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SURGICAL ENDOSCOPY
and Other Interventional Techniques

Controlled trial of the introduction of a robotic camera assistant (EndoAssist) for laparoscopic cholecystectomy

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Abstract
Background: The role of the human camera holder during laparoscopic surgery keeps valuable personnel from other duties. EndoAssist is a robotic camera-holding device controlled by the operator's head movements. This study assesses its introduction into clinical practice.
Method: Ninety-three patients undergoing laparoscopic cholecystectomy were randomized to have either the robotic (40) or a human (46) assistant. Seven patients converted to open operation were excluded. Six surgeons were evaluated. Operating time and subjective assessments were recorded. Learning curves were constructed.
Results: The mean operating time was less using the robotic assistant (66 min) than with human assistance (74 min) ($p < 0.05$, two-tailed t-test). The learning curves for operating time showed that within three operations surgeons were trained in using the robot. The device was safe in use.
Conclusion: The EndoAssist operating device is a significant asset in laparoscopic surgery and a suitable substitute for a human assistant. Surgeons became competent in the use of the robot within three operations. The robot offers stability and good control of the television image in laparoscopic surgery.

Key words: Medical robotics — Laparoscopic surgery

Laparoscopic cholecystectomy usually requires a skilled assistant to hold and manipulate the camera. Robotic technology offers devices to perform the role of holding the camera. With a shortage of trained medical and nursing staff in the National Health Service there has never been a better time to focus on sparing valuable personnel for other work. Furthermore, with a human assistant, the camera is often not steady or centered to the surgeon's satisfaction.

Alternative devices to replace the human camera-holding assistant have already been developed but all have disadvantages [10]. The simplest is a mechanical arm, but this must be repositioned by the operator manually — which causes delay. A voice-controlled device (AESOP) has been developed [13], but it is possible for background noise to be interpreted by the robot as commands, each surgeon requires a voice card, and this device must be mounted on the table at the start of the operation.

EndoAssist is a freestanding laparoscopic camera manipulator controlled by infrared signals from a headset worn by the operator. This is the first randomized clinical trial of EndoAssist and aims to assess its practical performance compared to a human camera-holding assistant.

Materials and methods

Ninety-three consecutive elective patients undergoing laparoscopic cholecystectomy were randomized to have the operation performed with either conventional human (manual) camera holder (50) or the Endoassist devices (43). Fifty-seven were female. Once it was confirmed that the operation was feasible by the laparoscopic technique, patients were randomized by the closed envelope method. Seven (3 robot- and 4 manual-assisted) cases were converted to open cholecystectomy (7%) and excluded. Forty-six in the manually assisted control group (Manual) and 40 in the EndoAssist robotic assisted group (EndoAssist) were completed in the study (Table 1). The mismatch in numbers was fortuitous and resulted from the randomization by random numbers. The EndoAssist device was supplied by Armstrong Healthcare Ltd., High Wycombe, Bucks, UK, and had been independently certificated to international safety standard IEC601.

EndoAssist is a freestanding unit which is wheeled to a position next to the operating table opposite the surgeon. The device is centred on the umbilicus and is then ready to use. The operating field is the same as for standard laparoscopic cholecystectomy (see Fig. 1). Pneumoperitoneum is established, then ports and laparoscope inserted. The laparoscope is then attached to EndoAssist by a sterilisable steel arm. The device has four degrees of freedom, with the entry port as its centre of goniometric focus. A detailed description of the EndoAssist design and function has already been presented by Finlay [4].

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Table 1. Demographic data

	Manual (n = 46)	EndoAssist (n = 40)
Mean age (years)	53	59
Age range (years)	15–81	22–82
Median age (years)	59	57
Female: male ratio	32:14	26:14

Table 2. Conversion to open cholecystectomy

EndoAssist (n = 3)	Obesity—1
	Adhesions—2
Manual (n = 4)	Difficult anatomy—1
	Obesity—1
	Adhesions—2

The surgeon wears a device on the head (Fig. 1) and movements are detected by an infrared sensor placed on the monitor the surgeon is watching. This moves the camera through pan, tilt, and zoom movements as it detects the signal from the headset. A footswitch must be pressed for the command to be carried out. The EndoAssist has a force sensor as an additional safety feature which inactivates the device if excessive resistance is encountered to the laparoscope's movement.

