TELEROBOTIC-ASSISTED ANTIREFLUX SURGERY: NISSEN FUNDOPLICATION

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Introduction

In open surgery, the flexibility of the surgeon's wrist and the hands inside the abdomen permits movement of all kinds and in every direction. In laparoscopy, however, the fact that the surgeon must work through a fixed opening means that the number of degrees of freedom is limited. The degrees of freedom that are allowed involve movement in and out, up and down and rotational and oscillatory, although oscillation is limited by the presence of the entrance port. Because the surgeon has to adapt his or her position relative to the location of the port, the operation often has to be performed from a difficult position [1]. The ideal solution to this problem would be to have an additional articulation inside the abdomen so the degrees of freedom that have been lost may be regained.

When one has an articulation inside and outside the abdomen, on both sides of a fixed point, it is logical and natural to introduce the concept of robotics, even more so because it is extremely difficult to manipulate two articulations with the same tool. The human brain is not up to the task. Robotics allows the surgeon to work at a distance from the operating table in an ergonomically correct position, instead of having to bend awkwardly above the patient [2].

Prototype for robotic-assisted abdominal surgery

In robotic-assisted surgery, the robot is positioned at the patient's side. It holds and activates surgical instruments, obeying the orders of the surgeon who is removed from the patient and is seated in front of a console in a perfectly comfortable position. The surgeon manipulates handles under the control panel of a three-dimensional monitor; three-dimensional vision is permitted by means of special glasses worn by the surgeon. The surgeon's movements are transmitted to the computer at the patient's side. These movements are actually improved by the computer. At the patient's side are the anesthesiologist, the engineer, the surgeon's assistant and the scrub nurse.

At the surgeon's side there is only a console and the computer, which is under control of two engineers. In the future the computer will be incorporated in the console. The patient's station and the surgeon's station are united by a cable. This is only a few yards long, but there is no practical limit to its length. The cable could be several kilometers long, or the impulses could be transmitted by satellite, which implies surgery from a distance.

After obtaining authorization from the Ethics Committee of Centre Hospitalier Universitaire Saint-Pierre in March 1997, one of the Authors (JH) performed the first laparoscopic cholecystectomy ever performed on a human being using the prototype described here [3]. Following that experience, we worked to improve the various components of the system: the surgical cart, the computer and the console. The most significant innovation was changing the shape of the clinical laparoscopic tools to handles that look like joysticks. In May 1998, one of the authors (GBC) performed the first two Nissen fundoplications procedures entirely performed by robot, in the Broussais hospital in Paris [4].

Mona robot system

In this new Mona setup (Intuitive Surgical, Inc., Mountain View, CA), the surgeon sits comfortably with his or her arms resting on a support. Manipulation of the articulated instruments is done by activating handles that are mounted just underneath a three-dimensional video screen, thereby eliminating the problem of hand-eye coordination. Impulses coming from the handles are transmitted to a computer that activates the robotic arms mounted on the operating table. The computer interface can translate large deflections of the handles into minute motions on the operative field (a process called downscaling). Minor involuntary motions such as physiologic tremor can be eliminated. The number of degrees of freedom is increased because the tips of instruments can move in a different plane from that of the instrument shaft. This device perfectly mimics the surgeon's wrist and fingers movements, bringing to fruition the concept of a master-slave robotic system.

After performance of the two first Nissen fundoplication procedures by robotic laparoscopic surgery, we realized that a comparison of this procedure with the classic laparoscopic procedure was necessary. We performed 24 robotically-assisted laparoscopic procedures in humans, including 12 Nissen fundoplications, we assumed we had completed the learning curve associated with this novel technique. We decided to compare, in a randomized prospective trial, the advantages and disadvantages of using a robot (Mona), with those of the conventional laparoscopic approach.

Materials and method

We performed a randomized, prospective trial on a group of 21 patients who are candidates for laparoscopic Nissen fundoplication. Eleven patients were treated by conventional laparoscopy and ten by telesurgery. The location of the trial was Mexico city (Department of Surgery, headed by Dr. Cabral). All procedures were performed by the same surgeon (GBC) who had an experience with more than over 400 laparoscopic Nissen fundoplications.

