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Evaluation of telesurgical (robotic) NISSEN fundoplication

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Abstract
*Background:*The laparoscopic surgical approach has proven its benefit for the patient. There are however several shortcomings, which have triggered considerable research for improvement. One improvement may be the introduction of telesurgery by the interposition of a computer interface between surgeon and patient.*Material and Methods:* A prospective randomized study was conducted in an advanced laparoscopic procedure, Nissen fundoplication. The control group underwent the conventional laparoscopic approach, while the investigational group underwent the telesurgical approach.
*Results:*Feasibility was 100%. The procedure was more time consuming in the Telesurgical group, at all stages of the operation. Mortality was nil and morbidity was comparable in both groups.
Conclusion: The telesurgical approach is feasible in advanced laparoscopic procedures like Nissen fundoplication. At the present time there is however no obvious added benefit from this new technique.

Key words: Ergonomics — Laparoscopic tools — Nissen fundoplication — Robotic — Telemedicine — Telesurgery

The basis of dexterity experienced in open surgery relies on the almost unlimited freedom of motion in wrist, elbow, and shoulder articulations. The freedom of motion in laparoscopic surgery is limited because instruments need to be long, and they are manipulated through fixed entrance sites (ports) [10]. Hence, in the laparoscopic approach, the surgeon must move around these fixed entrance ports, and awkward operating positioning ensues (Fig. 1) [1].

To solve these limitations, tools have been developed that have an articulation distal to the site of entrance into the abdomen or other body cavity (e.g., chest). This increases the number of degrees of freedom (Fig. 2) [16].

Addition of an articulation renders tool manipulation much more complex, and computer assistance is warranted because the human brain cannot efficiently handle articulated instruments by mechanical means [19].

Computer interfacing allows for remote control surgery (telesurgery) and for more precise manipulations by downscaling the surgeon's motions, and by allowing good ergonomic positioning of the surgeon as he is liberated from the restrains of the entrance ports. Human robotic surgery (master–slave concept) was introduced by our team in March 1997 when the first telesurgical laparoscopic cholecystectomy was performed [9]. The first telesurgical laparoscopic Nissen fundoplication also was performed by our team in May 1998 [3].

After performing 24 robotically assisted laparoscopic procedures in humans, including 12 Nissen fundoplications, we assumed we had assimilated the learning curve associated with this novel technique. The current study was established to compare, in a randomized prospective trial, the advantages and disadvantages of using a robot (Mona, Intuitive Surgical, Mountain View, CA, USA) versus a conventional laparoscopic approach.

Materials and methods

A randomized prospective trial was undertaken with a patient group of 21 candidates for laparoscopic Nissen fundoplication. Of these 21 participants, 11 were treated by conventional laparoscopy and 10 by telesurgery (TS).The location of the trial was Mexico city (department of Dr. Cabral). All procedures were performed by the same surgeon (G.B.C.), who experience with more than 400 laparoscopic Nissen fundoplications.

Patient characteristics

All the participants in this study suffered from operable pathologic gastroesophageal reflux, as documented by 24-h pH metry, gastroscopy, barium swallow, and esophageal manometry. All the patients presented low operative risk cases (ASA 1).

The control group consisted of 11 patients (3 women and 8 men) with a median age of 38 years (range, 18–52 years), and a median body mass index (BMI) of 27.3 kg/m^2 (range 22.3–29.7 kg/m^2). In the TS group there were 10 patients (3 women and 7 men) with a median age of 40 years (range, 29–62 years) and a median BMI of 28.5 kg/m^2 (range, 24.6–41.7 kg/m^2).

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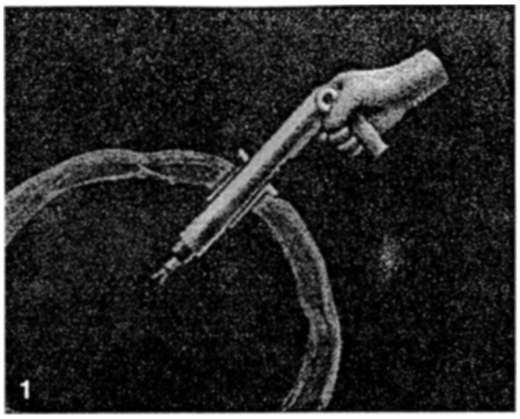

