Robot-assisted endoscopic surgery

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Robot-assisted endoscopic surgery

Robotgeassisteerde endoscopische chirurgie

(met een samenvatting in het Nederlands)

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Universiteit Utrecht

aan mijn Maartje

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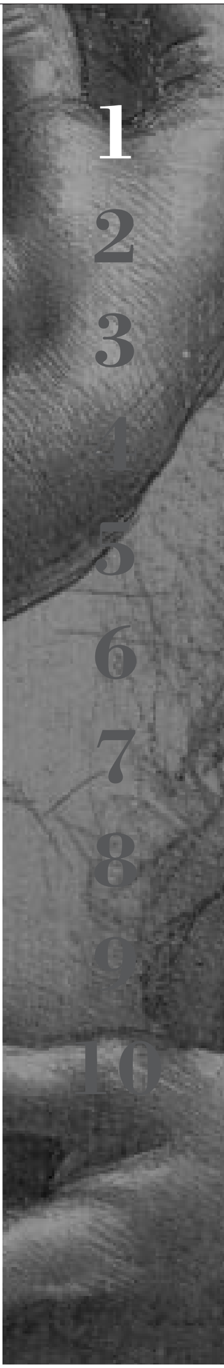
Chapter 1.1

General introduction



Robotic telemanipulation systems were introduced during the last decade of the 20th century. They were developed to support surgeons during endoscopic procedures, in which visualisation and manipulation are reduced as compared to traditional "open" surgery.

In June 2000, a da Vinci robotic telemanipulation system was acquired in a co-operation between the department of surgery of the University Medical Centre Utrecht and the Heart-Lung Centre Utrecht. At the same time, a second da Vinci system was installed for experimental use at the Central Laboratory Animal Institute.

On the 26th of June 2000, the first robot-assisted laparoscopic procedure in the Netherlands was performed in our hospital, followed by well over a hundred interventions on the digestive tract in the following years. In the animal laboratory, technically more challenging procedures were assessed.

This thesis describes the Utrecht experience in experimental and clinical applications of robot-assisted surgery. Feasibility of various robot-assisted procedures was assessed and in a later phase, experimental studies focussed on the comparison of robot-assisted surgery to standard "open" and laparoscopic techniques, aiming at assessing the benefits, challenges and potential pitfalls of using this new technology.

The aim of this thesis was to answer the following questions:

1. Is it feasible to perform both basic and more complex endoscopic procedures with the use of robotic assistance?
2. Does robot-assisted surgery offer benefits over standard endoscopic surgery?
3. Is there a role for robot-assisted surgery in day-to-day clinical practice?

The outline of this thesis

In chapter 1.2, a review of robot-assisted surgery is provided at the moment of acquisition of the robot-system in June 2000. This is followed by a description of the da Vinci system in chapter 1.3.

Chapters 2 to 5 focus on the clinical applications of robot-assisted surgery. Chapter 2 demonstrates our early experiences with robot-assisted surgery in a relatively simple procedure, the laparoscopic cholecystectomy. Chapter 3 goes into detail on time consumption during laparoscopic cholecystectomies, comparing robot-assisted and standard laparoscopic procedures. Chapter 4 describes our experience in Heller myotomies. Safety and efficacy of this procedure, both in functional and symptomatic parameters, were assessed. Chapter 5 summarises and discusses our overall clinical experience during the first three years of robot-assisted surgery and discusses our vision on the future directions of robot-assisted surgery.

Chapters 6 to 9 concentrate on our experimental experiences in animal studies. Chapter 6 addresses the safety and efficacy of robot-assisted laparoscopic intestinal anastomoses, compared to standard, hand-sewn, open anastomoses. Chapter 7 compares robot-assisted laparoscopic choledochojejunostomies to identical procedures performed through a laparotomy. In Chapter 8, the comparison of standard endoscopic versus robot-assisted endoscopic surgery is made while performing ex-vivo intestinal anastomoses. Finally, in chapter 9 robot-assisted endoscopic surgery and standard endoscopic surgery are compared in a pig model for end-to-end interposition grafts of the abdominal aorta.

Chapter 10, to conclude, discusses the content of this thesis in general.

Chapter 1.2

Robot-assisted surgical systems: a new era in laparoscopic surgery

Abstract

The introduction of laparoscopic surgery offers clear advantages to patients; to surgeons, it presents the challenge of learning new remote operating techniques quite different from traditional operating. Telemanipulation, introduced in the late 1990s, was a major advance in overcoming the reduced dexterity introduced by laparoscopic techniques. This paper reviews the development of robotic systems in surgery and their role in the operating room of the future.

Ruurda JP, van Vroonhoven ThJMV, Broeders IAMJ. Ann R Coll Surg Engl. 2002 Jul;84(4):223-6.

The widespread introduction of laparoscopic techniques during the last decade of the 20th century was one of the most prominent changes in modern surgical practice. Many open surgical procedures, such as cholecystectomy, inguinal hernia repair and oesophageal reflux surgery, have been reduced to minimally invasive interventions. This has benefits for the patient in a shorter postoperative stay in hospital, less pain, a better cosmetic result and a faster return to normal activity.

Despite a growth in the range of laparoscopic procedures, surgeons remain hampered by the limitations imposed by remote operating. The recent introduction of computer-aided instruments, such as robotic surgery systems, has the potential to revolutionise endoscopic surgery by allowing surgeons to use their traditional open surgery skills for laparoscopic operations.

Shortcomings of current endoscopic surgery techniques: the base for new developments in surgery support systems

In open procedures, the surgeon has unlimited flexibility in positioning his body, elbow, wrist and fingers; the operative field may be approached from various directions, and the surgeon controls his actions by visual and tactile feedback. During endoscopic surgery, the problem of working with long instruments through fixed entry points and looking at a screen greatly reduces this feedback. The surgeon's actions are further compromised by limitation of the movement of the instruments to only four degrees of freedom (DoF). The angular displacement of the instruments inside the body following a movement of the surgeon's hand hereby varies according to the length of the instrument that is introduced into the body. The hand-eye coordination is further reduced by the loss of the eye-hands-target axis, compromising normal oculo-vestibular input [1]. Basic surgical manoeuvres like suturing, therefore, demand highly developed technical skills that the surgeon needs to learn.

Looking at a two-dimensional screen, surgeons are handicapped by the loss of the visual perception of depth and, additionally, by the need for a human assistant to hold and move the camera. The latter causes discomfort, because the field of view is no longer under the surgeon's own control. Orientation errors and unstable camera control may compromise the smoothness of the operation.

Although many abdominal operations can be performed laparoscopically at this moment in time, performance of complex minimally invasive surgery is in the hands of a limited number of experts. Therefore, researchers have started to develop new tools for laparoscopic surgery to minimise the unsatisfactory aspects of the process. The launch of robotic telemanipulation systems heralds this development.

Robotic telemanipulation systems: history and current status

Reduced dexterity and impaired visual control were considered the major burdens of endoscopic surgery and initial attempts in developing robotic support systems aimed at enhancing the surgeons' control of the instruments and of the endoscope. The first applications of robotics in surgery were in the field of camera guidance systems.

In 1994, the American company Computer Motion was the first to obtain FDA approval for the use of the AESOP (Automated Endoscopic System for Optimal Positioning) robot arm in the operating theatre. This camera arm mimics the function of a human arm. It was designed to offer the surgeon direct control over the camera system by means of a foot pedal or voice control. The voice recognition system enables voice activation of the camera following previously recorded voice commands. The AESOP arm provides the surgeon with a steady and flexible view of the operative field, independent of the skills of a human camera assistant [2,3].

At the same time in Germany, the Tiska endoarm (a passive system) was developed which allowed a stable optic positioning by means of electromagnetic friction. This was controlled by a foot-pedal. The arm could also be used as an instrument retractor [4]. The point of trocar insertion into the abdominal wall is fixed protecting the patient against excessive forces at that point.

The Fips endoarm is an example of an active camera system where the surgeon moves this camera system either manually by a finger ring joystick, clipped on the handle of an operating instrument, or by voice [5].

In 1998, the British firm Armstrong Healthcare launched the Endoassist robotic camera assistant for laparoscopic surgery. It moves the camera in synchrony with the surgeon's head movements making intuitive control of the visual field possible. The camera only follows when a foot switch is pressed, allowing the surgeon to make head movements freely at all other times [6].

Whilst developments in imaging systems clearly progressed, dexterity problems remained a crucial problem. In the early 1990s, the concept of a master-slave telemanipulator was developed. This concept required the surgeon to control a manipulation system from a master console remote from the patient. A computer placed between the surgeon's hands and the end-effectors of the instruments, uses computing power to support the surgeon's dexterity. The surgeon moves two master devices made to resemble surgical instruments at the console, and each motion is translated to the robotic arms which scale down the movements at the end of the instruments inside the patient's body. The robotic slave arm follows all commands of the master arm in a natural way, comparable to manipulation in open surgery.

The original goal of developing these telemanipulators was to enable telesurgery. This would allow surgeons to operate on patients from a remote location thus avoiding hazardous environments, such as a battlefield, or inaccessible places, such as outer space. It would also allow them to perform surgery on patients who carry lifethreatening infections. The US Federal Government supported research in this field at Stanford Research Institute and, in the early 1990s, the first master-slave manipulator for surgery was developed. Only four DoF were available in this instrument and, since it filled almost half the operating theatre, it was not a feasible option [7]. In 1994, the technology was licensed to the company Intuitive Surgical.

In Germany in 1992, the ARTEMIS (Advanced Robotic Telemanipulator for Minimally Invasive Surgery) was made. This was the first system that provided instrument mobility with six DoF. It integrated the Fips Endoarm with a conventional technical telemanipulator, mastered by a joystick [8]. The prototype made it to the experimental phase, but neither commercial production nor clinical application was achieved [9].

At this moment, two US companies have received European Union clearance for clinical application of their telemanipulation systems for general and cardiac surgery. Intuitive Surgical and Computer Motion received FDA clearance in 2000 for general surgery applications with the da Vinci and Zeus telemanipulation systems. Both systems were initially developed for cardiac applications but are still waiting for complete FDA clearance for these procedures.

The Zeus robotic system (Figure 1) consists of three separate robotic arms attached to the sidebars of the operating table. Two arms hold and manipulate a variety of surgical instruments, and one arm handles the camera. The surgeon steers the surgical instruments through two egg-shaped control devices. The Zeus system has recently been integrated within the Hermes system, which gives the surgeon direct control of

Figure 1

A surgeon manipulating the Zeus system. The surgeon is using two manipulators and his voice in order to control the three arms of the system.

Figure 2

The da Vinci system at the University Medical Centre Utrecht. The surgeon is seated behind the console, the three-armed chart is located next to the operation table.

endoscopic add-ons. The camera, insufflator, light-source and other additional instruments are adjusted by voice or by a foot pedal. Three-dimensional (3D) vision is incorporated, but requires the use of goggles with shutter glasses.

The da Vinci robot (Figure 2) consists of a master console, where the surgeon sits, looking at a 3D binocular display of the operative field. A three-armed robot cart is at the operation table and the middle arm carries the two-channel optical system. Two independent video images are transmitted to the binocular where they merge thus providing a true 3D image of the operative field. The camera is controlled by the Navigator system, and enables the surgeon to pick up and move the camera by foot pedal. During the camera movement, the slave instruments stay in position. A second foot pedal freezes the instruments, which allows repositioning of the controllers and forearms to an ergonomically favourable position. The control devices have a configuration similar to regular surgical instruments. The surgeon's movements are transposed to the tips of tiny instruments, where the Endowrist system provides the surgeon with six DoF inside the patient's body. Control mimics the natural movements of open surgery.

The intuitive control of movements is improved in the da Vinci system by the integration of both the visual system and manipulators in the master console thus restoring the eye-hand target axis. The system goes into stand-by mode when the surgeon moves away from the 3D binoculars.

The major advantage of these newer master-slave robotic systems is the introduction of extra DoF at the end of the instruments, allowing surgeons to manipulate in a manner similar to that of open surgery.

The Zeus offers five DoF, the da Vinci offers six, both with an intuitive control mechanism. In addition, the unnatural opposite response of the instruments is corrected by the robotic telemanipulation systems. Tremors and trocar resistance are eradicated by the man-machine interface. The digital processing allows the scaling down of the surgeon's hand movements to a level where micro-vascular procedures are feasible. The ergonomic and reduced fatigue features will be a great advantage.

The first operation reported using a robotic telemanipulation system was a laparoscopic cholecystectomy performed on 3 March 1997 at the St Pierre Hospital in Brussels, Belgium [10]. Others have followed in the last few years, not only in general surgery but also in cardiac surgery, gynaecology and in urology. More than 1000 procedures have now been performed with the da Vinci system and almost the same number with the Zeus (Table 1). Instruments are being installed in hospitals in Europe and the US.

Table 1 **Number of robotic procedures performed on Jan 1 2002 (Numbers as provided by Intuitive Surgical and Computer Motion).**

	da Vinci system	**Zeus system**
General surgery	2220	100
Vascular/ thoracic surgery	1993	570
Urology/ gynaecology	1145	270

Robotic surgery systems: future perspectives

The benefits of robotic telemanipulators in the operating room are apparent, but many challenges remain. Proof of benefit for patients has yet to be determined. One of the major points of criticism is the lack of tactile feedback from the operating instruments. Currently, this is only partly compensated for by the 3D visual feedback.

The time to set up the equipment is acceptable for complicated surgery but still too long for daily practice. Whilst experience improves this, the size of the system compromises the proper positioning of the robot in relation to anaesthetic equipment, X-ray facilities, and space to allow the surgeon close to the patient. Integration of the systems into the design of the operating room by attachment to the ceiling or operating table may help.

Next to the usage in laparoscopic surgery, a potential application of this technology is in surgical skills' training. Virtual reality training programs can be integrated in the system computers and two consoles can be coupled to allow an experienced surgeon to adjust and correct the movements of the trainee. The tutor is able to take over the instruments and show the resident the way to do things correctly. Surgeons that currently use robotic telemanipulators report a significant learning curve in using the system [11]. A double console teaching set-up could considerably diminish this.

Robotic telemanipulation systems potentially offer great benefits for endoscopic surgeons, while enhancing ergonomics, providing additional DoF, three-dimensional visualisation and possibilities for surgical skills training. Challenges remain in implementing these systems in daily practice. In the upcoming years surgeons will have to prove that these systems will offer patients significant benefits that outweigh the additional efforts and costs that are still embedded in their usage.

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Chapter 1.3

The da Vinci system

The da Vinci system (Intuitive Surgical, Sunny Vale, Ca, USA) is one of the two robotic surgical systems currently available with CE mark/ and FDA approval for clinical use. In our experiments and clinical practice we used this system. It exists of three components connected by cables: the surgeon console, the surgical arm cart and the vision cart (Figure 1).

Figure 1
The surgeon console and robotic cart are connected by cables.

The surgeon console

The surgeon operates while seated at a console (Figure 2) with his eyes faced downwards to see the operative field in one line with his hands. Two manipulators, placed in line with the 3-D display of the surgical field, are shaped like traditional surgical pick-ups (Figure 3). The surgeon's fingers conduct the manipulators and the motions made are detected by sensors. The motions are translated to the tips of

Figure 2
The console of the da Vinci system.

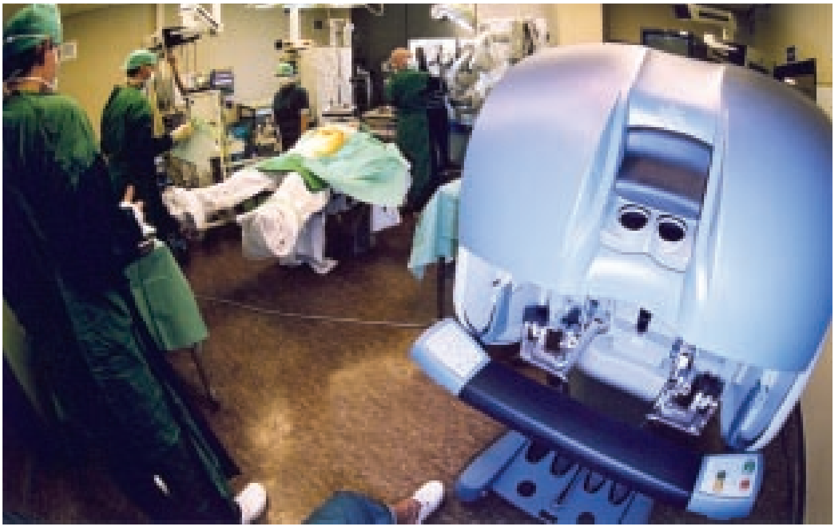

Figure 3
The console integrates two manipulators, placed in line with the 3-D display of the surgical field.

specially designed robotic instruments, which are being held by robotic arms, placed on the surgical arm cart. The 3D view is composed by two images of the operative field. A double (12-mm) endoscope generates these two images that are transposed through separate vision chains to two monitors inside the console. The surgeon's left and right eye see slightly different images resulting in perception of a 3D image (Figure 4).

Figure 4
Separate images for the left and right eye are displayed in the console, resulting in a true 3D-image of the operative field.

The console integrates a number of foot-pedals (Figure 5): one is for control of the camera system. Once pressed, the robotic instruments stay in position and a move-

Figure 5
The foot pedals (from left to right) for "clutching", camera control, future applications and diathermy. The middle pedal is for focus control.

ment of the manipulators is followed by a camera action. Another pedal controls the clutch function. This works similar to the camera pedal and allows the surgeon to manipulate the master controls without moving the robotic instruments or camera. Therefore it allows for repositioning of hand and forearms to an ergonomically favourable position. Other foot pedals control diathermy and focus control. Furthermore two basic control panels are integrated in the console. One allows for selection and calibration of the 3D scope, the second for selection of working distance and scaling factor. This last function enables downscaling of motions (2:1, 3:1 and 5:1, e.g. a 3:1 motion scale will move the instrument for 1 cm for every 3 cm of movement of the manipulator).

The surgical arm cart

Figure 6

The robotic arms stretched over a patient's head. The surgeon console is visible in the background.

The surgical cart (Figure 6-8) is placed at the operating table in respect to the patient's anatomy. It carries the three robotic arms. Two of these arms are for instruments and are connected to specially designed robotic trocars (Fig. 9). These trocars are introduced in the patient's body, with a marked pivot point at the level of the body cavity's wall. The arms move the instruments according to the degrees of freedom of standard laparoscopy and furthermore they control a cable driven mechanical wrist at the tip of the instruments. This wrist provides the surgeon with two addi-

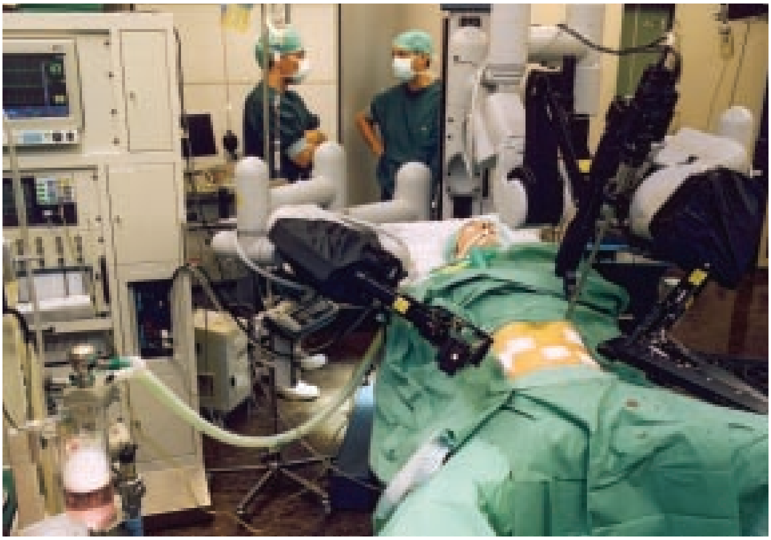

Figure 7

The three robotic arms: the camera arm in the middle and the two instrument arms at both sides.

Figure 8

Rear view of the robotic cart during Nissen fundoplication. the cart is placed over the patient's head.

tional degrees of freedom of motion compared to standard laparoscopic instruments (Figure 10). The human tremor is not transposed to the instruments but eradicated by a 6 Hz motion filter inside the console. The remaining, middle arm carries the endoscope. This arm is connected to a standard 12-mm trocar.

Figure 9

Robotic instrument trocar (diameter 8 mm).

Figure 10

The da Vinci instruments provide two additional degrees of freedom at the tip of the instrument.

The Vision Cart

This cart (Figure 11) holds all standard accessories for laparoscopy, including an insufflator, light sources, focus control, synchronisers and camera controls. Most important it holds a monitor for the tableside surgeon (Figure. 12). Therefore it is placed in line with the position of the tableside surgeon and the target area.

Figure 11
The video cart with (from top to bottom): monitor, insufflator, Sonosurg ultrasonic dissection generator (Olympus, Hamburg, Germany), video recorder, light source (2), camera unit (2), focus control and synchroniser (2).

Figure 12
The tableside surgeon and assistant looking at the monitor on the video cart.

Chapter 2

Feasibility of robot-assisted laparoscopic surgery:

an evaluation of 35 robot-assisted laparoscopic cholecystectomies

Abstract

Introduction: Laparoscopic surgery offers patients distinct benefits but is not without its disadvantages to surgeons in terms of manoeuvrability and visualisation. Robotic telemanipulation systems were introduced with the objective of providing a solution to the problems in this field of surgery.

Methods: The feasibility of robot-assisted surgery was assessed by performing 35 laparoscopic cholecystectomies with the da Vinci robotic system. Time necessary for system set-up and operation was recorded, as were complications, technical problems, postoperative hospital stay, morbidity, and mortality.

Results: Thirty-four of 35 cholecystectomy procedures were completed laparoscopically with the da Vinci system. Technical problems occurred in three cases, resulting in one intraoperative complication (a mini-laparotomy caused by the loss of an instrument part). Median hospitalisation was 2 days. There were no postoperative deaths or morbidity within 30 days after surgery. System set-up time decreased as the experience of the operating team increased. Operating times were comparable with those reported for standard laparoscopic cholecystectomy.

Conclusion: Robot-assisted surgery was repeatedly proven as a safe and feasible approach to laparoscopic cholecystectomy.

Ruurda JP, Broeders IAMJ, Simmermacher RKJ, Rinkes IHM, Van Vroonhoven ThJMV.

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Introduction

During the past two decades, laparoscopic surgery has become the treatment of choice for routinely performed surgical interventions in the abdomen, such as cholecystectomy and surgery for gastro-oesophageal reflux disease. The benefits of laparoscopic procedures for the patient, compared with those of open surgery, are clear and well described [1-6].

Although there are clear benefits to the patient, the surgeon faces distinct disadvantages. First, working through fixed abdominal entry points significantly diminishes manoeuvrability. Second, surgeons are handicapped by the loss of visual perception of depth that is intrinsic to working with a two-dimensional visualisation system.

Attempts have been made to solve these disadvantages by developing new surgeon-friendly instrumentation to support laparoscopic surgery. Recently, robotic telemanipulation systems have been introduced with the objective of providing dexterity and a view comparable with those of open surgery [7].

