# **Robotic Fundoplication: From Theoretic Advantages to Real Problems**

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## **ROBOTICS IN LAPAROSCOPIC SURGERY**

During the past decade, laparoscopy, through a dramatic worldwide diffusion, has become the gold standard in the surgical treatment of several conditions.<sup>1,2</sup> Currently, it is still spreading and gaining popularity in new fields of surgery.<sup>3-5</sup> Nevertheless, the laparoscopic technique has shown peculiar disadvantages and limitations intrinsic to this approach. Unlike traditional open surgery, in laparoscopy, the action of the surgeon's hand is mediated by rigid, unarticulated instruments, and the visual access is not direct, but is mediated by a camera. Obviously, these limitations reduce the laparoscopic surgeon's possibilities and increase technical difficulty, operative times, and risk of complications.

In an effort to improve surgical technique by avoiding some of the disadvantages of laparoscopy while maintaining the advantages brought by the miniinvasive approach (less postoperative pain, shorter hospital stay, and early return to normal activities,<sup>6</sup> robotics have been introduced in surgery. Domains range from general to urologic,<sup>7</sup> cardiac,<sup>8</sup> and gynecologic surgery.<sup>9</sup>

A decade after the first laparoscopic cholecystectomy, in 1987, the first telesurgical laparoscopic cholecystectomy formally opened the robotic era in general surgery.<sup>10</sup> Since then, the robotic approach has been used in several general surgery procedures, such as cholecystectomy,<sup>11-13</sup> gastroesophageal surgery,<sup>11,12,14</sup> obesity surgery,<sup>11,14</sup> and adrenalectomy.<sup>11,14</sup>

But despite early encouraging results and recent spectacular applications,<sup>15</sup> robotics have not yet witnessed wide, large-scale diffusion among general surgeons and are still considered "experimental approaches."

#### No competing interests declared.

### THE ROBOTIC SYSTEM

To reduce the limitations of laparoscopic surgery, robotic systems have been designed to give endoscopic surgeons the same quality of information and manipulation as they have when performing open surgery. These designs include: instruments and manipulators with all degrees of freedom, devices that provide surgeons with tactile feedback, and improved visual access.<sup>16</sup>

Until now, two robotic systems have been extensively tested in surgery: the Zeus (Computer Motion) and the Da Vinci (Intuitive Surgical) systems. Although both have shown to be effective and both are clinically promising,<sup>17</sup> it appears that the Da Vinci system allows for shorter operating times and steeper learning curves.<sup>18</sup> No comparison between these operative systems has yet been reported in general surgery procedures. To our knowledge, only the Mona-Da Vinci system has been used for robot-assisted laparoscopic fundoplication. Our experience refers to both the Da Vinci system and its precursor, the Mona prototype.

The Mona-Da Vinci system introduces several technologic innovations aimed at improving a surgeon's operating skills (Table 1). The greatest innovations of this system are the articulated arms. Whereas in open surgery the flexibility of the wrist and the hands inside the abdomen permits fully free movements, in laparoscopy, the presence of rigid, unarticulated instruments entering the abdomen through fixed openings (trocar sites) limits the number of degrees of freedom. Additional articulations inside and outside the abdomen may help recover the degrees of freedom that have been lost and regain some dexterity of the surgeon's hand in open surgery. The robot downscales a surgeon's movements (by a 10:1, 5:1, or 3:1 factor) and eliminates the physiologic tremor, increasing the accuracy of the surgeon's action.<sup>11</sup> A threedimensional monitor allows the surgeon to obtain more accurate visual control of the instruments and better motion coordination.<sup>19</sup>

Finally, because the robot is composed of two units, the patient's station and the surgeon's station, united by

Received September 26, 2002; Revised April 22, 2003; Accepted April 22, 2003.

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 Table 1. Theoretical Advantages of Robotic Laparoscopic
 Surgery

To recuperate several lost degrees of freedom
To modulate the amplitude of surgical motions by downscaling and stabilization
To increase the dexterity of the less performing hand (the left hand for right-handed surgeons)
To obtain better visual control of instruments thanks to three- dimensional vision
To allow a surgeon's perfect ergonomic position
To work at a distance from the patient

a cable, the surgeon is allowed to work from a distance in an ergonomically perfect position. Because the cable linking the surgeon's and patient's stations can be substituted by a satellite transmission or by any vehicle performing digital data transmission, the surgeon can in fact operate from any distance, even thousands of miles.<sup>15</sup> Do these theoretic advantages of robotics apply in the realization of a laparoscopic fundoplication?