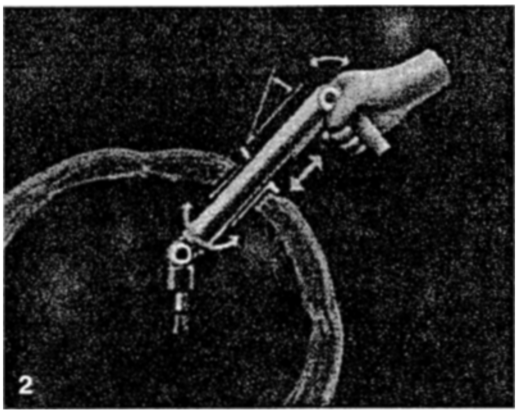

Fig. 1. Degree of freedom limitation by trocart hole.

Fig. 2. Degree of freedom restoring by intracorporeal articulation.

Robot description

Use of the robot (Mona) in humans had been approved by the local ethics committee. All patients had signed a fully informed consent document.

The robot was placed to the left of the patient. It held and manipulated articulated surgical tools. The surgeon was located 12 feet away from the patient and not scrubbed. He sat at a console and manipulated two handles in command of three robotic arms. The surgeon's movements accorded with a three-dimensional picture of the operative field he or she observed with binoculars. (Figs. 3 and 4).

The patient's abdomen was penetrated by five trocars. The trocar for the optic (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) contained the liver retractor attached to a fixed rigid retraction system, and the other (10 mm) was penetrated by a grasping forceps held by the assistant who was scrubbed and serving as standby. The trocars were introduced by the assistant, and the position of the trocars was slightly different from that described previously [4]. The modification in trocar placement was necessary to accommodate the significant bulk of the robot arms.

The surgeon's manipulation of the two handles created electrical impulses that were transmitted to the computer (Figs. 5 and 6). This information was digitalized and translated into impulses that commanded the robotic arms and the tools (effectors) attached to them. In this system the right handle also was in control of the optical system as soon as tool manipulation was deactivated.

Computer translation of the motions coming from the console was able to provide effective downscaling on the effector side. Hence deflections of 5 cm at the surgeon's end could result in a smaller deflection at the patient side (by a factor of 5/1 or 3/1). Physiologic trembling could therefore be virtually eliminated. The robot arms were connected to snap-on disposable tools of different shapes that all presented an articulation at 2 cm from their distal tip. They were introduced inside the abdomen via trocars attached to the mechanical arms as well. (Figs. 7 and 8).

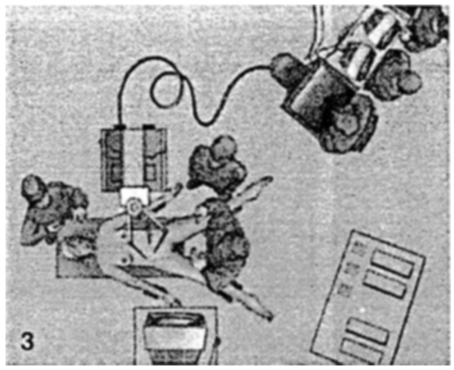

Fig. 3. View of operating room.

Fig. 4. View of operating room.

Nissen procedure

This procedure was described extensively in its laparoscopic version [4]. Five trocars were used. However, the placement of the trocars was slightly different in the robot group (see robot description). The first step in both groups was to free the greater curvature by the Harmonic Scalpel (Autosonic, Autosuture Norwalk, CT). In the laparoscopic group, this was accomplished with the aid of a 30° angled scope. In the robot group the three-dimensional Sony camera was used as for the rest of the procedure. The robot was activated only after full mobilization of the greater curvature had been performed. Hiatal dissection was performed along the pillars at a distance from the esophagus. The wrap was 4 cm long and fixed to the esophagus by three stitches. Subsequently, the wrap was sutured to the hiatus. Patients were discharged after a satisfactory gastrographin swallow had been obtained and adequate positioning of both the wrap and the patency of the gastric inlet had been documented.