Patient characteristics

All patients suffered from operable, pathological, gastro-esophageal reflux as documented by 24-hour blood gas, gastroscopy, barium swallow and esophageal manometry. All patients were determined to have low operative risk (ASA 1). There were 11 controls in trial group: three female and eight male patients; median age, 38 years (range, 18 to 52); median body mass index, 27.3 kg/m^2 (range, 22.3 to 29.7). In the telesurgery group there were ten patients: three females and seven males patients; median age, 40 years (range, 29 to 62); median body mass index 28.5 kg/m^2 (range, 24.6 to 41.7).

Robot description

Use of the robot (Mona) in humans had been approved by the local Ethics Committee of the hospital. All patients had signed a document of informed consent. For surgery, the robot was placed to the left of the patient. It held and manipulated articulated surgical tools (*Figs. 1* and *2*). The surgeon was located at a distance of 12 feet from the patient and was not scrubbed. He was seated at a console, manipulating two handles that commanded three robotic arms (*Fig. 3*). The surgeon's movements corresponded to three-dimensional images of the operative field, which he observed with binoculars. Five trocars had been placed in the patient's abdomen. The optical trocar (12 mm) and two operative trocars (8 mm) were snapped onto the robot's arms. Two additional trocars were placed for exposure: one (5 mm) housed the liver retractor that was attached to a fixed, rigid retraction system; and the other (10 mm) housed a grasping forceps that was held by the surgeon's assistant who was scrubbed and waiting on standby. The position of the

Fig. 1. Schematic view of the operating room

trocars, which were introduced by the assistant, varied slightly with the positions used previously [5]. This modification was necessary in order to accomodate the considerable bulk of the robotic arms.

Fig. 2. Photografic view of the operating room

Fig. 3. Surgeon at the console

Manipulation of the console handles created electrical impulses that were transmitted to the computer. This information was digitized and translated into impulses that commanded the robotic arms and the tools (effectors) attached to them. In this setup, the right handle was also in control of the optical system as soon as tool manipulation was deactivated. Translation by the computer of the motions coming from the console accomplished the necessary downscaling on the effector side. Thus, deflections of 5 cm at the surgeon's site resulted in a smaller deflection at the patient's side (by a factor of 5 to 1 or 3 to 1). For this reason, physiological trembling could be virtually eliminated. The robotic arms were connected to disposable tools of different shapes, featuring an articulation 2 cm from their distal tip. They were introduced inside the abdomen by means of trocars that were also attached to the mechanical arms.

Nissen fundoplication procedure

The laparoscopic version of the Nissen procedure has been described extensively [5]. For this procedure, five trocars were used; however, placement of the trocars was slightly different in the groups of patients undergoing telesurgery (see the previous robot description). The first step in the procedure for both groups was the freeing of the greater curvature by the Harmonic scalpel (Autosonic, Autosuture Norwalk, Conn.). In the laparoscopic group, this was done with the aid of a 30 degree angled scope. In the robot group, a three-dimensional camera was used for this maneuver and for the rest of the procedure. The robot was activated only after full mobilization of the greater curvature. Hiatal dissection was performed along the pillars at a distance from the esophagus. The wrap, 4 cm long and fixed to the esophagus by three stitches, was subsequently sutured to the hiatus.

Postoperatively, the patients were discharged after a satisfactory gastrograph recorded contrast study had been performed and adequate positioning of the wrap, as well as patency of the gastric inlet, had been documented.

Statistical analysis was done using Student's *t* test. The study protocol was designed in accordance with Food and Drugs Administration (FDA) regulations.

Results

Operative time was 52 minutes (range, 45 to 62) in the control group and 76 minutes (range, 59 to 130) in the telesurgery group (*Fig. 4*). The difference was significant ($p < 0.01$).

The mean time for dissection of the greater curve was 12 minutes (range, 5 to 23) in the control group and 15.5 minutes (range, 9 to 32) in the telesurgery group ($p = 0.139$) (*Fig. 5*).