The surgeons were 2 consultants, 1 associate specialist, and 3 specialist registrars (trainees). Surgeons were included in the trial after one practice operation using the EndoAssist. The human camera holders were medical personnel of all grades but experienced at controlling the camera. One other surgical registrar was excluded from the trial after 3 attempts with the EndoAssist and finding it unsuitable.

For each procedure the operation time (from port insertion to port removal), and any technical problems, conversion to open procedure, or complications were recorded. Operating time included setup time for the robot, a full pelvic inspection, and an operative cholangiogram, which was performed for all cases routinely. Patient age, sex, and surgeon's subjective assessment of the Endo Assist's performance by grading the nominal image quality and benefit of direct personal control with the EndoAssist were also collected. Data were analyzed using two-tailed Student's t-test.

Results

There were 7 conversions to open operations, 3 in the Endoassist group and 4 in the Manual group (Table 2). No conversions were caused by the use of the robot. Patients converted to open operation were withdrawn and their operating times were not recorded in the study.

The EndoAssist was safe in use with no instances of harm. It took less than 10 min to set up the robot intraoperatively, but this time rapidly decreased with familiarity. Dismantling the device was rapid as it could be rolled back from the operating table and the camera holding arm detached within a minute.

The mean operating time from port insertion to port removal for the EndoAssist group was 66 min (std dev = 17 min), and of the Manual group 74 min (std dev = 23 min) (p = 0.049, two-tailed t-test).

Learning curves

It was possible to construct learning curves showing operating time versus occasion for the group (Fig. 2). These show that the use of the EndoAssist is readily learned, and within three operations the operating times with EndoAssist are no different from those with a human assistant. The operating times for each individual surgeon with and without the robot were similar (Fig. 3).

The image provided by the EndoAssist was of high quality according to the subjective assessment of the operating surgeons — being stable, and equivalent to or better than that provided by a skilled attentive human camera holder.

Fig. 1. EndoAssist in use.

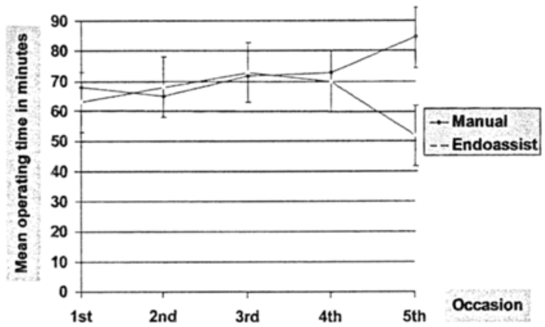

Fig. 2. Average operating time (minutes) versus occasion comparing manual (n = 46) and EndoAssist (n = 40) groups.

Discussion

The EndoAssist robotic camera holder performed effectively and reduced operating times compared to a skilled human camera-holding assistant in this trial, providing an excellent substitute for the human assistant during laparoscopic surgery. The EndoAssist's use was readily learned within three occasions. This study is the first randomized controlled trial of the EndoAssist in laparoscopic surgery, relying on operating time as a simple measurement to compare it to human assistance in a prospective randomized trial.

The search for an alternative to a human camera holder for economy as well as efficiency first led to the development of mechanical manipulators such as the Omnitract, Bookwalter, or, more recently, Boonpong holders, which are stable, but inherently slower in use compared to robotic systems [9, 10]. The operator must release instruments and interrupt the procedure to make

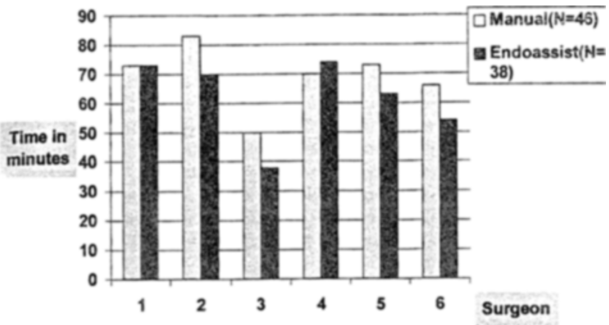

Fig. 3. Mean operating times (minutes) for manual and EndoAssist operated cases by individual surgeon.

operating field adjustments. This can be particularly difficult at a critical point in the operation. Robotic systems designed to avoid these delays have been introduced in urology as well as general surgery.

Using robot assistance, Partin and co-workers completed 14 of 17 (82%) urological laparoscopic procedures successfully including nephrectomy and pelvic node dissection [12]. Kavoussi et al. then compared the robot to a human assistant in a non randomized study where 11 patients undergoing bilateral urological procedures had human and robot assistance on opposite sides [8]. Robots replaced up to two human assistants successfully. They found no significant difference in operating times, but camera positioning was significantly steadier with the robot. The expanding use of robot assistance in urology is set to continue in the future, including their use for transurethral resection of the prostate [3].