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

Results

Operative time was 52 min (range, 45–62 min) in the control group and 76 min (range, 59–130 min) in the TS group. The difference was significant ($p < 0.01$) (Fig. 9). Mean time for dissecting the greater curve was 12 min (range, 5–23 min) in the control group and 15.5 min (range, 9–32 min) in the TS group ($p = 0.139$) (Fig. 10). Mean hiatal dissection time was 9 min (range, 5–14 min) in the control group and 15 min (range, 8–27 min) in the TS group ($p < 0.05$) (Fig. 11). Mean hiatal pillar closure time was 2.5 min (range, 1–5 min) in the control group and 4 min (range, 2–8 min) in the TS group ($p < 0.05$) (Fig. 12). Mean time for suturing the wrap was 6.5 min (range, 4–12 min) in the

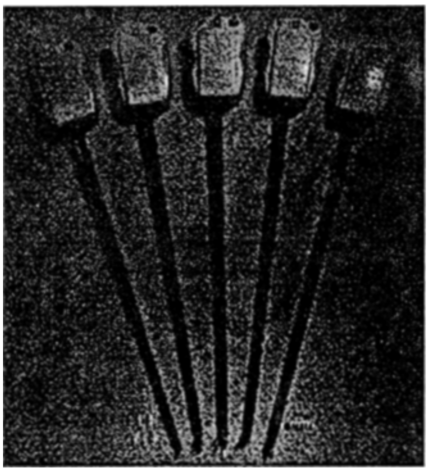

Fig. 5. Manipulator.

Fig. 6. Manipulator.

Fig. 7. Disposable instrumentation with articulations on the tip.

control group and 8 min (range, 6–13 min) in the TS group ($p = 0.151$) (Fig. 13).

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

There were two complications, one in each group. In the control group, immediately after anesthesia, a patient vomited forcefully, and intrathoracic migration of the wrap and the entire gastric fundus occurred. The patient suffered acute gastric dilation, with the wrap perforating in the mediastinum and into both pleural spaces. At laparoscopic reexploration, the perforated fundus was resected, and bilateral chest tubes were placed. The patient left the hospital on the fourth postoperative day. In the TS group, at insertion of the first trocar, a stomach perforation occurred. The perforation was immediately recognized and treated by laparoscopic suturing. The patient was allowed to leave the hospital on the fourth postoperative day.

Discussion

Laparoscopy undeniably presents a number of advantages over the conventional approach [6]. However, a number of

Fig. 8. Disposable instrumentation with articulations on the tip.

significant shortcomings still remain for the surgeon. The surgeon needs to perform his or her procedures with long, chop stick–like instruments introduced through fixed entrance ports, impairing freedom of motion. Moreover, surgery must be performed according to a two-dimensional picture watched on a videomonitor, which is relatively immobile, hence not always in the working axis [14]. The surgeon therefore often stands in an awkward position [1]. The eye–hand connection is no longer intuitive [18]. The interposition of a robot interface [3, 12] (a) adds to freedom of motion by allowing manipulation of an intracavitary articulation; (b) allows for ergonomically perfect positioning at a site remote from the patient; (c) allows for immersion of the surgeon in a three-dimensional picture, improving motion coordination [5], which is likely to reduce the surgeon's fatigue and to improve his or her dexterity; and (d) because of downscaling (translating one motion into a smaller motion on the operative field), enables the surgeon to perform more minute and more precise actions while eliminating physiologic tremor. Although the current study had demonstrated the apparent feasibility of the robotic procedure, the procedural time has not been decreased, nor has the quality of the operation improved (morbidity/mortality remain the same), and this despite all the theoretical advantages of the computer-assisted procedure. Indeed, operative time has become significantly longer with the telesurgical technique ($p < 0.01$). Because operative time did not decrease with experience in this trial, a hypothetical learning curve effect can be ruled out in cases requiring the same strategy as that used in classic laparoscopy.

Although not statistically different from the time needed for classic laparoscopy, the time required to dissect the greater curvature was somewhat longer in the TS group, despite the fact that the robot was not used at that stage. The probable reason is that the double optical system (Olympus) can be used only at a very short distance from the operative field and does not allow a wide view, which, in the opinion of the authors and others, is mandatory for a safe dissection [13]. Another plausible explanation is the possibly less efficient placement of the trocars, which must differ from that of classic laparoscopy to accommodate the bulk of robotic laparoscopy.

