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Human vs robotic organ retraction during laparoscopic Nissen fundoplication

B. K. Poulose,[1] M. F. Kutka,[1] M. Mendoza-Sagaon,[1] A. C. Barnes,[2] C. Yang,[3] R. H. Taylor,[3] M. A. Talamini[1]

[1] Department of Surgery, Johns Hopkins University School of Medicine, Blalock 665, 600 North Wolfe Street, Baltimore, MD 21287, USA
[2] Department of Mechanical Engineering, Johns Hopkins University, 122 Latrobe Hall, Baltimore, MD 21218, USA
[3] Department of Computer Science, Johns Hopkins University, 224 New Engineering Building, Baltimore, MD 21218, USA

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Abstract
Background: Advances in technique and instrumentation have enabled surgeons to perform an increasing number of complicated procedures through laparoscopy. However, these efforts have often been compromised by the exertion of excessive force when anatomical structures are retracted to create a clear view of the anatomy. Here, we present a comparative study of human and robotic performance in force-controlled organ retraction during laparoscopic Nissen fundoplication (LNF).
Methods: Six female pigs (20–25 kg) were anesthetized, intubated, and placed on mechanical ventilation; pneumoperitoneum (13 mmHg CO_2) was established. A force-sensing retractor (FSR) was constructed to record the forces applied in retracting the stomach during dissection of the esophageal hiatus. The FSR was calibrated using known forces and then operated by either human alone or robot under human guidance using the FSR data. The esophageal hiatus was visualized and dissected, and LNF was completed.
Results: Less force was needed for robotic (74.3 ± 10.5 g; mean ± standard deviation) than for human (108.9 ± 34.3 g) retraction ($p = 0.007$) to obtain an optimal view of the esophageal hiatus. No significant differences were observed for retraction setup time (robot, 14.3 ± 0.8 min; human, 13.7 ± 9.9 min; mean ± SD) or hiatal dissection time (robot, 14.0 ± 3.0 min; human, 14.0 ± 6.1 min; mean ± SD).
Conclusions: These preliminary results illustrate our continuing effort to develop and evaluate an automated surgical assistant for laparoscopy. As more personnel-intensive advanced laparoscopic procedures are performed, robotic retraction is likely to offer a superior alternative to human retraction; it minimizes the forces exerted on the organs while maintaining excellent anatomical view.

Key words: Surgical robotics — Retraction devices — Laparoscopy — Force feedback

Laparoscopic techniques are being applied to an ever-increasing number of general surgical procedures. Patients typically experience less post–operative pain, shorter hospital stay, and more rapid return to daily routines than when the same procedures are performed by the more traditional open technique [3, 9, 12]. As more complex laparoscopic procedures of longer duration are performed, the likelihood of iatrogenic injury to the patient increases. Often, the participation of assistants who are not familiar with laparoscopic techniques is unavoidable in personnel-intensive procedures. One of the tasks relegated to these assistants is the retraction of organs necessary to obtain an optimal anatomical view. Exposure is critical to both traditional and minimally invasive surgery, but it is even more important in laparoscopy, since the surgeons forfeit their primary sense of touch for visually based information. However, once the organs are retracted and an adequate view is established, the camera lens is focused mainly on the immediate operative field, not on the retracted organ. Thus, because the surgical assistants are regularly entrusted with the use of an unfamiliar instrument to retract an unseen organ for an extended period of time, the risk of iatrogenic harm is increased. Injury to visceral or vascular structures are potentially serious complications that can result in peritonitis, sepsis, intraabdominal abscess, or hemorrhage. Often, these injuries are not recognized at the time of the laparoscopic procedure, increasing the chance of a poor outcome [1].

The combination of surgical robotics, computer-integrated video, and laparoscopy promises to transfer time-consuming, repetitive tasks from human to robot, increasing safety and improving surgical outcome. Robotic camera control during laparoscopy, which is now standard, illustrates the feasibility and efficacy of employing surgical ro-

Correspondence to: M. A. Talamini

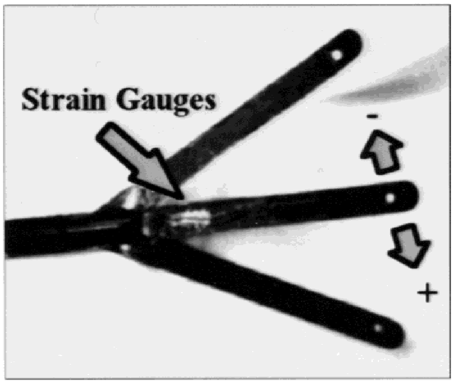

Fig. 1. Force-sensing retractor (FSR). Strain gauges bonded to standard organ retractor provide positive and negative force-sensing in principal retraction axis.

