ORIGINAL ARTICLE

Robotics May Overcome Technical Limitations of Single-Trocar Surgery

An Experimental Prospective Study of Nissen Fundoplication

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Objective: To compare laparoscopic and robotic-assisted single-trocar access (STA) Nissen fundoplication in a porcine model. The STA procedure is an emerging concept in minimally invasive surgery that presents technical difficulties and challenges compared with traditional laparoscopy. Using multiple instruments inserted through a single trocar generates internal and external conflicts. Achieving triangulation requires the instruments and surgeon's hands to cross over at the point of entry. Robotic-assisted surgery may overcome these difficulties owing to its capability of dissociating the hands of the surgeon from the instruments.

Design: Prospective study consisting of 18 randomly performed porcine STA Nissen fundoplications with and without robotic assistance.

Setting: A research institute.

Participants: Three surgeons with different experience.

Main Outcome Measures: Operative time, intraoperative complications, and the number of conflicts between the instruments and/or hands of the surgeons.

Results: All of the procedures were successfully completed. Mean operative time (45.6 ± 11.2 vs 65.4 ± 10.7 minutes; $P = .03$) and number of conflicts (1.0 ± 0.9 vs 3.8 ± 1.2; $P < .001$) were significantly reduced in the robotic series.

Conclusions: Use of the robotic platform allows the surgeon to select which hand will move which instrument. Inverting the control allows crossing of the instruments without any consequences to the surgeon. Moreover, this system offers instruments with multiple degrees of freedom. These factors could explain the clear improvement demonstrated in this study. As a result, robotics may play an essential part in the diffusion of STA surgery.

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During the past 5 years, new surgical models have driven changes in minimally invasive surgery. The concept of natural orifice transluminal endoscopic surgery has reinvigorated the challenge of procedures with fewer or no skin incisions, potentially less pain, and better cosmetic results.[1-3] Because of the lack of adequate platforms and instrumentation,[2,3] single-trocar access (STA) surgery was introduced as a bridge between conventional laparoscopic surgery and natural orifice transluminal endoscopic surgery.[4-14]

The rationale of STA still has to be addressed, the main concern being the larger trocar incision that increases the risk of local complications. Clinical studies are ongoing, but numerous challenges have already been identified. The use of 1 scope and 2 instruments operating through a single access creates internal and external conflicts, the latter of which is between the surgeon's hands. The use of deflectable instruments and/or instruments with different sizes reduces but does not eliminate these issues.

Such complex ergonomic difficulties might be solved by advanced surgical technologies such as robotics. The potential advantages of such devices are the articulated and rotating instruments with flexible sections and fine handling modalities. Reports of robotic-assisted STA procedures in urology are promising.[15-17]

The aim of this study was to compare the operative results of a laparoscopic Nissen fundoplication performed through an STA with and without a robotic platform (da Vinci Surgical System; Intuitive Surgical, Sunnyvale, California).

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METHODS

We performed a prospective study on a nonsurvival porcine model. Three surgeons with different clinical backgrounds underwent evaluation, including a senior upper gastrointestinal tract surgeon with ample experience in lapa-

Table. Definite Panel of Instruments Used in Each Type of Procedure

Laparoscopy	Robotics
One Endo Mini-Shears roticulator[a]	One 5-mm curved scissors[b]
One Endo Grasp 5-mm roticulator[a]	One 5-mm DeBakey grasper[b]
One Endo Dissect 5-mm roticulator[a]	One 5-mm curved dissector[b]
Two fenestrated graspers[c]	Two 5-mm fenestrated graspers[b]
One monopolar hook[c]	One 5-mm monopolar hook[b]
One curved scissors[c]	Two 5-mm needle holders[b]
One curved needle holder[c]	One 10-mm liver retractor[a]
One straight needle holder[c]	
One 10-mm liver retractor[a]	

[a]From Autosuture, Norwalk, Connecticut.
[b]From Intuitive Surgical, Sunnyvale, California.
[c]From Karl Storz, Tuttlingen, Germany.

roscopic Nissen fundoplications (>2000 procedures) (B.D.), a senior laparoscopic colorectal surgeon (J.L.), and a junior surgeon (P.A.). All three had no substantial background in robotic surgery. Each surgeon randomly performed STA Nissen fundoplications with conventional laparoscopic instruments in 3 pigs and used the robotic system in 3 other pigs.

