



A prospective study of the safety and usefulness of a new miniature wide-angle camera: the “BirdView camera system”

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Abstract

Background The performance of endoscopic surgery has quickly become widespread as a minimally invasive therapy. However, complications still occur due to technical difficulties. In the present study, we focused on the problem of blind spots, which is one of the several problems that occur during endoscopic surgery and developed “BirdView,” a camera system with a wide field of view, with SHARP Corporation.

Methods In the present study, we conducted a clinical trial (Phase I) to confirm the safety and usefulness of the BirdView camera system. We herein report the results.

Results In this study, surgical adverse events were reported in 2 cases (problems with ileus and urination). There were no cases of device failure, damage to the surrounding organs, or mortality.

Conclusions We evaluated the safety of the BirdView camera system. We believe that this camera system will contribute to the performance safe endoscopic surgery and the execution of robotic surgery, in which operators do not have the benefit of tactile feedback.

Keywords Endoscopic surgery · Laparoscopic surgery · Wide-view camera · Medical accident · Medical safety

Endoscopic surgery has quickly become widespread as a minimally invasive therapy. Endoscopic surgery for colorectal cancer has various advantages in comparison to open surgery: similar treatment effects [1, 2], higher esthetic outcomes, less pain, and a shorter hospital stay [3]. On the other hand, the incidence of perioperative complications such as bleeding, bowel injury, and solid organ injury, is reportedly

higher in comparison open surgery [4–7]. The high degree of difficulty of endoscopic surgery due to the need to establish a 3D image based on 2D information, a diminished sense of touch, the presence of blind spots (and other issues) is the main reason for the higher incidence of perioperative complications. Various efforts have been made to resolve these problems. In the present study, we report the results of a study on the “elimination of blind spots.”

The general viewing angle of cameras used for normal endoscopic surgery is 80°–90°, which makes it impossible to simultaneously obtain information from outside the field of view. Consequently, inadvertent organ injuries or bleeding in the blind spots outside of the camera’s field of view may be discovered late or overlooked. Moreover, as a forceps can only be operated within the observable range of the camera, there is no choice but to depend on the experience and instincts of the operator when the forceps is applied out of the camera’s field of view. Perioperative injuries may not only create a great physical burden, but also influence the post-operative course and prognosis during laparoscopic surgery, which is typically conducted for the purpose of reducing the physical burden on the patient.

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We therefore developed a system to compensate for the abovementioned blind spots by separately installing a miniature camera with a wide field of view in the abdominal cavity. To date, we have confirmed the safety of this device through animal experiments using a dry box and pig and have also confirmed the usefulness of the wide field of view. In the present study, we conducted a clinical trial (Phase I) to confirm the safety and usefulness of our camera system, which has a wide field of view, in human patients.

Study design

Methods

This study was an open-label single institutional, nonrandomized single-arm phase 1 clinical trial that was conducted between February 2017 and June 2017 to assess the safety of the novel wide-view camera system (BirdView Camera System; SHARP Corporation, Osaka, Japan). The study was performed independently at Hiroshima University. All patients provided their written informed consent prior to all study procedures. The protocol was approved by the Ethics Board of Hiroshima University Hospital (ref. Hiroshima University REC ID C-146) and was conducted in accordance with Good Clinical Practice and the Declaration of Helsinki. This study was registered with the University Hospital Medical Information Network (ref. UMIN CTR, number 000026168).

Patients

Patients were recruited from our outpatient clinic. The inclusion criteria were as follows: (1) 20–80 years of age at the time when the patient agreed to participate, (2) scheduled to undergo laparoscopic colorectal resection at our hospital (regardless of degree of progression of colorectal cancer), (3) performance status (PS; ECOG) of 0 or 1, (4) the patient's laboratory findings were acceptable (based on the latest examination values obtained within 30 days before registration: total bilirubin ≤ 1.5 mg/dL, AST [GOT] ≤ 200 IU/L; ALT [GPT] ≤ 200 IU/L; Cr ≤ 1.2 mg/L), and (5) the patient gave their written informed consent for participation in this study. The exclusion criteria were as follows: (1) a history of abdominal surgery, (2) currently or perioperatively treated with anti-coagulants, (3) a history of myocardial infarction or cerebral infarction, and (4) judged by the research doctor to be unsuited for participation in this study.