bots in the operating room [6]. In addition, passive systems have been developed to hold structures fixed in space during minimally invasive surgery [7]. However, these passive systems are unable to respond to anatomical shifts caused by changes in respiration, organ manipulation, and patient position. This technical advance will be particularly important in neurosurgery, since the force feedback robotic retraction system will permit the neurosurgeon to retract vital neural tissue with precision and minimal trauma [2]. The introduction of newer computerized surgical graspers has enabled physicians to obtain tactile information about the tissue, providing critical clinical cues to the laparoscopic surgeon [4, 5]. There are no data describing the effectiveness of force feedback surgical robotic systems designed to assist the surgeon with organ manipulation during laparoscopic procedures. This type of robot minimizes iatrogenic injury and maintains the anatomical view by sensing the force applied directly to the retracted organs and adjusting itself to maintain a constant force. Here, we present the first comparative study of human and robotic organ retraction during an advanced laparoscopic procedure, the laparoscopic Nissen fundoplication (LNF) in a porcine model. We used a novel force-sensing organ retraction system to measure the forces applied to a retracted structure and to complete the robotic sensor-effector loop. These preliminary results and their evaluation will be used to aid in our development of an automated laparoscopic surgical assistant system.

Materials and methods

Force-sensing retractor

The force-sensing retractor (FSR) was developed to directly measure the force applied to organs during surgical manipulation. A standard laparoscopic 'fan-type' liver retractor (United States Surgical, Norwalk, CT, USA) was modified in the following fashion to create the FSR: Two 350-ohm polyamide-encapsulated constant-strain gauges (model CEA-06-250-UN-350; Vishay Measurements Group, Raleigh, NC, USA) were bonded to the middle tine of the standard liver retractor in a bending beam configuration (Fig. 1). The strain gauges were connected to a strain indicator (model P-3500; Vishay Measurements Group), which produced a positive voltage output during positive deflection and a negative voltage output with negative deflection. The output of the strain indicator was then routed to a Grass Recorder (model 7D Polygraph; Grass Instruments, Quincy, MA, USA) and a PC workstation for continuous data collection of retraction forces. Before each experiment, the FSR was calibrated using known weights, and the linearity of force response to the test weights was confirmed (Fig. 2). A linear equation derived from calibration data was used to determine the force applied to the retracted organ. All forces are presented as mass equivalents in grams.

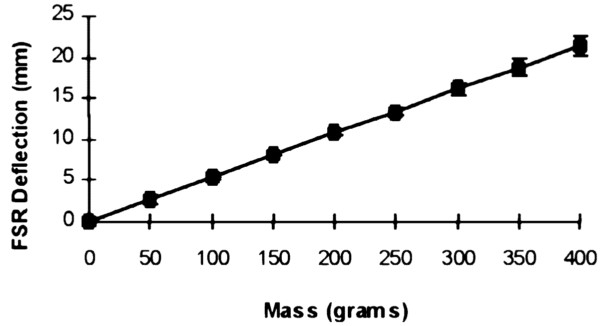

Fig. 2. Calibration of FSR. Linear force response to known masses is confirmed. The resulting linear function is used to calculate force exerted on the retracted organ for a recorded FSR deflection.

LARS surgical robot

The LARS robot [11] was developed jointly by Johns Hopkins University and IBM Research to aid surgeons in a wide variety of laparoscopic applications, including camera holding and precise instrument control for active assistance during laparoscopic procedures (Fig. 3). LARS possesses four degrees-of-freedom (three rotations and one depth of penetration centered at the entry port), image-guided camera aiming, and several safety features designed to minimize haphazard movement of instruments within the abdomen. Sensors mounted on the instrument carrier limit the amount of force and torque exerted on the surgical instruments. Should forces or torques exceed safety thresholds, the robot ceases all motion until they are again within safe limits or the operator intervenes.

