

Human Versus Robotic Organ Retraction During Laparoscopic Nissen Fundoplication

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Abstract. Advances in technique and instrumentation have enabled surgeons to perform a growing array of procedures through laparoscopy. However, these efforts have often been compromised by exerting excessive forces during retraction of the structures necessary for anatomical view. Here, we present a comparative study of human and robotic performance in force controlled organ retraction during laparoscopic Nissen fundoplication (LNF). Six female pigs (20-25 kg) were anesthetized, intubated, placed on mechanical ventilation, and pneumoperitoneum (13mm Hg CO₂) was established. A force sensing retractor (FSR) was constructed to record the forces applied in retracting the stomach during dissection of the esophageal hiatus (EH). The FSR was calibrated using known forces and then operated by either human alone or robot under human guidance using the FSR data. The EH was visualized, dissected, and LNF completed. Less force was utilized with robotic (74.3±10.5 grams) versus human (108.9±34.3 grams) retraction (p=0.007) to obtain proper anatomical view of the EH. No significant differences were observed for retraction setup time (robot 14.3±0.8 minutes and human 13.7±9.9 minutes) or hiatal dissection time (robot 14.0±3.0 minutes and human 14.0±6.1 minutes). These preliminary results present our continuing effort to develop and evaluate an automated surgical assistant for laparoscopy. As increasingly advanced, personnel-intensive laparoscopic procedures are performed, robotic retraction may present a superior alternative to human retraction by minimizing the forces exerted on organs yet maintaining excellent anatomical view.

Introduction

The benefits of 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 return to daily routines faster compared to the same procedures performed by more traditional “open” technique [3, 8, 11]. As an increasing array of more complex, longer duration laparoscopic procedures are performed, the likelihood of iatrogenic injury to the patient also increases. Often, participation of assistants not familiar with laparoscopic techniques is unavoidable in personnel-intensive procedures. A common task relegated to these assistants is the retraction of organs necessary to obtain proper anatomical view. This exposure, critical to both traditional and minimally invasive surgery, is especially important in laparoscopy as surgeons forfeit their primary sense of touch in favor of a more visually based technique. However, once organs are retracted and the proper view established, the camera view is mainly focused on the immediate operative field and not on the retracted organ. Thus, these surgical assistants are regularly entrusted to use an unfamiliar instrument to retract an unseen organ for an extended period of time, increasing the risk of iatrogenic harm. Injury to visceral or vascular structures are serious complications that can result in peritonitis, sepsis, intra-abdominal abscess or hemorrhage. Often, these injuries are not recognized at the time of the laparoscopic procedure, increasing the chance of a fatal outcome [1].

The union of surgical robotics, computer integrated video, and laparoscopy is attempting to transfer time consuming, repetitive tasks from human to robot in an effort to increase safety and improve surgical outcome. Considerable experience has been gained with robotic camera control during laparoscopy, displaying the feasibility and efficacy of using surgical robots in the operating room [5]. In addition, passive systems such as the “Iron Intern” have been developed to hold structures fixed in space during minimally invasive surgery [6]. However, these passive systems are unable to respond to anatomical shifts caused by changes in respiration, organ manipulation, and patient position. Pioneering work in active, force feedback robotic retraction systems will enable neurosurgeons to retract neural tissue with precision and minimal damage [2]. Newer computerized surgical graspers are enabling physicians to obtain tactile information about the tissue, providing critical clinical cues to the laparoscopic surgeon [4]. Experience is lacking regarding the effectiveness of force feedback surgical robotic systems that actively assist surgeons in organ manipulation during laparoscopic general surgical procedures. A surgical robot may be able to minimize iatrogenic injury and maintain anatomical view by sensing the force directly applied to retracted organs and by adjusting itself to maintain a constant retraction force. Here, we present the first comparative study of human and robotic organ retraction during an advanced laparoscopic procedure, the laparoscopic Nissen fundoplication (LNF). We employ 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 evaluation aid in our development of an automated laparoscopic surgical assistant system.

Materials and Methods

The Force Sensing Retractor (FSR) was developed to measure the force applied to organs during surgical manipulation. A standard laparoscopic retractor (United States Surgical, Norwalk, CT) was modified to create the FSR. Two 350 Ohm polyimide encapsulated constantan strain gauges (Model CEA-06-250-UN-350, Vishay Measurements Group, Raleigh, NC) were bonded to the middle tine of the retractor in a bending beam configuration (Fig. 1). The strain gauges were connected to a strain indicator (Model P-3500, Vishay Measurements Group, Raleigh, NC) which produced positive or negative voltages depending on FSR deflection (Fig. 1). The output of the strain indicator was then routed to a Grass Recorder (Model 7D Polygraph, Grass Instruments, Quincy, MA) and PC for continuous data collection of retraction forces.

