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Solo-surgical laparoscopic cholecystectomy with a joystick-guided camera device: a case–control study

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Abstract
Background This study aimed to evaluate the implementation of a joystick-controlled camera holder (Soloassist; Actormed, Barbing, Germany) in laparoscopic cholecystectomy as so-called solo-surgery compared with the standard operation.
Methods Of the 123 patients included in this study, 63 underwent laparoscopic cholecystectomy using the Soloassist system and were compared with 60 patients who underwent laparoscopic cholecystectomy with human assistance. The two groups did not differ significantly in terms of age, sex, body mass index, or American Society of Anesthesiology classification. The surgeons were divided into those highly experienced and those experienced with the new camera holder. The operation times were measured, including setup and dismantling of the system. The assessment also included complications, postoperative hospital stay, measurement of human resources in terms of personnel/minutes/operation, and subjective evaluation of the camera-guiding device by the surgeons.
Results The hospital stay and operation-related complications were not enhanced in the Soloassist group. The differences in core operation time ($p = 0.008$) and total operating time ($p = 0.001$) significantly favored the human assistant. Whereas the absolute duration of surgery was longer, the relative operating time (in personnel/minutes/operation) was significantly shorter ($p < 0.001$). In 4.8 % of the cases, the operation could not be performed completely with the camera-holding device. Clinically relevant postoperative complications did not occur. The experience of the surgeons did not differ significantly. The subjective evaluation regarding handling, image quality, effort, and satisfaction demonstrated high acceptance of the Soloassist system.
Conclusions The camera-guiding device can be implemented without increased complications. The Soloassist system is safe and can be operated even by colleagues without system experience. All the surgeons rated their satisfaction with the system as very good to excellent. Although the operating times were longer than with the standard camera guidance, the absolute overall staff time was reduced.

Keywords Cholecystectomy · Human/robotic · Surgical · Training · Camera holder · Solo-surgery

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The idea of minimally invasive solo-surgery, discussed frequently in the past 30 years, is seen as offering advantages including precision of surgical procedures, enhanced ergonomics for surgeons, and reduced health care costs by reduction in operating time and human resources.

One of the first surgical robots, called “PROBOT,” was developed at the Imperial College in London in the late 1980s to assist with transurethral resection of the prostate [1–3]. In the following years, various further robotic assistants were developed and evaluated.

One of the first commercially available robotic camera assistance systems, Automated Endoscopic System for Optimal Positioning (AESOP; Computer Motion, Sunnyvale, CA, USA), was incorporated into clinical practice during the early 1990s [4–6]. Introduced mainly into urologic clinical practice, AESOP still is there in use, with about 45,000 urologic operations [3].

Other active camera-holding devices have included the EndoAssist (Armstrong Healthcare Ltd., High Wycombe, UK) [7], the LapMan (Medsys, Sauvenière, Belgium) [8], and the FIPS Endoarm (Karlsruhe Research Centre, Karlsruhe, Germany) [9].

Prior studies showed that robotic arms could be used safely to perform laparoscopic cholecystectomies and other procedures in a solo-surgical manner, reducing time and saving resources [7, 10, 11]. Further advantages of robotic assistance during operation have been discussed, such as elimination of the camera assistant's fatigue as well as greater stability and accuracy of the view by reduction of tremor and small movements [12–15].

On the other hand, robotic camera control has specific technical challenges and surgical limitations in addition to the high investment and running costs, which lead to an ongoing controversial discussion. The systems of the first-generation active camera holders were comparatively heavy, bulky, or did not permit any change of the operating room table tilt. Mounting and demounting was time consuming, and the workload of the surgeon was increased [16].

For standard abdominal laparoscopic surgery, many limitations for each device were persistent, and human assistance was preferred for several reasons [16, 17]. As a result, none of the early active camera holders came to a breakthrough [17–19]. Even the most frequently used AESOP system currently is used less frequently for abdominal surgery. Although still applied for some urologic operations, its use is discussed controversially [19].

New camera devices have been developed and tested in small patient groups (e.g., the NAVIOT; Hitachi Co., Chiyoda, Tokyo, Japan) [20, 21] without major clinical impact.

Because cost pressure within the health care system is ever increasing, the simultaneous lack of surgical descendants becomes evident, and the topic of electromechanical camera control systems that can replace surgical personnel [7, 22] becomes interesting again.