Experimental design

All use of animals was approved by the Johns Hopkins Animal Care and Use Committee. Six female pigs (20–25 kg) were premedicated with intramuscular ketamine. General anesthesia was administered with intravenous pentobarbital. The animals were placed in the supine position. An endotracheal tube was placed and connected to a mechanical ventilator (model 613; Harvard Apparatus, Southnatick, MA, USA). A central venous catheter and arterial catheter were placed in the femoral vein and artery, respectively. A Veress needle was inserted into the peritoneal cavity, and CO_2 pneumoperitoneum was achieved with a standard insufflator (Olympus Surgical, Olympus America, Inc., USA) using an intraabdominal pressure of 13 mmHg. Five 10-mm trocars (Ethicon Endosurgery, Cincinnati, OH, USA) were placed as previously described for standard laparoscopic Nissen fundoplication [10]. A 30° laparoscope (Karl Storz Endoscopy, Charlton, MA, USA) was introduced into the umbilical port, and standard laparoscopic video equipment was used (Olympus Surgical, Olympus America, Inc.). The liver was retracted manually in all experiments to expose the stomach fully.

For the three pigs chosen for human retraction, the previously calibrated FSR was inserted into the port at the left anterior axillary line and sutured to the most cephalad portion of the gastric fundus. FSR data collection was confirmed, and the surgical assistant retracted the stomach using the FSR and one additional laparoscopic grasper to expose the gastroesophageal junction for dissection. The surgical assistant was blinded to the readings from the FSR.

The remaining three pigs were designated for robotic retraction. LARS was brough to the left side of the animal at the level of the left lower extremity. The FSR was placed into the LARS instrument holder, and the instrument was advanced into the abdomen via the left anterior axillary line port. The FSR was sutured into the most cephalad portion of the fundus, and the camera operator used an additional laparoscopic grasper to expose the esophageal hiatus. In this preliminary experiment, a human operator

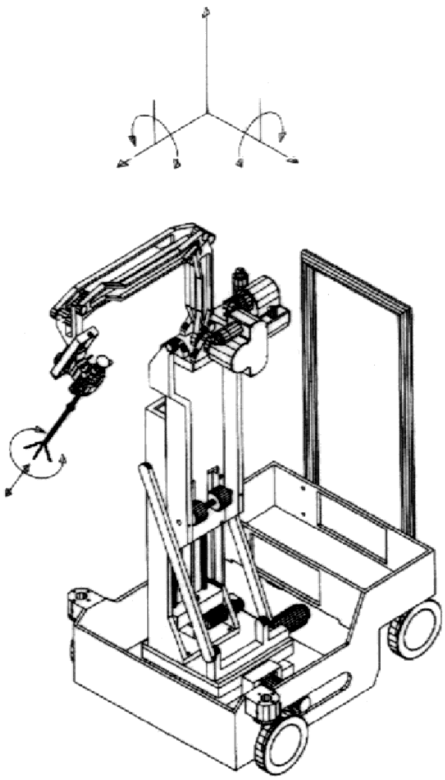

Fig. 3. LARS surgical robot.

closed the force feedback loop by monitoring the FSR output and modifying LARS placement as needed to maintain optimal anatomical view of the gastroesophageal junction for dissection. In future studies, this process will be automated by feeding FSR data into the robot's controlling computer, allowing the robot to analyze and change retractor position without human intervention.

In all surgeries, stomach retraction was required during esophageal hiatus dissection. Thereafter, the FSR was removed, the esophagus was mobilized, and standard laparoscopic Nissen fundoplication was performed. In addition to FSR data, retraction setup time (measured as the interval between first touch of the FSR and adequate hiatal exposure) and total retraction time (time from suturing of FSR to mobilization of the esophagus) were recorded. Ease of retractor placement, retractor maneuverability, anatomical view, and ease of removal were scored on a 1–10 scale (1 = worst, 10 = best) by the same primary surgeon.

Statistics

Continuous variables between the human and robotic groups were analyzed using the Student's *t*-test. Differences were considered statistically significant at $p < 0.05$.

Results

All six laparoscopic Nissen fundoplications were performed successfully, and organ retraction data was obtained for human and robot control of stomach retraction during esophageal hiatus dissection. The mean force applied during human retraction was 108.9 ± 34.3 g (mean ± standard deviation) (range, 52.5–180.7 g). For robotic retraction of the stomach, the mean force applied was 74.3 ± 10.5 g (range, 56.1–94.8 g ($p = 0.007$, compared to human retraction). Represented over time, the forces required were markedly less for robotic retraction than for human retraction (Fig. 4). Furthermore, retraction setup time and total retraction time did not differ significantly between human and robotic retraction (Table 1). In terms of more subjective measures, human and robotic retraction did not differ regarding ease of retractor placement, retractor maneuverability, anatomical view, or ease of removal (Table 2). In addition, one less surgical assistant was required when using the robot; the camera holder easily doubled as primary assistant in manipulating the second laparoscopic grasper needed to help retract the stomach.