ANIMAL PREPARATION

Our research institute is officially authorized to conduct animal experimentation. Our animal models were managed according to the Directive of the European Community Council. The interventions were accomplished under general anesthesia in female pigs weighing 25 to 30 kg that had been deprived of food for 48 hours. Anesthesia was induced with 1 mg/kg of propofol and 4 mg of pancuronium bromide. Endotracheal intubation was performed and sleep was maintained with isoflurane, 2%. At the end of the procedure, lethal doses of propofol and potassium chloride were successively administered.

PROCEDURE

The pigs were placed in a supine position. Under direct visualization, a 2.5-cm incision was performed 4 cm cranial to the umbilicus. Through this incision, a single-port device (QuadPort; Advanced Surgical Concept, Bray, Ireland) was introduced and secured. This disposable device is composed of an internal ring and an external platform, linked together by an elastic plastic sheet. It contains 4 sealed orifices of 15, 10, 10, and 5 mm and 2 insufflating valves. The pneumoperitoneum was established and maintained with carbon dioxide at a maximum pressure of 12 mm Hg. The pig was then placed in a reverse Trendelenburg position. A 10-mm laparoscopic liver retractor was introduced through a 12-mm port placed in the right hypochondrium to retract the left hepatic lobe. An additional 10-mm, 30°-angulated laparoscope (Karl Storz, Tuttlingen, Germany) was inserted through a 12-mm trocar in the left iliac fossa. This enabled a real-time visual assessment (to which the surgeon was blinded) by an external observer of the movements and conflicts inside the peritoneal cavity. All procedures were recorded and reassessed postoperatively.

A standardized floppy Nissen fundoplication with crural repair was performed. The following 4 operative steps were defined: (1) complete dissection of the gastroesophageal junction and both crura, (2) division of the short gastric vessels, (3) crural repair, and (4) wrap construction. Crural reapproximation was achieved with 2 interrupted stitches, using a 2/0 braided thread. The same suturing material was used to construct the fundic wrap with 3 stitches. All of the stitches were performed intracorporeally and secured with 5 knots.

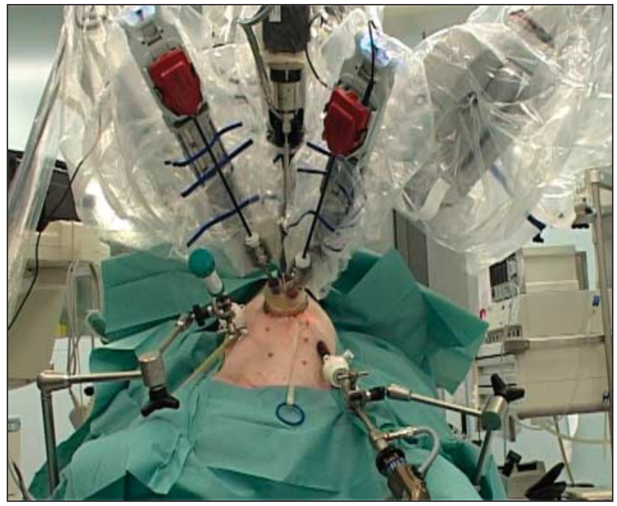

Figure 1. External view of the robotic setup during the procedure.

STANDARD STA FUNDOPLICATION USING LAPAROSCOPIC INSTRUMENTS

The standard procedure was performed in 9 pigs, under the visual control of a 60-cm-long, 30°-angulated, 5-mm high-definition laparoscope (Image 1; Karl Storz) passed through the single-port device. A fixed panel of deflectable instruments (Autosuture, a subsidiary of Covidien, Norwalk, Connecticut) and conventional laparoscopic instruments (Karl Storz) was used (**Table**).

ROBOTIC STA NISSEN FUNDOPLICATION

The robotic procedure was also performed in 9 pigs. The robotic cart was placed above the left shoulder of the pig (**Figure 1**). The procedures were performed under the visual control of a 30°-angulated 8.5-mm optic (Intuitive Surgical) inserted through the single-port device. The operative tools, 5-mm robotized instruments (Intuitive Surgical), were placed in 2 of the robotic system's arms. The same setup, shown in Figure 1 and **Figure 2**, was used for all procedures. The fourth arm was not used. The surgeon's control of both arms was inverted when using the console (**Figure 3**). This allowed handling of the crossed instruments by the ipsilateral hand (ie, the right instrument's tip, linked to the left robotic arm, is moved by the right hand). A fixed panel of instruments was offered (Table).