The Soloassist (ACTORmed; SOLOSURGERY, Barbing, Germany) is a newly developed, joystick-guided, and commercially available robotic camera-holding device of the second generation. This device was designed to avoid the specific shortcomings of former systems and to provide superior applicability. It is a lightweight, fluidically driven system that can easily be fixed to the operating room table. It needs less space than a human assistant and is significantly less expensive than earlier devices. Its exact application and use are described in the following discussion.

The first clinical use of the Soloassist has recently been described for ear, nose, and throat (ENT) surgery [23]. To date, no clinical trials for abdominal surgery have been published. Therefore, a study was conceived to assess whether this second-generation of camera holders such as the Soloassist is better suited for clinical practice.

In a prospective, comparative evaluation, the safety and feasibility of the camera manipulator versus human surgical assistance were analyzed in a standardized laparoscopic procedure with a large group of patients.

Materials and methods

The Soloassist camera-holding device

The Soloassist is guided by a sterile joystick, which can be clamped on every handle of laparoscopic instruments. The joystick can be operated easily with the index finger of the surgeon's nondominant hand during normal movements of the instrument's handle (Fig. 1A).

The joystick of the Soloassist moves the camera intuitively 360° by tipping (up-and-down and oblique movements). Furthermore, two small buttons offer the opportunity to move the camera diagonally forward and backward (in and out). With a small screw, the joystick can be fixed to every laparoscopic instrument, allowing common sterilization.

The directions of the camera arm have to be configured after the setup. After insertion of the first trocar, the tip of the camera holder is moved to the trocar point and configured by pressing a button on the console unit. The entrance point, movements, and directions are saved and defined in a system of coordinates for the complete procedure. For safety reasons, the system stops the movements when moves in the coordinate system are recognized as out of range. These measures minimize misguidance and unintended tipping of the joystick.

Patient inclusion criteria

The trial was conducted as a prospective group analysis. Between 2009 and 2012, a total of 123 patients were included in the analysis. Of these 123 patients, 63 were randomized for laparoscopic cholecystectomy with Soloassist assistance (group A) and 60 for standard laparoscopic cholecystectomy with a clinical fellow for camera control (group B). The cholecystectomy patients all had symptomatic gallstone disease. Patients with signs of acute cholecystitis were excluded from the study.

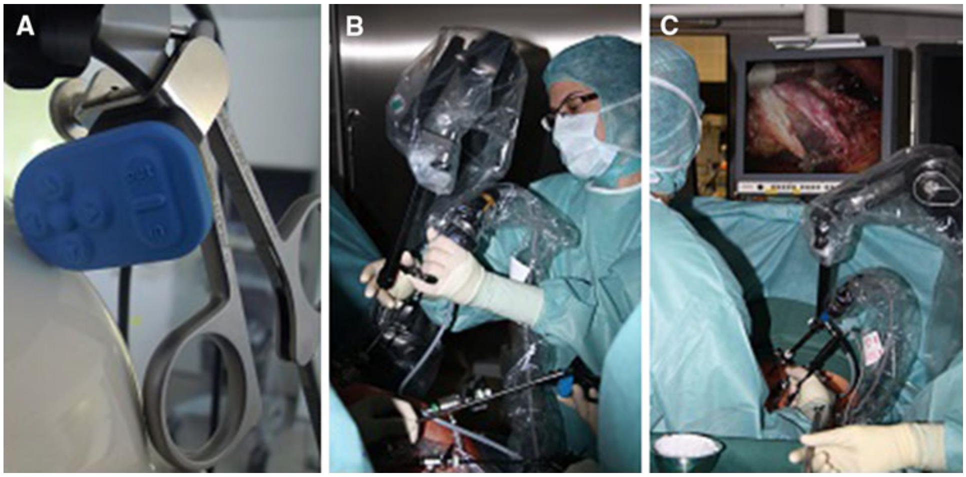

Fig. 1 Soloassist system clamped to the operating table after the complete setup. **A** Joystick clamped to the handle of an instrument in the surgeon's nondominant hand. The joystick can be operated 360° intuitively with the index finger of this hand while normal movements are performed with the handle of the instrument (e.g., straight grasper). Next to the joystick are two small buttons for in-and-out movement. **B** Clamping of a 5-mm laparoscopic camera to the sterile robotic arm. **C** Intraoperative view of the surgeon

All the patients underwent surgery on a standard operating table (MAQUET, Rastatt, Germany) in a supine position with standard laparoscopic equipment (Karl Storz GmbH and Co KG, Tuttlingen, Germany). The patients undergoing surgery with the Soloassist were chosen randomly depending on the operating day.