The BirdView camera system

The BirdView camera system was designed at Hiroshima University and manufactured by SHARP Corporation

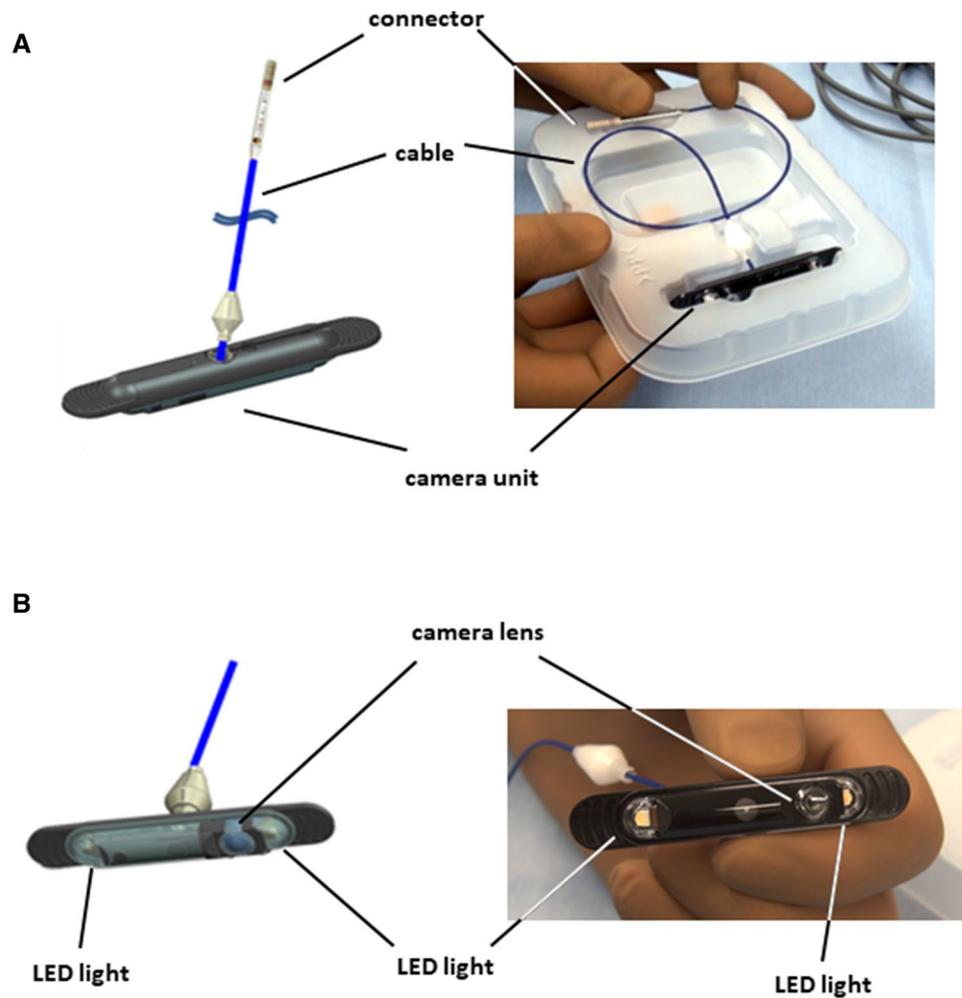
(Osaka, Japan). A preliminary version of this concept was described in a previous study [8]. The BirdView camera system, which is capable of providing a wide view of the internal organs during laparoscopic surgery, features a very wide viewing angle of 120° (in comparison to a normal viewing angle of 80°). This system consists of a camera unit for capturing images inside the body and a monitor to display the captured image for the surgeon. The camera unit includes a miniature wide-view camera with a color CMOS imager ($4.3 \times 3.5 \times 0.8$ mm³; 1280×720 pixels) that captures images of the operative field, and a plastic camera lens (f 0.7 mm, F 2.5, focusing range: 40– ∞ mm) and 2 LED lights (Fig. 1A, B). The camera base is molded from epoxy resin and covered by a water-repellent sheet for medical use. The camera has a gripper, which is curved so that it can be handled with a forceps. The length and weight of the entire camera are 62.2 mm and 6.0 g, respectively. The BirdView camera can be inserted into the abdominal space through a 12-mm trocar. The end of the cable of this camera is pulled out through a 3-mm trocar and connected to another cable leading to a control box.

