case of tracheitis, and one case of coronary heart disease. Three cases of operation-related serious adverse events were noted, including one case of rectovaginal fistula, one case of delayed anastomotic blood, and one case of incomplete intestinal obstruction, along with three cases of Clavien–Dindo grade II or higher complications. No significant differences were found in complications, adverse events, or serious adverse events between the two groups were found. After receiving systematic treatment, all symptoms disappeared, and the patients were safely discharged from hospital. There was no difference in postoperative hospital stay between the two patient groups ($P=0.684$). No significant difference was observed in the B-ultrasound examination four weeks after the operation. The upper and lower incisal margins ($P=1.000$) and the number of harvested lymph nodes ($P=0.835$) did not exhibit statistically significant differences (Table 3).

During the treatment of patients, we monitored the serum changes in WBC, NEUT, Hb, ALT, and AST to evaluate the differences in inflammatory response, liver function, and hemoglobin between the two groups. On the 1st day after surgery, the KD-SR group exhibited a more severe degree of inflammation compared with the DV group (WBC: median $12.5*10^9$/L [IQR 10.9 to 15.0] vs. median $9.5*10^9$/L [IQR 7.9 to 11.9]; $P=0.006$). However, this difference was not reflected in blood markers reexamined 3rd day after surgery (WBC: median $6.1*10^9$/L [IQR 5.0 to 6.8] vs. median $6.2*10^9$/L [IQR 5.3 to 7.3]; $P=0.426$). In addition, it is worth mentioning that

at 4th week post-surgery, variations were noted in ALT values (median 25.5 U/L [IQR 15.0 to 31.3] vs. median 14.5 U/L [IQR 9.0 to 22.3]; $P=0.019$). Nevertheless, considering that normal ALT ranges from 9 to 50 U/L, this discrepancy held no practical clinical significance (Supplementary Fig. 3 and Supplementary Table 1).

Treatment costs

We calculated treatment costs for both groups of patients (Table 4). Overall costs were lower for patients who underwent KD-SR robot-assisted surgery (median 65302.2 ¥ [IQR 60257.5 to 68461.4] vs. 90430.8 ¥ [IQR 85359.1 to 96509.4]; $P<0.001$), and the primary difference in cost-effectiveness between the two groups was observed in operation expenses (median 33602.1 ¥ [IQR 32275.7 to 36165.1] vs. 62310.2 ¥ [IQR 56561.5 to 64227.2]; $P<0.001$), which were significantly reduced for KD-SR surgery.

Table 4 Treatment costs of enrolled patients. $: UNITED STATES DOLLAR

	KD-SR Group($n=26$)	DV Group($n=24$)	*P*-value
Total hospital expenses			<0.001
Median(Q1,Q3),$	9267.1(8551.2, 9715.4)	12833.1(12113.3, 13685.7)	
Nursing expenses			0.751
Median(Q1, Q3),$	889.8(711.2, 1151.1)	972.0(656.3, 1136.6)	
Anesthetic expenses			0.244
Median(Q1, Q3),$	543.1(441.4, 581.0)	488.7(445.4, 523.9)	
Operation expenses			<0.001
Median(Q1,Q3),$	4768.5(4580.3, 5132.2)	8842.5(8026.7, 9114.5)	

Learning curve of the KD-SR group

The KD-SR group was subjected to subgroup analysis based on the surgical site, revealing no significant differences in docking time, console time, and duration of operation among the subgroups of right colon cancer, left colon cancer, and rectal cancer (Supplementary Table 2). The CUSUM learning curve was plotted in a chronological order. The learning curve was represented by a sixth-order polynomial best-fit model with an R^2 value of 0.9339 (Fig. 2A). Likewise, the CUSUM learning curves for console time and duration of operation were fitted using best-fit models as the seventh-order polynomial with the R^2 values of 0.9289 and 0.905 (Fig. 2B and C). In addition, the stable docking time(median 6.2 min [IQR 5.4 to 8.1] vs. median 4.4 min [IQR 4.0 to 6.4]; $P=0.020$), console time(median 75.2 min[IQR 68.2 to 100.0] vs. median 58.4 min [IQR 50.2 to 68.4]; $P=0.006$) and duration of operation(median 210.0 min [IQR 180.0 to 230.0] vs. median 175.0 min [IQR 165.0 to 205.0]; $P=0.024$) were achieved after performing 11 KangDuo robotic surgeries, which divided the learning curve into two phases (Supplementary Tables 3–5). After overcoming the learning curve, the mesenteric dissection time significantly decreased(median 80.4 min[IQR 75.9 to 93.2] vs. median 70.5 min [IQR 66.4 to 75.9]; $P=0.006$) (Supplementary Table 6). While comparing baseline features between these two stages, no statistically significant differences were observed (Supplementary Table 7).