Operation with the Soloassist camera-holding arm (group A)

Before the operation, in group A, the Soloassist camera was connected to the operating table with a quick-fastening clamp. After the robotic arm had been clamped to the operating table, the sterile overdraw could be put over the arm (Fig. 1C).

Operating procedure in both groups

Pneumoperitoneum was established using well-established safety procedures. The umbilical trocar then was inserted, and the surgeon first performed a 360° view of the abdominal cavity (Fig. 1B) to ensure that no complications had occurred during insertion of the trocar and to clear out any contraindications to the laparoscopic approach that may have been present.

In the next step, the standard laparoscopic 10-mm camera (Karl Storz GmbH and Co KG) was attached the Soloassist, which then was reinserted into the camera port. The operating procedure was equivalent in the two groups. Standard cholecystectomy with all the safety criteria, including a critical view of safety, was performed in both groups as described elsewhere.

Data acquisition and end points of the study

The primary end point of the study was comparison of the operating times (in minutes). The total operating time (TOR) was subdivided into three different periods: the preparation time (from the start of operating room nursing to the skin incision), the core operating time (from skin incision to skin closure), and dismantling time (from skin suture to the moment when the patient was ready to be rolled out of the operating room). The TOR per personnel was related to the number of staff members involved. The times/adverse events and complications were documented by an independent observer recording all the operations. The secondary end points were intra- and postoperative complications and the acceptance of the surgeons.

Three senior surgeons, all well experienced in laparoscopic surgery (>250 operations), took part in the trial. The one surgeon was experienced with the Soloassist, whereas the other two surgeons were not yet familiar with the system before the trial started. Manual camera guidance in group B was delivered by residents well experienced in laparoscopic surgery.

Manual camera guidance in group B was delivered by residents well experienced in laparoscopic surgery.

Postoperatively, a standardized questionnaire was completed by the surgeon for subjective evaluation.

In addition to demographic data (American Society of Anesthesiology [ASA] classification, body mass index [BMI], age, gender), the intra- and postoperative complications and postoperative hospital stay were assessed. In group A, the number of uncontrolled camera movements and conversion to manual assistance were documented.

Statistical analysis

The categorical variables are presented as frequencies and percentages and the continuous variables as medians and ranges. The study groups were compared at baseline for important demographic and clinical characteristics. Differences between the two groups were additionally evaluated using Chi square tests for categorical variables and independent sample *t*-tests for continuous data. In both study groups, comparison of the time needed for the surgery and the postoperative hospital stay and comparison of experienced and inexperienced surgeons were performed using exact Mann–Whitney *U* tests.

Statistical analyses were conducted with the use of IBM SPSS 20 (IBM, Armonk, NY, USA). All statistical tests were two-sided and not adjusted for multiple testing. The significance level was 0.05.

Table 1 Demographic data of the included 123 patients, age is given in years (median), including range; gender, BMI and ASA are given as absolute numbers, *p* values show that no significant differences can be found in the two groups

	OPs with Soloassist	OPs with human assistance	*p* value
Median age: years (range)	45 (15–77)	46 (15–79)	0.613
Total no. of patients	63	60	
Gender			
Females	50	45	0.668
Males	13	15	
BMI			
<30	38	38	0.710
>30	25	21	
ASA			
0	1	1	0.199
1	20	15	
2	40	36	
3	2	8	

OPs operations

Results

Demographics

Of the 123 patients (95 females and 28 males) included in the study, 63 underwent surgery with the Soloassist system, and 60 had surgery with human assistance. The patients ranged in age from 15 to 79 years (median, 44 years). The 123 patients included 76 with a BMI lower than 30 kg/m^2. Most of the patients had an ASA 2 status (Table 1). No significant or clinical important differences could be found between the two groups.

Operating times

In 3 of 63 operations, the Soloassist system had to be demounted during the operation due to the patient's safety. These three patients were not included in the further operating time analysis. The TOR ranged from 62 to 160 min. The median operating time for the group treated with the Soloassist was 104 min compared with only 90 min for the group that had human assistance. The difference in both the core operating time (median, 59 vs 48 min; $p = 0.008$) and the TOR (median, 104 vs 90 min; $p = 0.001$) favored the human assistance (Table 2). No significant difference could be assessed for preparation, setup, or demounting.