END POINTS

We studied the following 5 outcome measures:

1. The overall operative time and the time needed to complete each surgical step.
2. The intraoperative complications, such as visceral injury, hemorrhage, pleural effraction, and mortality.
3. The number of instrumental conflicts, defined as an internal or external physical contact between the instruments, the surgeon's hands, or the scope, that prevented or impaired the performance of a planned task. This end point was evaluated by the independent observer, using direct observation and the additional optic in the left iliac fossa.
4. The number of optical cleansings.
5. The overall carbon dioxide consumption, which indi-

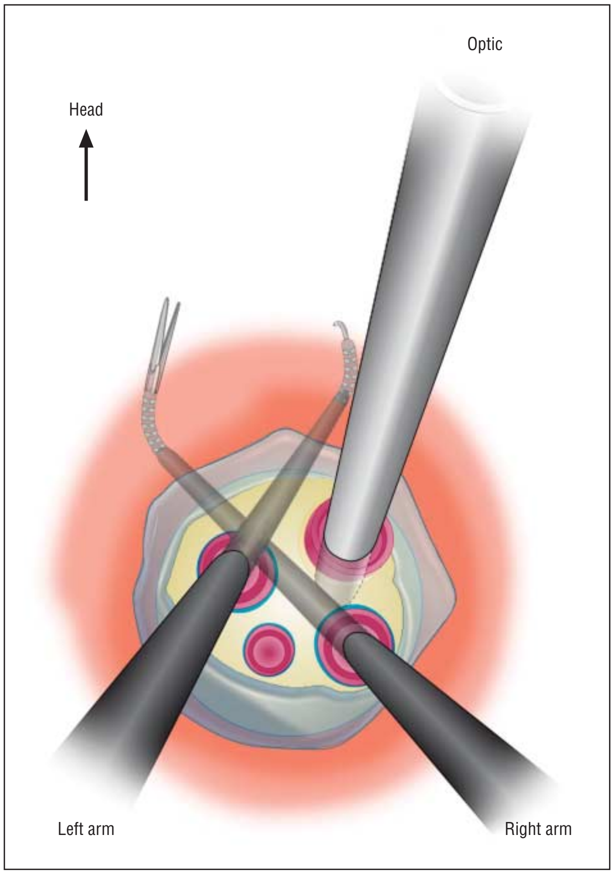

Figure 2. Setup of the 3 arms of the robotic system (da Vinci Surgical System; Intuitive Surgical, Sunnyvale, California).

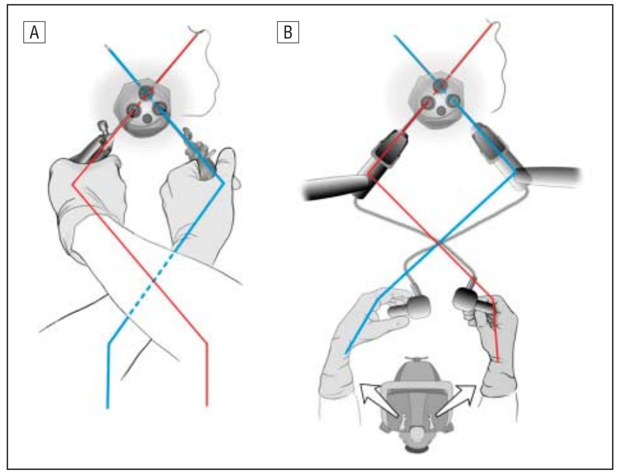

Figure 3. Comparison of the conventional (A) and robotic (B) single-trocar access stitching. The inverted controls of the robotic system allow the surgeon to operate without crossing his or her hands.

rectly reflects the length of the procedure and the movements of the instruments through the trocar (frequency of insertion/extraction).

STATISTICAL ANALYSIS

The data were collected and recorded in a commercially available database (Excel; Microsoft Corp, Redmond, Washington) for subsequent statistical analysis, using Linux-based software (R project under GPL license). Values are expressed as mean (SD). Continuous variables were analyzed using a 2-sided *t* test, and results were considered statistically significant at $P < .05$.

RESULTS

The procedure was successfully completed in both groups. No intraoperative deaths were observed. The complication rate was 44% in standard STA (1 iatrogenic liver injury, 1 spleen decapsulation, 1 vagal nerve injury, and 1 bleeding from the short gastric vessels) and 11% in robotic STA (1 injury of the left hepatic artery). The difference was not significant ($P = .13$).