To evaluate the feasibility of robotic surgery, we performed robot-assisted laparoscopic cholecystectomy in 35 patients. As a routinely performed procedure, this operation offered us the opportunity to assess the feasibility of operating with a robotic telemanipulation system under well-controlled circumstances.

Patients and Methods

Between June 2000 and September 2001, robot-assisted laparoscopic cholecystectomy was performed in 35 patients (25 females and 10 males). Selection criteria were identical to those for elective laparoscopic cholecystectomy in our institute. Indications for surgery were biliary colic (29 patients), recent biliary pancreatitis (2 patients), and chronic right upper quadrant pain (4 patients). Ultrasonography confirmed the presence of gallstones in all 35 patients. Median age was 46 years (range, 22–72), median weight was 84 kg (range, 55–143), and median body mass index was 28 (range, 18–45).

The surgical procedure was performed with the assistance of the da Vinci system (Intuitive Surgical, Mountain View, CA, U.S.A.), which consists of a three-armed, table-side robotic cart, carrying the camera system and instruments, and a master console, where the surgeon is seated. Both the articulated robotic instruments and the three-dimensional camera system can be controlled from the console with two manipulators.

Three experienced laparoscopic surgeons (I. B., R. S. and I. B. R.) were trained by a system engineer to perform the laparoscopic cholecystectomies with the da Vinci system. The da Vinci system was positioned over the patient's right shoulder (Figure 1). In every case, one of these surgeons controlled the master console while one of the other surgeons assisted at the operating table. After pneumoperitoneum was established, the camera trocar was introduced at the level of the umbilicus. The right

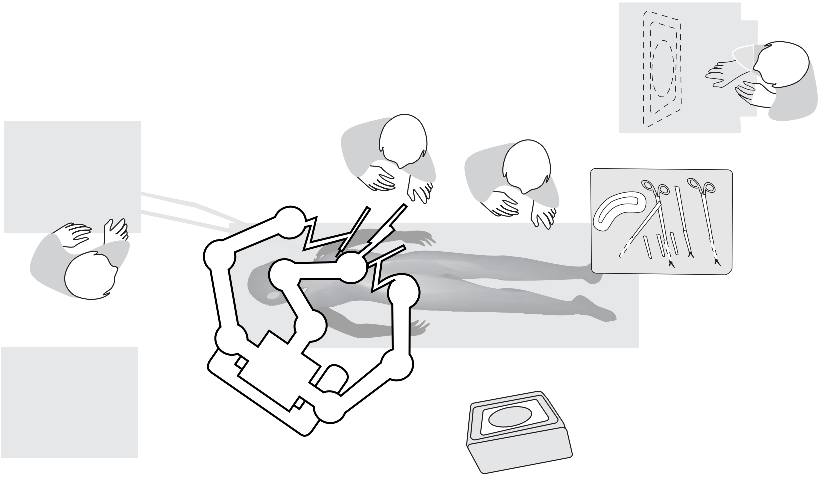

Figure 1

Schematic overview of operating-theatre set-up during robot-assisted laparoscopic cholecystectomy.

robot arm trocar was positioned in the left hypochondrium and the left arm in the right upper inguinal region. An additional trocar for an instrument to retract the gallbladder was placed in the epigastric region. The tableside surgeon assisted in retracting the gallbladder, clipping and changing the instruments. The console surgeon performed the actual cholecystectomy.

Complications and technical problems were noted and evaluated; postoperative hospitalisation, morbidity, and mortality were recorded; and the time necessary for system set-up and total operating room time were recorded.

Results

Acute cholecystitis, diagnosed by the finding of oedema around the gallbladder and attached omentum, was apparent at the time of surgery in 6 of 35 patients (17%). In 6 of 35 cases (17%), findings were chronic cholecystitis with attached omentum, fibrosis in Calot's triangle, and dense adhesions between the gallbladder and the liver bed. In the remaining 23/35 cases (66%), uncomplicated gallstone disease was found.

In 34 of 35 cases (97%), the cholecystectomy was completed laparoscopically with the da Vinci system. There was one conversion to an open procedure, caused by the surgeons' inability to expose the gallbladder sufficiently because of severe cholecystitis.

Mechanical problems occurred in three cases. In these cases the replaceable hook of the electrocautery instrument detached during the procedure. The hook could be removed laparoscopically in two of three cases, but this problem resulted in a 4-cm mini-laparotomy in one case. This was the single robot-related surgical complication.

Median total hospitalisation time was 2 days (range 1–10). Nine of 35 patients (26%) were dismissed on postoperative day 1, 23 of 35 (66%) on postoperative day 2, and 1 (3%) on postoperative day 3. The patient in whom a mini-laparotomy was performed stayed in the hospital for 4 days. The patient requiring conversion was hospitalised for 10 days because of simultaneous herniated nucleus pulposus repair. There were no postoperative deaths or morbidity within 30 days after surgery.

The median time needed to install and drape the robotic system was 15 minutes (range, 12–35). This set-up time decreased as the experience of the operating team increased, resulting in a reproducible time of 15 minutes in the last 25 cases (Figure 2). Median effective surgery time (skin to skin) was 82 minutes (range, 40–180) (Figure 2).

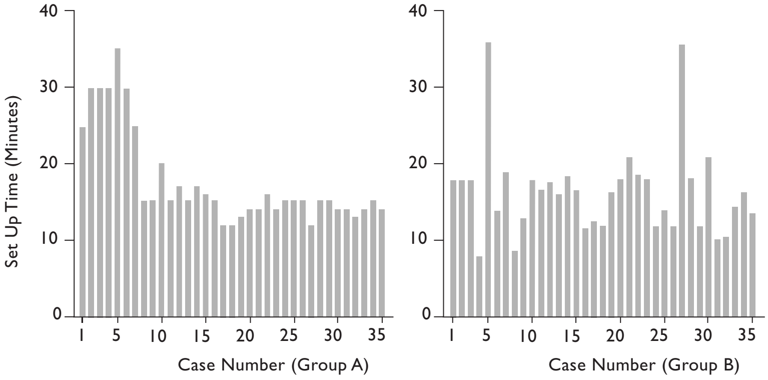

Figure 2

With increasing experience, the time needed for system set-up and draping decreased. Operating time remained constant during the 35 cases performed and was comparable to operating time in standard laparoscopic cholecystectomy.

Discussion

The surgeon's limited dexterity is the principal disadvantage in laparoscopic surgery. Working through fixed entry points limits manoeuvrability of the instruments inside the body cavity to five degrees of freedom (Fig. 3). Moreover, the fixed entry point introduces a momentum in the surgeon's movements, causing reversed instrument action and variability in the angular displacement performed outside the patient's body and the resulting effect inside.

Additional problems in laparoscopic surgery are the loss of the eye–instruments–target axis and the loss of visual perception of depth. With such limitations, laparoscopic surgery has become a skill requiring extensive training, and the technique is known to have a steep learning curve [8].

Computer-assisted instrumentation was developed to overcome the problems of laparoscopic surgery. A start was made with computer-assisted camera guidance systems, such as the robot-assisted AESOP (Computer Motion, Goleta, CA, U.S.A.), TISKA (Karl Storz GmbH and Co., Tuttlingen, Germany), FIPS (Karl Storz GmbH and Co.), and Endoassist (Armstrong Healthcare Ltd., Wycombe, UK) [9-13]. A breakthrough was the development of the concept of robotic telemanipulation systems.

With this concept the surgeon works from a remote master console, controlling a tableside robotic servant. A computer is placed between the surgeon's hands and the end-effectors (the instruments); thus, computer power is used to eliminate the disadvantages of laparoscopic surgery. The da Vinci system eradicates opposite instrument movement and variability in angular displacement, thus allowing the surgeon to perform laparoscopic manipulations while mimicking the natural movements of

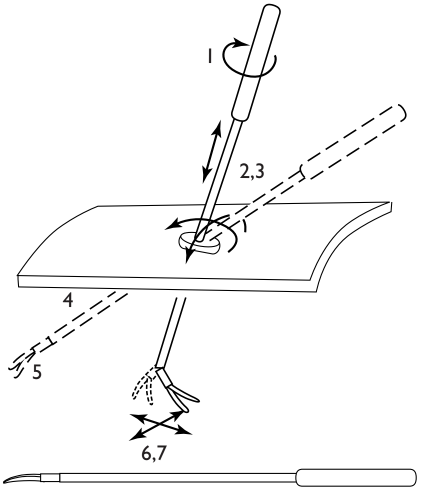

Figure 3

Rotation of the end-effector of the instrument is made possible in two planes around the instrument's tip, adding two degrees of freedom to the surgeon's range of motions (dotted, the five degrees of freedom of classic laparoscopic surgery).

open surgery. The intuitive control of surgical manipulation is enhanced by restoration of the eye–hand– target axis, due to the integration of the visual system and manipulators in the master console. The surgeon's manoeuvrability is vastly enhanced by two joints at the tip of the robotic instruments, offering two additional degrees of freedom, for a total of seven (Fig. 3). Tremors and trocar resistance thus are eradicated. Visual perception of depth is restored by a double optic system, providing separate images for both eyes, resulting in a true three-dimensional image.

Although laparoscopic cholecystectomy is a relatively simple procedure in which surgeons would not benefit most from these advantages, it offered us the opportunity to assess the feasibility of working with this novel technology in a well-known and safe environment. This study repeatedly demonstrated the technical feasibility of robot-assisted laparoscopic cholecystectomy. The number of procedures converted to an open procedure (1/35; 3%) is comparable to conversion rates reported for standard laparoscopic cholecystectomy [14-16]. The mini-laparotomy, resulting from loss of the replaceable hook of the electrocautery instrument, was the single technical complication resulting from use of the system. The reliability of the electrocautery instrument was optimised during this study by the introduction of a modified replaceable hook. Most patients in this study (32/35; 91%) were discharged from the hospital by postoperative day 2. These numbers correspond with those reported for standard laparoscopic cholecystectomy at our institute and in the literature [17,18].

Although set-up is still an issue of concern in relatively short endoscopic procedures, it decreased to 15 minutes in the last 25 cases because of the operating team's increasing experience. Effective surgery time did not contribute to this time decrease, because it was comparable with surgery time in standard laparoscopic cholecystectomy at our facility as well as in the literature [18,19]. The time loss should decrease further with improvements in the ergonomics of the system and the design of dedicated operating theatres, where the robotic systems may be easily integrated. In the near future surgeons will have the choice between the current tableside cart and a robotic servant attached to the ceiling or wall in the operating theatre.

Because the systems currently being used are the first generation of robotic telemanipulators, a number of shortcomings still need to be addressed. The most important is the lack of force feedback. Currently this has to be compensated for by visual feedback. In the reports on laparoscopic cholecystectomies, the lack of force feedback was not described as disturbing, although handling fragile tissue required some experience. For procedures demanding higher technical skills, such as knot tying, this issue becomes more apparent. There is a distinct learning curve for surgeons striving to understand forces applied by the system [20].

Costs of the robotic hardware and the disposable accessories are a considerable factor. A reduction of these costs and of the system size and weight would improve the ability to implement systems in daily practice. The devices must become easier to install to ensure the ideal placement for a procedure and to prevent conflicts with other equipment, such as operating lights and anaesthesia tools. Improved system ergonomics can also contribute to shorter installation times, alleviating pressure on tight operating schedules. In addition, a decrease in instrument and camera size must be achieved to minimise patient trauma. A broader range of instruments is required, with more surgeons in various disciplines working with the system.

Now that the feasibility of robot-assisted surgery in a routinely performed procedure has been evaluated, the use of these systems in more complex procedures will need to be assessed. Already, the use of these systems has shifted to procedures demanding higher manipulative capacities. Recently, there have been case reports on robot-assisted Nissen fundoplication, nephrectomy, adrenalectomy and Heller myotomy [21-23]. Even procedures that require microscopic suturing, such as coronary and tubal bypasses, have been reported [24,25]. In our clinic, the system is currently used for Nissen fundoplication, both abdominal and thoracic oesophageal myotomy, para-oesophageal hernia repair, and adrenalectomy. In our experimental laboratory the feasibility of intestinal anastomosis, biliodigestive bypass surgery, paediatric gastric fundoplication, and aortic reconstructive procedures is being assessed. After demonstration of the feasibility of robotic assistance in a broad spectrum of gastrointestinal surgical interventions, the demand will rise for prospective randomised trials to assess the true value of robot-assisted surgery.

In conclusion, laparoscopic surgery has entered a new era with the introduction of robotic telemanipulation systems. The results of the current study clearly support the feasibility of the use of this system in performing a standard laparoscopic surgical procedure. The value of robot-assisted surgery in other, more complex procedures will have to be assessed in the upcoming years.

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Chapter 3

Analysis of procedure time in robot-assisted surgery:

a comparative study in laparoscopic cholecystectomy

Abstract

Introduction: Robotic surgery systems have been introduced to deal with the basic disadvantages of laparoscopic surgery. However, working with these systems may lead to time loss due to additional robot-specific tasks, such as set-up of equipment and sterile draping of the system. To evaluate loss of time in robot-assisted surgery, we compared 10 robot-assisted cholecystectomies to 10 standard laparoscopic cholecystectomies.

Methods: The robot-assisted procedures were performed with the da Vinci telemanipulation system. The total time in the operating room was scored and divided into preoperative, operative and postoperative phases. These phases were further divided into smaller time-frames to precisely define moments of time-loss.

Results: The most significant difference between the two groups was found in the preoperative phase. Robot-related tasks led to time-loss in all time-frames of this phase. In the operative phase, the trocar entry time-frame was longer in robot-assisted cases than in standard procedures. Additionally, postoperative OR clearance was longer in the robot-assisted cases. Total operating time did not differ significantly between the two procedures.

Conclusion: Robot-assisted surgery leads to time-loss during preparation of routine laparoscopic procedures.

Ruurda JP, Visser PL, Broeders IAMJ. Comp Aid Surg. 2003 Sep; 8(1):24-29.

Introduction

Since their introduction in 1997, over two-hundred telemanipulation systems have found their way into operating rooms on four continents [1-5]. These systems have been developed with the objective to overcome the traditional problems of videoscopic surgery.

Telemanipulation systems, also robotic surgery systems, consist of a remote workplace for the surgeon and a tableside robotic manipulator. The remote workplace holds a computer, which exactly translates the motions of the surgeon to the robot-held instruments. Robot-assisted videoscopic surgery offers distinct advantages compared to standard videoscopic surgery such as restoration of the eye-hand target axis, three-dimensional (3D) imaging and extra degrees of freedom (DoF) of the instruments [1-5]. Surgeons working with these systems collectively recognise their additive value but are also aware of the challenge to translate the subjective gain into a statistically significant improvement in outcome with regard to performance, complications and procedure time in routine and advanced videoscopic surgery.

On the other hand, the disadvantages of working with complex technology are clear from the outset, especially when dealing with first generation systems. In the case of robotic surgery systems, the time needed for specific robot related tasks, such as system set-up and sterile draping, adds to the total burden for the operating time schedule [3,5]. Although time loss during start-up is acceptable in an experimental environment and may be compensated for in challenging procedures, it may be regarded as disadvantageous in routine videoscopic surgery.

Therefore, the aim of this study is to evaluate procedure time of routine robot-assisted videoscopic surgery and to define at what point time-loss occurs, with the objective to reduce time loss to a minimum. For this purpose, 10 robot-assisted laparoscopic cholecystectomies were compared to 10 standard laparoscopic procedures.

Materials and Methods

Patients

Twenty patients undergoing laparoscopic cholecystectomy were included in this study. Ten procedures (Group A) were performed with the da Vinci telemanipulation system (Intuitive Surgical, Mountain View, California). The remaining 10 procedures were standard laparoscopic cholecystectomies (Group B). Selection criteria were identical for both groups. All patients were operated for symptomatic cholelithiasis on an elective basis after cholecystolithiasis was confirmed by ultrasonography. Patients were included in consecutive order, following a visit to our outpatient clinic, and randomly distributed over both groups. Informed consent was obtained in all cases.

In both groups A and B, eight patients were female (80%). The median patient age was 46 years (range 29-72) in Group A, and 54 years (24-87) in Group B. During surgery chronic cholecystitis, defined by attached omentum, fibrosis of the liver hilum and dense adhesions between the gallbladder and the liverbed, was found in five patients (Group A: 4, Group B: 1). Body mass index was similar in both groups (Group A: 26 (18-47), Group B: 25 (22-30). None of the procedures was converted to open surgery.

Surgical technique

All patients were placed in supine position and standard preparation and draping was performed. Pneumoperitoneum was established at 14-mm mercury by Veress needle technique through a sub-umbilical puncture. A 12 mm (Group A) or 10 mm (Group B) camera trocar was introduced at this position, followed by the introduction of an 11 mm trocar in the subxiphoid position in both groups. In Group A, a 7-mm robotic trocar was then introduced in the right midclavicular line just above the umbilicus level and another was introduced in the left hypochondrium. In Group B, 5-mm instrument trocars were placed in both the lower right abdomen and the right subcostal position. An assistant retracted the gallbladder through the xiphoid (Group A) or the subcostal port (Group B).

In Group A, the dissection of the gallbladder was performed using the da Vinci system which consists of a console and a three-armed robotic cart, which is placed at the upper right side of the operating table. The centre of the cart is placed in the axis connecting umbilicus and gallbladder. The surgeon controls the robotic arms from the console, with two controllers. Two robotic arms are attached to the dedicated 7-mm trocars, through which the seven DoF robotic instruments can be inserted. The third, middle arm carries a 3D optical system. This arm is also steered by the console controllers, after pressing a footpad. In Group B the dissection was carried out, using conventional instruments.

Both the cystic duct and artery were clipped, and after completion of the gallbladder dissection, it was removed under direct vision through the subxiphoid port. In both midline ports the fascia was closed with Vicryl 2.0 sutures and the skin of all ports with Ethylon 3.0.

Three experienced surgeons and an assisting crew with an experience of over 15 da Vinci procedures performed all robot-assisted cases, hereby bypassing the initial learning curve of set-up [5]. Five surgical residents, supervised and assisted by a qualified surgeon, performed the standard laparoscopic cholecystectomies. This implies a limitation to the study design. Because the institution is a major surgical training centre, the Group B standard laparoscopic cholecystectomy procedures had to be performed by residents in training, resulting in a potential outcome bias of the intra-operative portion of the analysis. Although data will be provided for all three (pre, intra and post-operative) time periods, valid results will be available only for the pre- and postoperative periods.

Time analysis

Time needed for both the total procedure and the subsequent phases of surgery were compared in both groups (Figure 1). Total time at the operating room (OR) was defined as the time between the entry of the patient at the OR and their departure after surgery.

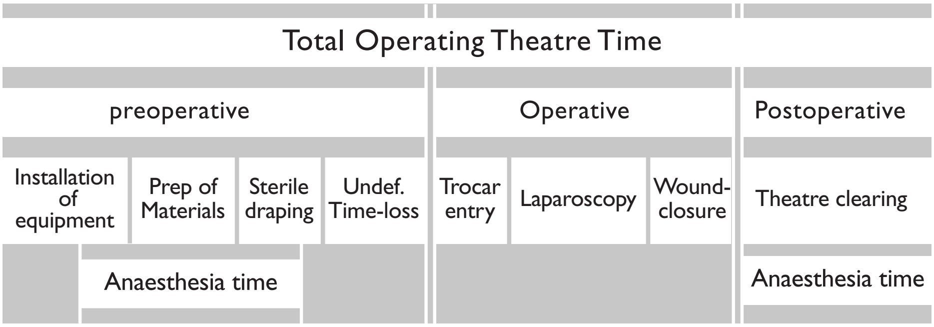

Figure 1

Phases scored within the total OR time, and the smaller time-frames that were measured within these phases.

On occasions when instruments or laparoscopy equipment were prepared or dismantled prior to the patient's entry or after their departure this time was added to the total OR time. The total OR time was divided into three phases: the preoperative phase, the operative phase and the postoperative phase.

The preoperative phase was defined as the time between the entry of the patient in the OR and the time of the first incision. The preoperative phase was divided into three smaller time-frames: the installation of the equipment, preparation of instruments and materials, and the draping of the sterile operative field. In Group A, the installation of equipment comprised placing and connecting the robotic cart, console and video cart, whereas for Group B it only consisted of installing the video cart. The draping of the sterile operative field involved the draping of patient and camera in both groups and the draping of the robotic arms in the case of robot-assisted surgery, which was also scored separately. The preoperative time that could not be attributed to any action related to preparation was scored as "undefined time-loss". Total preoperative anaesthesia time was separately scored, and defined as time between the entry of the patient and the moment of release for surgery.

The operative phase consisted of a trocar entry period, the period of the actual laparoscopic dissection and the wound-closure. The trocar entry phase started at the moment of the first incision and ended with the introduction of the first laparoscopic instrument. During this phase, the pneumoperitoneum was established and the trocars were introduced. In the robot-assisted cases, the trocar entry phase included the time needed for attaching the robotic system to the trocars. This time-frame was also scored separately. The laparoscopic dissection time ended at the moment of gallbladder removal. Wound-closure after trocar removal completed the operative phase. In Group A, it included the de-attachment of the robotic arms from the trocars.

The time between wound-closure and patient departure from the OR was defined as the postoperative phase. Total time needed for OR clearance after surgery was recorded and started after wound-closure and ended at the time that all materials had been properly dismantled and the equipment stored at the dedicated location. In robot-assisted cases, the OR clearance time included the de-installation of robotic equipment, which was also scored separately.

All data were analysed using SPSS 7.5. According the Shapiro-Wilk test, the distribution of all phases and time-frames was non-normal. The Mann-Whitney-U test was applied to determine which phases accounted for any significant difference ($p<0,05$). All data are expressed as median time and (range).

Results

Total OR time for Group A was 144 minutes (111- 234) versus 119 minutes (71-189) for the standard procedures (Table 1). The preoperative phase in Group A was longer than in Group B ($p<0.001$, Table 1).

Table 1 **Total operating room time and the time spent for the different phases of the procedure. Data are expressed in minutes as median and (range).**

Phase	Robot	Conventional	p
Total OR time	144 (111-234)	119 (71-189)	0,131
Preoperative	47 (33-69)	27 (21-38)	<0,001
Operative	82 (59-178)	79 (42-150)	0,650
Postoperative	16 (8-30)	12 (8-22)	0,129

Also, all individual time-frames in the preoperative phase were longer in Group A, except for the time-frame "undefined time-loss" (Table 2).

The operative phases were comparable in both groups, with a median of 82 minutes (59-178) in Group A, and 79 minutes (42-150) in Group B. Trocar placement, including attachment of the robotic arms, was longer in Group A ($p<0,001$, Table 2). The laparoscopic dissection time required 43 minutes (30- 149) in Group A and 64 minutes (28-127) in Group B. Wound-closure time, including de-attachment of the robotic arms, was found to be 11 (8-21) minutes in the robot-assisted cases and 9 minutes (3-15) in Group B.