Procedures

Ten eligible patients were enrolled (male $n = 6$; female $n = 4$; median age 59.0 years; range 49.0–68.0 years). Procedures were performed under general anesthesia with endotracheal intubation. Each patient with left-sided colon and rectal cancer was placed in the lithotomy position. As shown in Fig. 2, after anesthesia, the first 12 mm trocar was inserted through the supraumbilical incision, and another 4 were inserted sequentially. In addition, a 3-mm diameter trocar (Ethicon, Inc., Cincinnati, OH, USA) was inserted in the abdominal space for the BirdView Camera during the lower and upper abdominal operations. The BirdView camera unit was placed within the patient's abdominal space in three steps (Fig. 2). First, the camera was inserted into the abdominal space through a 12-mm trocar in the right lower quadrant, and the head of the brace was inserted into the abdominal space via the additional 3-mm trocar (Fig. 2A, B). Second, with the guidance of an endoscopic image, the end of the cable for the camera connector was pulled by the head of the brace using powerful magnets (Fig. 2C, D). Third, the camera connector was fixed to the cable of the control box, and the images captured by the CMOS camera were displayed on a monitor (Fig. 2E, F).

Laparoscopic surgery was performed using a medial-to-lateral approach with left colic artery-preserving lymphadenectomy according to the Japanese Classification of Colorectal Carcinoma (6th edition) to maintain a good blood supply on the oral side of the colon. The specimen was then removed through the incision, and reconstruction was performed in the abdominal cavity under laparoscopy.

Fig. 1 The schema of BirdView camera system. **A** The BirdView camera unit and its cable. **B** The details of the camera unit



In cases of intersphincteric resection or abdominoperineal resection, however, the specimen was removed from the anal side. After the specimen had been removed, the BirdView camera was removed in two steps. First, the camera connector was disconnected from the cable of the control box. Then, with the guidance of an endoscopic image, the camera was grasped with forceps and removed from the abdomen via the 12-mm trocar.

Safety and efficacy assessments and endpoints

The primary outcome was safety, which was determined by assessing the profile of all surgical adverse events during the perioperative period (within 28 days). A surgical adverse event was defined as an unintended injury or complication resulting in harm that was caused by healthcare management and not by the patient's underlying disease [9]. The secondary outcomes of efficacy were the operative time, bleeding, duration of hospital stay, operator's mental stress, and the rate of mechanical failure. The test operator's mental stress was evaluated for each camera system

using a NASA-TLX questionnaire, which was completed after surgery. The NASA-TLX is a subjective workload assessment technique that relies on a multidimensional construct to derive an overall workload score based on six weighted subscales: mental demand, physical demand, temporal demand, performance, efforts, and frustration level.

Statistical analysis

No formal power calculations were performed for this phase I study. Summary and descriptive statistics and graphs were used to describe the data. All continuous variables were expressed as the median (range), and 95% confidence intervals were calculated. All discrete variables were expressed as frequencies and percentages and 95% confidence intervals were calculated by the Clopper–Pearson exact method. Statistical analyses were performed using the SAS Platform JMP Pro software program (version 12.0.0, SAS Institute Inc., Cary, NC, USA).