The development of a robot for laparoscopic surgery was reported by Begin et al. [2] and used to perform laparoscopic cholecystectomy in three human patients in 1994 [5]. They found that use of the robotic assistant allowed safe and rapid surgery. Geis and colleagues reported on a series of 24 elective procedures (cholecystectomy, hernia repair, and fundoplication) where the robot reduced operating time and required fewer lens cleanings [6]. However the use of the robot was not directly compared to human assistance in this study.

A prospective controlled series with 129 patients having laparoscopic cholecystectomy was reported by Gracia [7]. Twenty-six percent of their patients were not randomized, and 30% of the robot-assisted cases were converted to human assistance. Operating time was less in the robotic cases, and the laparoscope lens required fewer cleanings. However, the incomplete randomization makes it difficult to interpret their results.

A series of 20 patients undergoing laparoscopic cholecystectomy using a self-guiding robot has been reported by Omote et al. and compared with historical controls. There was no significant difference in operating time [11].

The question remained: how would the robot compare to human assistance in everyday use? Our study based in a district general hospital aimed to answer this question using the simple measure of operating time. The reduction in operating time with the robot is statistically significant, although this does not represent a clinically significant reduction. For a single operator exposed to more cases the reduction could be even greater, which could then also be of clinical significance. This offers interesting possibilities for improving the efficiency of theater usage, as well as freeing personnel for other work. With waiting lists reaching record levels [16] and trained staff in short supply, the use of robotic assistance has considerable potential. Furthermore the robot can work 7 days a week, 52 weeks a year.

One concern with robot use in theater is that setup and dismantling times might be increased. We did not find this a problem with the EndoAssist, which took 5–10 min to set up. As it was wheeled into position and free of attachment to the operating table the robot could be moved quickly and easily by one person. The setup and dismantling times were included in the operating times for the robotic assisted group. In their study Partin et al. recorded mean setup and breakdown times (43 and 9 min, respectively) that were no different with or without the robot [12]. Omote and colleagues had a setup time averaging 21 min [11].

Theater teams also learned how to set up the robot without difficulty. The scrub nurse was able to concentrate on his/her task without having to hold the camera, which was welcomed. We found the design to be very practical, confirming previous clinical studies [4, 15].

The EndoAssist robot has been designed to be intuitive by responding to head movements. Although all surgeons taking part had experience in laparoscopic surgery, the short learning curve confirms that the head movements to control EndoAssist are rapidly learned. However, not all surgeons will find this suitable. One trainee had to convert 2 of 3 EndoAssist cases to manual ones. Other robotic devices are available which are controlled by footpedal or voice [2, 13, 14] or are self-guiding [11]. Their use in laparoscopic surgery has been described in nonrandomized [1] or retrospective [17] series. Different devices may be found more useful depending on the surgeon.

The EndoAssist proved to be a practical, reliable, and safe substitute for a human camera holder on the basis of our study, and could be introduced into any operating theater for use by any laparoscopic surgical team. It has since been used in our hospital for other laparoscopic operations including appendicectomy, diagnostic laparoscopy, and gastric fundoplication.

During the study it emerged that trainees could operate assisted by the robot with their trainer in the theater and available to advise but not scrubbed and holding the camera. This proved beneficial to the trainees, giving a sense of independence, and freed the consultants to attend to other matters while remaining available to help in theater. This unexpected benefit to trainees answered initial concerns that a robotic camera holder might take away opportunities to train from junior surgeons. However, the concerns are valid. Junior team members such as house officers or senior house officers who often perform the role of camera holder may feel they are losing a training opportunity. If robotic assistance proves economical and efficient this will need to be addressed. Ideally each junior trainee's education needs to be considered as a whole, developing in several areas, and maybe time allowed for them to train during or after the operation in a more active role, such as guiding the laparoscopic survey or dissecting the gallbladder bed. These concerns reflect a wider issue of surgical education in a time of political and media focus on waiting lists and throughput, which do not sit easily with training. Robotic technology is not to blame for current difficulties in training, and this should be kept in perspective.

This study compared robotic assistance with human camera holders in a scientific controlled way. It has established that the EndoAssist is a practical, reliable tool suitable to substitute for humans, which has the potential to improve the efficient use of theater time and free the camera assistant for more productive work.

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