The postoperative phase in robotic cases averaged 16 minutes (8-30), including extra time for equipment clearance after departure of the patient. OR clearance took a median of 14 (8-20) minutes including the de-installation of the robotic equipment, with a median time of 10 minutes (4-14). In Group A, the anaesthesia time was longer than OR clearance time in two cases, thereby determining the end of the postoperative phase. Median postoperative anaesthesia time was 11 minutes (3-30). In standard laparoscopic cholecystectomy, the postoperative phase comprised 12 minutes (8-22), being identical to the postoperative anaesthesia time in all cases (Table 2). OR clearance was shorter in Group B compared to the robot-assisted cases (p=0,041).

Table 2 **The time spent for the subsequent time-frames during the different phases of the surgical procedure. Data are expressed in minutes as median and (range).**

Time-frame	Robot	Conventional	p
Set-up of equipment	7 (6-11)	2 (2-5)	<0,001
Preparation of materials	18 (15-22)	11(8-23)	0,003
Sterile draping	9 (4-11)	3 (2-6)	<0,001
Robot draping	6 (4-8)		
Non-specified time-loss	12 (4-36)	7 (2-18)	NS
Preoperative anaesthesia	19 (13-40)	18 (14-27)	NS
Trocar entry	20 (13-31)	10 (7-16)	<0,001
Robotic arm attachment	4 (2-8)		
Dissection	43 (30-149)	64 (28-127)	NS
Wound-closure	11 (8-21)	9 (3-15)	NS
Robotic arm detachment	1 (1-4)		
OR clearance	14 (8-20)	9 (3-20)	0,041
De-installation robotic equipment	9 (3-10)		
Postoperative anaesthesia	11 (3-30)	12 (8-22)	NS

Discussion

Although median scores differed 25 minutes, total OR time was not significantly longer in robot-assisted laparoscopic cholecystectomy than in standard procedures (p=0,131). In both the operative and postoperative phase there was no significant difference between both groups. This may be due to the relative small sample size. On the other hand, the preoperative phase of the robotic procedure appeared to be significantly longer than in standard procedures. All separate time-frames of the preoperative phase attributed to this difference.

The time-loss during installation of equipment can be explained by the need to set-up the robotic cart, console and video cart for each procedure, as compared to the set-up of just the video cart in standard procedures. Time-loss during preparation can be explained by the need for additional materials required for the robotic system. As well as the standard laparoscopic set, two sets of robotic instruments, including sterile adapters and trocars, must be prepared. Obviously, sterile draping took longer, because the three robotic arms of the chart require draping with dedicated covers. The excess undefined time-loss may be explained by the novelty of the system, which still tends to create an 'academic' atmosphere and brings spectators that may attribute to time loss by starting procedure related discussions. The preoperative phase exceeded the median time needed for anaesthesia by 19 minutes in robot-assisted cases, as compared to only 9 minutes in standard procedures.

In the operative phase, the trocar entry time-frame was significantly longer in the robotic group, but this was only partly caused by the time needed to attach the robotic arms to the trocars. An adjuvant reason for the longer introduction phase might be the time needed for the calibration of the 3D-camera system. The median laparoscopic dissection period time was 21 minutes shorter in robotic cases. This could be explained by the improvement of the surgeon's manoeuvrability, offering a smooth dissection, but the results are biased by the relatively small groups and the difference in skill level between experienced surgeons and residents [6-8]. Therefore no conclusions can be drawn regarding any difference in the dissection time in this study. The de-attachment of the robot from the trocars did not cause a difference in wound-closure time.

In the postoperative phase, the median time of robot-assisted cases did not significantly exceed that of standard cases. The time needed for clearance of the OR was longer in the robot-assisted cases (14 compared to 9 minutes), and was longer than anaesthesia time in 8/10 cases in Group A. The de-installation of the robotic equipment, comprising the disconnection of the various components and storage of the system accounted for a major part in this phase, with a median duration of 9 minutes. In Group B anaesthesia time was longer than OR clearance in all cases, which explains the comparable outcome of postoperative time in both groups.

These data clearly demonstrate that the use of a currently state of the art robotic system causes time-loss in the current OR set-up, mainly in the preoperative phase of the surgical procedure. Though one might accept time-loss in complex laparoscopic surgery, where the advantages of robotic telemanipulators are obvious, this can not be accepted in a routine procedure, where the benefits of robot-assisted surgery are not yet clear. This implies that distinct measures must be taken to limit time-loss while performing robot-assisted surgery.

The most obvious solution to deal with time-loss during interventions using high-tech equipment is to design technology-dedicated workplaces. Clearly, the current concept of using similar OR's with a broadly educated but non-dedicated surgical support team can no longer support the operation of complex surgical devices in an efficient manner. In the case of robot-assisted surgery, one should strive for a spacious videoscopic surgery suite with a permanent robotic equipment set-up. The preoperative installation of the apparatus could thereby be eliminated as well as the postoperative time needed for removal and storage of equipment. In our study, this would have shortened the preoperative phase by approximately 7 minutes and the OR-clearance phase by approximately 9 minutes, making it shorter than time needed by the anaesthesia team to prepare the patient for surgery and wake him afterwards.

Another option to limit time-loss in the preoperative phase is the efficient use of the interval between two surgical procedures. Set-up and sterile draping of the robotic system can be performed during this period and a start can be made on the preparation of instruments. This places a demand on the team with regard to efficiency and dedication, but a serious reduction of OR time will thereby be effected.

Finally, further development of the robotic systems is required to diminish pre- and postoperative time needed for preparation and clearance of robotic equipment. The time-consuming draping of the robotic arms and the preparation of the materials will be simplified in next generation devices by improving the ergonomics of drape and trocar connectors, offering space for another 11 minutes of time-reduction (Table 2.).

In conclusion, robot-assisted surgery with a first generation device led to time-loss in routine laparoscopic surgery in a standard OR. In this study, the moment and amount of time-loss were registered to identify areas requiring improvement to increase efficacy of these promising surgical tools. Time loss may be greatly reduced by the use of dedicated surgical workplaces, further development of the robotic systems and by optimising time management by the surgical team.

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Chapter 4

Early experience in robot-assisted laparoscopic Heller myotomy

Abstract

Introduction:	Heller myotomy for achalasia is routinely performed laparoscopically. This offers patients significant benefits compared to open surgery. Surgeons, however, are limited in their manipulation and visualisation during laparoscopic interventions. Robotic telemanipulation systems were introduced with the objective to alleviate these limitations. The purpose of this study was to demonstrate the efficacy and safety of performing a Heller myotomy with the use of a robotic telemanipulation system.
Methods:	Fourteen patients were operated with the da Vinci robot system. Robotic system set-up time, per- and postoperative complications, blood loss, operating time and hospital stay were recorded. Follow-up included manometry and symptom score.
Results:	The robotic system set-up time was 15 minutes (10-15). Thirteen procedures (13/14: 93 %) were completed by laparoscopic surgery, one was converted for reason of inadequate exposure. One peroperative mucosal perforation was closed laparoscopically. The median blood loss was 10 ml (10-200). Median operating time was 90 minutes (75-150). Hospitalisation ranged from 2 to 8 days (median 3). No complications occurred in a 30 days postoperative period. Dysphagia was relieved in 12/14 patients (86%). Heartburn was present postoperatively in 2/14 patients (14%). Manometry showed a significant decrease in median lower oesophageal sphincter (LOS) pressure from 2,9 preoperatively to 1 kPa postoperatively (p=0,008).
Conclusion:	Robot-assisted laparoscopic Heller myotomy was demonstrated to be safe and effective in reducing basal LOS pressure and dysphagia. The results of this study clearly support the feasibility of the use of this system in performing a delicate laparoscopic surgical procedure. The use of a robotic system was experienced as highly supportive in manipulation and visualisation by the surgical team involved.

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Introduction

Surgical treatment of achalasia consists of a myotomy of the longitudinal and circular musculature of the lower oesophageal sphincter as described by Heller [1]. This procedure was traditionally performed through a laparotomy. A laparoscopic approach was introduced by Shimi in 1991 [2]. This minimally invasive intervention leads to a reduction in the operative trauma which results in potential benefits for the patient such as diminished hospitalisation, reduced postoperative pain, faster convalescence and cosmetic advantages [3,4].

However, laparoscopic surgery imposes technical challenges on the surgeon. These challenges mainly concern a limitation of both visualisation and manipulation. Robot-assisted laparoscopic surgery [5-7] puts the minimally invasive treatment in a new perspective by dealing with these technical challenges.

The purpose of this study was to demonstrate the efficacy and safety of the robot-assisted Heller myotomy and to document the short-term effectiveness, both by clinical and functional outcome parameters.

Patients and Methods

Fourteen patients (10 females, 4 males, median body mass index 24 (18-31), median age 39 (18-73)) were operated on an elective basis between June 2001 and April 2003. The diagnosis ‘achalasia’ was confirmed on the combination of symptoms and oesophageal manometry. Subjective severity and frequency of dysphagia were scored on a scale from 1 to 5 (Table 1). This was also performed for heartburn to evaluate the postoperative presence of gastro-oesophageal reflux. A water-perfused silicone catheter containing 8 sideholes and an incorporated sleeve sensor (Dentsleeve, Bel Air, Australia) was used for manometry. In all patients manometry showed an incomplete to absent lower oesophageal sphincter (LOS) relaxation and simultaneous oesophageal contractions. Gastro-oesophageal reflux disease was excluded in all cases by 24-hour pH-metry.

In all patients balloon dilatation was attempted prior to surgery. In two patients, initial treatment was with circular botulinum toxin injections. This offered no or only short-lasting patient satisfaction (<3 months). In one patient previous treatment consisted of a long thoracoscopic myotomy for the diagnosis of diffuse oesophageal spasm. After absence of symptom relief, manometry was repeated and showed a LOS-resting pressure of 3 kPa without relaxation after wet swallowing. Prior manometry did not demonstrate these findings. In retrospect, this patient most probably suffered from vigorous achalasia.

All patients were operated upon with the da Vinci robotic telemanipulation system (Intuitive Surgical, Sunnyvale, Ca, USA). Patients were positioned in a supine, reversed Trendelenburg (20-30°) position with the assisting surgeon standing between the patient’s legs. A 12-mm camera trocar was introduced under direct sight in the midline, halfway between the xiphoid and umbilicus. Two 8-mm trocars with special adapters for the robotic system were introduced in the left and right subcostal space. Additional trocars were introduced in the right flank (12 mm) and left lower abdomen (11 mm) to host a liver retractor and an assisting instrument respectively (Figure 1).

Figure 1
Trocar placement for robot-assisted Heller myotomy.

After introduction of a 30-degree scope, facing down, a liver retractor was introduced. The gastro-oesophageal junction was exposed and an anterior myotomy was performed. The circular and longitudinal muscle fibres of the LOS and the first two centimetres of the gastric cardia were divided using electrocautery.

Robotic system set-up time, per- and postoperative complications, blood loss, operating time (first incision-wound closure) and hospital stay were recorded. Follow-up included a quantitative symptom index score for severity and incidence of dysphagia and heartburn and a standard oesophageal manometry. Data were analysed using SPSS and are expressed as medians and range. The decrease in LOS amplitude and decrease in symptom score after the procedure were analysed with a Wilcoxon signed ranks test.

Results

The time required for preparation of the robotic equipment was 15 minutes (10-15). Thirteen procedures (13/14: 93 %) were completed by laparoscopic surgery. In one patient, the laparoscopic procedure was converted to an "open" approach due to an inadequate exposure of the distal oesophagus. One intraoperative mucosal perforation could be closed laparoscopically. The median blood loss was 10 ml (10-200). Median operating time was 90 minutes (75-150, Figure 2).

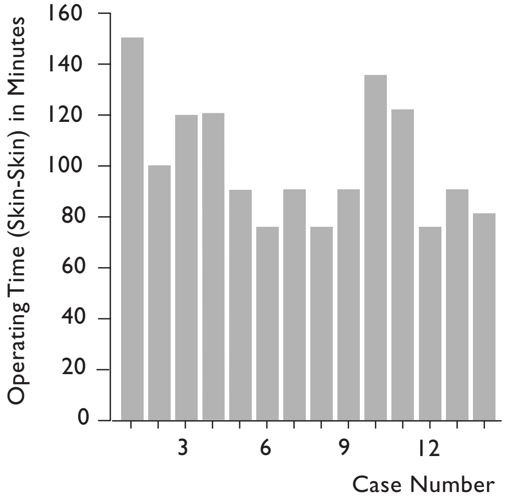

Figure 2
Operating times (minutes) for robot-assisted Heller myotomy.

Hospital stay ranged from 2 to 8 days (median 3). No complications occurred postoperatively and during 30-days follow-up.

Follow-up ranged from 2 to 24 months (median 11). All but two patients showed a decrease by two or more points of incidence and severity of both heartburn and dysphagia (Table 1). The patient with vigorous achalasia was one of the two patients (2/14) with absence of dysphagia relief. A barium oesophagogram revealed kinking of the distal oesophagus. Re-operation included an extensive re-myotomy, gastropexy and an anterior fundoplication. The patient was symptom free since this second operation, though the two-month follow-up was short. The other patient with persisting dysphagia was operated recently (< 3 months ago). Currently, she also reports severe heartburn and was diagnosed with a reflux oesophagitis at endoscopy, which was treated with a proton pump inhibitor. One more patient reports an increase of heartburn postoperatively (total 2/14: 14 %). In this patient, pathological gastro-oesophageal reflux (16 % of total time) was diagnosed at 24-hour pH-metry, necessitating an additional Dor fundoplication. Hereafter her complaints resolved. Manometry showed a significant decrease in LOS-pressure from 2,9 to 1 kPa (p=0,008) in all.

Table 1 **An incidence score of 1 represented absence of symptoms, a score of 2 for less than once a month, 3 for less than once a week, 4 for less than once a day and 5 for more than once a day. Severity score 1 represented absence of the symptom, 2 represented mild symptoms, 3 considerable symptoms, 4 severe symptoms and 5 represented very severe symptoms.**

	Pre-op	**Post-op**	**p**
Heartburn frequency	4 (1-5)	1.5 (1-4)	0,06
Heartburn severity	4 (1-5)	2 (1-4)	0,05
Dysphagia frequency	5 (5)	2,5 (1-5)	0,007
Dysphagia severity	5 (5)	2 (1-5)	0,01
LOS-pressure (kPa)	2,9	1	0,008

Discussion

Treatment of achalasia aims at symptomatic relief through lowering the LOS-pressure. Since a medical treatment offers little improvement of symptoms [8,9], this is either performed through an endoscopic or a surgical approach. Two endoscopic approaches exist: intrasphincteric injection of botulinum toxin and dilatation of the LOS. Considering the botulinum toxin treatment, initial success rates of over 80 % are reported, but long-term efficacy is established in fewer than 40 % of patients [10-14]. This results in repeated injections. Endoscopic dilatation of the LOS offers excellent short-term results and initial relief of symptoms in up to 90% of patients, but on long-term, efficacy decreases to 70% or less [14].

The surgical treatment of choice is a Heller myotomy and offers better long-term results. Symptom relief is established in over 90% of patients for over 5 years of time [15,16]. The discussion on the access, thoracotomy or laparotomy, has been renewed by the introduction of a minimally invasive laparoscopic approach [2]. Laparoscopic surgery reduces the operative trauma, resulting in distinct advantages for patients. The treatment of achalasia through a laparoscopic approach has been demonstrated to be equally effective as an open operation [3,4,17,18].

However, in laparoscopy surgeons have to deal with some disadvantages compared to conventional "open" surgery. The first disadvantage relates to visualisation. Working through trocars sets a limit to direct visualisation. The image of the operative field therefore needs to be provided by a camera and to be projected on a tv-screen. Not only does this method of imaging provide a two-dimensional image, which inhibits perception of depth, the projection on a screen also interrupts the natural eye-hand-target working axis. A second disadvantage concerns manipulative capacities. Working with long instruments through fixed entrypoints in the abdominal wall limits the degrees of freedom of motion. Other issues concerning manipulation are problems with opposite instrument and hand action, scaling of motions and friction on the instruments, caused by valves inside the trocars.

In 1997 telemanipulation systems -also called surgical robotic systems- were first used in gastro-intestinal surgery [19]. The introduction of these systems aimed at providing a solution towards the difficulties in laparoscopic surgery mentioned. Currently, two robotic telemanipulation systems have EU- and FDA clearance for usage in digestive surgery. The first was the da Vinci system, followed by the Zeus system (Computer Motion, Goleta, Ca, USA).

In the system we used (da Vinci) the surgeon is seated at a console. From this console he conducts three robotic arms, placed on a cart. These arms carry the surgical instruments and the camera and exactly copy the surgeon's movements. Working with this system, the perception of depth (by a 3D-camera system) and the natural eye-hand-target axis are restored. Manipulation is improved by articulations of the tip of the robotic surgical instruments. Next to this, opposite movement of instruments and hands, tremors and friction of the trocar-valves are eradicated. The option to have motions scaled further contributes to manipulative capacities [5,20,21].

For robot-assisted laparoscopic Heller myotomy, literature remains limited to case reports [22-25]. This was also demonstrated in our cases. The assistance of the robotic system was experienced as very helpful for this specific procedure. Not only does the 3D vision support proper imaging of the circular muscle fibres, the articulated instruments also enable working in a parallel line with the oesophagus, approaching the circular muscle fibres perpendicularly. The minuscule movements needed to safely dissect the musculature while keeping the mucosa intact could be performed with ease and precision. The option to scale down the movements performed by the robotic instruments further contributes to working with the scrutiny needed to complete this procedure. In our experience and current perception, the benefits of the robotic system return the surgical precision of open surgery to the operating surgeon, while maintaining the benefits of minimally invasive surgery for the patient.

The single intraoperative complication we encountered, a mucosal perforation, could not be attributed to the use of the robotic system. In this case, the myotomy was extended distally on the stomach, according to peroperative manometry. At the most distal part, the mucosa was perforated.

However, lack of force feedback might attribute to mucosal perforations in inexperienced hands. The surgeon receives no force feedback in the manipulators and therefore no tactile information of forces that are applied. The 3D visual clues compensate this problem for a great deal, but in our opinion, force feedback remains an essential for future generations of these advanced surgical support devices.

The robotic system set-up time of 15 minutes was not experienced as disturbing. In most cases this time could be incorporated in the time needed by the anaesthesia-team for patient preparation.

The postoperative presence of dysphagia (2/14 patients) in one patient was attributed to the presence of a kink in the aperistaltic oesophagus following the long myotomy. In retrospect, this patient should not just have had a laparoscopic Heller myotomy, but rather the extensive myotomy, gastropexy and anterior fundoplication, which she finally underwent, in the same session. After this course of action, dysphagia improved substantially although follow-up is still limited (2 months).

In the other patient, we attribute the dysphagia to the postoperative presence of gastro-oesophageal reflux. The subjective symptom of dysphagia could not be related to persis-tent absence of LOS-relaxation in any of our patients.

The number of two of 14 operated patients experiencing symptoms of gastro-oesophageal reflux postoperatively was comparable to the number mentioned in a recent meta-analysis for Heller myotomies without additional anti-reflux procedure [26].

In conclusion, robot-assisted laparoscopic Heller myotomy was repeatedly demonstrated to be safe and effective in terms of decreasing LOS-pressure and early relief of symptoms. The results of this study clearly support the feasibility of the use of this system in performing a delicate laparoscopic surgical procedure. The use of a robotic system was experienced as highly supportive in manipulation and visualisation by the surgical team involved.

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Chapter 5

Three years experience in robot-assisted endoscopic surgery

Abstract

Background: Robotic telemanipulation systems were introduced recently with the objective to overcome the challenges in manipulation and visualisation during laparoscopic surgery. In order to assess the safety, efficacy, pitfalls and challenges of using these robotic systems in gastrointestinal surgery, robot-assistance was evaluated in 119 minimal invasive digestive procedures.

Methods: Between July 2000 and July 2003, 40 laparoscopic cholecystectomies (LC), 29 Nissen fundoplications (NF), 17 para-oesophageal hernia repairs (POHR), 17 Heller myotomies (HM), 8 long oesophageal myotomies (LM), a leiomyoma resection (LR), 5 ileocecal resections (IR) and two sigmoid colostomies (SC) were performed. All procedures were performed with the da Vinci system.

Results: Robotic system set-up time mediated 14 minutes (12-35). Operating time for different procedures was 82 (LC), 120 (NF), 135 (POHR), 90 (HM), 130 (LM), 150 (LR), 95 (IR), 75 (SC). A total of 7 conversions occurred: four for inadequate exposition (LC, NF, LM and HM), two for mucosal perforations (HM), and one for the need of an additional Collis procedure (POHR). Additionally, one mucosal perforation could be managed laparoscopically. Two more intra-operative complications occurred: a mucosal perforation (HM) and a laceration of the left superior epigastric artery. Blood loss mediated: 10 (LC), 10 (NF), 50 (POHR), 10 (HM), 125 (LM), 100 (LR), 75 (IR) and.5 (SC). Equipment related problems appeared in three cases (LC). In these cases the replaceable hook of the electrocautery instrument detached during the procedure and was subsequently removed from the abdomen. Hospitalisation mediated 2 (LC), 3 (NF), 3 (HM), 5 (POHR), 6 (LM), 6 (LR), 6 (IR) and 6 (SC) days. Four postoperative complications occurred: sepsis due to a subphrenic abscess (NF), wound abscess (CP), delayed gastric emptying due to a laceration of the vagus nerve (POHR) and a recurrent hernia (POHR).

Conclusion: The efficacy and safety of robot-assisted laparoscopic surgery were demonstrated in these cases. The surgical team involved was impressed by the capacities of the robotic system, however stresses the need for objective data demonstrating the improvement in quality of care using these tools.

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Submitted for publication.

Introduction

Endoscopic surgery of the gastrointestinal tract has risen considerably since the introduction of laparoscopic cholecystectomy in 1985 [1]. Proof of the advantages for patients is inconsistent, but include shorter hospitalisation, reduced postoperative pain, faster rehabilitation, fewer complications and better cosmetic results [2-9]. The surgeon, however, is confronted with obvious disadvantages. The technical challenges of minimal invasive surgery comprise not only a limitation in manipulation of the rigid laparoscopic instruments as compared to "open" surgery, but also the visual handicap of working with a two-dimensional image of the operative field and loss of the natural working axis [10-12]. These disadvantages hinder surgeons performing complex surgical manoeuvres during endoscopic surgery, such as challenging dissections and suturing. Although many surgical procedures of the digestive tract have been performed laparoscopically, elaborate interventions, such as oesophagus resections and biliodigestive reconstructions, require extensive training and therefore remain in the hands of a small number of experts [13-15].

Robotic systems have been pursued as a solution to these limitations [16-18]. The concept of the systems has been described in detail recently in this journal [19,20].

In July 2000, we started assessing robotic assistance in endoscopic digestive surgery. This paper describes our initial experience in 119 consecutive cases, focussing on feasibility and possible advantages, but also on the pitfalls and challenges of using robotic systems in endoscopic surgery.

Equipment and Methods

Between July 2000 and June 2003 119 patients were operated on with the da Vinci robotic telemanipulation system (Intuitive Surgical, Sunnyvale, Ca).