The mean time for hiatal dissection time was 9 minutes (range, 5 to 14) in the control group and 15 minutes (range, 8 to 27) in the telesurgery group ($p < 0.05$) (*Fig. 6*).

The mean hiatal pillar closure time was 2.5 minutes (range, 1 to 5) in the control group and 4 minutes (range, 2 to 8) in the telesurgery group ($p < 0.05$) (*Fig. 7*).

The mean suturing time of the wrap was 6.5 minutes (range, 4 to 12) in the control group and 8 minutes (range, 6 to 13) in the telesurgery group ($p = 0.151$) (*Fig. 8*).

Postoperative blood loss was evaluated at less than 10 ml in both groups. Median hospital stay was 1 day in the telesurgery group (range 1 to 4 days) and 1 day in the control group (range, 1 to 18). There were no conversions to open surgery in either group. There were no deaths.

There were two complications, one in each group. Immediately after induction of anesthesia, one patient in the control group vomited forcefully, causing intrathoracic migration of the wrap and of the entire gastric fundus. The patient suffered acute

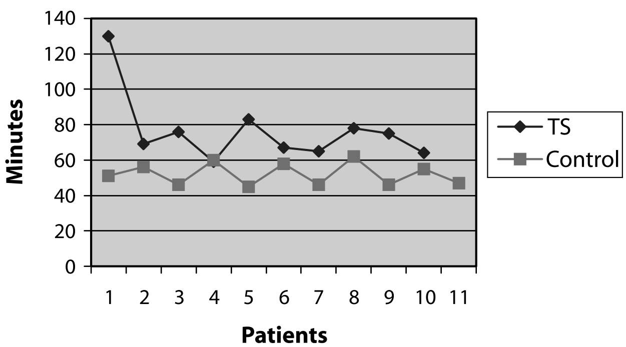

Fig. 4. Operative time

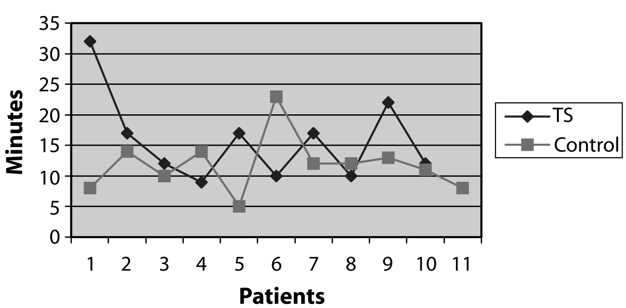

Fig. 5. Time for dissection of the great curve

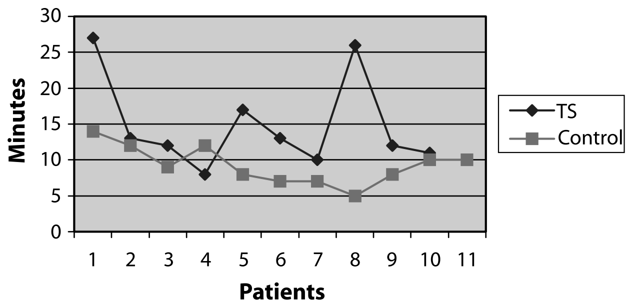

Fig. 6. Hiatal dissection time

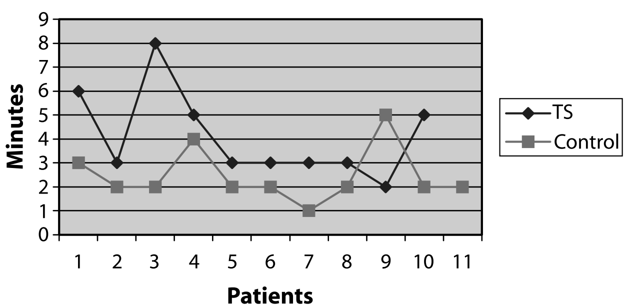

Fig. 7. Hiatal pillar closure time

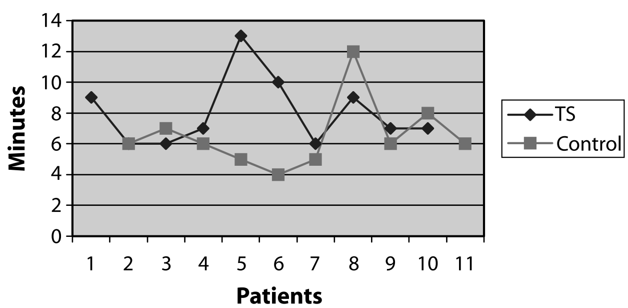

Fig. 8. Suturing time of the wrap

gastric dilation; the wrap perforated in the mediastinum and into both pleural spaces. At laparoscopic reexploration, the perforated fundus was resected and bilateral chest tubes were inserted. The patient left the hospital on the fourth post-operative day. The complication for the patient in the robot group occurred when there was a stomach perforation at the insertion of the first trocar. The perforation was immediately recognized and treated by laparoscopic suturing. The patient was allowed to leave the hospital on the fourth postoperative day.

The absence of morbidity directly related to this new technology is reassuring and encourages us to continue operating in this manner.

The *da Vinci* robot system

Experience with the robotic system led us to see the need for incorporating the computer in the surgeon's console, thus abolishing the need of an engineer. After many improvements in robotic systems, we began performing the Nissen fundoplication with a new prototype, *da Vinci*, which was installed in our hospital.