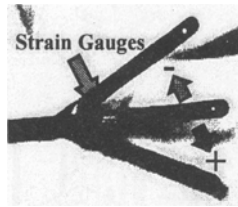


Fig. 1. Gauges bonded to standard organ retractor provide force sensing in main retraction axis

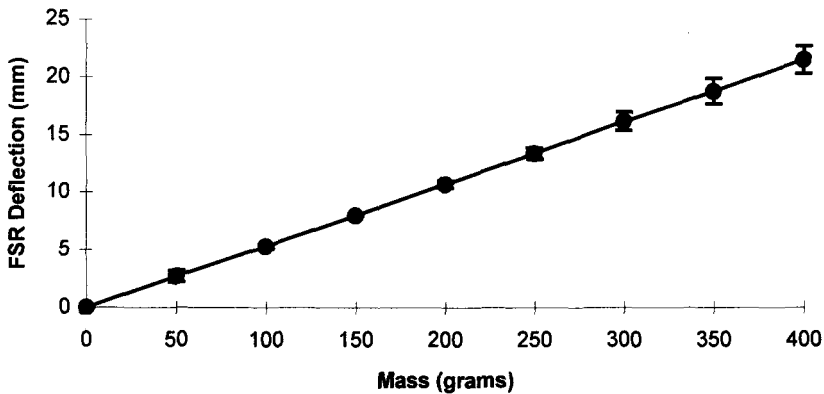


Fig. 2. Linear force response to known masses is confirmed

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 equa-

tion derived from calibration data was used to determine the force applied to the retracted organ. All forces are presented as mass equivalents in grams.

The LARS robot [10] 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 4 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.

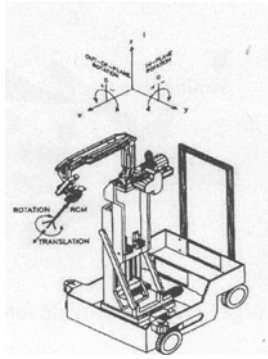


Fig. 3. LARS surgical robot

Six female pigs (20-25 kgs) were premedicated with intramuscular ketamine and 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 (Harvard Apparatus Model 613, Southnatick, MA). 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 CO₂ pneumoperitoneum was achieved with a standard insufflator (Olympus Surgical, Olympus America, Inc.) using an intra-abdominal pressure of 13mm Hg. Five 10mm trocars (Ethicon Endosurgery, Cincinnati, OH) were placed as previously described for standard laparoscopic Nissen fundoplication [9]. A 30° laparoscope (Karl Storz Endoscopy, Charlton, MA) 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, fully exposing the stomach.

For the three pigs undergoing human retraction, the previously calibrated FSR was inserted into the port at the left anterior axillary line and was 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, exposing the gastro-esophageal junction for dissection. The surgical assistant was blinded to the readings from the FSR.

The remaining three pigs underwent robotic retraction. LARS was brought 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 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 closed the force feedback loop by monitoring the FSR output and modifying LARS placement as needed to maintain proper anatomical view of the gastro-esophageal 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, after which the FSR was removed, esophagus 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 proper 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.

Continuous variables between 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 funduplications were performed successfully and organ retraction data 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 with a range of 52.5g to 180.7g. Using robotic retraction of the stomach, the mean force applied was 74.3 ± 10.5 g with values ranging from 56.1g to 94.8g ($p = 0.007$ compared to human retraction). Represented over time, 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).