The overall mean operative time was significantly longer in standard STA than in robotic STA (65.4±10.7 vs 45.6±11.2 minutes; $P = .03$). The mean operative time of the 4 surgical steps is reported for both groups in **Figure 4**. Statistically significant differences were observed in steps 3 (19.1±7.4 vs 11.8±4.3; $P = .03$) and 4 (24.0±11.2 vs 14.8±4.4; $P = .03$).

The mean rate of conflicts (internal and external) per intervention was higher in standard STA (3.8 [1.2] vs 1.0 [0.9]; $P < .001$). Differences between the other collected data, such as the mean number of laparoscope cleanings (2.2 [0.9] vs 0.7 [0.5]; $P = .08$) and the mean carbon dioxide consumption (230 [47] vs 144 [72] L; $P = .06$), were not statistically significant.

There was no statistical intragroup difference in operating time between the surgeons. Concerning intergroup analysis, the robotic procedure was significantly shorter for the senior laparoscopic colorectal surgeon (36.0±4.3 vs 60.7±4.0 minutes; $P < .001$) and the junior surgeon (42.7±11.2 vs 86.7±18.4 minutes; $P < .001$). No difference was observed for the senior upper gastrointestinal tract surgeon (59.0±11.2 vs 49.0±10.7 minutes; $P = .052$).

The junior surgeon's mean operative time when using the robotic system (42.7±11.2 minutes) was similar to the mean operative time of the senior upper gastrointestinal tract surgeon using the laparoscopic approach (49.0±10.7 minutes; $P = .61$) or the robot-assisted approach (59.0±11.2 minutes; $P = .32$).

The mean setup time of the robotic system was 17.2±16.0 minutes (**Figure 5**).

COMMENT

Reducing surgical trauma and improving patient comfort are the main goals of minimal access surgery. Several reports demonstrated that reducing the number and size of the laparoscopic trocars has an effect on the surgical outcome in terms of postoperative pain and cosmetic results.[18-25] Performing laparoscopic surgery through an STA is a further option that might fulfill the goals of minimal access surgery, if the size of the single incision allows for an adequate passage and manipulation of a minimal amount of instruments while avoiding related wound complications.

Initial experimental and clinical experiences with STA surgery highlighted this issue,[4-14] demonstrating that this technique is far from straightforward owing to the sub-

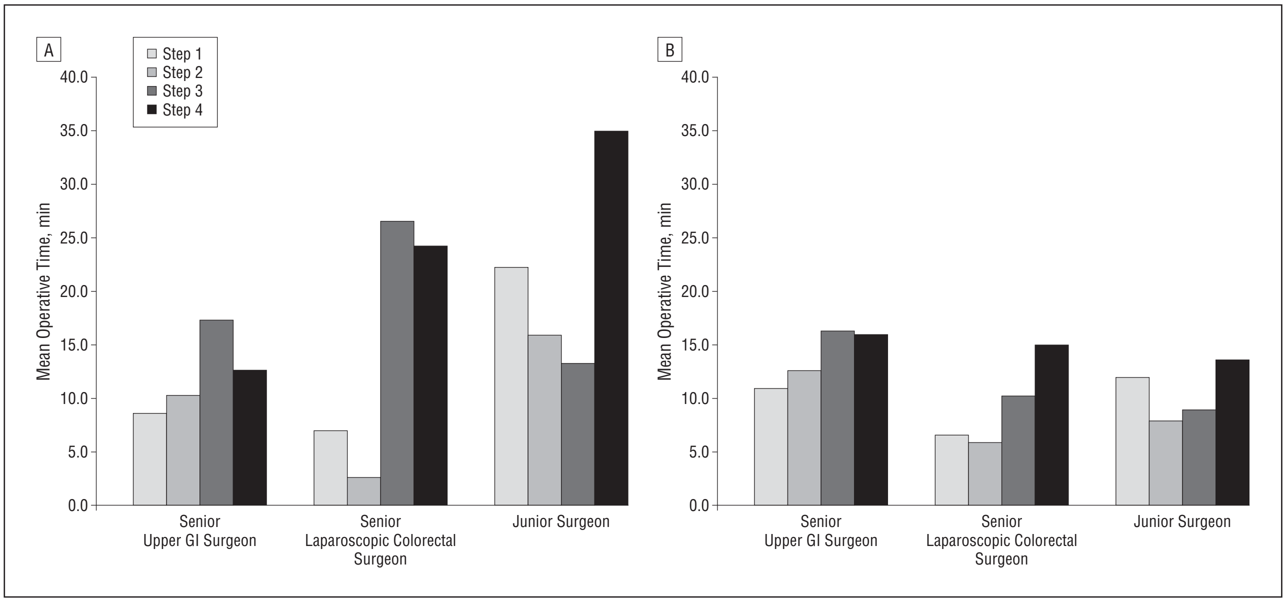

Figure 4. Mean time of all operative steps during the laparoscopic (A) and robotic (B) procedures. Step 1 indicates hiatal dissection; step 2, division of the short gastric vessels and fundus mobilization; step 3, crural repair; and step 4, wrap construction. GI indicates gastrointestinal.