Dissection time of the hiatus actually became more time

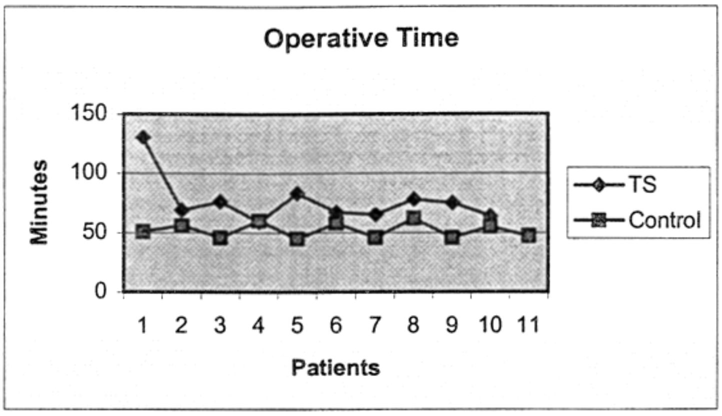

Fig. 9. Operative time.

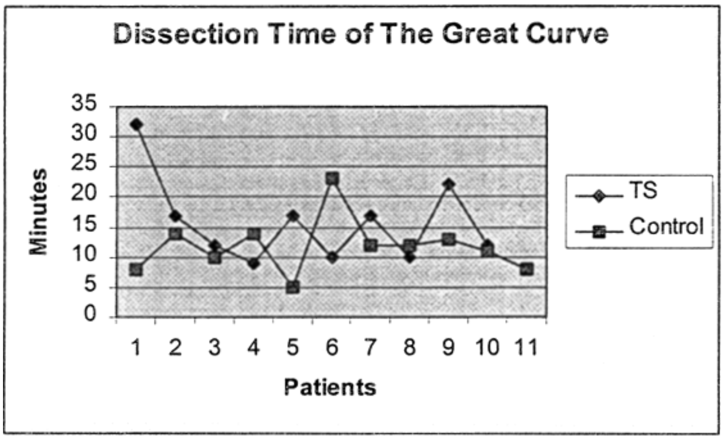

Fig. 10. Dissection time of the great curve.

consuming in the TS group despite the use of the intra-abdominal articulations. This probably is partly due to the Olympus visual optical system, which needs to be kept at a very short distance from the operative field so a three-dimensional picture can be obtained. Hence, with the current model, in which dissection must be interrupted during the camera changes, frequent interruptions of the operative procedure were needed.

A second possible explanation for the longer TS time involves the narrow tips of the new tools, which are shaped more like needle holders and thus are substantially more traumatic than the usual laparoscopic tools. Therefore, greater care and hence more time must be used in manipulating them safely. A similar problem was encountered at the very beginning of laparoscopic experience [2].

A third possible explanation is the presence of distally located tool articulations. Whereas these articulations allow for very minute manipulations in a small operative field, as in cardiac surgery [8] or Fallopian tube reanastomosis [11], they seem to offer no benefit in the current context.

In its current form, the robot makes sense only for very meticulous procedures performed in a very limited field, when sutures of 4/0 or smaller are used, as has been demonstrated [7]. In wide-gestural procedures such as dissecting an esophageal hiatus or passing the wrap behind the esophagus, more proximally located articulations as well as wider and longer instrument beaks might be more advantageous, allowing for more expeditious task accomplishment while permitting wider amplitude of motion.

Although suturing the wrap with silk 2/0 was not significantly slower with the TS, tying knots during pillar closure was significantly slower with the TS system, most likely because knot tension can hardly be evaluated with this system, [17] and because the technique becomes quite different with the additional articulation. It more closely resembles knot-tying in open surgery, which, paradoxically, is more difficult for a laparoscopically trained individual [15]. It is likely, however, that surgeons without experience in laparoscopy might experience fewer difficulties and improve the time needed.