Major differences between Mona and *da Vinci*

(1) Overall, the Mona system was an early version of the *da Vinci* system. Mona had manually initiated mode transitions, inferior optics, and a reduced set of tools, compared with *da Vinci*.
(2) Control of the Mona system was done by an intuitive engineer through a graphical user interface. In other words, every mode transition (master of robot clutch, camera control, tool change, etc.) had to be voiced by the surgeon and then activated with a push button on a computer screen. This was slow and laborious, compared with the current setup where transitions are fast, seamless, and intuitive.
(3) Camera control for Mona was performed by a force-controlled joystick, whereas we now have a navigator algorithm. This arrangement was analogous to the mouse button on a laptop computer: the harder you push, the faster the pointer moves, as opposed to the action of the regular hand-held mouse. With Mona, it was difficult for the surgeon to go in the desired direction, and the transition time into camera control was slow because of the need to move the right master handle. The *da Vinci* provides intuitive and seamless navigator control.
(4) The procedures in Mexico City were done with a low-quality, single optical, three-dimensional system. This visual system did not provide the stereo separation or the resolution of our current insight visual system.
(5) The Mona system had no self-starting capabilities. As a result, a whole battery of tests had to be performed manually every morning prior to surgery.
(6) The set of instruments for Mona consisted of only rudimentary graspers and low-force needle drivers. Various types of graspers and more forceful needle drivers are now available to us. The instruments have since been adapted to Nissen fundoplication (*Figs. 9* and *10*).

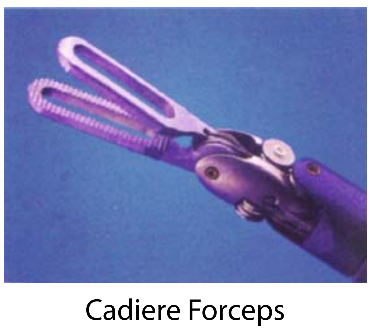

Fig. 9. Cadière Forceps

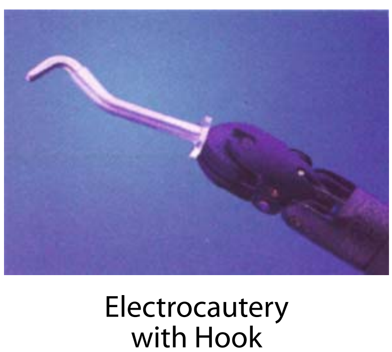

Fig. 10. Electrocautery with hook

We performed 39 procedures for gastroesophageal reflux (36 Nissen fundoplications and 3 Toupet procedures). In these procedures, we found that the ideal position for the robot was with the surgical cart located to the patient's right, at the level of the patient's head, at a 45-degree angle with the operating table axis. Three trocars are used for the robotic instruments and scope, another trocar is used for the liver retractor and a fifth trocar is used by the assistant (*Figs. 11* and *12*).