This system consists of a console and a three-armed cart positioned at the operating table. The surgeon is seated at the console and controls the movement of his instruments by two manipulators. Robotic arms carry the instruments and the camera. A double camera system provides separate images for both eyes. These images are projected on two monitors, integrated in the console. This restores depth perception by creating a true 3D image of the operative field. The image is projected in line with the surgeon's eyes, hands and instruments, enabling a natural working axis. The fact that a robotic arm holds the camera eliminates camera-tremor and returns vision-control to the hands of the surgeon.

Articulations of the tip of the robotic surgical instruments provide additional degrees of freedom of motion as compared to standard laparoscopic surgery. In addition, opposite movement of instruments and hands, tremors and friction of the trocar-valves are eradicated. The option to have motions scaled may contribute to manipulative capacities during delicate tasks.

A minimum of three trocars was used in all procedures: a 12 mm trocar to host the camera and two 8 mm trocars for the robotic instruments. The camera and robotic instrument trocars were positioned in a triangular fashion, similar to the basic ergonomic concepts of standard endoscopic surgery. After placing the trocars, the robot was positioned and connected to the trocars. The operating surgeon left the sterile field at this point of time in order to operate from the console. Communication between the operating surgeon and his assistant at the operating table was established via wireless communication headsets.

The procedures performed and patient characteristics are depicted in table 1. For all procedures we assessed ideal placement of the robotic cart, trocar positioning, operating time (skin-skin), blood loss, intra-operative complications, equipment related problems, hospitalisation and post-operative complications. All values are expressed as median and range. For the total number of procedures, the robotic system set-up time was assessed and is expressed as mean and range.

Results

The mean time needed to set up the robotic system was 14 minutes (12-35). A steep learning curve was experienced in the first 10 cases, after which the set-up time never exceeded 15 minutes. Operating times, blood loss and hospitalisation are presented in tables 1 and 2.

Table 1 **Number and type of endoscopic procedure, diagnosis and method of establishing diagnosis.**

Procedure	No.	Sex	Age	BMI	OR-time
Cholecystectomy	40	F:27 M:13	45 (22-72)	28 (18-45)	82 (40-180)
Nissen fundoplication	29	F:11 M:18	45 (27-65)	26 (19-35)	120 (90-180)
Para-oesophageal hernia repair	17	F:12 M:5	64 (36-81)	27 (24-42)	135 (85-210)
Heller myotomy	17	F:10 M:7	41 (18-73)	24 (18-31)	90 (75-150)
Long oesophageal myotomy	8	F:7 M:1	56 (39-75)	27.5 (22-35)	130 (95-180)
Leiomyoma resection	1	F:1	33	21	150
Ileocecal resection	5	F:3 M:2	26 (18-52)	25 (18-26)	95 (70-120)
Sigmoid colostomy	2	F:1 M:1	70 (69-71)	22 (20-24)	75 (60-90)
Total	119	F:72 M:47	46 (18-81)	26 (18-45)	

In one case, the robotic system needed to be restarted. This was caused by a rude instrument disconnection resulting in a mismatch in the robot's positioning sensors. In a separate case (long oesophageal myotomy), the patient needed to be repositioned in order to obtain adequate exposure of the oesophagus. Therefore, the robotic system was replaced and reconnected. In two other cases (Nissen fundoplications), inadequate placement of the left robotic arm trocar led to collisions between the arm and the camera arm. After repositioning the trocar approximately 3 cm further laterally, the procedure could be continued.

Seven procedures were converted to open surgery (7/119, 6%). Four of these were due to inadequate exposure: one cholecystectomy was converted due to impaired gallbladder mobility in chronic cholecystitis, one Nissen fundoplication and one Heller myotomy for hepatomegaly in obese patients and a long myotomy in a patient with pulmonary adhesions due to previous lung biopsies. Two conversions occurred during the second and third Heller myotomy for mucosal perforations, which could not be managed laparoscopically. The final conversion was necessary for an additional Collis procedure in a Nissen fundoplication.

Table 2 **Operating time (skin-to-skin), blood loss, conversions and hospitalisation for each procedure.**

Procedure	Blood loss	Conversions	Intraoperative Complications	Postoperative Complications	Length of Stay
Cholecystectomy	10 (0-300)	1	1	0	2 (1-10)
Nissen fundoplication	10 (0-500)	2	0	1	3 (2-10)
Para-oesophageal hernia repair	50 (0-200)	0	0	2	4 (2-10)
Heller myotomy	10 (0-500)	3	3	0	3 (2-8)
Long oesophageal myotomy	125 (10-800)	1	0	0	6 (3-12)
Leiomyoma resection	100	0	0	0	6
Ileocecal resection	75 (10-200)	0	0	0	6 (5-7)
Sigmoid colostomy	5 (0-10)	0	0	0	6 (5-7)

Two additional intra-operative complications occurred: a mucosal perforation in a Heller myotomy, which was closed laparoscopically, and a laceration of the left superior epigastric artery at trocar introduction in a laparoscopic cholecystectomy, which was ligated.

Equipment related problems appeared in three cases, where the replaceable hook of the electrocautery instrument detached during the procedure. The hook could be removed laparoscopically in two patients, but resulted in a 4-cm mini-laparotomy in one.

Four postoperative complications occurred during 30-day follow-up: sepsis due to a subphrenic abscess after Nissen fundoplication and a wound infection 5 days following ileocecal resection; both required drainage.

Following para-oesophageal hernia repair, one patient was diagnosed with a delayed gastric emptying, possibly due to an iatrogenic laceration of the posterior vagus nerve. This was treated with pro-kinetic drugs.

Another patient was re-operated on the third postoperative day for a recurrent para-oesophageal hernia due to a dehiscence of the hiatoplasty. At re-operation, the knot was intact, but the suture had eroded through the muscle.

Discussion

Worldwide, over 12,000 procedures have been performed with robotic assistance (>90 % performed with the da Vinci system). Approximately 4,000 of these were surgeries on the digestive tract (Intuitive Surgical and Computer Motion, pers. Comm. mid 2003). The initial reports in literature were on cholecystectomy [16,21-25], followed by reports on Heller myotomy, Nissen fundoplication, oesophagus and stomach resection and Whipple procedures [21,26-33].

When starting to work with robotic systems, we considered laparoscopic cholecystectomy the ideal intervention to safely learn to work with robotics and to understand the essential differences with standard endoscopic surgery [17]. Working from the console was experienced to be most intuitive. For an experienced endoscopic surgeon (>250 cases) it was feasible to perform a laparoscopic cholecystectomy with a prepared and connected system after less than one hour of in vitro training. Our learning curve was merely related to ergonomic issues of the robotic cart and to the process of interaction between the console surgeon and the team at the operating table.

During the cholecystectomies, no objective benefit from robotic assistance could be demonstrated, but there might be a role in more complex procedures, for example in severe cholecystitis and cases requiring bile duct exploration or biliodigestive reconstructions. For standard endoscopic cholecystectomy, the operating times and conversion rate were comparable to those mentioned in literature [34,35]. Combined with the additional costs involved, these findings do not justify routine use of this robotic system for laparoscopic cholecystectomy.

In our opinion robotic telemanipulation systems will add significant benefit to procedures requiring more delicate manoeuvring in a small, defined space. For instance, during the precise manipulation in Heller and long oesophageal myotomy, 3D vision supported proper imaging of the circular muscle fibres. Furthermore, the articulated instruments enabled working in a parallel line with the oesophagus, approaching the circular muscle fibres perpendicularly and without tremor, providing the dexterity needed for delicate dissection of the circular musculature. For para-oesophageal hernia repair we found dissection of the top of the hernia-sac much easier with the articulated instruments compared to standard laparoscopy and for Nissen fundoplication we experienced the dissection behind the oesophagus and suturing the crus to be easier than with standard instrumentation.

In vitro studies and animal experiments show more precise performance and faster learning of suturing and knot-tying tasks [36]. In our animal laboratory experience, we have also been able to demonstrate a benefit of robotic assistance for aortic interposition grafts and intestinal anastomosis [37-41]. For the clinical situation, two comparative studies on robot-assisted vs. standard laparoscopic Nissen fundoplication have already been published [26,42]. Both report on the safety and efficacy of the procedure with no complications, however no benefits from robotic assistance (with longer operating times and similar clinical outcomes) were found.

Some important ergonomic issues encountered during these 120 cases need to be addressed. The set-up of the robotic system is one of these. First, the place of the robotic cart in respect to the patient's anatomy needed to be defined. In general, the ideal position for the cart is at the far end of a line through the position of the camera trocar and the target area (Figure 1.). For example in a laparoscopic cholecystectomy, the cart was placed over the patient's right shoulder in line with the camera at the umbilicus and the hepatic hilum.

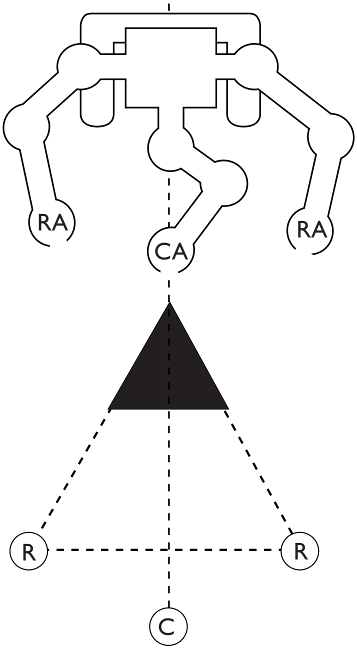

Figure 1

Schematic drawing of the placement of the trocars and the robotic cart in respect to the patient's anatomy: The grey triangle depicts the surgical target area. RA: robotic instrument arm, CA: Camera arm, R: robotic instrument trocar, C: Camera trocar.

Next, the components of the system needed to be connected and the cart needed to be draped sterilely. An additional set-up time of 10-15 minutes was required for these actions, as was prospectively demonstrated in our comparative study on procedure time in robot-assisted- and standard laparoscopic cholecystectomy [43]. This time-loss is only acceptable in a developmental phase of robotic surgery. Working in dedicated operating theatres with a permanent set-up of robotic equipment and a devoted team has reduced the time needed for robotic system draping in between procedures to seven minutes. This allows for a straightforward integration in routine clinical practice and has enabled us to perform the last five of our cholecystectomies on a single day, between 8 am and 4.30 pm, using a standardised operating theatre set-up.

Furthermore, alteration of the ideal trocar positions results in a limitation of the range of motion, as the robotic arms will collide. In general, the trocars are placed in a triangular fashion, with a 30° angle between the camera trocar and both instrument trocars (Fig. 1). Also, the instrument trocars were placed at least 8 centimetres apart from the camera trocar. A challenge of robot-assisted surgery is the restriction of movements imposed by the fixed set-up of trocars in relation to the robotic cart. Procedures requiring large instrument excursions, such as laparoscopic colectomy, may lead to collisions of the robotic arms. Most of the time these collisions can be avoided by optimal trocar positioning, but this again requires experience in robot-assisted surgery. In both our series of clinical procedures and experience in various experiments [44], we noticed no significant advantages of robotic assistance during procedures requiring large instrument excursions. More so, most instruments are designed for delicate tissue handling and instruments that are regularly used in digestive surgery, such as non-traumatic forceps or diathermic scissors, are not yet available as robotic instruments.

Due to the virtual separation of the operating surgeon and his team and the physical barrier of being at a distance and behind a console, the surgeon feels "immersed" in the console. The operating surgeon has no awareness of the relation of his instruments to the patient's anatomy and may experience difficulties to retrieve instruments in the field of view when out of sight. Also, the verbal contact with the staff in the operating room is sub-optimal. This problem was solved by working with headsets, enabling easy communication between staff-members. In the current versions of the robotic system, a communication interface is integrated.

Next to the ergonomic aspects, the considerable expenses of using a robotic system limit its widespread introduction. In our opinion cost-efficacy is not within reach in this early stage of development. Reduction in costs correlates with the number of robotic systems installed and used and if this number increases prices should go down.

Further introduction of robot-assisted surgery will be facilitated if the lack of force feedback will be compensated for. In the robotic systems currently available, the surgeon receives neither tactile sensation or force feedback via the manipulators and therefore receives no information of forces applied. This lack has to be compensated for by visual information. In their early experience, surgeons need to adapt to the visual clues and during this stage and misinterpretation of the optical input might result in tissue damage. Force feedback is a prerequisite in such delicate surgery support systems and it should be integrated into future generations of robotic telemanipulation systems.

In conclusion, the results of this study clearly support the feasibility of using this robotic system in routine laparoscopic procedures. The surgical team was impressed by the capacities of the robotic system, however stresses the need for objective data demonstrating the improvement in quality of care using these tools. In both laboratory and clinical setting, we will continue to explore new potential applications of robot-assisted surgery and demonstrate the additive value of robotic assistance.

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Chapter 6

Robot-assisted laparoscopic intestinal anastomosis:

an experimental study in pigs

Abstract

Introduction:	Robotic telemanipulation systems have been introduced recently to enhance the surgeon's dexterity and visualisation in videoscopic surgery in order to facilitate refined dissection, suturing, and knot tying. The aim of this study was to demonstrate the technical feasibility of performing a safe and efficient robot-assisted handsewn laparoscopic intestinal anastomosis in a pig model.
Methods:	Thirty intestinal anastomoses were performed in pigs. Twenty anastomoses were performed laparoscopically with the da Vinci robotic system robot-assisted group), the remaining 10 anastomoses by laparotomy (control group). OR time, anastomosis time and complications were recorded. Effectiveness of the laparoscopic anastomoses was evaluated by postoperative observation of 10/20 pigs of the robot-assisted group for 14 days and by testing mechanical integrity in all pigs by measuring passage, circumference, number of stitches, and bursting pressure. These parameters and anastomosis time were compared to the anastomoses performed in the control group.
Results:	In all cases of the robot-assisted group the procedure was completed laparoscopically. The only perioperative complication was an intestinal perforation, caused by an assisting instrument. The median procedure time was 77 min. Anastomosis time was longer in the laparoscopic cases than in the controls (25 vs. 10 min; $p < 0.001$). Postoperatively, one pig developed an ileus, based on a herniation of the spiral colon through a trocar-port. For this reason it was terminated on the sixth postoperative day. All anastomoses of the robot-assisted group were mechanically intact and all parameters were comparable to those of the control group.
Conclusion:	Technical feasibility of performing a safe and efficient robot-assisted laparoscopic intestinal anastomosis in a pig model was repeatedly demonstrated in this study, with a reasonable time required for the anastomosis.

Ruurda JP, Broeders IAMJ. Surg Endosc. 2003 Feb;17(2):236-41.

Introduction

Although widely accepted for its merits, videoscopic surgery is known for its limitations regarding the surgeon's dexterity and depth perception. Working through trocars limits the degrees of freedom of movement and introduces an inverted instrument response and variability in the excursion of the instrument tip, directly related to the part of the instrument that is brought into the body cavity. Besides this, surgeons are confined to an indirect, two-dimensional view of the operative field, inherent in working with a camera system. As a result the natural eye–hand–target working axis is lost [1-3].

These disadvantages hinder surgeons in performing complex surgical manoeuvres during videoscopic surgery, such as challenging dissection and videoscopic suturing. Although many surgical procedures of the digestive tract have been performed laparoscopically, difficult interventions still require considerable skill and time [4,5].

Recently, telemanipulation systems such as the da Vinci (Intuitive Surgical, Sunnyvale, CA) and Zeus (Computer Motion, Goleta, CA) were introduced with the objective of enhancing the surgeon's view and dexterity during videoscopic procedures [6-8]. These systems alleviate most of the previously mentioned disadvantages and should therefore be able to support surgeons in performing sophisticated videoscopic procedures in a precise and efficient way.

This might expand the list of indications for routine laparoscopic surgery and bring high-end procedures such as vascular reconstruction, pancreatic surgery, and completely laparoscopic intestinal resections in a broader perspective. In this study, the efficacy of robot-assisted suturing with the da Vinci system was investigated, with the aim of testing the applicability of this device to supporting laparoscopic digestive tract surgery including a hand-sewn intestinal anastomosis.

Materials and Methods

Thirty female pigs with a median weight of 65 kg (49–90) were operated. The rectum was divided at ±15 cm above the anus and a side-to-side rectal anastomosis was performed. Twenty pigs were operated with the da Vinci robotic telemanipulation system. The initial 10 pigs were terminated directly following surgery (robot-assisted group A). This initial experiment was performed to investigate technical feasibility. The following 10 pigs were operated in a similar way and subsequently observed for 14 days followed by autopsy in order to prove safety of this procedure in experimental set-up (robot-assisted group B). Ten pigs used for training in robot-assisted cardiac surgery underwent an open surgical procedure followed by direct postoperative termination (control group).

Robot-assisted laparoscopic surgical procedure: robot-assisted groups A and B

The da Vinci system was used in both robot-assisted groups. This system integrates two controllers and three footpads in a console, from which the surgeon directly controls two robotic instruments, which are carried by robotic arms. Next to the two arms that hold the instruments, the surgeon controls a third arm, carrying the optical system. The arms are placed on a special cart, positioned directly at the operating table. The da Vinci system increases dexterity by two additional degrees of freedom of motion at the tip of the instruments. A true three-dimensional view of the operative field is provided by a double optic system, with separate images for both eyes [9].

The animals were operated in the supine Trendelenburg position. After establishing a 14 mmHg pneumoperitoneum with the Veress needle technique, a 12-mm trocar was introduced at the umbilicus to host the camera. Two 8-mm trocars with special adapters for the robotic arms were introduced both in the right and left lower quadrant. A fourth trocar (12 mm) for assisting instruments was placed in between the umbilicus and the right robotic-arm trocar (Figure 1).

For this procedure the robot was positioned at the bottom end of the operating table (Figure 2). The robot was subsequently attached to the camera and instrument trocars.

The surgical procedure started with exposure of the distal colon (±10–14 cm above the peritoneal fold). After dissection of the mesocolon, an endoscopic stapling device (Endopath, Ethicon Endosurgery, Amersfoort, the Netherlands) was introduced through the assisting port to divide the colon. The proximal and distal part of the rectum were placed in a side-to-side position and subsequently incised. A single-layer anastomosis was performed in two steps, with two running Vicryl 4.0 sutures. Individual suture length was 19 cm.

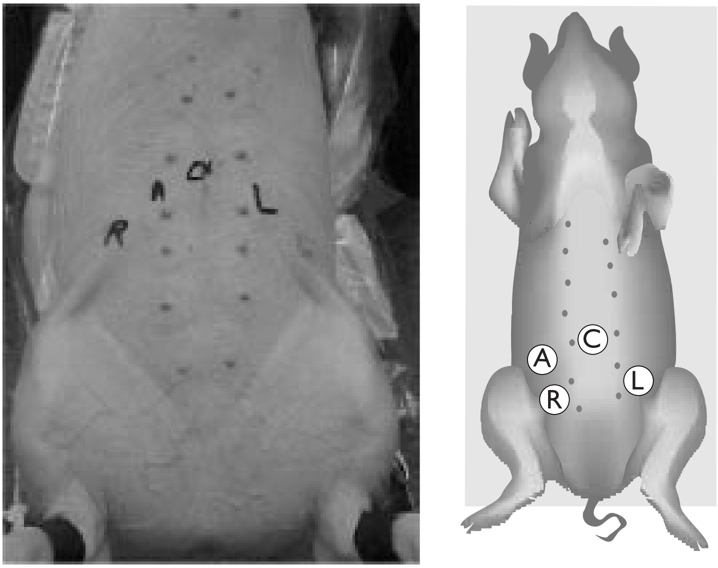

Figure 1

Trocar placement for robot-assisted rectal anastomosis in pigs. C, Camera-trocar, umbilicus; R, right robot-arm trocar; L, left robot-arm trocar; A, assisting instruments.

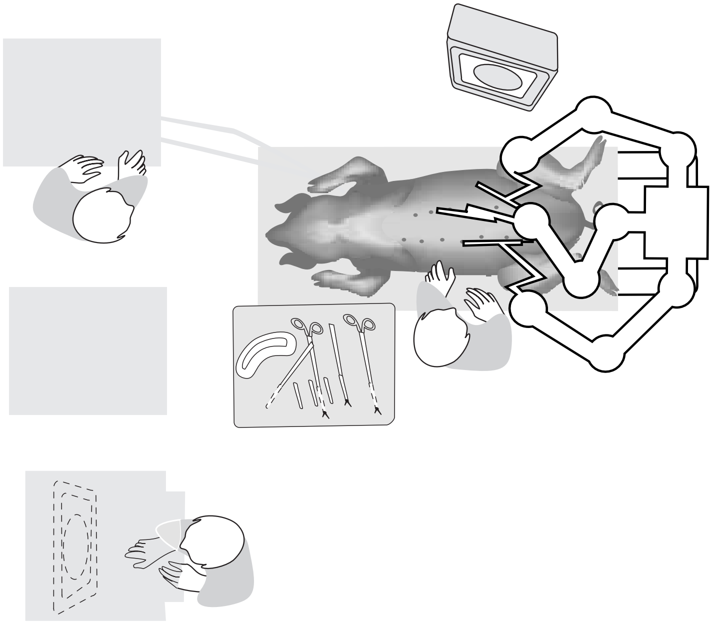

Figure 2

Schematic overview of operating-theatre set-up during robot-assisted rectal anastomosis.

Open surgical procedure: Control group

These animals were positioned in a horizontal supine position. The rectum was exposed by a 20-cm midline incision. The mesocolon was dissected and the colon was divided by an identical stapling device as in the laparoscopic procedures. Approximation of proximal and distal parts as well as the anastomosis technique was identical to the laparoscopic procedure.

Conversions and complications were recorded in all groups. System set-up time was recorded in all robot-assisted cases. Total surgery time (skin-to-skin, not including system set-up time) and intraoperative blood loss were scored in robot-assisted group B only, because the animals in robot-assisted group A and the control group were also used for training involving other organ systems during the same session. Anastomosis time was scored in all groups. In robot-assisted group B, the postoperative course was evaluated, focusing on meals, stools, and complications. At autopsy the anastomosis and peritoneal cavity were explored. In all groups the number of stitches and the circumference of the anastomosis were recorded as well as the mean distance between stitches (circumference/number of stitches). The mechanical integrity of the anastomosis was evaluated by testing the bursting pressure. For this experiment, the anastomosis was connected to a pump and filled with water. A pressure canula was introduced in the intestinal lumen. Pressure was recorded until a sudden decline in the pressure curve was noted, followed by visible leakage. The highest measured pressure was recorded as the bursting pressure. All data were entered in SPSS and are expressed as median and range. Data were compared using the Mann–Whitney U-test, with significance at p values <0.05.

Results

All procedures in the robot-assisted groups could be completed laparoscopically. Intraoperative complications did not occur in robot-assisted group A and the control group. In robot-assisted group B, an assisting instrument caused an intestinal perforation while retracting the spiral colon. This perforation was closed with a Vicryl 4-0 suture and did not cause any problem during follow-up.

System set-up time mediated 14 min (range, 12–16). Total operative time (skin-to-skin) was 77 min (75–120) in robot-assisted group B. A constant operating time of 75 min was reached in the last 5 cases, after a learning curve of 15 cases (Figure 3).