The TOR per personnel (overall staff time) for estimation of the financial aspects and human resources was significantly shorter in the group treated with the Soloassist because only one surgeon was performing the operation, whereas in the group with human assistance, at least two surgeons completed the operation and were required during the entire operating time (median time/operation/surgeon, 104 vs 180 min; $p < 0.001$).

Comparison of inexperienced and highly experienced surgeons

In this comparison, 47 operations were performed by one surgeon highly experienced with the Soloassist and experienced in laparoscopic surgery, whereas 16 operations were performed by two surgeons inexperienced with the Soloassist but experienced in laparoscopic surgery.

In one operation by the surgeon with system experience (2.13 %) and in two operations (12.5 %) by the surgeons with no system experience, the Soloassist system had to be demounted.

No obvious learning effect could be detected for either the surgeons with no system experience or the surgeon experienced with the system. The median TOR was 72 versus 81 min for the surgeon with system experience and 109 versus 102 min for the surgeons without system experience ($p = 0.30$).

No significant difference could be seen between the surgeon highly experienced with the Soloassist and the surgeons with no Soloassist experience in terms of preparation and setup (29 vs 30 min; $p = 0.77$), postoperative complications, or operative hospital stay (3 vs 3 days; $p = 0.23$). Interestingly, demounting of the system required significantly less time for the surgeons with no system experience (6 vs 10 min; $p = 0.01$).

Table 2 Median operation times in minutes with range and *p* values. There was a significant difference for the total operation time, but not for the preparation and setup

	OPs with Soloassist		OPs with human assistance		*p* value
	Median	Range (min–max)	Median	Range (min–max)	
Core operation time (min)	59	30–112	48	24–87	0.005
Total operation time (min)	104	72–160	90	62–132	0.001
Preparation and setup time (min)	30	11–47	30	13–50	0.855
Dismantling time (min)	10	3–28	10	4–28	0.014
Time in minutes and personnel	104	72–160	180	124–264	<0.001
Postoperative days	3	2–12	3	2–11	0.607

Concerning personnel per minutes it was significantly shorter in the group being operated with the Soloassist, as only surgeon was performing the operation, whereas in the group with human assistance at least two surgeons completed the operation

OPs operations, *min* minimum, *max* maximum

Complications and adverse events

The postoperative hospital stay was comparable between the two groups. In 4.8 % (3/63) of the operations, the Soloassist system had to be demounted during operation and the assistance taken over by a resident due to intraoperative complications. In one of these three cases among the 123 laparoscopic operations, a conversion to open surgery was needed. No adverse events were noted during the perioperative period. Clinical relevant postoperative complications did not occur. The median number of uncontrolled camera movements was 2 (range, 0–10 per operation).

Subjective evaluation

We were able to obtain subjective evaluations for the 63 operations performed with the Soloassist. After each operation, the surgeons completed a standardized questionnaire concerning handling, quality of performance, and satisfaction with the system. The answers were given on a Likert scale ranging from 1 (very good) to 5 (very bad). All the surgeons seemed to be very content with the system. The median evaluation score recorded for all the questions answered was 2 (good) (Fig. 2).

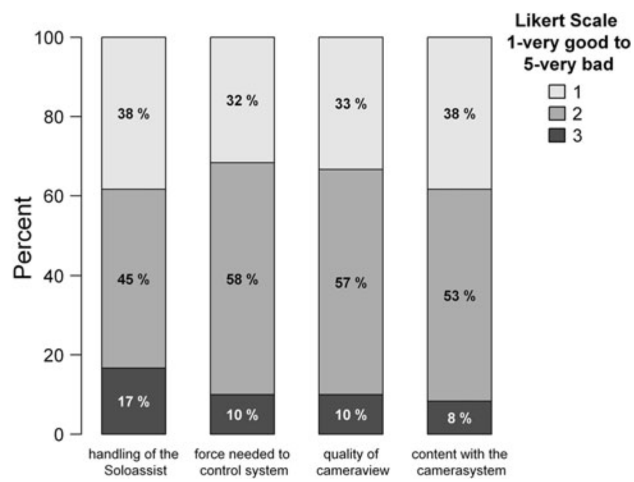

Fig. 2 Subjective evaluation of the 63 operations performed with the Soloassist. After each operation, the surgeons completed a standardized questionnaire concerning handling, quality, and satisfaction with the system. Answers were given on a Likert scale ranging from 1 (very good) to 5 (very bad)

Discussion

The Soloassist is one of the newly developed robotic camera assistants designed to enable solo-surgical procedures. In the past 30 years, many trials, even randomized controlled trials, have been conducted to prove the feasibility and performance of different camera-holding systems [7, 24]. In general, good satisfaction and acceptance concerning handling have been shown by the surgeons. Reduced operating times with a proficient team are postulated. Furthermore, higher accuracy and stability of view are mentioned. Less fatigue and better concentration are assumed. However, general implementation of such systems into general clinical routine has not taken place to date, and most systems have already disappeared from the market. Some authors suggest loss of comfort and limitations in practice and application, with only marginal resource benefits [16, 18].