Throughout the experiment, the LARS robot and FSR performed reliably without significant alteration to standard surgical procedure. Minor changes in port placement were required to provide adequate clearance for full range of motion for the robot. In one instance, software difficulty caused the robot to become unresponsive, but safety was maintained simply by loosening the FSR from the robot with a quick-release clamp and removing it from the immediate operative field. The robot was soon rebooted, the FSR was placed into position again, and the operation continued. Electrocautery caused significant fluctuations in FSR output, but data collection returned to normal immediately after use without the need for recalibration.

Discussion

Surgical robotic systems are destined to play a central role in the development of surgery in the 21st century. Even now, passive systems are widely used in the preclinical and clinical general surgical realms to control the laparoscopic camera and perform rudimentary structure-grasping actions. Progress has already been made in developing active robotic force feedback systems for neurosurgical applications [2]. In general surgery, systems have been designed to enhance the laparoscopic surgeon's senses by providing tactile information about the tissue retracted by a laparoscopic grasper [4]. These systems provide an important adjunct to the usual audio and visual information presented to the surgeon.

One of the goals in surgical robotics is to develop a fully automated, active surgical assistant capable of analyzing its actions and responding appropriately and safely. This robot should be designed to have its own intelligence and to perform the intended task more effectively than a human [8]. To develop these systems, we need a reliable means of obtaining data from the robot's environment as well as baseline preclinical studies to evaluate these force feedback robotic systems. Herein, we present a unique means of measuring the forces applied directly to retracted organs in a preclinical laparoscopic model. This preliminary study compares human laparoscopic retraction with robotic retraction. From these baseline retraction data, streamlined algorithms can be developed to set operating constraints on active robotic surgical assistants, ensuring patient safety.

In retracting the gastric fundus for esophageal hiatus visualization and dissection, the LARS robot performed better than a human by greatly minimizing the force exerted on the stomach. By keeping retraction forces as low as possible, the risk of direct injury to retracted viscera was minimized. In this study, the manipulator of the FSR during human retraction was blinded to the output of the device.