The median system time of the 21 Saint-Pierre Hospital patients was 82 minutes (range, 54 to 125). We had two complications: one perforation of the stomach by a trocar, which was repaired by robotic suturing; and one bleeding at the greater curvature, which was treated laparoscopically. The median hospital stay was 2 days (range, 1 to 4) (*Fig. 13*).

Discussion of global results

We believe that all procedures performed with a telemanipulated robot were actually world premieres for this type of surgery. Because of the novel character of the procedures, we were obliged to fully inform our patients on all possible implications of this new technology. It was also necessary to promptly determine if there was any morbidity specifically connected to the use of the robotic technique.

The operating times of the Nissen fundoplication for gastroesophageal reflux disease correlated with several parameters: (a) different operating locations (Paris, Brussels, Mexico City), (b) training of the entire team of doctors, nurses and technicians for this new technology, (c) surgeon's learning curve, as for any new operation, and (d) ongoing improvements in the system in terms of ergonomics, console setup, computer performance and tool development. Operative time depended not only on the surgical dissection, but also on installation of the system; it was comparable to that reported by the Academic Robotics Group (6). The procedure time, including all the setup, depended on the intensive training results of

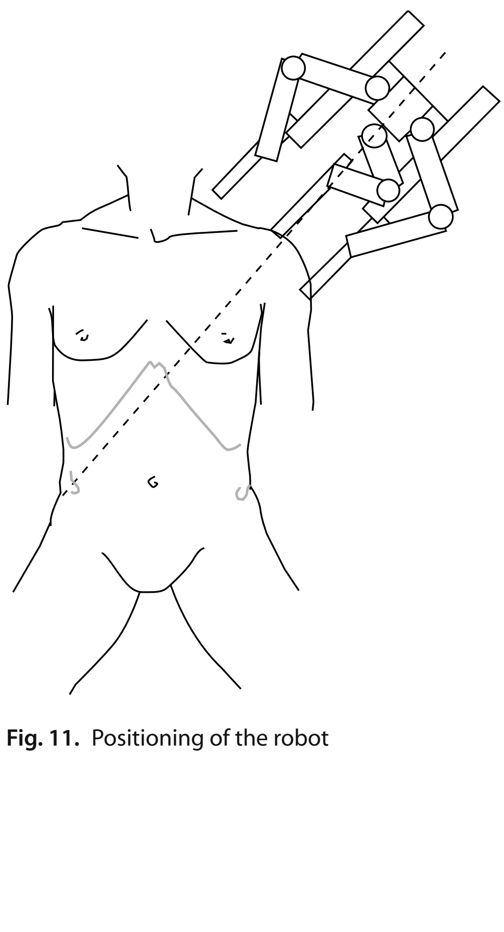

Fig. 11. Positioning of the robot

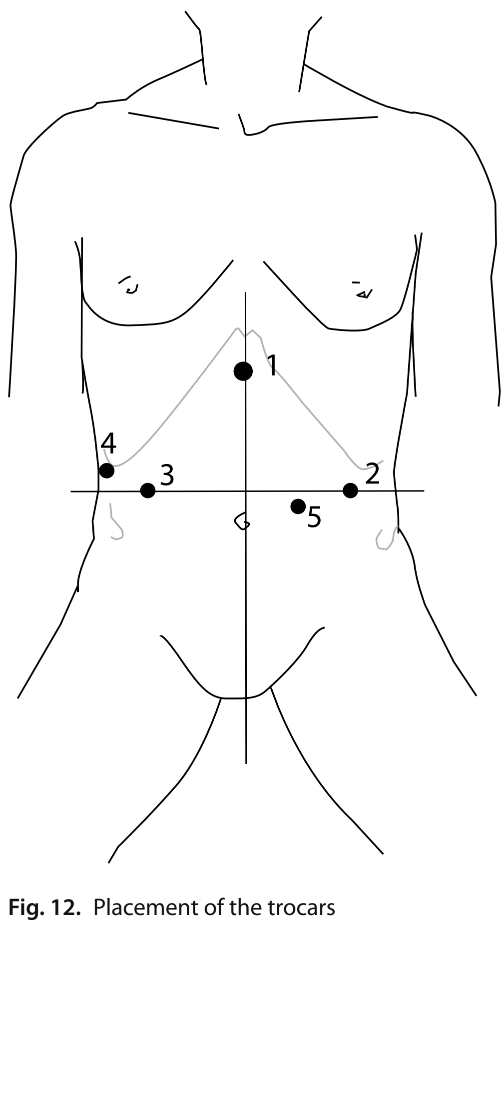

Fig. 12. Placement of the trocars

the surgical team. This novel type of surgery indeed created the need for a new team, a person dedicated exclusively to the well functioning of the robot during the procedure. We chose to call this person a clinical technician. This person needs a clinical as well as a technical background. His or her competence influences the time and the safety of the procedure. We encountered no morbidity specifically related to the use of robotics and the length of hospitalization was comparable with that of the conventional laparoscopic approach. Same results were also confirmed by the Academic Robotics Group [6].