The Soloassist is an active camera-holding device of the second generation.

It is guided by a sterile joystick clamped to the handle of any instrument in the nondominant hand of the surgeon, which can easily be directed with the index finger. The small round joystick moves the camera intuitively 360° by tipping. With two additional buttons, it can be moved forward and backward (in and out).

After configuration of the system by defining of the trocar entry point in a coordinate system, it also contains safety measures. This means the camera is stopped when moves might lead to risks for the patient due to wrong guidance or unintended pressing of buttons.

With the Soloassist system, the problems and limitations of the first-generation systems in relation to handling, time for setup, and loss of comfort for surgeons were overcome and precisely eliminated. However, to date, no valid data on its clinical implementation for laparoscopic procedures exist.

This prospective study was designed to evaluate the risks and benefits of the Soloassist camera-guiding system and to evaluate its benefits for overcoming the limitations experienced with the first-generation of active camera-holding devices.

Two comparable groups of patients were analyzed, including a total of 123 patients receiving laparoscopic cholecystectomy.

In our experience, we found that endoscopic solo-surgery is applicable to clinical practice in a standardized setting, even for an inexperienced team, without enhancing complications or lengthening the postoperative hospital stay. Unexpected camera movements numbered only a few (2 per operation).

Handling of the camera-holding device has proved easy to acquire even for inexperienced surgeons and does not lead to prolonged operating times. Rapid learning curves with robotic camera-holding systems have similarly been shown in other studies [7]. In our study, no defined learning curve or effect was evident for either the surgeon with Soloassist system experience or the surgeons without system experience. In the inexperienced group, two conversions to common laparoscopic procedure were necessary, whereas only one conversion was necessary for the experienced surgeon, leading to a conversion rate of 12.5 versus 2.1 %.

The number of cases managed by the surgeons without system experience in this study was very small (16 vs 47 operations). Therefore, for evaluation of a learning curve, we suggest to a further study focusing on this aspect.

In our study, the total operation times were prolonged when the Soloassist was used, but we also could show that the resources of manpower could be reduced significantly. The costs for the Soloassist per operation are estimated to be ~90 € after initial equipment acquisition (~50,000 € for the Soloassist system). The significantly shortened operating time and the use of fewer surgeons seem to be an important argument, especially in times of personnel shortages. Interestingly, the demounting time was significantly shorter in the group operating with the Soloassist. This supports the quick learning curves for the surgeons and operating room personnel in setup and use of the Soloassist and underscores the system's general feasibility.

Finally, in their evaluations, all the surgeons in our study (experienced and inexperienced) stated that operating with the Soloassist system was for them generally very positive. Positive aspects of robotic camera holders have been described and proven in small series of patients or in experimental setups in several studies and reviews [9, 14, 21].

One large review could show that during in vitro trials, all surgeons highlighted the ease of using robotic assistance [24]. Similar to our trial, even inexperienced surgeons acquired the competence to perform the operation without any difficulties.

In this review, joystick-controlled camera holders were described as intuitive and even more comfortable than other control devices [24]. We also could show good results in subjective evaluation of handling, needed force, and satisfaction.

Conclusion

Robotic assistance by the joystick-guided Soloassist in standardized laparoscopic procedures appears to be a safe and feasible technique, with slightly prolonged operating times but fewer overall personnel resources required. Introduction of the Soloassist into general clinical practice might have advantages in terms of a more precise camera view and a consequent reduction in operating room costs.

Skill in using the system was easy to acquire. No prolonged operating times were measured, even for inexperienced surgeons. The time required for setup was comparable with that for standard operations, and all the surgeons appreciated working with the system. Nevertheless, larger trials focused on efficacy and acceptance are needed to determine the benefits, the impact on surgical training programs, and the cost effectiveness of the Soloassist system.

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