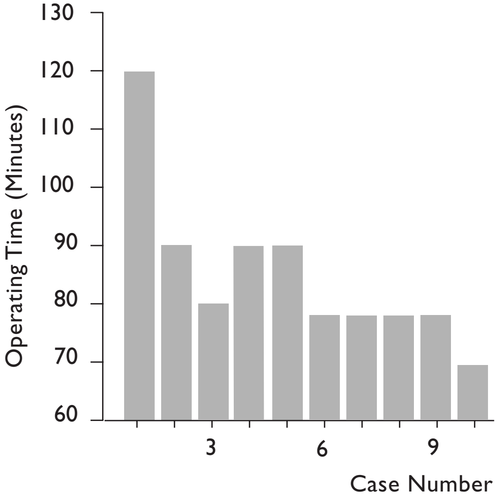

Figure 3

Operating time in for robot-assisted intestinal anastomosis in group B. After 15 cases (10 in robot-assisted group A and 5 in group B) a reproducible operating time of 75 minutes was established.

Blood loss in this group comprised less than 10 ml in 9 cases and 100 ml in one. Anastomosis time was shorter in the control group than in the robot-assisted groups (10 min versus 33 min (group A) and 25 min (group B); $p < 0.001$; (Table 1). After a learning curve of 14 cases, a constant reproducible anastomosis time of 25 min or less was accomplished in the last six robot-assisted cases (Figure 4).

Postoperatively, all 10 pigs in group B had their first meal and stool on postoperative day 1. There were two complications. One animal suffered from a traumatic arthritis of the right lower knee joint, probably caused by fixing the limb to the OR table. The arthritis was treated by anti-inflammatory analgesics. Another pig suffered from an ileus with progressive abdominal distension. Spontaneous improvement was not to be expected after 6 days and the animal was terminated for autopsy

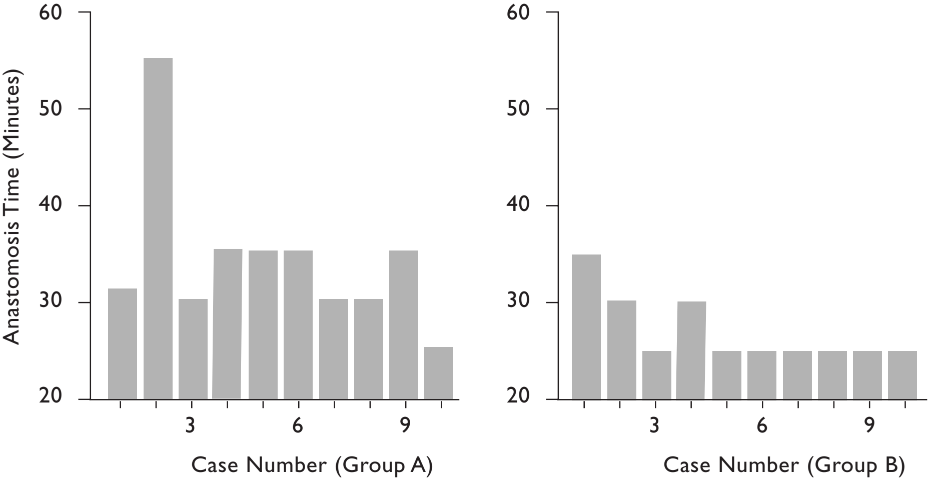

Figure 4

Anastomosis time for robot-assisted intestinal anastomosis. After 14 procedures a reproducible anastomosis time of 25 min was established.

at that time. The ileus was caused by herniation of the spiral colon through an abdominal wall defect at the point of the 12-mm help trocar insertion. There were no signs of leakage, (micro) abscesses, or peritonitis in any pig. In eight out of 10 cases, there were loose adhesions with the overlying uterine adnex. These adhesions could be removed easily by careful manual manipulation.

The passage of the anastomosis was adequate in all groups, and no anastomotic narrowing was encountered. The number of stitches and the circumference of the anastomosis were higher in the control group than in robot-assisted group A (Table 1, $p < 0.001$). There was no difference in these parameters between the control group and robot-assisted group B. The distance between stitches did not differ between groups. Bursting-pressure tests showed no significant difference between robot-assisted group A and the control group (Table 1). In both groups, one burst occurred at a relatively low pressure (25 and 37 mmHg), at a point where the distance between two stitches was close to 1 cm. The location of burst (Table 2) was within 0.5 cm of the anastomosis in four cases in robot-assisted group A. In four cases it occurred at the staple closure and in another two at distance from suture lines. In the control group, the burst occurred at the anastomosis in six cases and at the staple closure in three. In robot-assisted group B, bursting pressure was 145 mm Hg (117–178), with four bursts at the anastomosis and six at locations remote from any suture.

Table 1 **Comparison between robot-assisted laparoscopic handsewn intestinal anastomoses (Groups A and B) and control anastomoses, performed through laparotomy.**

	Group A	Group B	Control	(A-Control)	(B-Control)
Anastomosis Time	33 (25-55)	25 (25-35)	10 (9-12)	P<0,001	P<0,001
Circumference	8,5 (8-10)	11,7 (10-15)	13 (11,5-13,5)	P<0,001	NS
Number of Stitches	17 (14-18)	18,5 (17-22)	22,5 (20-26)	P<0,001	NS
Distance between Stitches	0,53 (0,47-0,61)	0,62 (0,48- 0,88)	0,55 (0,50-0,61)	NS	NS
Burst Pressure (mm Hg)	65 (25-125)	145 (117-178)	70 (37-123)	NS	NS

Table 2 **Bursting-pressure in mmHg and site of bursting: 1: Within 0,5 cm distance from the anastomosis 2: Staples 3: Other location.**

	Group A		Group B		Control	
Case No	**Burst**	**Location**	**Burst**	**Location**	**Burst**	**Location**
1	25,00	1	149,00	3	111,00	2
2	70,00	1	130,00	3	63,00	1
3	100,00	3	140,00	3	89,00	1
4	90,00	1	137,00	3	65,00	3
5	50,00	2	150,00	1	123,00	1
6	125,00	3	155,00	1	74,00	2
7	60,00	2	174,00	3	62,00	1
8	71,00	1	137,00	1	37,00	1
9	60,00	2	117,00	1	66,00	2
10	55,00	2	178,00	3	85,00	1

Discussion

Robotic systems for videoscopic surgery were introduced in the late 1990s to enhance manoeuvrability, visualisation, and ergonomics for minimally invasive thoracoscopic and laparoscopic surgery [6-8]. Endoscopic beating-heart surgery was the initial field of interest because the technical challenge of this procedure surpassed the reach of traditional videoscopic techniques [10-12]. During the past 2 years interest has expanded to laparoscopic surgery.

Although surgeons working with these systems express enthusiasm for the gain in control and visualisation, the imminent advantages of robotic systems in abdominal surgery are less apparent compared to cardiac surgery [8,13-15]. Therefore, statistical proof of its merits will be hard to get in the short term, within the spectrum of well-documented routine laparoscopic interventions. Robotic surgery systems may prove to be excellent tools for routine videoscopic surgery in the future, but comparison to state-of-the-art equipment will be disappointing because of ergonomic issues in the current OR design and practical shortcomings of first-generation robotic systems [16]. At this point, the subjectively apparent advantages of robotic surgery systems will therefore have to be proven by facilitating or supporting advanced laparoscopic interventions, such as procedures requiring suturing and knot tying.

Gastrointestinal hand-sewn videoscopic anastomosis is still regarded as a challenging manoeuvre. Stapling devices can deal with a large number of laparoscopic anastomosis, but interventions such as gastroenterostomy and bilio- or pancreaticointestinal anastomosis still require videoscopic suturing and knot tying. Additionally, the hand-sewn robot-assisted anastomosis technique can be used at locations that are difficult to reach for endoscopic stapling devices.

Robot-assisted laparoscopic suturing has recently been introduced in various procedures, with promising initial experience [17-19]. We chose a rectal side-to-side anastomosis in a pig model to demonstrate technical feasibility and safety of a complete laparoscopic sutured intestinal anastomosis with the help of the robotic system.

The complications that were encountered are directly related to videoscopic techniques, but could not be attributed to the use of the robotic system [5,20-26]. The absence of signs of leakage of the anastomosis at autopsy supported the feasibility of performing a safe intestinal anastomosis in the pig (Group B). The technical quality of the laparoscopic anastomosis was further demonstrated by the results of the comparison of robotic group A to the control group when measuring the bursting pressure. This measurement is often used in experiments when evaluating anastomotic healing [27] [28] but was used in this experience to assess the technical correctness of the anastomosis. Although the bursting pressure could not be compared to a control group in group B, it revealed no mechanical failures and showed an expected trend toward a higher bursting pressure, after a period of anastomotic healing [29]. The finding of adequate passage through the anastomosis, without strictures in all cases, and a constant distance between stitches further supported feasibility and efficacy. Although the use of a robotic surgery system for laparoscopic intestinal suturing has been proven feasible in a pig model, its true value is yet to be proven in clinical practice.

Apart from proving safety and efficiency, data were gathered to find support for the additional value of robotics in advanced laparoscopic surgery. The relatively short anastomosis time might express these advantages. Although it took longer in the laparoscopic groups than in open surgery, the reproducible time of 25 min in the last five pigs (group B) appears promising to the authors. This mean anastomosis time was established after a relatively short learning curve of 14 cases (Fig. 5). These data support our sense of the ease of adaptation to robotic techniques in videoscopic surgery. A laparoscopic control group was not included in this feasibility study, but when evaluating the anastomosis time in comparison to the results of other experiments on laparoscopic intestinal anastomosis, the time needed for the robot-assisted running suture compares favourably to time needed for laparoscopic hand-sewn intestinal anastomosis by standard instruments. Standard laparoscopic suturing time is documented to be approximately 90 min [30-33], more than three times the time required for anastomosis in this experiment. The total operating time showed an identical short learning curve (Fig. 4). System set-up time was not included in this operating time. The median set-up time found in this study was comparable to results of clinical research. We reported earlier on a reproducible set-up time of 15 min or less that can be obtained after a learning period of approximately 10 cases [34].

When looking at future developments with special regard to training, robot-assisted surgery might offer potential benefits in decreasing learning curves and increasing safety in a teaching environment. Virtual reality training programs will be integrated in the robotic system computers. This will diminish the gap between surgical simulation environments and actual surgery. After successful completion of computer-aided training programs, future residents can be supported during initial clinical experience by coupling two consoles of the robotic surgery system. This allows the tutor to take over at any desired moment, or to literally take the resident by the hand to guide him or her in videoscopic manoeuvres.

These advantages result from the concept of telesurgery, where the first surgeon no longer joins the team at the OR table and where advanced computer technology is used to enhance vision and manoeuvrability. Recent experiments have demonstrated the feasibility of performing videoscopic surgery from beyond the OR theatre to even another continent, which brings the technical options of distant expert support within reach [35,36].

In conclusion, this study demonstrated the feasibility of hand-sewn laparoscopic intestinal anastomosis with the use of a robotic system. Under circumstances where laparoscopic surgery becomes very challenging with traditional four-degrees-of-freedom instruments, the equipment is expected to be of significant support. Continuing research will therefore focus on proving advantages in technically challenging procedures, such as biliodigestive and vascular anastomosis.

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Chapter 7

Robot-assisted laparoscopic choledochojejunostomy:

comparison to the open approach in an experimental study

Abstract

Introduction: Endoscopic stenting is currently the treatment of choice for palliative relief of biliary obstruction by a periampullary tumour. If treated surgically, a choledochojejunostomy and Roux-en-Y diversion is still performed by laparotomy in a large number of cases due to technical challenges of the biliodigestive anastomosis in the laparoscopic approach. Robotic systems may enhance dexterity and vision and might therefore support surgeons in delicate laparoscopic interventions.

The purpose of this study is to assess the efficacy and safety of performing a laparoscopic choledochojejunostomy and Roux-en-Y reconstruction with the aid of a robotic system.

Methods: Ten laparoscopic procedures were performed in pigs with the da Vinci robotic system and compared to ten procedures performed by laparotomy (controls). OR-time, anastomoses-time, blood-loss and complications were recorded. Effectiveness of the anastomoses was evaluated by postoperative observation for 14 days and by measuring passage, circumference and number of stitches.

Results: OR-time was significantly longer in the robot-assisted group than in the controls (140 vs. 82 min, $p<0,05$). The anastomoses times were longer in the robot-assisted cases, although not statistically significant (biliodigestive anastomosis 29 vs. 20 min, intestinal anastomosis 30 vs. 15 min, NS). Blood-loss was less than 10 cc in all robot-assisted cases and 30 cc (10-50) in the controls. In both groups, there were no intraoperative complications. In the control group, one pig died of gastroparesis on postoperative day 6. In the robot-assisted group, one pig died on postoperative day 7, caused by a volvulus of the jejunum. At autopsy, a bilioma was found in one pig in the robot-assisted group. In all pigs, the biliodigestive and intestinal anastomoses were macroscopically patent with an adequate passage. Circumference and number of stitches were similar.

Conclusion: The safety and efficacy of robot-assisted laparoscopic choledochojejunostomy was proven in this study. The procedure can be performed within an acceptable time frame.

Ruurda JP, van Dongen KW, Dries J, Borel Rinkes IHM, Broeders IAMJ. Surg Endosc. In press.

Introduction

Endoscopic stenting is currently the treatment of choice for palliative relief of biliary obstruction by a periampullary tumour [1,2]. However, a surgical approach is recommended in case of accompanying gastric outlet obstruction, in case of failure of endoscopic treatment and in patients with relatively good projected survival [3-6]. The surgical procedure, a biliary bypass combined with gastric bypass, is usually performed through a median laparotomy.

During the last years, laparoscopic choledochojejunostomy and Roux-en-Y jejuno-jejunostomy has been reported as an alternative to the open approach [7-10]. A laparoscopic biliodigestive anastomosis appears to be feasible, but technically challenging [11-14]. For this reason the open approach is still regarded as standard procedure.

The advantages of robotic surgery systems might offer an answer to the technical obstacles in the laparoscopic approach and thereby enable surgeons to perform this delicate procedure without extensive time loss and learning curves [15,16].

The purpose of this study is to assess the feasibility of performing a safe and effective laparoscopic choledochojejunostomy and jejunum Roux-en-Y reconstruction with the aid of a robotic surgery system and compare this procedure to today's standard approach.

Methods

Twenty female pigs (weight 48-70 kg, median XX) were randomly divided in two groups. Ten pigs (robot-assisted group) underwent a laparoscopic jejunum Roux-en-Y reconstruction and choledochojejunostomy with use of the da Vinci robotic system (Intuitive Surgical, Sunnyvale, California) [16]. The remaining 10 pigs were operated through a median laparotomy (control group). A single surgeon (IB) with extensive experience with the robotic system but no experience in laparoscopic biliodigestive procedures operated on all pigs. The pigs were observed for 14 days postoperatively.

In the robot-assisted group, the animals were operated in supine Trendelenburg position. A 14 mmHg pneumoperitoneum was established using a Veress-needle. A 12 mm camera port was introduced at the umbilicus and two 8 mm robotic arm trocars were placed in the left subcostal space and in the right middle quadrant. Two assisting trocars (5 and 12 mm) were introduced in between the camera port and the right or left robotic port respectively (Figure 1). The robot was positioned over the pig's right shoulder (Figure 2) and the three robotic arms were connected to camera and 8 mm trocars.

The proximal jejunum was identified and, after dissection of the mesojejunum, divided using an Endostapler (Ethicon Endosurgery, Amersfoort, the Netherlands). The proximal jejunum was reconnected approximately 20 centimetres distal to the stapling line (Roux-en-Y reconstruction). A Monocryl 4.0 suture (Ethicon, Amersfoort, the Netherlands) was used for the jejuno-jejunostomy. The anastomoses were performed in a running fashion, with separate 16 cm wires for the anterior and the posterior parts.

The common bile duct was identified, dissected and ligated with a Vicryl 3.0 suture (Ethicon, Amersfoort, the Netherlands). The Roux-en-Y loop was approximated to the proximal duodenum and the antrum of the stomach with two Vicryl 3.0 sutures to avoid tension on the biliodigestive anastomosis. An enterotomy was made in the afferent Roux-en-Y loop and the common bile duct was divided slightly proximal to the ligature. An end-to-side biliodigestive anastomosis (choledochojejunostomy) was performed with two 8-cm running sutures, starting at the posterior site using Monocryl 6.0.

In the control group, an identical procedure was performed with the use of the same stapling device and suturing materials, but access was through a 20-cm median laparotomy.

System draping time was recorded in all robot-assisted cases. Total surgery time (first incision tot closure) was recorded and divided in a start-up phase (from incision until the start of the dissection), dissection phase (time needed for preparation and dissection of the Roux-en-Y loop and ligation of the biliary duct), time required for both the biliodigestive and intestinal anastomoses and wound closure time. Intraoperative blood-loss and complications were scored during the surgical procedure. The number of stitches of both biliodigestive and intestinal anastomoses was documented. Also, the times the stitch was broken during suturing was registered.

The postoperative course was evaluated, focussing on meals, stools and complications. At autopsy the biliodigestive and intestinal anastomoses and peritoneal cavity were explored with special interest for signs of anastomosis leakage.

In both groups, the diameter of the biliodigestive anastomosis was measured by introducing dilators with increasing diameters. The circumference of the biliodigestive anastomosis was measured using a digital image of the cross-section and dedicated measuring software (UTHSCSA Image Tool). In the same manner, the circumference of the common bile duct, one centimetre proximal to the biliodigestive anastomosis, and the intestinal anastomosis were measured. The mean distance between stitches was calculated (circumference/number of stitches).

All data were entered in SPSS for windows and are expressed as median and range. Data were compared using the Mann-Whitney U-test, with significance at P values <0.05.

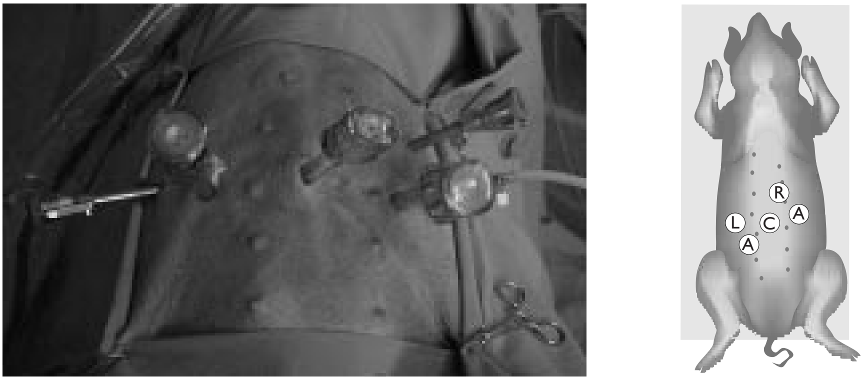

Figure 1

Trocar-positioning for robot-assisted laparoscopic biliodigestive anastomosis and Roux-en-Y reconstruction. C: camera L: left robotic arm R: right robotic arm A: assistant trocars.

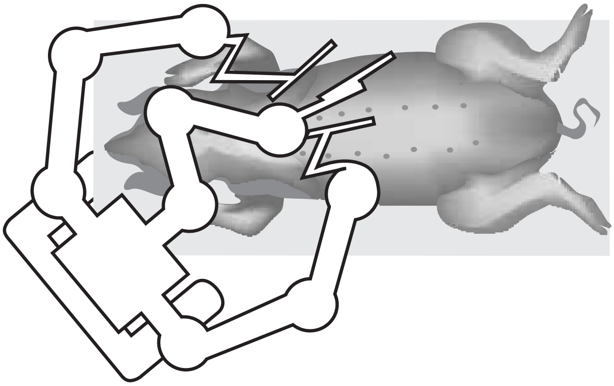

Figure 2

Positioning of the robot in relation to the pig. The pig is in supine anti-Trendelenburg position, with the robot approaching over the pig's right shoulder.

Results

The median time for robotic system preparation with sterile drapes was 6 minutes (4-9). Total operating time was 140 min in the robot-assisted group compared to 81.5 min in the control group (p<0,001; Table 1). Except wound closure, all separately scored phases of the procedure were longer in the robot-assisted cases, with statistical significance in the dissection phase (Table 1).

Table 1 **Time in minutes needed for separate phases of the procedure.**

	Robot-assisted group	Controls	P
Total Operating Time	140 (120-175)	81,5 (60-115)	<0,001
Start-up phase	15 (8-19)	10 (5-15)	NS
Dissection	55 (44-62)	25 (13-40)	<0,001
Intestinal anastomosis	30 (19-45)	15 (14-20)	NS
Biliodigestive anastomosis	29 (25-60)	20 (9-30)	NS
Wound closure	12 (10-15)	15 (9-25)	NS

We could not demonstrate a learning curve in the robot-assisted group for any of the separate time phases (Figure 3).

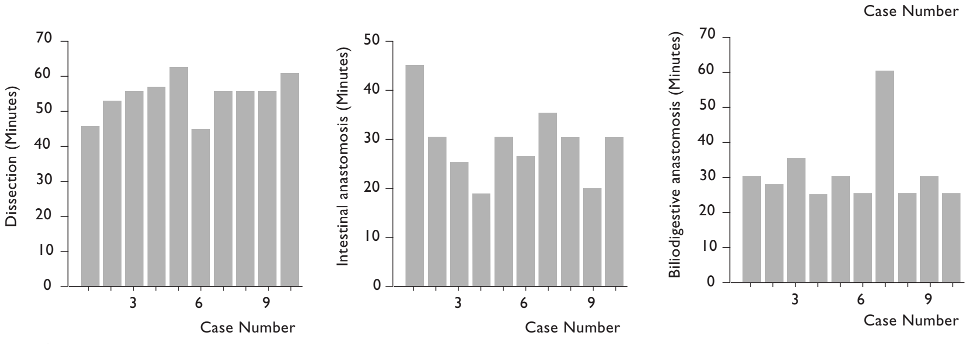

Figure 3

Times for separate phases of the operative procedure: No learning curve could be detected.

Blood-loss was less than 10 cc in all robot-assisted cases and mediated 30 cc (10-50) in the control group. In both groups, there were no intraoperative complications and all robot-assisted procedures were completed laparoscopically. In three robot-assisted cases, the 6.0 Monocryl stitch was torn during suturing of the biliodigestive anastomosis, necessitating a restart of the anastomosis.

Postoperatively, all pigs had their first stool on the first postoperative day and accepted their first meal on day two after surgery. In the control group, one pig died of gastroparesis on postoperative day 6. In the robot-assisted group, one pig died on postoperative day 7, caused by a volvolus of the jejunum.

At autopsy, signs of leakage of the biliodigestive anastomosis were found in one pig in the robot-assisted group. In this pig, a bilioma of approximately 10x10x10 cm was found. In retrospect, this pig had a diminished appetite on postoperative days two to five, but recovered afterwards.

In all twenty pigs, the biliodigestive and intestinal anastomoses were macroscopically patent with an adequate passage. The circumference of the anastomoses and common bile duct, the number of stitches and the distance between stitches were comparable in both groups (Tables 2 and 3).

Macroscopic distension of the biliary tract occurred in one pig in each group. These findings were supported by measurement of the duct and anastomosis circumference (24 vs 18 mm in the robot-assisted group, 18 vs 13 mm in the controls) The postoperative course was uneventful without signs of biliary congestion.