Discussion

In view of the current problems in minimally invasive surgery, such as camera-positioning error, operational anti-leverage effect, and limited freedom of surgical instrument movement, the three-dimensional field of view and flexible mechanical arms system of robotic surgical systems show significant advantages in colorectal surgery. The tendency in the evolution of modern surgery toward greater precision and minimally invasive procedures is reflected in the rise of robot-assisted endoscopic surgery. The Da Vinci Surgical System is considered the benchmark in surgical robotic products. According to the findings of the REAL study, robotic surgery demonstrates superior oncology quality, reduced surgical trauma, and improved postoperative recovery in cases of low and medium rectal cancer, compared to traditional laparoscopic surgery [6]. Similarly, a propensity score-matched retrospective cohort study conducted demonstrated that robot-assisted right hemicolectomy had the advantages

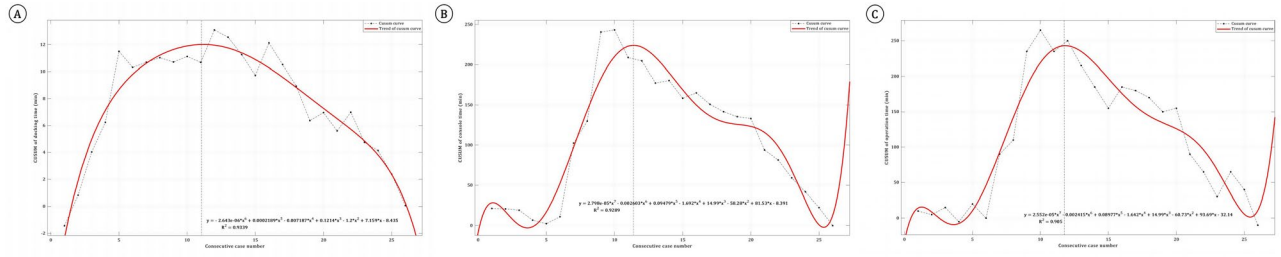

Fig. 2 CUSUM curves for different parameters for KD-SR robot-assisted colorectal tumor. surgery. (A) Docking time; (B) Console time; (C) Duration of operation

of expedited recovery of bowel functions and earlier postoperative discharge [12]. The reports of these authoritative studies confirm the safety and feasibility of robotic surgical systems with laparoscopic surgery in oncology quality and survival, increasing our confidence in robotic minimally invasive surgery.

KangDuo robot is a surgical robot system independently developed by China, and its surgical efficacy has been validated during the animal experimentation phase [13, 14]. In addition, urology clinical trials have also reported favorable results [8–11]. In this clinical study, we demonstrated that the overall efficacy and safety of the KangDuo robotic system in radical colorectal cancer surgery were substantially equivalent to the Da Vinci Surgical System.

A total of 50 patients were included in this study and randomly divided into an experimental group (KD-SR group) and a control group (DV group). Initially, the baseline characteristics were effectively equilibrated, thereby ensuring comparability in the assessment of efficacy and safety between the two groups. The primary endpoint of this study was the success rate of surgery, which was satisfactory 100% in both groups. Efficacy, including time to first flatus, intraoperative NASA-TLX rating scale, and operating sensation score, was a crucial outcome measure. The time to first flatus signifies the rate and extent of intestinal recuperation, and the index did not differ significantly between the two groups. In conjunction with the operation sensation score, the NASA-TLX rating scale was used to evaluate the surgeon's workload during robot-assisted endoscopic surgery and to track changes in operational proficiency [15, 16]. Performance, effort, frustration, mental demand, physical demand, and temporal demand were all components of the NASA-TLX rating scale. Noteworthily, the distinction in mental demands was observed between the two groups. During surgical procedures, surgeons must account for factors beyond mere anatomical structure and tumor concerns. Surgeons, assistants, and nursing teams necessitate a transitional phase to acclimate to novel surgical equipment, during which they develop fresh communication routines and enhance cognitive abilities. This may account for the difference in mental demand. More particularly, robotic surgery has, to some degree, mitigated the neck and shoulder strain as well as eye fatigue caused by the prolonged static posture and isometric muscle contraction in previous laparoscopic procedures (Supplement Fig. 4). Furthermore, the KangDuo robot's novel console and accompanying 3D glasses have further reduced this fatigue and are more ergonomic [17]. Based on the assessment outcomes of the efficacy indicators, it can be concluded that the experimental device is capable of effectively assisting surgeons in performing colorectal cancer surgery.