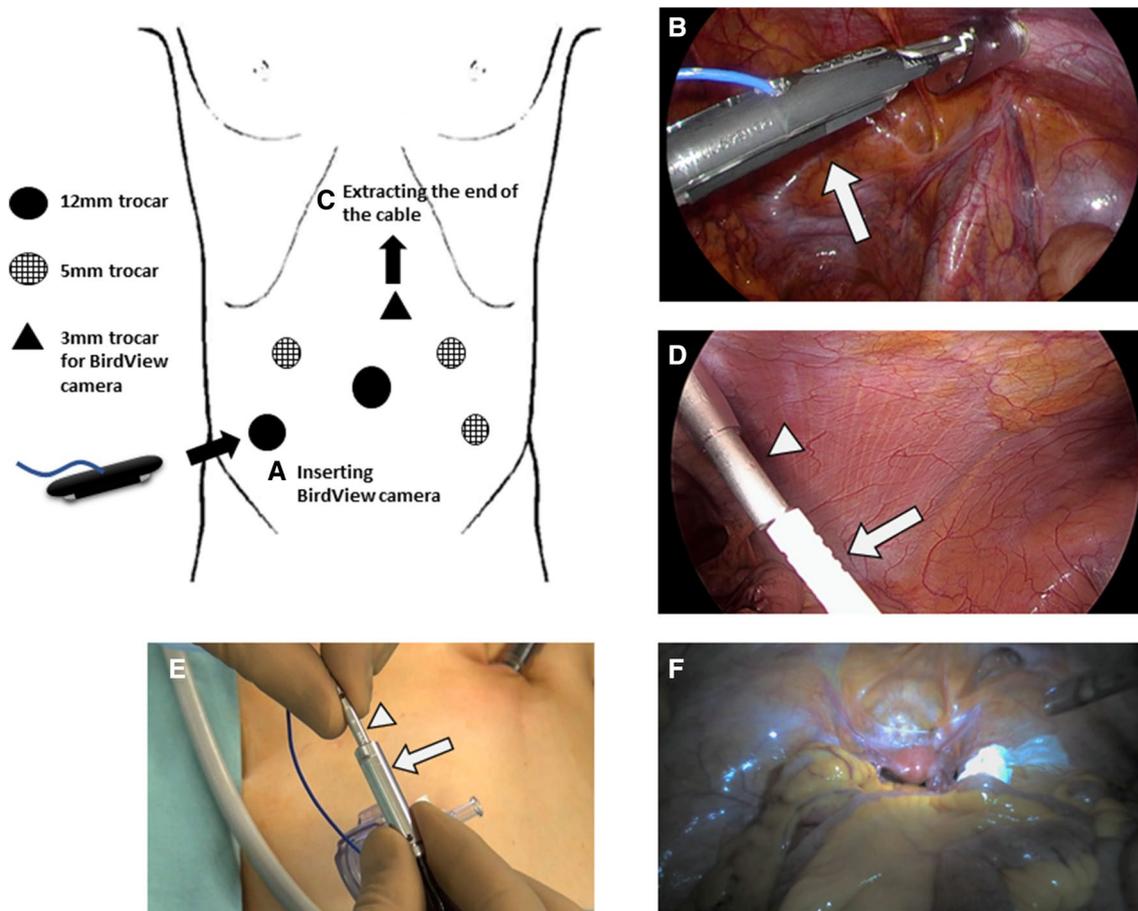


Fig. 2 An example of trocar placement for sigmoid colon cancer and rectal cancer. The steps of inserting and fixing BirdView camera from view of laparoscope. The left-sided pictures show the view from the outside, and right-sided pictures show the view from inside of the body. **A** The BirdView camera is inserted in the body via a 12 mm trocar of right lower quadrant. **B** The picture from laparoscope shows inserting BirdView camera. (The arrow indicates the BirdView camera.) **C** The end of cable of camera connector is pulled by the head

of rod, using the powerful magnetic force via 3-mm trocar of upper abdomen. **D** The picture from laparoscope shows pulling the end of the cable with powerful magnetic rod. (The arrow indicates the end of cable, and the arrow head indicates the tip of magnetic rod.) **E** The camera connector is fixed to the cable of control box. (The arrow indicates the end of the cable of control box, and arrow head indicates the camera connector.) **F** The image captured by the CCD camera is displayed on a monitor

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The BirdView camera system developer provided the BirdView camera system and was involved in discussions about drafting the report.