Table 2 **Measurements for biliodigestive anastomosis and common bile duct (CBD).**

	Robot-assisted group	Controls	P
Diameter (mm)	9 (7-10)	8 (7-9)	NS
Circumference (mm)	1,7 (1,2-2,7)	1,4 (1,1-1,7)	NS
Number of stitches	10 (8-11)	9 (8-10)	NS
Distance between stitches (mm)	2 (1-3)	2 (1-2)	NS
CBD circumference (mm)	1,9 (1,3-2,7)	1,6 (1,3-1,8)	NS

Table 3 **Measurements for intestinal anastomosis.**

	Robot-assisted group	Controls	P
Circumference (mm)	38 (29-45)	43 (33-55)	NS
Number of stitches	16 (15-18)	18 (14-20)	NS
Distance between stitches (mm)	2,3 (1,8-2,8)	2,5 (2,1-2,9)	NS

Discussion

In this study, two surgical approaches for the treatment of permanent biliary obstruction are evaluated. Currently biliary stenting through endoscopic retrograde cholangiopancreatography (ERCP) is regarded as the treatment of choice in patients suffering from biliary congestion. Randomised clinical trials have established the effectiveness of endoscopic biliary stenting and demonstrated no significant differences in survival compared to a surgical approach 6,17. Moreover, the minimal invasive endoscopic approach results in a lower 30 days mortality and morbidity and a shorter hospital stay [17,18]. Also, endoscopic stent-placement has been proven to be cost-effective [1,19,20]. For these reasons, surgery as the initial treatment for biliary congestion is largely replaced by the endoscopic approach.

Long-term patency of endoscopically placed biliary stents, however, appears to be inferior to surgical biliary drainage. Recurrent obstructive jaundice, caused by clogging of the stent due to duodenobiliary reflux or tumour ingrowth occurs in 20% to 50% of the patients treated with endoprostheses [19,21-23].

After a surgical biliary bypass, 0% to 16% of patients show recurrent obstructive jaundice [24-26]. In patients with a relatively high life-expectancy (over 6 months), a surgical approach is therefore recommended [2,26,27]. Not only does the surgical approach offer a good long-term patency of biliodigestive drainage with low readmission rates; it also offers opportunities for additional gastric by-pass, in order to avoid gastric outlet obstruction, which develops in 10% to 20% of patients with unresectable pancreatic cancer. Altogether, surgical biliary drainage is indicated in patients with a relatively high life-expectance (over 6 months) and in patients requiring a simultaneous gastric outlet by-pass [2].

The surgical treatment of choice consists of a choledochojejunostomy with or without a simultaneous gastrojejunostomy [3,28]. A controlled randomised trial by Smith 6 showed a procedure-related mortality of 14 %, a major complication rate of 29 % and a total hospital stay of 26 days. Other studies show lower mortality rates, but similar results concerning morbidity and hospitalisation [17,26,27]. Most authors emphasise that surgical palliation goes mainly accompanied with early (<30 days) complications, resulting in a longer initial hospital stay. This reflects the time spent recuperating from the operative trauma [26].

The surgical trauma can be minimised using a laparoscopic approach. For procedures routinely performed through laparoscopy, such as laparoscopic cholecystectomy and Nissen fundoplication, the benefits for the patient, compared with open surgery are clear and well described. Decreased hospitalisation, diminished postoperative pain, cosmetic advantages, lower complication rates and economic considerations are examples of these benefits [29-33].

Theoretically, laparoscopic choledochojejunostomy could offer identical advantages compared to the open surgical treatment. Thereby, it combines a minimal invasive approach with long-term patency and the option for an additional gastric bypass. A number of authors have described the feasibility of the laparoscopic approach [8-12,14,34,35]. A case control study comparing 14 laparoscopic cases to open palliative procedures demonstrated a significant reduction of postoperative hospitalisation (21 vs. 9 days, p<0,06), morbidity (43 vs. 7 %, p<0,05) and mortality (29 vs. 0%, p<0,05) [9]. However, to date no large series have been published and the approach is not widely accepted yet as a competing alternative. An explanation for this might be the technical complexity of this approach.

Most authors emphasise that a laparoscopic choledochojejunostomy procedure is technically challenging. During laparoscopic surgery, working through fixed abdominal entrypoints significantly diminishes manoeuvrability. Surgeons are also handicapped by the loss of visual perception of depth, intrinsic to working with a two-dimensional visualisation system [36]. A major obstacle during the laparoscopic approach, due to these limitations, appears to be suturing an anastomosis the size of the common bile duct [12-14]. Handling the delicate tissue of the thin and fragile bile duct wall and visualising the collapsing bile duct opening, with bile running through it, is technically demanding, even if proper exposition is acquired in the first place [12-14]. Although feasible for trained surgeons, the procedure remains time-consuming, with operating times of over 3 hours [11].

Being so complex, surgeons developed alternative techniques replacing the sutured biliodigestive anastomosis, such as anastomotic devices, stapled cholecystojejunostomies and a combined laparoscopic and endoscopic biliary stenting approach [14,28,35,37-39]. Despite these efforts, the laparoscopic approach remained technically challenging and has not developed towards a suitable alternative for the open approach for a surgeon without extensive experience in this field of surgery.

Robotic surgical systems may prove to be of support in dealing with delicate laparoscopic procedures, such as the biliodigestive anastomosis. The system used in this experiment, the da Vinci system, enhances visualisation by a true three-dimensional view based on a double optical system. In addition, the natural working axis is restored and the surgeons viewing axis is always in line with the image acquisition axis. The surgeon can optimise the field of view due to personal control of the optical system. Additional degrees of freedom of motion, filtering of tremor and friction and the ability to downscale the movements of the robotic instruments can contribute further to the feasibility of advanced laparoscopic suturing [15,40,41]. The aim of this study was to compare this new laparoscopic robot-assisted approach to the current standard, and evaluate whether it could be a competing alternative for the open surgical approach. The open approach was the procedure of choice in human surgery for the surgical team involved because their yearly caseload was regarded insufficient to gain enough experience in the standard laparoscopic approach and as such to deliver an optimal level of care.

In our experiments, robot-assisted laparoscopic choledochojejunostomy and Roux-en-Y reconstruction was repeatedly proven safe and effective. The safety of the procedure was reflected by the comparable dimensions of the anastomotic parameters in the open and robot-assisted groups. The postoperative deaths could not be attributed to failure of anastomoses or to other technical inaccuracy caused by the robotic system.

Apart from safety and efficacy, the additional value of robot-assisted surgery was expressed in the relatively short operating times in this study. The operating times were significantly longer compared to the control group, but remained within reasonable limits for surgical practice by the opinion of the authors. When evaluating procedure times of standard laparoscopic biliodigestive procedures published so far, averaging over 3 hours in experienced hands, the median operating time of 140 minutes in the robot-assisted cases appears to be relatively short [8,12,14]. Robotic system set-up time was not included in the operating time but is limited to 15 minutes or less in experienced hands [15,16,40]. Time-loss was shown in our previous studies to occur mainly during set-up of the equipment [42]. In the experimental laboratory, a dedicated operating theatre with a permanent system set-up eradicated this time-loss. Still, sterile draping of the robotic system consumed 6 minutes.

One would expect to attribute the time-loss during surgery merely to the actual suturing of the biliodigestive anastomoses, as most challenges are faced during this part of the procedure in standard laparoscopic surgery [11-14]. However, in this experimental study the choledochojejunostomy was proven to be feasible within a reasonable time frame. Also the time needed for the jejuno-jejunostomy remained limited. However, the dissection was accountable for most of the time-loss compared to the control group. It was experienced as complex, with difficulties in identification of the jejunum in order to create the Roux-en-Y loop in the pig model, as was also emphasised previously by others [13]. Defining the afferent and efferent small bowel loops requires handling and retracting a large segment of intestine. The large excursions of the robotic instruments and camera required tend to cause collisions between the three robotic arms. Obviously the robotic system is designed for delicate motions [43], but it does not seem to offer advantages in large-scale movements which require a large field of view. The difficulty in identifying the jejunum could therefore partly be explained by the pig's anatomy, but also by the limited mobility of the camera and robotic arms.

The short and reproducible anastomosis times from the start of the experiment on, without a significant learning curve, reflected the additional value of robot-assistance, as did the safe and bloodless dissection of the meso-jejunum and common bile duct. The robotic system seems to offer an adequate answer to the technical challenges of the procedure. The 3D-visualisation and restoration of eye-hand-target axis were regarded most helpful by the operating surgeon when suturing the four to five mm wide common bile duct to the jejunum. The additional degrees of freedom of motion, tremor and friction eradication and the ability to downscale the movements of the robotic instruments were experienced as beneficial while suturing the delicate tissue.

The main problem encountered while suturing the anastomoses was suture disruption. This occurred in three out of ten cases and resulted in a longer anastomosis time. We attribute the rupture of sutures to the lack of force feedback in the robotic instruments. While putting force on the suture in order to accomplish a patent anastomosis or a secure knot, the 6-0 sutures are easily broken. This could only partly be compensated for by visual control, as was also emphasised by others [43]. Obviously the problem of tearing thin wires may decrease when experience of the surgeons increases. Nevertheless, future generations of the robotic system should offer information on pulling and pushing forces applied, similar to standard videoscopic surgery, in order to avoid tissue crush and tears and damage to wires and needles.

In our experience and supported by the results presented, the use of a robotic system offers the opportunity to alleviate the surgical challenge of laparoscopic biliodigestive anastomosis. Hereby, the laparoscopic approach towards palliative treatment of bile duct and gastric outlet congestion might come within hands for more surgeons and therefore make the minimal invasive approach more widely accepted.

In conclusion robot-assisted laparoscopic choledochojejunostomy has been proven effective and safe in an experimental model. The procedure can be performed with acceptable time-loss. Therefore the robot assisted laparoscopic technique may prove to be reproducible in clinical practice and thereby support the minimally invasive approach as the treatment of choice for palliative surgical relief of biliary congestion. We will start with robot-assisted laparoscopic biliodigestive anastomosis supported by the results of this experimental study. The true additive value of the robotic system for this procedure can be proven only by a randomised study, but such a study should be conducted by one of those few centres that perform a large number of these interventions yearly.

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Chapter 8

Manual versus robot-assisted videoscopic suturing:

time-action analysis in an experimental model

Abstract

Introduction: Robotic surgery systems were introduced to overcome the disadvantages of videoscopic surgery. The goal of this study was to assess whether robot-assistance could support videoscopic surgeons in performing a complex videoscopic task.

Methods: Five experienced videoscopic surgeons performed end-to-end anastomosis on post-mortem porcine small intestine. The procedure was performed with both standard videoscopic techniques and with robotic assistance (da Vinci system, Intuitive Surgical, Sunny Vale, Ca) . It was performed in three different working directions with a horizontal, vertical and diagonal position of the bowel. Anastomosis time, number of stitches, knots, time per stitch, suture ruptures and the number of stitch errors were recorded. Also, an action analysis was performed.

Results: Anastomosis time, number of stitches and the number of knots did not differ significantly between the two groups. The time needed per stitch was significantly shorter with robot assistance (81,4 seconds/ stitch vs. 95,9 seconds/ stitch, p=0,005). More suture ruptures occurred in the robot group (0(0-2) vs. 0 (0-0) p=0,003). In the standard group more stitch errors were found (2 (0-5) vs. 0(0-3) p=0,017). These results were comparable for three different working directions. The action analysis, however, showed significant benefits of robotic assistance. The benefits were greatest in a vertical bowel position.

Conclusion: Robot-assistance was demonstrated to be of added value to experienced videoscopic surgeons in the performance of a small bowel anastomosis in this experimental model.

Ruurda JP, Broeders IAMJ, Pulles B, Kappelhof FM, van der Werken Chr. Submitted for publication.

Introduction

Videoscopic surgery has taken a considerable rise during the last decades. Advantages for patients in comparison to open surgery include shorter hospitalisation, reduced post-operative pain, faster rehabilitation, fewer complications and a better cosmetic result [1-4].

On the other hand, videoscopic surgeons have to cope with limitations in visualisation and manipulation. These disadvantages hinder surgeons in performing complex manoeuvres, such as performing an intestinal anastomosis. The fact that the ideal approach of instruments relative to the tissue is usually not achievable further contributes to the limitations of videoscopic surgery [5].

Surgical robotic systems could help surgeons to overcome these limitations [6-11]. The goal of this study was to assess whether robot-assistance could be of added value to experienced videoscopic surgeons in performing a complex surgical task, e.g. suturing an intestinal anastomosis.

Materials and Methods

Five-experienced videoscopic surgeons performed anastomoses on porcine small bowel. All surgeons involved perform videoscopic suturing on a regular basis (>20 anastomoses performed in clinical practice). None of the surgeons had previous experience with robot-assisted surgery. Prior to the experiment, they were trained for five minutes on the da Vinci system (Intuitive Surgical, Mountain View, California, Figure 1) and were allowed to practice for the same amount of time with standard instrumentation. The small bowel was derived from pigs (60-80 kg), used in other experiments, and was cut into segments of approximately 10-15 cm. These pieces were fixed at the bottom of a videoscopic training box in which the anastomoses were performed.

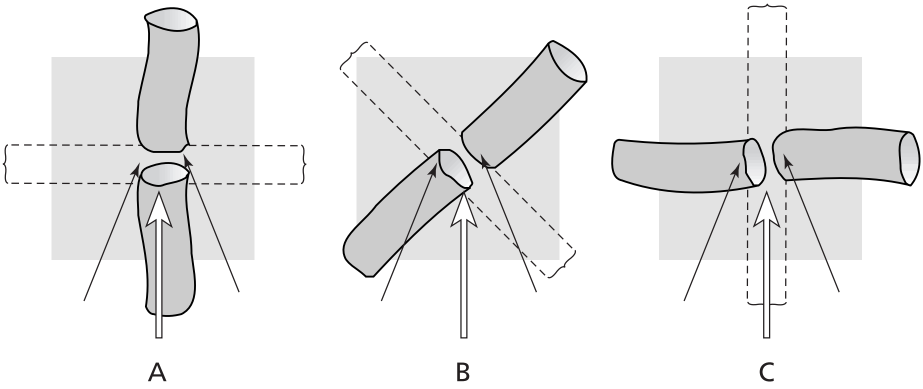

Figure 1

Three different positions of the small intestine and consequent suturing direction: A: Vertical placement with horizontal suture line. B: Diagonal position and suturing line C: Horizontal bowel position with vertical suture line. The black arrows indicate the instruments, the white arrow the camera. The grey "tube" mimics the small intestine, the dotted line indicates the suturing plane.

All surgeons performed six anastomoses, all with the use of two running sutures (4-0 Vicryl (Ethicon Amersfoort, the Netherlands), cut at a length of 15 cm. The anastomoses were either performed in a standard videoscopic fashion (control group) or with robotic assistance (robot group).

In the control group, a needle holder (Karl Storz, Tuttlingen, Germany) and a dissection forceps (BBraun, Tuttlingen, Germany) were used. A 30° endoscope was fixed in a passive camera-holder, according to the surgeon's preference. The monitor was placed on a vision cart at a distance of 1,5 meters from the training box. The training box was set on a table of adjustable height.

In the robot group, all surgeons used the da Vinci system, which integrates a true 3D-image of the operative field, dealing with the loss of depth perception of standard videoscopic surgery. This image is projected inside a console, in line with the surgeon's eyes and hands, restoring the natural eye-hand working axis [12,13]. The use of articulated instruments, which mimic the movements of the surgeons' wrists, enhances manipulation and accounts for two additional degrees of freedom of motion. The opposite movements of the instruments and the surgeons' tremor are eradicated by this system. Furthermore, opportunities to scale down motions are included as well [14,15]. Two needle drivers with articulating tips were used in this group and the 30 degrees camera was set in a fixed position, according to the surgeon's preference.

In both groups, each surgeon performed the two anastomoses respectively in a horizontal, a diagonal and a vertical direction in random order (Figure 2).

For each procedure, we assessed time to complete the anastomosis, number of stitches, knots and accidental breaking of the suture. In order to evaluate the quality of the anastomosis, we examined the anastomotic line for macroscopically large steps between stitches, with > 5 mm considered to be too large, and as stitch error. Next to this, all procedures were analysed using a time/action analysis [9,16,17]. To perform this analysis, the procedures were recorded using a SVHS video recorder and evaluated independently by two medical students (BP, FK).

For the time/action analysis, the procedure was divided in a suturing and a knotting phase. Within these phases, different actions were evaluated (table 1). The total time and the actions of the stitching phase were analysed in relation to the number of stitches. The actions of the knotting phase were analysed in relation to the total number of knots. All anastomoses were analysed and a sub-analysis was performed for the three working directions. All data were analysed using SPSS and are expressed as median and range. Statistical significance was assessed using the Mann-Whitney-U test, with significance at $p<0,05$.

Table 1 **Description of the scored actions in the stitching and knotting phase.**

ACTIONS SCORED	Description
Stitching Phase	
Grasping the needle	Grabbing the needle, or wire in order to grab or position the needle before entering it in the tissue
Failure to grasp the needle	Making a grabbing motion without actually grabbing the needle, or wire
Grasping tissue	Grabbing the tissue in order to position the needle before entering
Failure to grasp tissue	Making a grabbing motion without actually grabbing the tissue
Entering the needle	Entering the needle with penetration of the tissue
Failure to enter the needle	Making an entering motion without penetrating the tissue
Exiting the needle	Grab the tip of the needle after penetration of the tissue
Failure to exit the needle	Closing the tips in order to grab tip of needle without grabbing it
Pulling through	Pull the needle/wire through tissue, in which passing over & pulling is considered as one action
Failure to pull through	Failure to grab the wire/needle
Total successful actions	The sum of all successful action in the suturing phase
Total failed actions	The sum of all failures in the suturing phase
Knot Phase	
Grabbing the wire	Grabbing the wire, or needle prior and directly after looping
Failure to grab wire	Making a grabbing motion without actually grabbing the wire, or needle
Looping	Looping the wire around one of the instruments, resulting in a stable loop before pulling through
Failure to loop	Looping without result, or the sliding off of a loop
Pulling through	Pulling the loop over the instrument and tightening the knot
Failure to pull through	Pulling motion, which does not result in a knot
Total successful actions	The sum of all successful action in the knot phase
Total failed actions	The sum of all failures in the knot phase
Both phases	
Needle drop	Unintended dropping of the needle

Results

All anastomoses were patent at inspection. The total time needed to complete the anastomosis was 20,5 minutes (16,2-39,1) in the robot group compared to 21,5 minutes (16,5-52,2, p=NS) in the standard group. The number of stitches was 14 (10-25) in the standard group and 16 (10-36, p=NS) in the robot group. The anastomotic time divided by the number of stitches was significantly shorter in the robot group (81,4 seconds/ stitch (61,6-97,0)) than in the standard group (95,9 seconds/ stitch (68,4-164,8 p=0,005)). The number of knots was equal in both groups (3 (2-4)).

In the standard group more stitch errors were found (2 (0-5)) than in the robot group (0(0-3) p=0,017), but in the latter, more suture ruptures occurred (0(0-2) versus 0; p=0,003)

Regarding the subgroups for the three directions of small bowel placement, the anastomosis time, number of stitches, number of knots, time per stitch and number of macroscopically large stitches did not differ significantly between the robot group and the control group.

The results of the action analysis are shown in table 2. All failures except the "failure to pull through" occurred significantly less frequent in the robot group. Next to this, "entering the needle" was less frequent. "Pulling through" was less frequent in the standard group. When reviewing the total number of successful actions in the stitching and the knotting phase, no significant differences were demonstrated between both groups, but the total number of failed actions in the stitching and knotting phase was significantly lower in the robot group.

In all three working directions, it took surgeons fewer manipulations to perform certain actions in the robot group (Table 3).

Table 2 **Results of the action analysis without making a distinction between the different directions; Numbers of actions are expressed as median and range. NS = not significant (p>0,05). p calculated with Mann-Whitney U test.**

	Robot	**Control**	**p**
Stitching Phase			
Grasping the needle	2,4 (1,2-3,3)	2,5 (1,7-4,1)	NS
Failure to grasp the needle	0,1 (0,0-0,4)	0,4 (0,0-1,6)	0,000
Grasping tissue	2,8 (2,1-4,3)	3,2 (2,0-4,3)	NS
Failure to grasp tissue	0,2 (0,0-0,6)	0,4 (0,1-1,1)	0,025
Entering the needle	1,3 (1,1-1,5)	1,4 (1,1-1,69)	0,011
Failure to enter the needle	0,2 (0,0-0,3)	0,7 (0,3-1,3)	0,000
Exiting the needle	1,3 (1,0-1,9)	1,4 (1,1-2,5)	NS
Failure to exit the needle	0,1 (0,0-0,3)	0,5 (0,1-2,5)	0,000
Pulling through	2,6 (1,4-3,2)	1,9 (1,1-2,9)	0,003
Failure to pull through	0,1 (0,0-0,3)	0,2 (0,0-0,6)	NS
Total successful actions	10,3 (7,5-12,9)	10,5 (7,5-13,1)	NS
Total failed actions	0,8 (0,4-1,3)	2,3 (0,8-6,4)	0,000
Knot Phase			
Grabbing the wire	7,7 (4,5-12,3)	6,0 (0.3-12,3)	NS
Failure to grab wire	0,7 (0,3-3,0)	2,0 (0,0-5,0)	0,047
Looping	3,3 (2,0-4,0)	3,0 (2,0-4,3)	NS
Failure to loop	0,7 (0,0-2,5)	2,0 (0,7-8,0)	0,008
Pulling through	5,0 (3,7-8,0)	4,0 (3,0-6,5)	0,005
Failure to pull through	0,0 (0,0-0,5)	0,0 (0,0-0,7)	NS
Total successful actions	17,3 (12,3-23,7)	14,0 (7,7-21,3)	NS
Total failed actions	2,3 (0,3-4,0)	3,7 (1,0-13,0)	0,011
Both phases			
Needle drops	0 (0-0)	1 (0-10)	0,001

Table 3 **Results of time/action analysis in the three different directions of small intestine anastomosis. Only significant results are presented. P calculated with Mann-Whitney U test. Data presented are expressed as median and (range).**

Table 3a **The horizontal direction.**

	Robot	**Control**	**p**
Stitching Phase			
Failure to grasp the needle	0,2 (0,0-0,4)	0,4 (0,2-1,6)	0,021
Failure to enter the needle	0,1 (0,1-0,3)	0,5 (0,4-1,2)	0,009
Failure to pull through	0,2 (0,1-0,3)	0,2 (0,1-0,5)	0,018
Failed actions	0,7 (0,4-1,2)	1,6 (1,2-3,8)	0,047
Knot Phase			
Pulling through	5,0 (4,3-7,0)	3,7 (3,0-6,5)	0,021

Table 3b **The diagonal direction.**

	Robot	**Control**	**p**
Stitching Phase			
Failure to grasp the needle	0,1 (0,1-0,2)	0,4 (0,2-0,6)	0,012
Entering the needle	1,2 (1,1-1,3)	1,4 (1,3-1,5)	0,036
Failure to enter the needle	0,3 (0,1-0,4)	0,5 (0,3-0,8)	0,047
Failure to exit the needle	0,1 (0,0-0,1)	0,4 (0,2-1,4)	0,009
Pulling through	2,7 (1,7-3,2)	1,7 (1,4-2,9)	0,012
Failed actions	0,7 (0,4-1,2)	1,6 (1,2-3,8)	0,009
Knot Phase			
Failure to grab wire	0,3 (0,3-1,0)	1,7 (0,7-5,0)	0,026

Table 3c **The vertical direction.**

	Robot	Control	p
Stitching Phase			
Grasping the needle	2,4 (1,7-3,1)	3,3 (2,2-3,6)	0,047
Entering the needle	1,2 (1,1-1,3)	1,5 (1,3-1,7)	0,028
Failure to enter the needle	0,1 (0,0-0,5)	1,1 (0,7-1,3)	0,009
Failure to exit the needle	0,1 (0,0-0,2)	0,6 (0,2-1,0)	0,009
Failed actions	0,8 (0,4-1,3)	4,1 (1,3-4,3)	0,016
Knot Phase			
Failure to loop	0,5 (0,0-2,5)	2,3 (1,0-7,0)	0,047
Failed actions	0,8 (0,3-3,8)	6,0 (1,3-10,3)	0,047

Discussion

Robotic systems have been introduced to overcome the limitations encountered in videoscopic surgery [14,15,18]. Performing surgery with robotic assistance offers some potential advantages over standard laparoscopy.