In clinical practice, radical resection of colorectal cancer is a challenging surgery. It involves various surgical procedures, including grasping, cutting, suturing, coagulation, traction, dissection, and ligation, to complete the free mesangium, ligation of blood vessels, tumor resection, digestive tract reconstruction and other surgical tasks. Hence, the utilization of surgical instruments necessitates a high level of precision, thus emphasizing the utmost importance of conducting a comprehensive safety assessment for robotic equipment. Significant differences were observed in console time (median 68.3 min [IQR 56.4–79.7] vs. 50.8 min [IQR 40.1–67.6]; $P = 0.022$) and total operative duration (median 192.5 min [IQR 170.0–221.3] vs. 155.0 min [IQR 141.3–168.8]; $P < 0.001$) between the KangDuo (KD-SR) and Da Vinci (DV) groups. These disparities primarily stemmed from the surgical team's adaptive process to the novel robotic platform, including initial instrument familiarization and workflow optimization. Notably, even post-learning curve, surgeons adopted conservative strategies (e.g., increased tissue dissection verification) to align KangDuo's technical nuances with prior Da Vinci expertise, potentially prolonging early-phase operative efficiency. However, subsequent proficiency gains were evident: after the transition period (TP), the median operative time for KD-SR decreased from 210 to 175 min, closely approximating DV performance (Supplementary Table 5). This trajectory underscores both the learning curve impact and the technical translatability between robotic systems, albeit tempered by deliberate caution during skill integration. Significantly, the oncology outcomes remained consistent between the two groups, including a comparable number of harvested lymph nodes and negative incisal margins.

This study primarily compared the technical performance between the KangDuo and Da Vinci robotic systems, while indirect comparisons with laparoscopic literature further clarified robotic surgery's clinical advantages. As shown in Table 1, both the KangDuo and Da Vinci groups achieved 100% procedural success rates, with no cases requiring conversion to laparoscopy or open surgery—a marked improvement over the 9.2% conversion rate reported in recent laparoscopic studies [18]. Regarding postoperative recovery, a multicenter RCT reported a postoperative complicaion (Clavien-Dindo grade II or higher) rate of 23.1% and median time to first flatus of 44 h (IQR: 30.1–62.8) following laparoscopic surgery [6]. In contrast, both the KangDuo and Da Vinci robotic cohorts demonstrated superior outcomes (Tables 2 and 3). Although no direct laparoscopic control group was included, the consistency of these findings with existing evidence suggests that robotic platforms—through enhanced 3D visualization, articulating instruments, and tremor filtration—may represent

an optimized minimally invasive approach for colorectal cancer surgery.

To further investigate the potential mechanism of the beneficial effects of KangDuo robot-assisted surgery on short-term recovery of patients, we analyzed serum levels of inflammatory indicators (WBC, NEUT), Hb, and liver function indicators (ALT, AST). Prior research has indicated that robotic devices can mitigate physiological tremors, leading to enhanced operational stability, decreased abdominal wall strain, attenuated immune cascade activation, and reduced systemic inflammation [19, 20]. This finding is in line with the outcomes of our study. The postoperative inflammation indexes of the two groups tended to stabilize and gradually recovered to the preoperative level. There were no stage IV patients included in this study, thus the impact of the surgical procedure on liver function was minimal. As a result of the timely replenishment of postoperative body fluids and the relatively stable blood loss in both groups, the postoperative Hb level remained elevated. Sustained enhancements in liver function indicators, Hb, and markers of inflammation following surgery could offer insights into possible rationales for favorable patient outcomes, and the experimental device was deemed secure for clinical use in light of the aforementioned safety evaluation indicators.

Next, we compared treatment costs in the cohorts, including the costs of nursing, anesthesia, operation, and hospital stay. It was noteworthy that the cost-effectiveness of KD-SR group was higher, and the implementation of the novel robotic surgery significantly alleviated the financial strain on patients, which remained a favorable aspect. Besides, it is anticipated that the console time and duration of operation of the KangDuo robot system will diminish and ultimately stabilize as the team's expertise in robotics advances, thereby mitigating the expenses associated with device maintenance and labor incurred during device operation [19]. Certainly, we need a comprehensive lifecycle cost analysis for this new robotic system to assign greater health-economic value.