#### **ROBOTIC FUNDOPLICATION**

Similar to what happened in the early 1990s, when Nissen fundoplication was one of the first procedures performed with the miniinvasive approach,<sup>20</sup> in the late 1990s, the introduction of robotics in laparoscopic surgery led surgeons to attempt the Nissen procedure using robot technology.<sup>21</sup> At that time, laparoscopic fundoplication for gastroesophageal reflux disease had already proved an effective treatment in patients resistant to medical therapy.<sup>22</sup> It had successively challenged longterm omeprazole therapy <sup>23</sup> and, finally, had been recommended in the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) guidelines.<sup>24</sup>

The location and characteristics of the lower esophagus and the skills required in gastroesophageal surgery led surgeons to take advantage of the robotic approach in several procedures involving the gastroesophageal junction, such as Nissen,<sup>11,12,25-27</sup> Toupet,<sup>11,14</sup> and Thal fundoplications,<sup>27</sup> and Heller myotomy.<sup>14,28</sup> The necessity of dissecting a relatively fragile retroperitoneal organ and of performing a wide range of surgical tasks (suturing, knotting, etc) in restricted and not easily reachable spaces made the use of robotic technology attractive, at least from a theoretic point of view.

But now, 5 years after the first robotic fundoplication (RF), the role of robotics in this array of procedures is still uncertain and its true benefit unproved. Because robotics have only recently been introduced in surgery,

medium and longterm outcomes for patients are still unknown. All articles describing RFs (reported in Table 2), involve small series,<sup>11,12,25-27</sup> or even sample cases.<sup>14,21,29-32</sup> So comments can be based only on preliminary results, technical feasibility, and early morbidity.

As reported in a recently published article,<sup>11</sup> laparoscopic treatment of gastroesophageal reflux is the second most frequently performed robotic-assisted procedure at St Pierre Hospital in Brussels, Belgium (27% for treatment of gastroesophageal reflux versus 33% for cholecystectomy). To our knowledge, the series of 39 RFs for gastroesophageal reflux disease is the largest series reported in literature. These procedures were performed over a 5-year period (March 1997 to February 2001), working with the engineers of Intuitive Surgical, using the Mona prototype at the beginning and, more recently, the Da Vinci system. During this evolution, 11,21,25 the robot has been significantly reduced in size and has found its ideal position in the operating theater (it has been moved from the upper left to the upper right side of the patient). An engineer was no longer needed, and constant improvement in ergonomics and electronic performance was noted. All surgeons experienced a very steep learning curve and reported an almost immediate familiarity with the robotic system.

From a technical point of view, realization of RF has shown peculiar advantages and disadvantages to the operating surgeon (Table 3). The articulated robotic arms seem to allow easier passage around and behind the esophagus during its dissection and easier mobilization of the greater curvature of the stomach. Suturing the wrap and the crura are more straightforward because of the increased mobility and dexterity of the system. On the other hand, lack of tactile feedback proved to be a significant problem in evaluating tension while tying knots and in retracting tissues.

The quality of the image is actually improved by the magnification of the three-digital camera,<sup>16</sup> but the field of vision is very narrow, when compared with the conventional laparoscopic approach,<sup>11</sup> and does not permit the surgeon to control the whole operating field.

Last, interaction with the team at the patient's side is difficult (in particular, with the assisting surgeon). Because in robotic surgery the assisting surgeon has greater autonomy because of the distance from the surgeon's console, poor interaction means a more laborious procedure, a higher intraoperative risk of complications, and longer operating times.