Despite these supposed advantages, studies to assess these benefits have demonstrated variable and largely disappointing results [6-9,19,20]. Many of these studies use a training model with relatively simple manipulation skills, such as moving beads around and passing a rope. These exercises barely represent the difficulties encountered in complex videoscopic procedures, such as suturing and knot tying. Furthermore, some of these studies use a robotic system without 3D visualisation and articulated instruments [8,9,19].

In this experiment, we chose to use the technically challenging model of suturing a small bowel anastomosis. Our hypothesis was that the use of the robotic system might be of greater benefit in this procedure than in less complex manipulative manoeuvres.

The benefit of robotic-assistance is clearly demonstrated by our results, in terms of a shorter time needed per stitch, a lower number of stitch errors and the results of the time/action analysis. The anastomosis time was not found to be shorter, most probably due to an inter-surgeon variability in the number of stitches applied. When the anastomosis time was divided by the total number of stitches used, however, it was significantly shorter, demonstrating the benefit of the robot.

No significant differences were found when comparing the three suturing directions, except for the time/action analysis. This was most probably due to the small size of the subgroups. However, even in these small numbers, the benefit of the robot was most apparent in the vertical direction of placement of the small intestine (horizontal suturing plane), with a greater number of actions being performed less frequently than in the other two directions. This finding supports the fact that suturing in normal videoscopic fashion is demonstrated to be most difficult in this direction [5].

The only factor in the time/action analysis that appeared to be in contradiction to the other results, is the number of actions needed for "pulling through" of the needle. These results and the higher risk of "breaking the wire" when using the robot are attributed to the complete absence of force feedback in the robotic system, so that the surgeon receives no information on the applied forces. Where the loss of force feedback might partly be compensated for by the 3D visual clues, in situations where the instrument gets out of sight, it might result in tissue or suture damage [10,12,21]. The surgeons were warned of this risk beforehand. They were instructed to keep the instruments in sight, and therefore repositioning of instruments was necessary more frequently than in the control group.

In conclusion, this study demonstrates that robot-assistance is of added value to experienced videoscopic surgeons in the performance of a small bowel anastomosis in an experimental set-up.

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Chapter 9

Robot-assisted versus standard videoscopic aortic replacement:

a comparative study in pigs

Abstract

Background: Reconstruction of the infrarenal aorta for aneurysms is routinely performed through laparotomy. A less invasive videoscopic approach has not gained wide acceptance, due to technical difficulties. Robotic systems could potentially improve imaging of the operative field and surgeon's dexterity during videoscopic surgery and therefore might facilitate the performance of this procedure.

The aim of this animal study was to compare the safety and efficacy of a robot-assisted videoscopic aortic replacement to the standard videoscopic approach.

Methods: In 10 female pigs, the infrarenal aorta was partially replaced by a 10-mm polytetrafluoroethylene (PTFE) interposition graft through a videoscopic retroperitoneal approach, using the da Vinci robot system (robot group). Ten other pigs were operated in a similar fashion, using standard videoscopic instruments (control group). Relevant procedure times, blood loss and complications were registered. Efficacy of the anastomoses was evaluated by measuring patency and blood loss after removing the clamps. Furthermore, circumference and number of stitches were evaluated at autopsy.

Results: The procedure-, suturing and clamping times were significantly shorter in the robot group and blood loss was less. In the control group, the inferior vena cava was injured in one pig. In two cases in the control group, haemostasis could not be established after clamp removal.

At autopsy, all anastomoses in the robot group were adequate. In the control group, a stitch crossing the aortic lumen was found in two distal anastomoses and a large distance (>3 mm) between two stitches was encountered at least once in 12/20 suture lines. All 20 grafts were patent. No anastomotic narrowing was encountered. The number of stitches used for proximal and distal anastomosis was higher in the robot group.

Conclusion: This study demonstrates the superiority of robot-assisted videoscopic aortic replacement over standard videoscopic techniques in an animal model.

Ruurda JP, Wisselink W, Cuesta MA, Verhagen HJM, Broeders IAMJ. Eur J Vasc Endovasc Surg. In Press

Introduction

The gold standard for abdominal aortic aneurysm repair is exclusion of the aneurysm, and interposition with a tube- or bifurcated prosthesis. This is usually performed through a midline laparotomy [1,2]. In 1993, the first laparoscopy-assisted intervention for infrarenal aortic occlusive disease was performed by Dion and Gracia [3]. In the following years, completely laparoscopic techniques for abdominal aortic repair for both occlusive and aneurysmatic disease were developed [4-7].

A videoscopic approach limits the operative trauma and might therefore diminish postoperative pain complications and hospitalisation and offers patients cosmetic advantages. However, the technical challenges of this procedure are emphasised in most published papers [4-7]. First of all, proper exposition of the aorta must be accomplished for dissection, cross-clamping and aortic replacement. Second, suturing an anastomosis on the aorta is technically challenging with standard videoscopic instruments and therefore time-consuming, if feasible at all.

The technical challenges derive from an impairment of dexterity and the loss of 3D-visualisation in standard videoscopic surgery. Robotic telemanipulation systems were introduced with the objective to alleviate these challenges [8-10]. Feasibility of robot-assisted videoscopic surgery for aortoiliac occlusive disease was recently demonstrated [11]. The advantages offered by robotic systems might support surgeons in dealing with the technical challenges of standard videoscopic aneurysm repair without extensive time-loss and learning curves.

The purpose of this study is to compare the efficacy of robot-assisted videoscopic aortic replacement for aneurysmatic disease to a standard videoscopic approach in a porcine model.

Materials and Methods

Between November 2002 and February 2003, the infrarenal aorta of 20 female pigs (80-110 kg) was partly replaced by an interposition graft, either with use of the da Vinci (robotic telemanipulation system (Intuitive Surgical, Sunny Vale, Ca, robot group, n=10), or in a standard videoscopic fashion (control group, n=10). All procedures were performed by one of three surgeons: a vascular surgeon (WW) and a videoscopic surgeon (MC) both with limited experience with robot-assisted surgery, and another videoscopic surgeon with extensive experience in robot-assisted surgery (IB). At the start of the experiment, all surgeons were trained to get familiar with the equipment by performing five ex-vivo anastomoses using both techniques.

Operative technique

The pigs were positioned in supine position and a pneumoperitoneum was established using a Veress-needle. A 12 mm trocar was introduced at the umbilicus and the peritoneal cavity was inspected. The pigs were then repositioned to a right semilateral position and a two cm incision was made in the left midaxillary line at a level just below the lower pole of the left kidney. Through this incision, blunt retroperitoneal dissection was performed using digital manipulation and an inflatable balloon (BBraun Aesculap, Tuttlingen, Germany). This was performed under direct visual control through the umbilical trocar. In this way, a retroperitoneal cavity from the upper pole of the kidney to the level of the aortic trifurcation was created. A 12 mm blunt-tip balloon-trocar (Tyco Healthcare, Basingstoke, UK) was introduced through the flank incision and the retroperitoneal cavity was insufflated to a pressure of 15 mm Hg. Three more trocars were introduced: two working ports (8 mm in the robot group and 5 mm in the control group) and an assisting port (12 mm) (Figure 1).

Following the surface of the psoas muscle, the aorta was identified and circumferentially dissected from the surrounding fat tissue in order to enable controlled clamp placement. Two to three lumbal arteries (at the level of the renal artery, inferior mesenteric artery and in between) were identified and clipped prior to clamping. The aorta was clamped just infrarenally and above the trifurcation with the use of detachable vascular clamps with a length of 45 mm and a clamping pressure of 4,41 N (BBraun/ Aesculap, Tuttlingen, Germany). The aorta was transected and a short segment of aorta removed. A 10 mm polytetrafluoroethylene (PTFE) graft (stretch, standard wall, W.L. Gore and associates, Flagstaff, Arizona) was cut at the appropriate length (range 3 to 5 cm). At both sides a double armed CV 5.0 PTFE suture, with a PH 13 needle (W.L. Gore and associates, Flagstaff, Arizona) was sutured to the graft and cut at a length of 7 cm at each end. Before introducing the prosthesis into the retroperitoneal cavity, the first knot was tied. End-to-end aorta-graft anastomoses were sutured proximally and distally.

Total operating (skin-to-skin) time was recorded and divided into separate phases: trocar introduction time, time required for dissection and exposition, total clamping time, proximal anastomosis time, and distal anastomosis time. Additionally, total

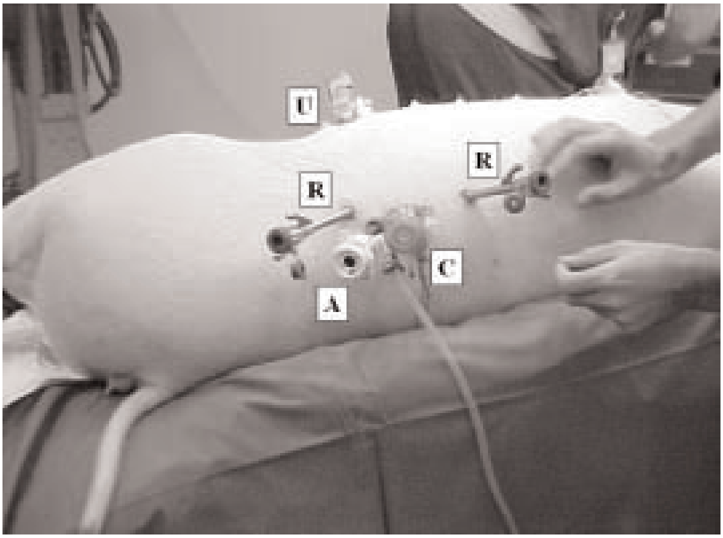

Figure 1

Trocar placement for robot-assisted retroperitoneal videoscopic aortic replacement in pigs. The pig is positioned in right semi-lateral position. U: umbilical camera trocar, C: camera trocar, R: robot trocars, A: assisting trocar.

blood-loss, blood-loss after clamp removal, complications, suture breaks and technical problems were registered. The primary end-point of the procedure was defined as complete haemostasis after clamp removal with adequate circulation in both lower limbs.

Efficacy of the anastomosis was evaluated by intraoperative inspection of leakage and by palpable pulsations in the pig's groin. Next, the pig was sacrificed by an intravenous overdose of barbiturates. Autopsy was performed immediately hereafter in order to evaluate the mechanical integrity and patency of the anastomosis by inspection. A distance of > 3mm in between stitches was considered an error. The number of stitches was recorded, as well as the distance between individual stitches and the circumference of the anastomosis. All data were analysed using SPSS and are expressed as median and range. Statistical significance was assessed using the Mann-Whitney-U test, with significance at $p<0,05$. The study protocol was approved by the Institutional Review Board for animal experimentation of the University Medical Centre Utrecht and conforms to the Guidelines for the Care and Use of Laboratory Animals, published by the US National Institutes of Health (NIH Publication No. 85-23, revised 1996).

Results

Total operating time, clamping time and time needed to perform the anastomoses were shorter in the robot group (Table 1). No intraoperative complications occurred in the robot group. In the control group, the vena cava was injured in one case and subsequently compressed with gauzes and blunt instruments before continuing the procedure. Total blood-loss and blood-loss after clamp removal were also less in the robot group (Table 1). In two control cases, haemostasis could not be established after clamp removal, resulting in termination of the experiment. In all cases, palpable pulsations in both groins were identified.

At autopsy, all robot anastomoses were adequate (Figures 2&3). In the control group, a stitch crossing the aortic lumen was found in two distal anastomoses and a large distance (>3 mm) between two stitches was encountered 15 times in 12 suture lines.

All 20 grafts were without anastomotic narrowing. The number of stitches for proximal anastomoses and distal anastomoses was higher in the robot group (Table 1). In the robot group, a rupture of the suture during suturing occurred in 4 cases compared to 3 suture ruptures in the control group. In these cases, the anastomosis was either finished with the other end of the double-armed suture or a new suture was introduced and tied to the first one. Also, in two cases in the control group, the knot was not securely tied, resulting in anastomotic dehiscence during manipulation at autopsy.

No significant differences in performance between the three surgeons could be demonstrated.

Table 1 **Comparison of robot-assisted and standard videoscopic aortic replacement (times in minutes, blood loss in millilitres). P calculated with Mann-Whitney-U test).**

	Robot group	Control group	p
Total OR-time	164 (116-225)	205 (162-244)	0.008
Aorta exposition time	30 (20-55)	38 (20-50)	NS
Dissection time	38 (31-78)	32 (20-78)	NS
Clamping time	63 (37-95)	106 (79-151)	0.0003
Proximal anastomosis	22 (15-37)	40 (31-75)	0.0003
Distal anastomosis	22 (14-40)	41 (28-46)	0.001
Blood-loss total	55 (0-300)	280 (105-1700)	0.004
Blood-loss after clamp removal	28 (0-200)	200 (50-1500)	0.01
Stitches proximal	15 (11-17)	13 (11-14)	NS
Stitches distal	14,5 (11-18)	9 (9-12)	0.001
Time per stitch proximal (sec)	93 (53-149)	180 (143-409)	0.001
Time per stitch distal (sec)	83 (56-185)	246 (180-294)	<0.0001

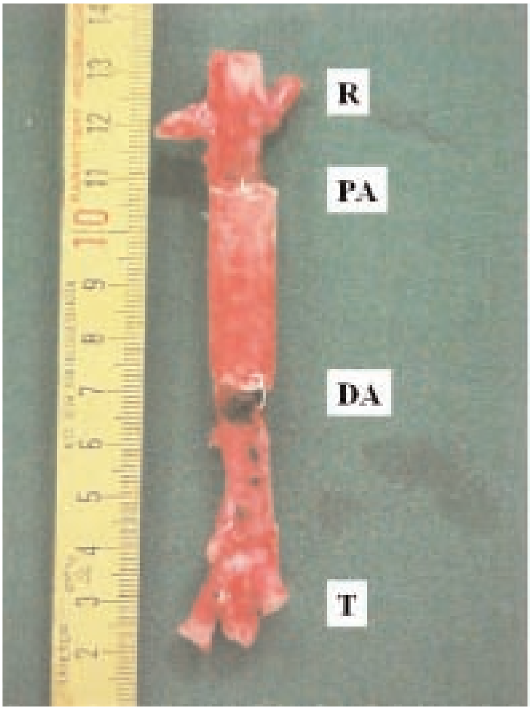

Figure 2
The aortic replacement graft. The renal arteries (R) and aortic trifurcation (T) with the anastomosis placed in-between. The proximal and distal anastomoses are marked PA and DA.

Figure 3
Close-up of the anastomotic line in the robot group. A regular suture distance without distances > 3mm is visible.

Discussion

The gold standard for abdominal aortic aneurysm repair is exclusion of the aneurysm, and interposition with a tube- or bifurcated prosthesis. This is usually performed through a midline laparotomy [1,2]. Traditional surgical AAA repair holds significant morbidity and mortality, partly caused by the extensive surgical trauma. Therefore, an endovascular approach was introduced in the early nineties of the past century [12]. Enthusiasm for this minimally invasive technique has increased over the last decade due to the good initial outcomes in terms of reduced blood-loss, less peri-operative complications, faster recovery and high patient satisfaction [13-15].

However, a distinct number of patients remain unfit for endovascular surgery, with only half of the patients with an infrarenal aneurysm estimated to have a suitable anatomy for endograft repair [13-15]. Next to this, long-term durability and performance of endografts have not yet been established. Serious problems like graft migration and endoleakage have been reported in 20% to 30% of cases, requiring treatment in over 10% [14-16]. Therefore, surgical intervention remains indicated in over 50% of patients.

In a thrive to limit surgical trauma pioneers started applying videoscopic techniques in vascular surgery. Dion and Gracia described the first videoscopy assisted aortobifemoral bypass in 1993. The dissection of the aorta was performed videoscopically, but the anastomosis was made through a mini-laparotomy 3. The first completely videoscopic procedures for aortoiliac occlusive disease were described by Berens and Dion in 1995 [17,18]. The next challenge was videoscopic aneurysm repair. In 2001, the first case of complete laparoscopic aneurysm repair was published 5.

Although proven feasible, most authors emphasise the technical challenges of the procedure. The first troublesome issue is the exposition of the aorta. This is either performed by a transperitoneal or a (left) retroperitoneal approach or by a combination of both techniques [19]. The main advantage of the laparoscopic, transperitoneal route is the accessibility of the dissection plane at the right side of the aorta, but a disadvantage is the difficulty to keep intestines out of the operative field. This can partly be compensated for by positioning the patient in Trendelenburg position and tilting to the right [20,21].

This problem does not exist in the retroperitoneal approach. However, it is technically challenging to develop the retroperitoneal cavity, without creating defects in the peritoneum. Even a small rent in the peritoneum will impair visualisation, since carbondioxide will leak to the peritoneal cavity and make the retroperitoneal space collapse. Another drawback is the visualisation of the right side of the aorta and the right common iliac artery. Additionally, the retroperitoneal cavity only comprises a small volume. If suction is applied, the cavity might easily collapse, resulting in impaired visualisation. A solution for this problem might be the use of mechanical tissue retractors [22]. The combination of both approaches, the APRON-approach, in which a peritoneal flap is attached to the anterior abdominal wall, offers an adequate working space, without the drawbacks of the trans- and retroperitoneal approaches, but requires a significant amount of time [23].

In our retroperitoneal exposition, no peritoneal leaks occurred, most probably due to the laparoscopic control while carefully creating the cavity. We used a 30-degree angled scope to compensate as much as possible for the impaired visualisation of the right side of the aorta. After acquisition of a proper exposition, the dissection of the aorta could be performed in a smooth way in both groups.

The second challenge is videoscopic clamping of the aorta. Most authors described the use of specially designed- or standard vascular clamps positioned through a keyhole entrance [4,24]. This necessitates one or two small additional incisions. Detachable vascular clamps were used in this experimental study. These clamps could be applied through the 12-mm assisting trocar. They deliver sufficient force to clamp the pig's healthy aorta with a relatively small diameter, but will need to be modified in order to clamp a sclerotic human aorta.

The third and most important challenge appears to be suturing the aorto-prosthetic anastomoses. Handling the delicate tissue of the fragile aortic wall and placing sutures tangential to the aortic wall is technically challenging mainly due to the limitations in visualisation and manipulation in standard videoscopic surgery. Most surgeons prefer therefore a hand-assisted approach in which the anastomosis is performed through a mini-laparotomy [24,25].

Robotic surgical systems offer a solution to the technical difficulties of videoscopic surgery. The system used in this experiment enhances visualisation by a true three-dimensional view based on a double optical system. In addition, the natural working axis is restored and the surgeons viewing axis is always in line with the image acquisition axis. The surgeon can optimise the field of view due to personal control of the optical system. Additional degrees of freedom of motion, filtering of tremor and friction and the ability to downscale the movements of the robotic instruments can contribute further to the feasibility of advanced videoscopic suturing [8-10]. The aim of this study was to compare this new robot-assisted videoscopic approach to the current standard videoscopic approach.

Our results clearly demonstrate that the procedure can be performed safer and more efficient with the use of the da Vinci robot system. The time-loss during the standard videoscopic procedures occurred while suturing the anastomosis, leading to a significantly longer clamping time. After as little as three cases, every surgeon was capable of suturing an anastomosis with robotic assistance in approximately 20 minutes or less. However, the number of cases per surgeon in this study is low and we expect to find a continuing learning curve leading to shorter anastomoses times in both approaches and for all surgeons involved.

Also, the success rate and the significantly decreased blood-loss in the robot group indicate the increased safety of this procedure. A superior quality of the anastomoses was not only reflected by the decreased blood-loss but also by an increased number of stitches, the absence of distances > 3mm in between stitches and absence of knot failures in the robot cases. However, the two surgeons with limited experience with the da Vinci system both broke two sutures while tying a knot. This problem was reported earlier and is attributed to the lack of force feedback in the robotic instruments [8,26].

Whether our results are deductible to the human situation will have to be proven. The pig model has definite advantages compared to clinical practice. First of all, retroperitoneal fat is almost absent in the pig which facilitates aortic dissection. Second and even more important, the quality of the healthy pig's aortic wall is incomparable to the fragile, calcified aortic wall in diseased patients. Furthermore, the presence of an aneurysm sac in patients might impose a further challenge to this procedure.

In conclusion, this study demonstrates the efficacy and safety of robot-assisted videoscopic aortic replacement in a porcine model. The procedure could be performed faster, with fewer complications and lower blood-loss with robotic assistance than through a standard videoscopic approach, with technically superior anastomoses.

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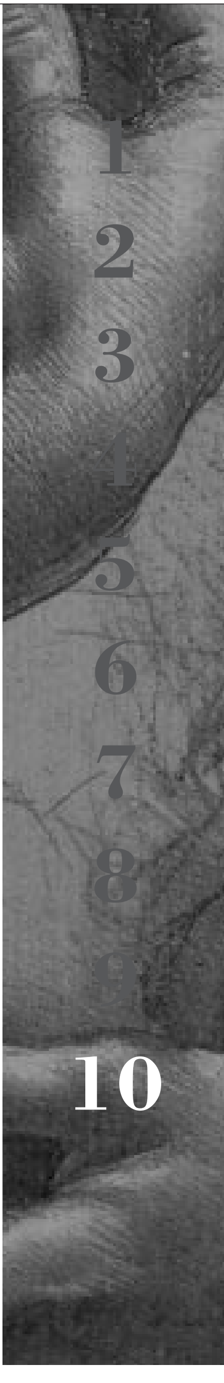
Chapter 10

General discussion, summary and conclusions



During the last three years, robot-assisted surgery systems are increasingly being applied in endoscopic surgery. Currently, over 165 da Vinci systems have been world-wide. This number was approximately 30 at the start of the robotic project in the University Medical Centre Utrecht.