Results

Ten patients who underwent laparoscopic surgery with a BirdView camera between February and April 2017 were assessed for their safety. The background characteristics of the patients are shown in Table 1. The median age of the patients was 59 years, and the BMI values ranged from 17.4

to 26.9 kg/m². In half of the patients, the ASA score was 1 or 2. In 90% of the patients, the PS score was 0. The locations of colorectal cancer were the transverse colon in 10% of the patients, the sigmoid colon in 20%, the rectosigmoid colon in 20%, the Ra rectum in 10%, and the Rb rectum in 40%.

As shown in Fig. 3, the BirdView camera system was used for laparoscopic low-anterior resection. As expected, this system was able to achieve a wider field of view in comparison to conventional laparoscopy.

Regarding the primary endpoint, the safety-evaluable population included all 10 patients. Surgical adverse events were in two cases (20%) [problems with ileus (Clavien-Dindo classification grade III) and urination (Clavien-Dindo classification grade II)] (Table 2). There were no cases of device failure or damage to surrounding organs. There was no external evidence of heat-induced trauma on the

Table 1 Characteristics of patients who underwent laparoscopic surgery with BirdView camera for colorectal cancer ($N=10$)

Variables	
Age (year)	
< 60	5 (50.0%)
≥ 60	5 (50.0%)
Sex	
Male	6 (60.0%)
Female	4 (40.0%)
BMI (kg/m ²)	
< 25	3 (30.0%)
≥ 25	7 (70.0%)
PS	
0	9 (90.0%)
1	1 (10.0%)
ASA-score	
1	5 (50.0%)
2	5 (50.0%)
Location	
Transverse colon	1 (10.0%)
Sigmoid colon	2 (20.0%)
Rectosigmoid	2 (20.0%)
Ra rectum	1 (10.0%)
Rb rectum	4 (40.0%)
Stage	
I	9 (90.0%)
IIIa	1 (10.0%)

BMI body mass index, *PS* performance status, *ASA* American Society of Anesthesiologists, *Ra* rectum area above the peritoneal reflection, *Rb* rectum area below the peritoneal reflection

abdominal wall from using an LED. Finally, no mortalities were observed in association with the use of the BirdView camera system.

Fig. 3 The picture shows BirdView camera system for laparoscopic low-anterior resection. Left side is the monitor reflects the image of the laparoscope and right side is the monitor reflects the image of BirdView camera during operation of initial medial-to-lateral approach. A distant view can be obtained by BirdView camera system and the small bowel can be seen in front



Regarding the secondary endpoint, as shown in Table 2, the median operative time was 299.5 min (range 220.0–393.0 min; 95% confidence interval, 233.0–356.0 min), the median blood loss was 35.5 mL (range 6.0–72.0 mL; 95% confidence interval 10–50 mL) and the median post-operative hospital stay was 8 days (range 7–11 days; 95% confidence interval 7–11 days). These values were similar to the average operative time, blood loss, and duration of hospital stay of patients who undergo conventional laparoscopic surgery in our institution. In terms of the operator's mental stress, the subjective performance increased and the subjective temporal demand decreased during laparoscopic surgery using the BirdView camera system. The subjective performance during laparoscopic surgery with the BirdView camera system was increased (95% confidence interval 7.94–9.46). On the other hand, the subjective temporal demand decreased (95% confidence interval –3.13 to –0.27).