Lead author, journal, year	Operative system	No. of cases (type of procedure)	Operative time, min (range)	Intraoperative complications	Conversion to conventional laparoscopy	Hospital stay, d
Cadière						
Ann Chir, 1999 <sup>21</sup>	Mona	2 (Nissen)	180 (90-270)	—	—	_
Surg Endosc, 2001 <sup>25</sup>	Mona	11 (Nissen)	76 (59–130)	1 (gastric perforation)	—	1 (median)
World J Surg, 2001 <sup>11*</sup>	Mona-Da Vinci	39 (36 Nissen, 3 Toupet)	83 <sup>†</sup> (54–125)	2 (gastric perforation, greater curvature hemorrhage)	1 (greater curvature hemorrhage)	2 (median)
Chapman						
J Laparoendosc Adv Surg Tech A, 2001 <sup>29</sup>	Da Vinci	1 (Nissen)	165	—		1
Hanisch						
Chirurg, 2001 <sup>30</sup>	Da Vinci	1 (Nissen)	135	_	_	3
Horgan						
J Laparoendosc Adv Surg Tech A, 2001 <sup>14</sup>	Da Vinci	2 (1 Nissen, 1 Toupet)	NR	—	—	NR
Chitwood						
Ann Surg, 2001 <sup>12</sup>	Da Vinci	14 (Nissen)	73 (mean)	_		1.0 (mean)
Meininger						
Surg Endosc, 2001 <sup>31</sup>	Da Vinci	1 (Nissen)	197	—	—	6
Anaesthesist, 2001 <sup>32‡</sup>	Da Vinci	2 (Nissen)	197, 200	_	_	6.6
Melvin						
J Gastrointest Surg, 2002 <sup>26</sup>	Da Vinci	20 (17 Nissen, 3 Toupet)	140 (88–271)	—	—	1.1 (mean)
Gutt						
Surg Endosc, 2002 <sup>27</sup>	Da Vinci	12 (9 Thal, 3 Nissen)	146 (105–180)	—	—	5-6
Total						
11 articles	Mona-Da Vinci	91 (75 Nissen, 9 Thal, 7 Toupet)	107 (54–271)	See above	See above	2.2 (approximate mean)

#### Table 2. Authors Reporting the Realization of Robotic Fundoplication

No mortality, morbidity, or conversion to laparotomic access was described.

\*The series includes the patients reported in the previous articles.

<sup>†</sup>Duration of surgery calculated on the base of last 21 procedures.

<sup>‡</sup>The series includes the patients reported in the previous case report. NR, not reported.

# OPERATIVE TIME, COMPLICATIONS, AND HOSPITAL STAY

If and how the reported technical advantages of robotics (Table 3), experienced by the operating surgeon, become objective, quantifiable advantages when performing an RF is debatable.

Until now, the only prospective randomized trials<sup>25,26</sup> comparing conventional and robotic approaches (Mona<sup>25</sup> and Da Vinci<sup>26</sup> systems) to laparoscopic RF (Nissen procedure) did not show advantages in terms of morbidity, but they demonstrated longer operative times for the whole procedure and for most of the steps of the procedure (hiatal dissection, pillar closure time,

wrap closure time).<sup>25</sup> Longer operative time in the performance of standardized tasks with the robotic system when compared with a conventional laparoscopic approach has been reported also using the Zeus system.<sup>33</sup> But if we retrospectively compare the patients from one of these series<sup>25</sup> operated on by robot to the first 80 conventional laparoscopic interventions performed in the same environment,<sup>34</sup> no significant difference is noted concerning operating time. Interestingly enough, whereas 3 hours are needed to accomplish the first few cases (the articles that describe only the initial one or two cases report a cumulative mean operating time of 178 minutes,<sup>14,21,29-32</sup>) after a few procedures the operating

ile perception of tension when grasping organs or
knots
d general view of the operating field
lt interaction with the team (in particular, with ssisting surgeon)

Table 3. Technical Advantages and Disadvantages of Robotics During Fundoplication

time falls to 2 hours (the articles based on series of 10 to 20 patients report a cumulative mean operative time of 121 minutes<sup>12,25-27</sup>). Significantly, the further reduction in the mean operating time (83 minutes) of the last 21 procedures of Cadière and coworkers' series of 39 patients<sup>11</sup> indicates a continuous improvement of surgeon performance (Fig. 1). On the other hand, if we roughly compare these latter data with the mean duration of laparoscopic fundoplication performed by the same surgeon (GBC) during the same period (October 1999 to February 2001), the operating time of RF is still significantly longer than that of the traditional laparoscopic approach (83 minutes versus 60 minutes, p < 0.05) (Fig. 1). Nevertheless, it is important to note that, at that time, the cited surgeon was beginning his robotic experience, but he had already performed more than 500 laparoscopic fundoplications.