The placement of the trocar was slightly different from that used in conventional laparoscopy because of the space occupied by the articulating robotic arms. Operative times compared favorably with our first 80 conventional laparoscopic procedures. Dissection behind and around the esophagus was clearly improved with the use of articulated tools. This finding suggests that may be possible in the future to perform a less extended dissection of the gastric cardia at the level of the peritoneal attachments. This dissection is performed only in the laparoscopic approach and only for reasons of safety. The articulated tools make the procedure easier, safer and more like open technique.

Another phase of the operation in which the articulation tools proved valuable was in the dissection of the short gastric vessels, facilitated by the fact that the tools could always be brought perpendicular to the vessels. On the other hand, we did become aware of a significant drawback of the robotic system in its present configuration: the three-dimensional optical system has a very narrow field of vision. Because of this, we had to continually interrupt dissection to reposition the optics. These frequent interruptions, as well as the absence of a general view of the operative field, may have been responsible for the bleeding we encountered while dissecting the greater curvature with the robotic system. This complication prompted the conversion to conventional laparoscopy.

The articulated tools made suturing the wrap a more straightforward procedure because it was easier to follow the curve of the needle while driving the suture through tissues. We also noticed a decided improvement in tying the knots. On the other hand, evaluating the tension on the knots is more difficult because there is no tactile feedback. The theoretical advantage gained by downscaling in the robotic technique we found to be insignificant [7].

Conclusion

We used robotic-assisted surgery and demonstrated the feasibility of having a standard robotic laparoscopic surgery without specific morbidity and within acceptable operative times. In its present configuration, the system seems to provide the greatest benefit for microsuturing within the abdomen or in very confined spaces. Improved ergonomic conditions and improved instrument dexterity at the level of the distal articulation appear to be of value in routine abdominal procedures. More research is needed for further improvement in tool design and optics arrangement. The robotic approach requires new operative strategies and modification of the pattern of trocar placement.

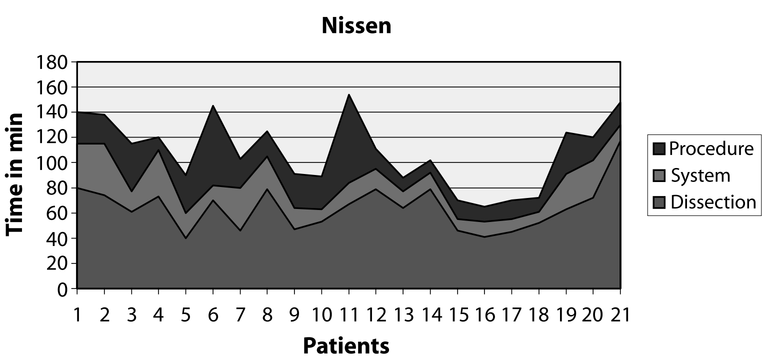

Fig. 13. Operative time for the latest 21 Nissen fundoplication procedures

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