Because this was a first-in-man phase I trial, the median installation time of the BirdView camera was 12 min (range 7–21 min; 95% confidence interval 9–21 min, Fig. 4). In the first 10 cases, a decreasing trend was observed in the installation time.

Discussion

“Blind spots” are one of the disadvantages of laparoscopic surgery. We believe that the use of a device that reduces this disadvantage to the maximum possible extent will improve the safety of laparoscopic surgery. We therefore initiated the development of this camera system.

Tamadazte et al. conducted a study to obtain a wider viewing field by installing a supporting camera at the tip of a laparoscopic camera as a device to reduce blind spots [10]. While this ensured a wider viewing field in comparison to a

Table 2 Operative and post-operative results

Variables	Median (range)/no.	95% CI
Operative results		
Operation time (min)	299.5 (220.0 to 393.0)	233.0 to 356.0
Blood loss (mL)	35.5 (6.0 to 72.0)	10 to 50
Post-operative results		
Hospital stay (days)	8 (7 to 11)	7 to 11
Complication (no.)	2 (20%)	2.5 to 55.6%
NASA-TLX		
Mental demand	−0.5 (−2.0 to 2.0)	−2.0 to 2.0
Physical demand	0 (−5.0 to 2.0)	−3.0 to 1.0
Temporal demand	−2.0 (−5.0 to 2.0)	−3.0 to 0
Performance	8.5 (7.0 to 10.0)	8.0 to 10.0
Effort	1.0 (−3.0 to 6.0)	0 to 5.0
Frustration	−0.5 (−5.0 to 2.0)	−3.0 to 1.0

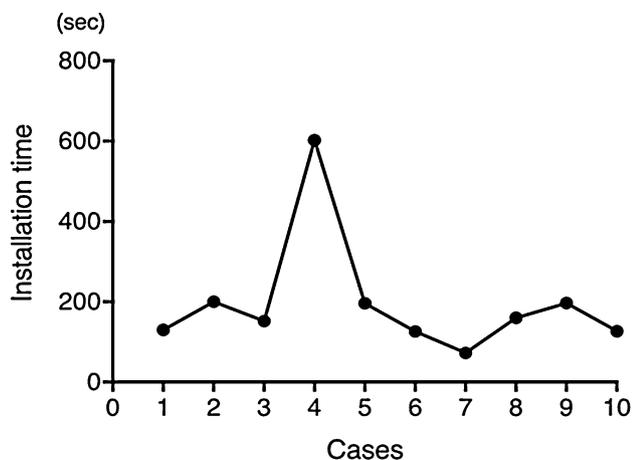


Fig. 4 The learning curves of installation time of the BirdView camera (One same surgeon). Installation time indicates the time from when the camera is installed and the safety is confirmed until the operation is resumed. Dashed line indicates linear regression line

normal laparoscopic camera, this does not improve the blind spots at the back of the laparoscopic camera, and it remained possible to overlook injuries outside the view.

To date, we have proposed the BirdView camera system as a device to overcome mirror imaging during laparoscopic surgery and have demonstrated its usefulness [8]. This report demonstrated a significant reduction in the operating hours required to complete a task imitating laparoscopic surgery in which a wide-angle camera was installed in a dry box. Subsequently, by introducing this wide-angle camera into practice, we intended to establish it as a device that not only overcomes mirror imaging but also improves the safety of laparoscopic surgery. In order to realize this idea, we conducted joint research with SHARP Corporation and advanced the development of the camera.

It was necessary to miniaturize the supporting camera body in order to allow it to be installed in the abdominal cavity under a laparoscope and to prevent it from interfering with the surgical procedure. Furthermore, because the intra-abdominal cavity was darker than expected, it was also necessary that the light illuminating the viewing field be strong while generating minimal heat. We decided to place small LED lights at both ends of the supporting camera to meet these requirements. Integrating the supporting camera and LED lights and making the cable connecting them to the external device detachable enabled the camera to be inserted from a trocar and for the image to be transmitted to the external device. We devised a small-diameter cable that was able to pass through the existing (off-the-shelf) 3-mm trocar. Furthermore, integrating the 3-mm trocar with the supporting camera enabled us to adjust the location of the supporting camera and the viewing field. We made repeated improvements while testing the system in pigs until practical use in humans finally became possible in this phase I study of the BirdView camera system.