The only two major intraoperative complications reported during RF—one gastric perforation and one greater curvature hemorrhage—were reported in the St Pierre's hospital series.<sup>11</sup> Although a suture of the gastric perforation was performed robotically, management of the greater curvature hemorrhage required a conversion to a conventional laparoscopic approach.

Concerning the systemic effects of surgery, the robotic approach to fundoplication showed no difference when compared with conventional laparoscopic fundoplication. In the clinical trials already reported,<sup>25,26</sup> robotic and conventional fundoplication were comparable in terms of morbidity. Despite the longer operative time, no intraoperative or early postoperative cardiovascular or pulmonary complications occurred. Even though the total number of patients operated on by robot was too small to draw statistically significant conclusions, no systemic complications related to robotics have been reported with RF.<sup>11,12,14,21,25-27,29-32</sup> The safety of RF, despite the long operating time, has been recently confirmed by Meininger and colleagues<sup>32</sup> and Gutt and associates,<sup>27</sup> who reported no significant changes in pH, arterial oxygen and carbon dioxide pressures ( $PaO_2$  and  $PaCO_2$ ), heart rate, and mean arterial pressure during RF.

Even when considering the hospital stay, no significant difference was noted between robotic and conventional laparoscopic approaches.<sup>25,26</sup> These data are confirmed by the overall approximate mean hospital stay of 2.2 days (Table 2).

None of the articles reported in Table 1 evaluated cost data. In order to allow an evaluation of robotics' costs, in Table 4 we report a rough cost comparison for the lapa-



**Figure 1.** Cumulative mean operating time of robotic fundoplication and how it relates to the number of procedures performed. \*References 14, 21, 29–32. †References 12, 25–27. †Mean operating time has been calculated on the basis of the last 21 of 39 robotic procedures, performed by one surgeon (GBC) at St Pierre Hospital (Brussels, Belgium) from October 1999 through February 2001 (Reference 11). <sup>§</sup>The mean operating time of 83 traditional laparoscopic fundoplications performed by one surgeon (GBC) at St Pierre Hospital (Brussels, Belgium) from October 1999 through February 2001.

Table 4. C	Cost Co	mparison	* Betwe	een the l	Laparoso	opic In-
struments	Used	for Robot	tic (Da	Vinci) ar	nd Lapar	oscopic
Nissen Fun	doplica	tion at St	Pierre H	ospital, B	srussels,	Belgium

Laparoscopic instruments and accessories	Cost for robotic fundoplication (Da Vinci) (Euros)	Cost for traditional laparoscopic fundoplication (Euros)	
Drape set and accessories	136.5 <sup>†</sup>	34.64	
		(Allegiance)	
Veress's needle (Storz)	$1.21^{\ddagger}$		
Trocars <sup>§</sup>			
Disposable (Ethicon)	101	101	
Reusable (Aesculap)			
10 mm	3.29 <sup>‡</sup>	$2 \times 3.29^{\ddagger}$	
5 mm	3.17 <sup>‡</sup>	$3 \times 3.17^{\ddagger}$	
reductors	0.26 <sup>‡</sup>	$2  imes 0.26^{\ddagger}$	
Liver retractor (US Surg)	188		
Atraumatic grasping forceps	210		
	(2,100 for 10		
	uses-trocar		
	included) <sup>†</sup>		
	12.07 <sup>‡</sup> (Micro France)	$3 \times 12.07^{\ddagger}$	
		(Micro	
		France)	
Coagulating hook	210	1.93*	
	(1,680  for  8  uses)	(Wolf)	
<u></u>	trocar included)		
Needle holder	231	/./6*	
	(2,310 for 10	(Jarit)	
	included) <sup>†</sup>		
Endoscopic sutures	5 × 17 11	2 × 17 11	
Endoscopie sutures	(Ethicon)	(Ethicon)	
	(Luncon)	209	
		(US Surg)	
Suction-Irrigator (Jarit)	3.12 <sup>‡</sup>	× 0/	
Scissors (Ethicon)	142		
Endoscopic clips (Ethicon)	) 231		
Total	1,558.17	1,006.70	
Plus taxes (25% <sup>¶</sup> )	1,947.71	1,258.37	
Difference	+ 689.34 (+54.77%)	,	

\*Prices are net and may be deducted up to 40% from price list.