To our excitement, the learning curves of KangDuo robotic surgery for colorectal cancer could be divided into two phases: the initial learning period (1st–11th case), the proficiency period (12th–26th case), and primary technical competence in reducing the operation time was achieved after the initial learning period. Further analysis of temporal trends in key surgical tasks revealed a significant reduction in mesenteric dissection time during the proficiency phase (median: 80.4 vs. 70.5 min, $P = 0.014$), likely attributable to optimized robotic arm manipulation and reduced intraoperative redundant verification steps. While this single-center study precluded direct comparison with the Da Vinci system, meta-analytic data suggest that the Da Vinci platform typically requires 15–30 cases to surpass its initial learning curve [21]. The shorter adaptation phase observed with KangDuo (11 cases) indicates efficient skill transfer between platforms, likely facilitated by shared ergonomic principles. This technical advantage has the potential to provide universal support for surgeons across varying levels of clinical experience, particularly in reducing the reliance on operator-dependent technical expertise during surgical procedures, demonstrating significant value for junior surgeon populations. Subsequent research should systematically evaluate the standardized implementation efficacy of this technology through the establishment of a hierarchical training framework.

At present, the Da Vinci robot is the "star product" occupying the international surgical robot market. However, the high introduction and treatment costs are constraints for its promotion to the economically underdeveloped areas. The KangDuo robot system is an emerging product independently developed in China, with complete independent property rights, and the research and development standards are fully in line with the laws and regulations of China [10]. Furthermore, it is estimated that its cost for research, development, and manufacturing was about 25–30% of the Da Vinci robot system, which can greatly reduce the economic burden on hospitals and patients. The KangDuo robot had demonstrated comparable treatment efficacy to the Da Vinci robot in radical urology surgery and colorectal cancer surgery. This achievement is expected to facilitate the dissemination and adoption of novel technologies as well as facilitate an incremental entry of KangDuo into the global market. Despite the encouraging results of the research, a few limitations of the study should be addressed. While our study provides critical evidence on procedural safety and early postoperative outcomes, the follow-up duration (median 18 months) precludes definitive conclusions on long-term oncological efficacy. Such analyses require extended observation periods beyond 3–5 years, which will be addressed in future work. Furthermore, while the single-center design reduces confounding variables, it may introduce biases such as homogeneity in patient demographics and limited reproducibility across different surgeons. Therefore, we advocate for a multi-center clinical study to further validate the safety and efficacy of the new robotic system in colorectal cancer surgery.

Conclusion

The preliminary findings of this study indicate that the KD-SR-01 system exhibits feasibility, safety, and efficacy in treating colorectal cancer in comparison to similar robotic systems. However, further investigation involving larger cohorts and follow-up periods is necessary to assess the outcomes related to tumor progression and functional recovery.

Device or production

Name of Material/ Equipment	Company	Catalog Number	Comments/Description
Kangduo-SR-01® Surgical Robot-01(KD-SR-01)	Sagebot(Harbin, China)	KD-SR-01	Endoscopic surgical robot
da Vinci Xi Surgical System	Intuitive Surgical	4200	Endoscopic surgical robot

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

Supplementary Material 5

Supplementary Material 6

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Author contributions
CLW, TYM, HQH, YHJ, QCT and GYW made the conception/design of the study. All authors participated the provision of study material or patients. CLW, YXL, XZ, YHRY, XW and JX participated in the collection and/or assembly of data. YLMW, YKZ and HZ performed the data analysis and interpretation. CLW and GYW wrote the manuscript. All authors read and approved the final manuscript.

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Data availability
The datasets generated during the current study will be available from the corresponding author on reasonable request after the publication of the main findings.

Declarations

Ethics approval and consent to participate
This study was performed in line with the principles of the Declaration of Helsinki. This study was initiated by the Second Affiliated Hospital of Harbin Medical University. Ethical review board approval was obtained and informed consent was obtained from the medical ethics committee (2022-45, September 29,2022). All of our study participants conducted the clinical trial after fully understanding the instructions and obtaining their informed consent.

Consent for publication
All authors in our study group agreed on the order of authorship and publication. All participants provided written informed consent for the publication of their personal or clinical details along with any identifying images in this study.

Competing interests
The authors declare no competing interests.

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