Because our BirdView camera system can look down in the abdominal cavity from the rear of the laparoscope, it can obtain real time information, even for the laparoscope's blind spots. Furthermore, it provides an overview for surgery. Our experience with this system leads us to believe it that it will improve the safety and efficacy of laparoscopic surgery.

The BirdView camera system is associated with the following three problems: (i) An extra incision is necessary to install the BirdView camera system; (ii) further surgical procedures and time are added to install the BirdView camera system; and (iii) operating room space is required to accommodate the BirdView camera system.

Regarding (i), a technique exists to anchor a device in the abdominal cavity using magnetic force from the abdominal wall, called MAGS; some authors have reported using this technique to fix a camera or retractor [11–13]. This is a breakthrough method by which a camera can be placed in the abdominal cavity without an extra incision and has the advantage of allowing a camera to be freely placed. However, the use of magnetic force is associated with the following problems: it may interfere with metal surgical equipment, metal grafts, and pacemakers; if the abdominal wall is too thick it is not possible to obtain sufficient fixation. In the BirdView camera system, the installation of a camera through a 3-mm port was enabled by repeated improvement and miniaturization. We believe that a skin incision of 3 mm is acceptable for obtaining a wide field of view.

Regarding (ii), we devised the system to be installed very easily. With the experience of several cases, the camera can be installed in approximately five minutes (Fig. 4). We do not consider the time and effort required to use this system to be problematic.

Regarding (iii), although it is necessary to add a monitor, we believe that the monitor can be installed next to the normal laparoscopic monitor to take advantage of this camera system; in the future, it will also be possible to introduce a picture-in-picture functionality.

The present study is associated with some limitations, including the fact that the results were narrow in terms of safety due it being a phase I study. Although there were two cases of perioperative complications, these were not believed to have been caused by the use of the camera system; thus, the safety of this camera system was ensured.

These results revealed the safety and feasibility of laparoscopic surgery with the BirdView camera system for colorectal cancer. In the future, we would like to conduct studies on the safety and usefulness of the system by continuing to improve the system and arranging controlled studies. This study is, to the best of our knowledge, the first report on the use of a separately installed downward facing camera in the abdominal cavity in laparoscopic surgery. Since the BirdView camera system is a monitoring camera, we have created it as a dual imaging modality system to cover the surgical field. However, further technical developments may enable the performance of operations solely with the BirdView camera system by providing close-up views of any points in the viewing field. Furthermore, we consider it to be more suitable for robotic surgery, which has no tactile feedback, as it would provide console surgeons and assistants with a wider view of the surgical field. We believe that the BirdView camera system has the potential to contribute to safe endoscopic surgery and the performance of robotic surgery.

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Author contributions YS participated in treatment of these patients, literature search, and draft the manuscript. HE participated in treatment of these patients and helped to draft the manuscript. MH helped to do statistical analysis and helped to draft the manuscript. TS, MT, TA, HS, and SM participated in treatment of these patients. YK advised to us as an engineer. HO participated in treatment planning of these patients. All authors read and approved the final manuscript.

Compliance with ethical standards

Disclosures We jointly developed equipment. SHARP corporation owns the production cost. The test was conducted with the provision of SHARP corporation's equipment. We have not received funds or reward from SHARP corporation. Drs. Yusuke Sumi, Hiroyuki Egi, Minoru Hattori, Takahisa Suzuki, Masakazu Tokunaga, Tomohiro Adachi, Hiroyuki Sawada, Shoichiro Mukai, Yuichi Kurita, and Hideki Ohdan have no conflicts of interest or financial ties to disclose.

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