<sup>†</sup>As provided by Intuitive Surgical.

<sup>‡</sup>Reusable instruments. The cost is calculated on the basis of 100 cases done and cost of instruments plus 15% (rough estimate of the added costs of sharpening, repair, sterilization, etc).

<sup>§</sup>Robotic instrument (grasping forceps, coagulating hook, and needle holder) prices include trocars.

Endo-Stitch + No. 2 recharges.

<sup>1</sup>Actual tax amount may vary due to changes in local laws.

roscopic instrumentation we use to perform robotic and traditional laparoscopic fundoplication. The cost of the laparoscopic instruments used to perform a robotic fundoplication is higher (55%) than those used for a traditional laparoscopic procedure (1,947.71€ versus

Table 5.	Costs of Purchase,	Delivery, and	Installation	of the
Da Vinci	System			

Components	Cost (Euros)
Da Vinci system, including:	956,550
Surgeon console	
Surgical cart with instrument manipulators	
3-D digital camera	
Installation and testing	
0° Endoscope	16,500
30° Endoscope	16,500
Sony 20' monitor	3,800
Starter set of training instruments (multi-	
specialty)	11,815
Starter set of accessories and disposables	16,645
Total price of base system (net price)	1,021,810
Taxes (25%*)	255,452.50
Delivery costs <sup>†</sup>	10,000
Total cost	1,287,262.50

\*Actual tax amount may vary due to changes in local laws.

<sup>†</sup>Approximate average delivery cost in Europe (as provided by Intuitive Surgical).

1,258.37€). The costs of initial purchase, delivery, and installation of the Da Vinci System are reported in Table 5. The cost of the maintenance contract is  $110,000 \in$  per year. The approximative additional cost per procedure because of robotics is 1,882.97€ (Table 6).

#### DISCUSSION

Presented as a possible second revolution in general surgery after the introduction of laparoscopy during the last few years, the robotic approach to miniinvasive surgery has only partially fulfilled the promises. Now, 5 years after introduction, the use of robots in laparoscopic surgery is slowly diffusing outside the pilot centers.<sup>11-14</sup> There are many reasons for this slow diffusion of robotics into general surgery: the cost of the machinery and

**Table 6.** Approximate Additional Cost per Procedure Because of Robotics

	Performing 200 procedures per year
Cost of the machinery per procedure* (Euros)	1,193.63
Additional instrumentation's cost per procedure from robotics <sup>†</sup> (Euros)	689.34
Total	1,882.97

\*The cost of the machinery per procedure has been calculated as follows: total cost of purchase, delivery, installation, and maintenance of the machinery/10 years (supposed duration of use of Da Vinci)/200 procedures per year. \*The additional instrumentation's cost from robotics is the difference between

<sup>†</sup>The additional instrumentation's cost from robotics is the difference between the costs of instrumentation needed to perform a single robotic fundoplication and a traditional laparoscopic fundoplication. tools, the slow development of increasingly sophisticated instruments, the setting up of partially new procedures, the need for a new and specific training, and (in some countries) the new ethical and legal questions raised by use of a robot.

At present, the robotic approach to RF has already proved feasible and safe. Operating time decreases with practice, becoming comparable to conventional fundoplication after a few procedures, confirming a steep learning curve for robotics.<sup>11,12</sup>

But there does not seem to be a clear benefit in low- or medium-difficulty procedures (such as fundoplication), in which conventional laparoscopy has produced excellent results and has already become the "gold standard",<sup>6,23</sup> which is, consequently, hard to improve. The clearest advantage of robotics can be expected in longer and technically more demanding procedures in which ergonomics may play a more significant role.