From the aforementioned hypotheses it could be concluded that Nissen fundoplication with robotic technology might become shorter in time if

1. better positioning of the trocars is obtained, which results in regained degrees of motion freedom and better adaptation to the external articulation of the robot arms.
2. a different strategy can be established in accordance with the improved dexterity and angulation of the articulated arms.
3. the bulk of the articulated arms can be reduced.
4. changes in the optical command system can be made to render it independent of the tools command, which would avoid continuous halts in dissection. The optical

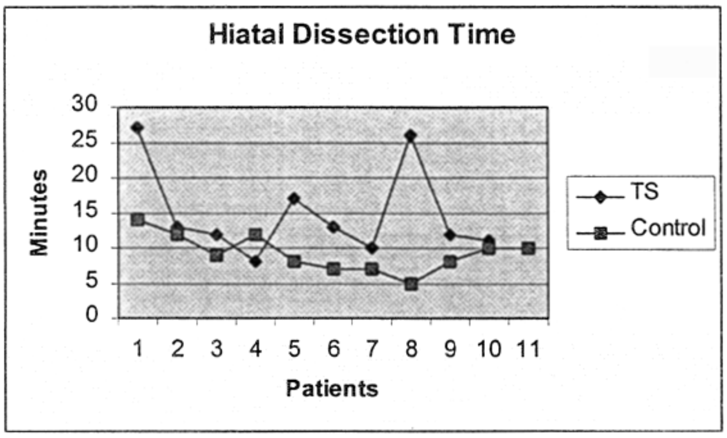

Fig. 11. Hiatal dissection time.

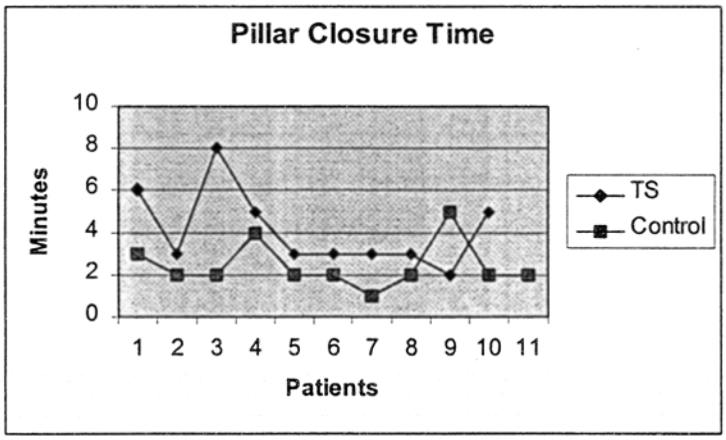

Fig. 12. Pillar closure time.

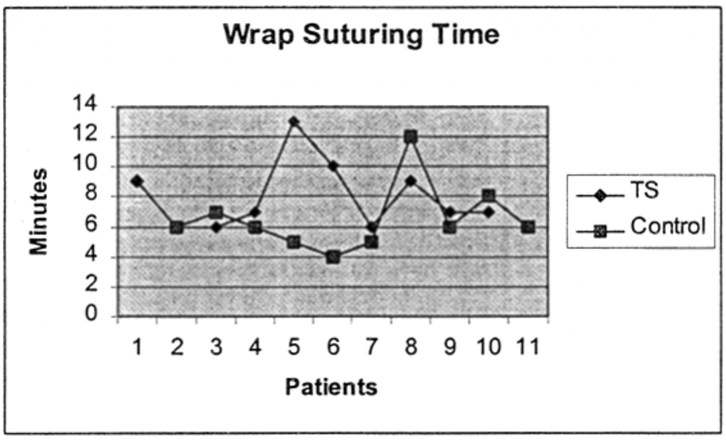

Fig. 13. Wrap suturing time.

system also should be positioned at greater distance from the operative field to give a broader field of vision and avoid continuous changes of incidence.

5. changes can be made in the position of the intra-abdominal articulation and the size of the tool tips. When the target organ is larger (as in general surgery), the operative field automatically becomes wider and operative motions become less minute. Therefore, the intra-abdominal articulation needs to be located more proximally and the grasping area of the tools wider, so that sufficiently wide motions can be made and safe, efficient grasping of the organ can be performed.

We currently are working on the design of tool tips to make them more suitable for digestive surgery.

As for now, the surgeon is sitting at his console a few feet away from his patient, linked to the latter by cables providing input and output. If the cable connection can be replaced by a telematic link, true telesurgery should be possible, with the operation controlled miles away from the patient. The patient still would be surrounded by surgeons, however, only to initiate the procedure. For the rest, they would be merely in a standby position.

Improvements are needed, but our study did prove the feasibility of performing laparoscopic Nissen fundoplication in a telesurgical setting, thanks to the use of Mona. It seems likely that robotics will take an ever-increasing place in the operating theater of the future. Technical improvements to the robot will allow the surgeon to work more precisely and more comfortably.

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