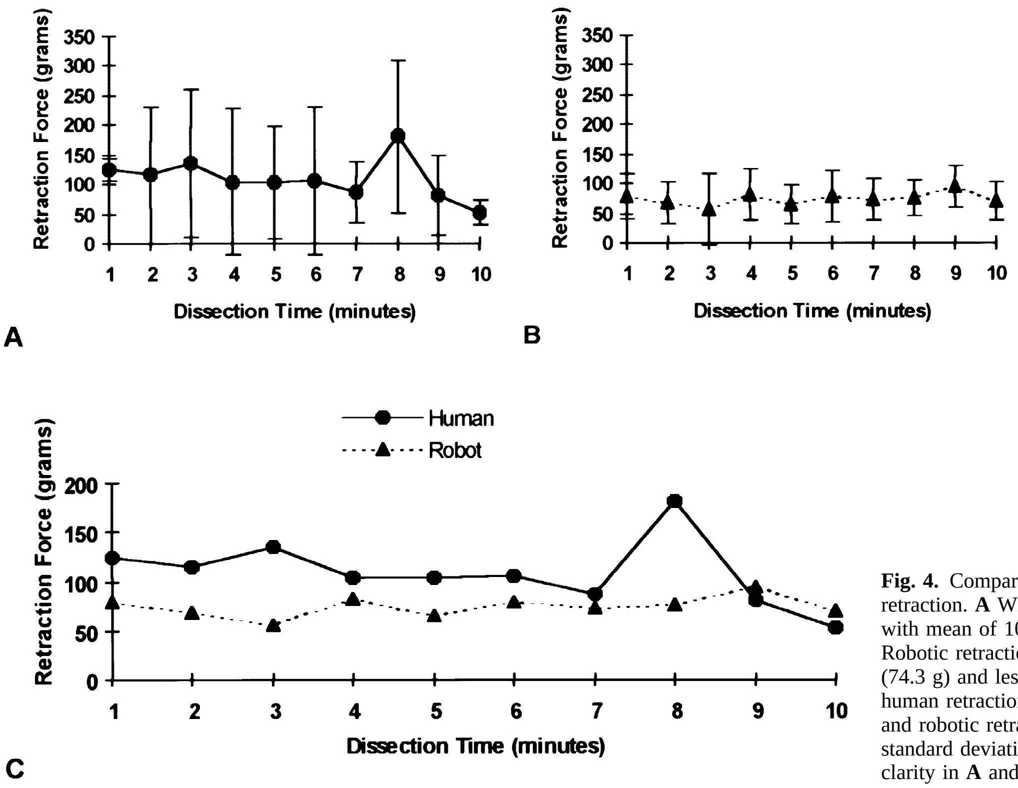

Fig. 4. Comparison of human and robotic organ retraction. **A** Wide variation in retraction force with mean of 108.9 g for human ($n = 3$). **B** Robotic retraction ($n = 3$) with lower mean force (74.3 g) and less variation ($p = 0.007$ versus human retraction). **C** Composite view of human and robotic retraction forces (data are mean ± standard deviation; negative axes omitted for clarity in **A** and **B**; error bars omitted in **C**).

Table 1. Retractor setup and hiatal dissection times (mean ± SD)

Parameter	Human ($n = 3$)	Robot ($n = 3$)
Retraction setup time (min)	13.7 ± 9.9	14.3 ± 0.8
Hiatal dissection time (min)	14.0 ± 6.1	14.0 ± 3.0

Table 2. Comparison of human and robotic retraction in ease of placement, maneuverability, anatomical view, and ease of removal (mean value tabulated: 1 = worst, 10 = best)

Retractor parameter	Human ($n = 3$)	Robot ($n = 3$)
Ease of placement	7.0	7.7
Maneuverability	7.0	7.7
Anatomical view	7.7	7.0
Ease of removal	8.7	7.7

The LARS robot was manipulated by joystick, while a human checked the FSR data to adjust the robot and maximize the anatomic view. This difference in FSR monitoring was deemed necessary to closely simulate actual operating room conditions in the human group and to complete the force feedback loop in the robot group.

Nevertheless, wide variations were found during human retraction (Fig. 4A) that were not seen during robotic retraction (Fig. 4B). When the robot performed the organ retraction, the forces exerted on the stomach were minimal, and there was much less variation in force. This decreased variation in force is probably due to the minimal movement of the FSR and the reduction in movement of the organs around the robot-controlled FSR.

Repositioning the robot occasionally forced the surgical assistant to remove one hand from the camera, resulting in an interruption of the flow of the procedure. Once the FSR data stream can be coupled to the robot's computer and drive motors, we expect to create a fully autonomous robot with an even further decrease in retraction forces, given the robot's ability to make instantaneous adjustments in space.

The data obtained in this experiment will help us to develop safe operating parameters for active robotic organ retraction. In this experiment, force information was available in the main retraction axis using data supplied from the center tine of the FSR. However, a more complete system now being developed in our lab utilizes six strain gauges placed on all three tines of the FSR. Using this information, the robot can not only respond to changes in the main axis of retraction, but it can also rotate about its longitudinal axis to allow a more human-like movement and further minimize retraction force. This system would also account for the load placed on the side lines of the retractor, which was not measured in this experiment.

Additional data suggest that there is no significant difference between human and robot in retraction setup time and total retraction time. Often, new surgical technologies entail steep learning curves for the surgeon that may compromise efficiency [8]. In our experiment, LARS was easily mated to the FSR and brought to the operating room table, and the FSR was inserted into the abdomen without difficulty. Furthermore, robotic retraction and manipulation did not significantly increase the time of surgery as measured by total retraction time. Although a more subjective analysis was used, the anatomical view obtained was fairly consistent when using either human or robotic retraction.

Further uses of the FSR include new applications to increase safety in human laparoscopic retraction and in telerobotic force feedback systems. Since the main laparoscopic view in most procedures is focused on the surgical site and not on retracted organs, the FSR could provide critical information to the human assistant by informing him or her of excessive forces applied on the retracted organ, without disrupting the primary surgeon's view. With the planned integration of FSR data with the LARS robot, a unique telerobotic system for use with force feedback control can be created. This would allow remote or telementoring surgeons full video, audio, and force-responsive manipulating capability, even though they are many miles away from the operative site.

Recent advances in laparoscopy have permitted the general surgeon to offer the benefits of minimally invasive surgery to a wider range of patients with varied surgical needs. As these procedures increase in complexity and operative time, potential complications and the risk of operator-caused injury also increase. Force-sensing laparoscopic instruments represent one means of making organ retraction during complex procedures safer. Robotic surgical systems that use this force-sensing technology for organ retraction can improve on human retraction by minimizing the force exerted on organs, decreasing the chance of iatrogenic injury, and making laparoscopic procedures safer.

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