In order to allow a further improvement in robotic surgery and to extend the use of robotics to more complex procedures, some deficits of the robotic system have to be addressed. In our opinion, enlargement of the three-dimensional laparoscopic view should be realized. This could increase the surgeon's awareness of the operating field, allowing him to have better control of the procedure and avoiding time-consuming camera replacement. Even though the improvement of highresolution, three-dimensional cameras may compensate for haptic loss,<sup>33</sup> a great benefit to robotic laparoscopic surgeons will come from development of a tactile feedback at the console. Effective tactile feedback will be fully appreciated in increasingly difficult procedures and tumor surgery, in which the possibility of evaluating by palpation should allow definition of tumor location and margins.16

In laparoscopic surgery, instrument exchange is time consuming,<sup>34</sup> disrupts the flow of the procedure,<sup>35</sup> and may potentially be the cause of trauma when the instruments cannot be seen by the surgeon;<sup>36</sup> in robotic laparoscopic surgery, because of the limited view of the camera and the increased complexity of this maneuver, instrument exchange is likely to be even more troublesome. Even though recently developed tools have simplified the maneuver of changing instruments, development of multifunctional instruments<sup>36</sup> and multiinstrument robotic arms will reduce the difficulty of the procedure and the operating time, and, together with enlargement of the three-dimensional laparoscopic view, the risk of unseen visceral traumas.

Last, in robotic surgery the operating surgeon is much more dependent on the assisting surgeon(s) and instrument nurse, but less in a position to interact with them. Intuitively, this difficulty is increased in case of intraoperative complications. Considering the management of the reported complications,<sup>11</sup> suture of the gastric perforation was easily accomplished robotically, confirming the high dexterity of the robot in "manual" skills; significantly, on the other hand, a sudden and rapidly deteriorating complication, such as a greater curvature hemorrhage, could not be successfully managed by the robot. Even though the robotic approach is theoretically more dexterous, in this case, the need for immediate and harmonious team work, aside from inexperience with handling complications robotically, required a conversion to the conventional laparoscopic approach. According to Chitwood and coworkers,12 specific "team" training should be considered in order to develop a harmonious and complementary operating team. Obviously, this demand will become even more important with the diffusion of long-distance telesurgery.

Concerning the costs of RF, even though a mere comparison of the costs of the instrumentation needed for two standard procedures clearly does not allow evaluation of the total operative and hospital charges, it shows that, until now, RF is not cost effective. The rough cost of instruments needed for RF is higher than those for traditional laparoscopic surgery. The cost of purchase, delivery, installation, and maintenance of the machinery has to be considered.

Until now, it has been difficult to foresee if and when there will be any economic advantage by performing robotically a fundoplication, and how many procedures will be needed to amortize the initial purchase of the system. If we hypothesize about using the Da Vinci system for 10 years, and performing 200 robotic procedures per year, we estimate that the additional cost per procedure from robotics is 1,882.97€ (Table 6), which is relevant for a technique that is not significantly superior.

Nevertheless, it is likely that in the future, technologic progress and greater turnover of patients undergoing increasingly difficult robotic procedures, together with lower prices of robotic systems and tools, will allow the greatest advantage, both in terms of results and costs, in specialized centers. The possible multidisciplinary use of the robot, ranging from general to urologic, cardiac, and gynecologic surgery, will also play a role in reducing the costs of robotics in large hospitals.<sup>11</sup> Clearly, randomized prospective studies are needed to assess the real costs of RF in comparison with the traditional laparoscopic approach.

In conclusion, the evolution of surgery from laparoscopy to robotic laparoscopy is somehow changing the profile of the general surgeon and challenging his role in the operating theater. The "robotic surgeon" operating at a distance from the patient will focus solely on the operative targets,<sup>37</sup> but at the same time will be less aware of what is happening outside the frame of his camera. He will be technically more dexterous, but less in a position to lead his team and to deal with unforeseen events.

RFs and many other robotic procedures are still in a transitional phase in which true benefits in the patient's care are unclear, in spite of higher costs. Only technologic upgrades will allow the extension of robotic surgery toward increasingly difficult procedures and its diffusion into nonspecialized environments. Controlled randomized studies on larger series of patients will determine if there are actually benefits to patients undergoing robotic laparoscopic procedures, and if robotics will eventually play a significant role in general surgery in the next decades.

#### **Author Contributions**

Acquisition of data: Costi Analysis and interpretation of data: Costi, Bruyns Drafting of manuscript: Costi Critical revision: Himpens, Cadière Supervision: Cadière

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