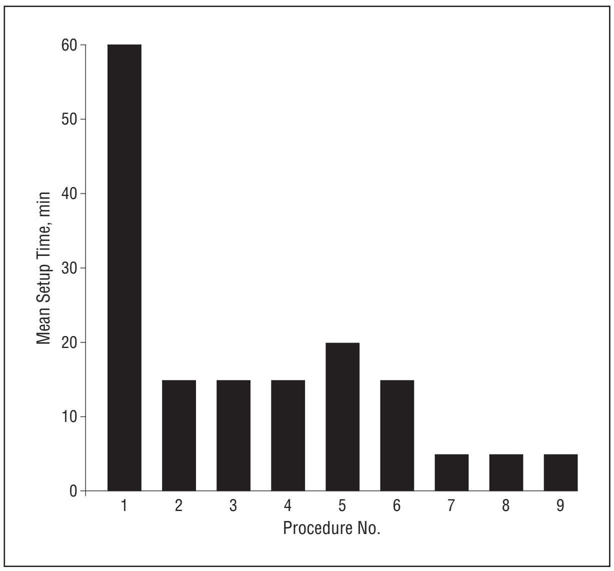

Figure 5. Setup time for the robotic system.

stantial conflicts between the instruments and the laparoscope that are passed through an incision less than 20 mm wide. Moreover, triangulation, retraction, and exposure of the operative field are obtained by an unusual and inadequate positioning of handheld instruments outside the abdominal wall. Achieving triangulation of the instruments requires the surgeon to cross the instruments through the port and his or her hands, a position that substantially reduces the surgical performance. This becomes even more complex when suturing or tying knots. The robotic system allows the surgeon to select the instrument that will be controlled by the right and the left hands, regardless of the robotic arm that holds the instrument. This allows the surgeon to control with the right hand the instruments that are visualized on the right side of the operative screen even if, out of the trocar, the robotic arm is coming from the left and vice versa. Therefore, crossing the instruments out of the trocar has no additional consequences for the surgeon.

The advantages of the robotic technology compared with conventional instrumentation were demonstrated in this comparative study of STA Nissen fundoplication, a procedure that integrates various surgical tasks. The overall operating time was significantly reduced, and complex surgical tasks such as suturing and knot tying were greatly enhanced by the robot. In addition to the possibility of assigning the instruments to the surgeon's corresponding hand, these tasks confirmed the well-known advantages of the multiple degrees of freedom of the "wristed" robotic tools.[26-32] Additional factors, such as less lens cleansing and diminished conflicts between the instruments, helped to lower the overall operating time.

With the conventional instrumentation, both of the skilled senior surgeons compensated for the faults of the single-port access with efficient but nonreproducible hand positioning and unusual maneuvers of the instruments. The difference with the junior surgeon was obvious. When using the robot, these differences were significantly attenuated, and the junior surgeon's performance dramatically improved and became comparable to those of the skilled senior surgeons. The intuitive character of the robotic system, which has already been recognized in several studies,[26,27] and adequate hand positioning probably explain this improvement.

The reported overall operating time did not include the setup of the robotic system. The mean setup time was 17 minutes, ranging from 5 to 60 minutes. Because a learning curve was observed (5 minutes for the last 3 procedures), this setup time should not be a significant drawback of the technique. Alternatives to this robotic system for STA surgery are currently in development. Laparoscopic instruments that are malleable or bendable or that rotate may overcome some issues such as triangulation but still do not completely resolve the problems with ergonomics and intuitiveness.

Single-trocar access surgery needs clinical validation. A technique that facilitates the surgical gesture would allow for a more objective and realistic evaluation of the potential of what is theoretically a less invasive access. This may pave the way to new applications for robotics, the advantages of which have never been clearly demonstrated in laparoscopic digestive surgery.[28-32] In addition, minimizing the differences between skilled and less experienced surgeons is another important factor that could improve patient safety and clinical outcomes in such technically challenging procedures.

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