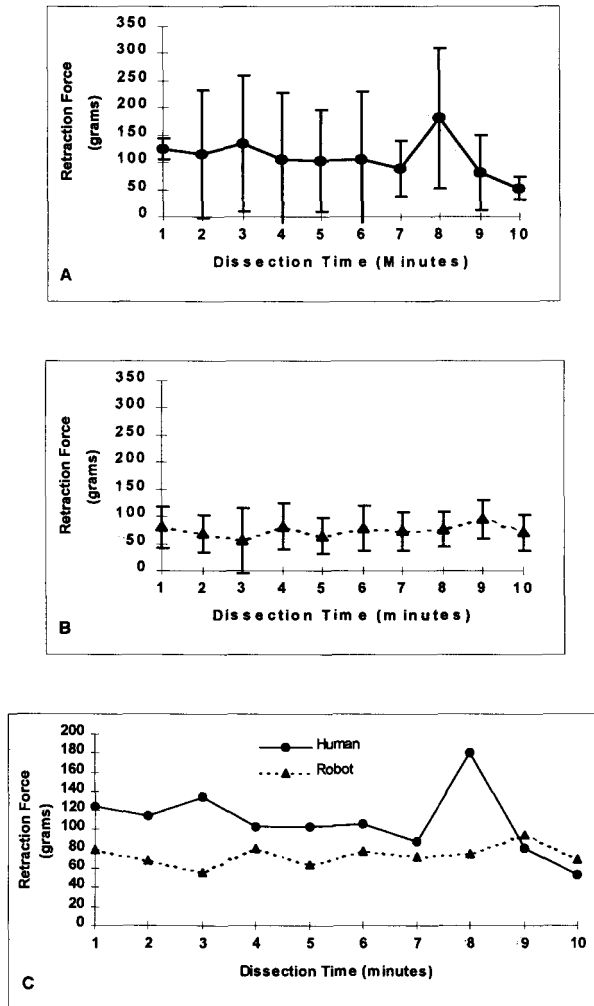


Fig. 4. Panel A shows wide variation in human retraction force with mean of 108.9g (n=3). Panel B displays robotic retraction (n=3) with lower mean force (74.3g) and less variation (p=0.007 vs human retraction). Composite view of human and robotic retraction forces are seen in Panel C (negative axes omitted for clarity in Panels A and B; error bars omitted in C)

Table 1. Retractor setup and hiatal dissection times were similar for human and robot

Parameter	Human (n=3)	Robot (n=3)
Setup (mins)	13.7±9.9	14.3±0.8
Dissection (mins)	14.0±6.1	14.0±3.0

Examining the more subjective measures, human and robotic retraction did not differ regarding ease of retractor placement, retractor maneuverability, anatomical view, and ease of removal (Table 2). In addition, one less surgical assistant was required when using the robot (Fig. 5); the camera holder easily doubled as primary assistant in manipulating the second laparoscopic grasper used to help retract the stomach.

Table 2. Human and robotic retraction afforded similar ease of placement, maneuverability, anatomical view, and ease of removal (1=worst, 10=best)

Parameter	Human (n=3)	Robot (n=3)
Ease of Placement	7	7.7
Maneuverability	7	7.7
Anatomical View	7.7	7
Ease of Removal	8.7	7.7



Fig. 5. Robotic retraction of stomach during laparoscopic Nissen fundoplication. With the robot, only two people were needed to complete the surgery versus the usual three person team (in this view, person at far left is adjusting robot and did not assist in surgery)

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. One incident of software difficulty caused the robot to become unresponsive, but safety was maintained simply by loosening the FSR from the robot using a quick-release clamp and removing it from the immediate operative field. The robot was soon rebooted, FSR 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 re-calibration.

Discussion

Surgical robotic systems present an extremely useful tool to the laparoscopic surgeon. To date, most experience in the pre-clinical and clinical general surgical realms utilizes passive systems to control the laparoscopic camera and to perform rudimentary structure-grasping actions. Progress has 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. An eventual goal 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 its function more effectively than a human in the intended task [7]. To develop these systems, not only is a reliable means of obtaining data from the robot's environment needed, but baseline pre-clinical studies must be performed to evaluate these force feedback robotic systems. In this study, we present a unique means of measuring the forces applied directly to retracted organs in a pre-clinical laparoscopic model. This preliminary experiment compares "head to head" human laparoscopic retraction and robotic retraction. From this 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. Although the operator of the FSR during human retraction was blinded to the output of the device (and thus could not adjust his performance to achieve a biased result) the results may have differed to a larger extent had he not been aware that his performance was being "measured." Because of this knowledge, the operator may have been more careful than usual in not exerting excessive forces on the retracted organ. Nevertheless, wide variations existed during human retraction (Fig. 4A) that were not observed during robotic retraction (Fig. 4B)--even with operator knowledge of performance monitoring. In these experiments, the LARS robot was manipulated by joystick, utilizing a human viewing the FSR data to complete the force feedback loop to maximize proper anatomic view. With the robot performing organ retraction, forces exerted on the stomach were minimal, with much less variation in force compared to human. This decrease in force variation is likely due to the minimal movement of the FSR and less motion of organs around the robot-controlled FSR. Repositioning the robot occasionally forced the surgical assistant to remove his hand from the camera, resulting in an interruption of the "flow" of the procedure. As the FSR data stream is 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. Although force information in this experiment is available in the main retraction axis using data supplied from the center tine of the FSR, a more complete system 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 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 tines of the retractor, which was not measured in this experiment.

Additional data suggest no significant difference between human and robot in retraction setup time and total retraction time. Often, new surgical technologies present large learning curves to the surgeon—possibly compromising efficiency [7]. Here, LARS was easily mated to the FSR, brought to the operating room table, and the FSR inserted into the abdomen without difficulty. Also, 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 while many miles away from the operative site.

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

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