The robotic systems were introduced with the objective to overcome the challenges of standard endoscopic surgery. With the improvements in manipulation and visualisation that robotic-assistance offers, technologically complex procedures can be performed endoscopically and standard endoscopic procedures can be performed easier and with greater comfort to the surgeon. This serves the purpose of improvement of quality of care.

The goal of this thesis was not only to assess the feasibility of various robot-assisted procedures both in experimental and clinical settings, but also to compare robot-assisted surgery to standard "open" and laparoscopic interventions. All studies aimed at assessing the benefits, challenges and potential pitfalls of using this new technology. In specific, we tried to answer the questions defined in the general introduction. This chapter will discuss and summarise our findings by answering those questions.

Is it feasible to perform both standard and complex endoscopic procedures with the use of robotic assistance?

During the past years many authors have dedicated themselves to demonstrating the safety and efficacy of robotic assistance in standard endoscopic surgery. In 1997, the first report on a successful case of robot-assisted laparoscopic cholecystectomy appeared. Other interventions were assessed in the years thereafter and demonstrated the safety of robot-assisted endoscopic procedures such as Nissen fundoplication and Heller myotomy [1-8].

In chapters 2 to 5 of this thesis, our clinical experience with robot-assisted surgery is presented. This started with a series of 40 laparoscopic cholecystectomies as described in chapter 2. This relatively simple procedure was carried out repetitively in order to learn how to work with the, at that time, new technology of robotic assistance under accustomed circumstances. During these procedures only one conversion and no intra-operative complications occurred demonstrating it's safety.

In our consecutive series of Nissen fundoplications, Heller and long oesophageal myotomies, para-oesophageal hernia repairs, ileocecal resections etc., as described in chapters 4 and 5, the number of conversions and complications was also low.

Concerning the efficiency, operating times were comparable to times mentioned in literature and to times in our institute for procedures performed with standard endoscopic instrumentation. The critical remark that needs to be made, however, is the considerable set-up time we encountered in our series. The time needed to install and sterilely drape the equipment averaged 15 minutes. In chapter 3 we took a closer look at the time-loss and realised that robotic assistance in our institution will burden the operating schedules by approximately 20 minutes per procedure. This time-loss needs to be reduced in order to use robotic systems on a daily basis. This can be accomplished in various ways, including a permanent set-up of the robotic equipment in a dedicated theatre, modification of sterile drapes and working with devoted teams.

As mentioned before, robots are employed with the objective to overcome the challenges of standard endoscopic surgery. Thereby they could enable technically complex procedures to be performed endoscopically. We, amongst others [3,9-13], assessed this issue in experimental models, as described in chapters [6-9]. The procedures compared all included endoscopic suturing, which tends to be one of the limiting factors in standard endoscopic surgery. All studies demonstrated the feasibility, safety and efficacy of robot-assisted surgery for their specific indication.

In chapters 6 and 7 of this thesis, two challenging (robot-assisted) laparoscopic surgical procedures were compared to the standard "open" procedure. It was noticed to be achievable to perform anastomoses with great ease and with a similar result as through the open approach, even though we had no previous experience with performing these procedures in a laparoscopic fashion.

During the choledochojejunostomies and Roux-and-Y diversions in chapter 7, we noticed time was mainly lost during dissection and identification of the jejunum, for which large instrument excursions are necessary. Working outside the cone defined by the three trocars and the target area leads to collisions between the three robotic arms. This brings up the need for a modification of trocar placement compared to standard endoscopic procedures. Teams starting with robot-assisted surgery need to be trained in order to adept to these changes in trocar and robotic cart position and thereby increase the safety of the procedure.

Another issue to address is the need for the surgical team to figure out the ideal placement of the robotic equipment in for every specific procedure. In general, the robotic cart should be placed in line with the camera trocar and the target area. For a cholecystectomy for example, it will be placed in line with the camera position at the umbilicus and the target area in the hepatic hilum. Therefore it will be positioned over the patient's right shoulder.

Furthermore, a major disadvantage of robot-assisted surgery is the lack of force feedback. Although this can be partly compensated for by visual control, some hinder is experienced form it, mainly while tying knots. This resulted in a number of suture tears in the early stage of our experience. Force feedback is also a prerequisite for subtle tissue handling. Therefore, it should be integrated into future generations of robotic telemanipulation systems.

A final challenge in working with the da Vinci system is the difference in perception of the situation in the theatre between the surgeon and his tableside assistant. The surgeon feels "immersed" in the patient's body cavity and imagines to be touching the tissue with is own hands. Hereby, the surgeon has no feel of the relation of his instruments to the patient's body and might experience difficulties to bring instruments in the field of view. For that reason, an instrument that goes out of sight, needs to be recovered under visual control rather than blindly. Also, the contact with the staff in the operating room is troublesome. This is caused both by the "immersion" and the physical barrier of being at a distance and behind a console. Working with headsets, enabling easy communication between staff-members solved this problem and is integrated now in the da Vinci system.

In conclusion, both standard and complex endoscopic procedures with the use of robotic assistance were repeatedly demonstrated feasible.

Does robot-assisted surgery offer benefits over standard endoscopic surgery?

This, of course, is the ultimate question to be answered in order to justify working with robotic instrumentation. It will be hard to demonstrate the advantages and defend the use of a million-Euro surgical tool for use in standard laparoscopic procedures.

During the more complex procedures described in chapters 4 to 7, we did experience benefits from robotic assistance. For instance, during the precise manipulation in Heller and long oesophageal myotomy, the integrated 3D vision supported proper imaging of the circular muscle fibres. Furthermore, the articulated instruments enabled working in a parallel line with the oesophagus, approaching the circular muscle fibres perpendicularly and without tremor, providing the dexterity needed for delicate dissection of the circular musculature. For para-oesophageal hernia repair we found dissection of the top of the hernia-sac facilitated by the articulated instruments much easier compared to standard laparoscopy. For Nissen fundoplication we agree with other authors that robotic assistance smoothens the progress of the dissection behind and around the oesophagus [2]. For the anastomoses in chapters 6 and 7, we appreciated the additional degrees of freedom, which allowed us to perform equally effective anastomoses as through open surgery. Our positive subjective findings were not compared to those of standard laparoscopy and need to be objectivated before any conclusions can be drawn towards the real benefits of robotic assistance.

In thrive to provide some answers towards potential benefits of robot-assisted surgery over standard laparoscopy at this point of time we started a randomised trial comparing robot-assisted to standard laparoscopic Nissen fundoplication. This might not be the procedure in which most benefit is to be expected, but it requires precise suturing and delicate dissection. Also, Nissen fundoplication is performed relatively frequent so that a sufficient number of cases to proof a difference might be realised within a reasonable time frame. Hereby, we focus on demonstrating an anatomically superior positioning of the fundoplication, next to functional and symptomatic differences.

Furthermore, two comparative experimental studies were performed. Both robot-assisted retroperitoneal aortic replacements in pigs and ex-vivo intestinal anastomoses, as described in chapters 8 and 9, were compared to standard endoscopic surgery. We chose these procedures since they require suturing of an anastomosis, which we think is a manoeuvre benefiting most from robotic assistance. For both procedures, clear advantages from robotic assistance were experienced. The vascular anastomoses were performed faster, with fewer errors and lower blood-loss with the use of the robot. A time/action analysis was performed for the intestinal anastomoses and it was demonstrated that even experienced laparoscopic surgeons performed better with use of the robot, even though they had no previous exposure to robot-assisted surgery.

In conclusion, we demonstrated benefits of robotic assistance over standard endoscopic surgery in experimental models. We also experienced benefit of the robotic system during our clinical procedure, which need to be objectivated in the near future.

Is there a role for robot-assisted surgery in day-to-day clinical practice?

To integrate robotics in day-to-day surgery, it should not only be demonstrated to be feasible, as was done in chapters 2 to 9. It should also bring clear advantages over standard endoscopic surgery either in terms of improving performance or enable more complex procedures. This should result in an improvement of quality of care.

Chapters 8 and 9 demonstrate the advantages of robotic assistance over standard endoscopic surgery in an experimental setting. Thereby robotic assistance enabled technically complex procedures to be performed endoscopically. Once these benefits are reproduced in clinical practice, two critical issues need to be addressed in order to implement robot-assisted surgery in day-to-day clinical practice.

First, the costs of robot-assisted surgery need to be evaluated in the relation to the benefit it brings. In other words, a cost-efficacy analysis needs to be performed. Until now, this analysis was not performed for the reason of the current price of the robotic systems. Most probably this price will drop with more systems installed and cost-efficacy might come in sight. For robot-assisted mitral valve repair it was recently demonstrated that total hospital costs did not increase with a minimally invasive robot-assisted approach compared to the standard "open" approach. The higher operative costs were compensated due to a trend toward decreased ICU and hospital stay for robotic patients [14]. Investment in this technology might be justified if minimally invasive surgery procedures are enabled that could not be accomplished with minimally invasive techniques using standard instrumentation.

A second point to address is the time-loss during robot-assisted surgery, which occurs mainly during set-up of the equipment. More time results in increasing costs, inhibiting the cost-efficacy of robot-assisted surgery. Therefore, the set-up times as mentioned in chapter 3 needs to be diminished or it needs to be demonstrated that procedure times and therefore operating-room times are shorter with the use of robotic assistance. This was already demonstrated in the experimental setting for complex laparoscopic procedures, with shorter operating times, as described in chapters 8 and 9. The feasibility of shortening set-up times was demonstrated when five robot-assisted laparoscopic cholecystectomies were performed on single day, between 8 AM and 4.30 PM, with a time needed for re-instalment of the robot in between procedures of 7 minutes.

On the basis of our clinical and laboratory experiences, we conclude that the application of robot-assisted surgery offers benefits, but that it requires investment of costs and time. At the moment, this inhibits broad implementation in day-to-day clinical practice.

Future perspectives

One of the additional potential applications of the concept of robotic telemanipulation, with a computer between the hands of the surgeon and the end-effector of the instruments, is the integration of robot-assisted surgery and virtual reality. Currently only the real-time image of the operative field is displayed, similar to conventional laparoscopy. Opportunities include projecting anatomical information of pre-and intra-operative images over the real-time image. In doing so, important structures could be accentuated and structures hiding below the surface of an organ could be overlaid on top of the operative view [15]. In this way, the surgeon would be able to visualise non-visible structures, such as arteries, hiding below the surface of an organ.

Taking this concept one step further, one might project the pre-operative image in the console prior to surgery and simulate the surgical manoeuvres. This allows for planning and rehearsal of the procedure. If surgery can be simulated inside the console, robot systems might become an ideal tool for surgical education. Residents can practice a new procedure until they possess sufficient skill to transfer their technique to the clinical situation. Their skills can be evaluated using the computing power of the robot. Once their skills are sufficient, they can start performing a procedure under the supervision of a qualified surgeon. This concept clearly adds value to standard laparoscopy simulators [16].

Also, in a future model for robot-assisted surgery, the supervisor will no longer be watching the novice perform, but will have a separate console, coupled to the novice's console. This "driving-lesson" set-up will allow the supervisor the ability to intervene and assume control of the instruments in situations requiring expert guidance. These features may make surgery safer and shorten the novice's learning curve for new procedures.

Conclusion

This thesis demonstrates that robot-assisted surgery is safe and efficient in both standard and complex endoscopic interventions. Robotic assistance was proven to offer distinct benefits over standard endoscopic surgery. To implement these systems in day-to-day surgery, the benefits will have to be demonstrated to outweigh the considerable investment of costs and time.

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Summary in dutch

Samenvatting

Op 26 juni 2000 werd in het Universitair Medisch Centrum Utrecht (UMCU) de eerste robotgeassisteerde laparoscopische operatie in Nederland verricht. Deze operatie werd gevolgd door meer dan 120 operaties aan het maagdarmkanaal in de afgelopen drie jaar. Dit proefschrift beschrijft de ervaringen met klinische en experimentele robotchirurgie in het UMCU in de periode juli 2000-juli 2003. In de kliniek werd onderzocht of robotchirurgie mogelijk en veilig is. In het Gemeenschappelijk Dierenlaboratorium (GDL) van de Universiteit Utrecht werden experimentele studies uitgevoerd. Deze richtten zich op de vergelijking tussen robotchirurgie en standaard open en laparoscopische technieken. Alle studies waren gericht op het beoordelen van de voor- en nadelen, uitdagingen en mogelijke valkuilen van de robotchirurgie.

Achtergrond

Het opereren van patiënten via een aantal kleine sneetjes wordt wel een kijkoperatie of endoscopische chirurgie genoemd. Op deze manier is het niet meer noodzakelijk een grote snee te maken om de operatie te verrichten zoals bij standaard "open" chirurgie. Endoscopische chirurgie heeft voor patiënten een aantal voordelen ten opzichte van open chirurgie. Niet alleen is er sprake van een cosmetisch voordeel, ook is er vaak een kortere opnameduur, een verminderd aantal wondcomplicaties, verminderde postoperatieve pijn en een sneller herstel naar dagelijkse werkzaamheden.

Voor de chirurg heeft endoscopische chirurgie echter nadelen ten opzichte van open chirurgie. In de eerste plaats is de chirurg beperkt in de vrijheid van manipuleren. Het werken met lange instrumenten door een vast entreepunt in de huid beperkt het aantal vrijheidsgraden van beweging. De beweging van de instrumenten is tegengesteld aan de beweging van de handen van de chirurg en de uitslag van de bewegingen varieert. De kleppen, die in de buisjes zitten die door de huid gaan en waardoor geopereerd wordt (trocars), zorgen voor wrijving op de instrumenten.

Ook op het gebied van de visualisatie zijn er handicaps: het normale zicht ontbreekt doordat wordt gewerkt met een camera, die eveneens door een van de trocars wordt ingebracht. Deze camera projecteert het beeld op een tv-scherm. Niet alleen is dit beeld tweedimensionaal, waardoor er slechts een beperkte waarneming van diepte bestaat, ook wordt de natuurlijke werk-as tussen ogen, handen en het doel verbroken. Vanwege deze beperkingen wordt endoscopische chirurgie op dit moment alleen op grote schaal uitgevoerd voor relatief eenvoudige ingrepen, zoals galblaasverwijderingen.

Aan het eind van de jaren negentig van de vorige eeuw werden robotsystemen geïntroduceerd ter ondersteuning van de endoscopische chirurgie. Zij werden ontworpen met het doel de beperkingen van de endoscopische chirurgie ten opzichte van open operaties te verhelpen. In juni 2000 werd een da Vinci robotsysteem aangeschaft door het UMCU. Tegelijkertijd werd in het GDL een tweede da Vinci robot geïnstalleerd.

In alle studies beschreven in dit proefschrift werd dit robotsysteem gebruikt. Het bestaat uit een console, een drie-armige robot en een videotoren. De chirurg zit tijdens de ingrepen achter de console en bestuurt met twee "joysticks" de instrumenten en de camera, die worden gedragen door de armen van de robot. Twee van de drie armen van de robot dragen instrumenten, die alle bewegingen van de joysticks exact kopiëren. Deze instrumenten hebben aan het uiteinde twee extra gewrichten (polsjes), die de chirurg twee extra vrijheidsgraden van beweging geven. Daarnaast worden de omgekeerde instrumentbeweging, de variabiliteit van de uitslagen en de frictie door de kleppen geëlimineerd. De derde, middelste robotarm draagt de camera. Deze camera is een dubbele endoscoop, die twee separate beelden genereert. Deze beelden worden op twee schermen in de console geprojecteerd, één voor het linker- en één voor het rechteroog. Hierdoor wordt de diepteperceptie hersteld. Tevens wordt dit driedimensionale beeld geprojecteerd in lijn met de ogen en handen van de chirurg, waardoor de natuurlijke werk-as wordt hersteld.

De uitvoerbaarheid van diverse robotgeassisteerde procedures werd klinisch onderzocht en de experimentele studies richtten zich op de vergelijking tussen robotchirurgie en standaard open en laparoscopische technieken en op het beoordelen van de uitvoerbaarheid van complexe endoscopische ingrepen. Doel hierbij was het beantwoorden van de volgende vragen:

1. Is het mogelijk om standaard en meer complexe endoscopische ingrepen met behulp van een robotsysteem te verrichten?
2. Zijn er voordelen van robotchirurgie ten opzichte van standaard endoscopische chirurgie?
3. Is er een rol voor robotchirurgie in de dagelijkse praktijk?

Is het mogelijk om standaard en meer complexe endoscopische ingrepen met behulp van een robotsysteem te verrichten?

In hoofdstuk 2 tot 5 van dit proefschrift wordt onze klinische ervaring met robotgeassisteerde chirurgie beschreven. Er werd voor gekozen om te starten met een serie van 40 laparoscopische cholecystectomieën ofwel galblaasverwijderingen, zoals beschreven in hoofdstuk 2. Deze relatief eenvoudige procedure werd gekozen om te leren omgaan met de op dat moment nieuwe technologie bij een routinematig uitgevoerde en daardoor veilige ingreep. Tijdens deze operaties trad slechts één complicatie op en was het één keer nodig te converteren naar een open procedure. In de hierop volgende serie operaties (aan maag, middenrif, slokdarm en darmen), zoals beschreven in hoofdstuk 4 en 5, was het aantal complicaties en conversies eveneens laag. De operatietijden waren vergelijkbaar met de tijden voor soortgelijke ingrepen met standaard endoscopisch instrumentarium.

Eén kritische kanttekening moet hierbij wel worden geplaatst. Voor elke operatie is een aanzienlijke tijd nodig om het robotsysteem op te stellen, aan te sluiten en steriel af te dekken. Gemiddeld bedroeg die tijd 15 minuten. In hoofdstuk 3 wordt het tijdverlies tijdens robotchirurgie nader onder de loep genomen. In ons ziekenhuis bedroeg het totale tijdverlies tijdens een robotgeassisteerde laparoscopische cholecystectomie 20 minuten. Om robots dagelijks in te kunnen zetten zonder het operatieprogramma onnodig te belasten zal dit tijdverlies moeten worden gereduceerd. Dit kan bijvoorbeeld door te werken in speciaal ingerichte operatiekamers met een permanente opstelling van de robotapparatuur, door aanpassing van het steriele afdekmateriaal of door te werken met gespecialiseerde operatieteams.

Zoals hiervoor reeds aangegeven, worden robotsystemen gebruikt om de onvolkomenheden van standaard endoscopische chirurgie te verhelpen. Daardoor kunnen technisch meer uitdagende procedures endoscopisch worden uitgevoerd. De haalbaarheid van dit soort procedures werd onderzocht in dierexperimentele modellen, zoals beschreven in hoofdstuk 6-9. Alle onderzochte procedures vereisten endoscopisch hechtwerk, dat lastig is om met standaard endoscopisch instrumentarium te verrichten. Alle studies toonden de veiligheid en efficiëntie van robotchirurgie aan voor de specifieke ingreep.

In hoofdstuk 6 en 7, werden twee uitdagende (robotgeassisteerde) laparoscopische ingrepen vergeleken met de standaard open procedure. De darmnaden en verbindingen (anastomoses) tussen galwegen en darmen konden met grote precisie en gemak worden verricht. Het resultaat was vergelijkbaar met dat via de open benadering, ondanks het feit dat de opererende chirurg geen ervaring had met dit soort ingrepen op standaard laparoscopische wijze.

Wat opviel tijdens deze procedures was het tijdverlies tijdens het identificeren van het benodigde deel van de darmen. De grote bewegingsuitslagen van instrumenten die hiervoor nodig zijn kunnen leiden tot botsingen tussen de drie robotarmen. Door een juiste, aangepaste plaatsing van de trocars kon dit in de meeste gevallen worden voorkomen. Een ander punt van aandacht is de plaatsing van de robot ten opzichte van de patiënt voor elke procedure. Teams zonder ervaring in de robotchirurgie moeten hierin worden getraind, zodat ze de procedures veilig kunnen uitvoeren.

Een nadeel van robotchirurgie is het gebrek aan krachtterugkoppeling. Tijdens het opereren voelt de chirurg niets van de krachten die door de instrumenten worden uitgeoefend. Dit werd bijvoorbeeld ervaren tijdens het aantrekken van knopen, waarbij de hechtdraad soms werd gebroken. Toenemende ervaring met robotchirurgie leidt ertoe dat dit probleem kan worden gecompenseerd door visuele informatie. Toch blijft krachtterugkoppeling een punt van aandacht bij verdere ontwikkeling van deze techniek, ook om geen schade te verrichten aan de weefsels.

Een verdere uitdaging tijdens het werken met het da Vinci systeem is het verschil in waarneming van de situatie in de operatiekamer tussen de chirurg achter de console en de assistentie aan tafel. De chirurg verdwijnt in de console en heeft het gevoel dat hij zich in de buik van de patiënt bevindt en dat hij het weefsel met zijn handen aanraakt. De relatie tussen de positie van de instrumenten en de anatomie van de patiënt wordt hierbij niet opgemerkt. Als een instrument buiten het gezichtsveld raakt kan het daardoor moeilijk zijn dit weer in beeld te brengen. Ook is het onderlinge contact tussen de chirurg en het operatieteam moeizaam door de onderlinge afstand en het feit dat de chirurg opgaat in de console. Dit probleem werd goeddeels opgelost door te werken met een draagbaar systeem van koptelefoons met microfoontjes.

Concluderend werd er aangetoond dat zowel standaard, als meer complexe endoscopische ingrepen uitvoerbaar zijn met behulp van het da Vinci robotsysteem.

Zijn er voordelen van robotchirurgie ten opzichte van standaard endoscopische chirurgie?

Deze vraag dient te worden beantwoord om de toepassing van robotchirurgie te rechtvaardigen. Het zal lastig zijn om de meerwaarde van robotchirurgie aan te tonen, en de investering van ongeveer een miljoen Euro te billijken voor gebruik tijdens 'standaard' laparoscopische procedures. Tijdens de meer complexe ingrepen, zoals beschreven in hoofdstuk 4 tot 7, werd al een duidelijk voordeel ervaren. De driedimensionale visualisatie en toename van het manipulatievermogen maakten het mogelijk om de doelorganen goed te visualiseren en de benodigde handelingen onder vaak lastige hoeken fijnzinnig uit te voeren. Deze bevindingen tijdens deze procedures werden echter niet vergeleken met standaard endoscopische procedures. Pas wanneer dat wordt gedaan en onze subjectieve bevindingen worden geobjectiveerd, kunnen harde conclusies worden getrokken betreffende de meerwaarde van robotassistentie tijdens endoscopische chirurgie. In ons streven antwoorden te verschaffen betreffende deze meerwaarde werd inmiddels een onderzoek gestart, waarin robotgeassisteerde en standaard laparoscopische operaties voor de gastro-oesophageale refluxziekte (met als belangrijkste klacht brandend maagzuur) worden vergeleken.

Daarnaast werden reeds twee vergelijkende experimentele studies verricht, zoals beschreven in hoofdstuk 8 en 9. In een varkensmodel werd het endoscopisch vervangen van de grote lichaamsslagader (aorta) met behulp van de robot vergeleken met een zelfde procedure zonder robotassistentie, en in post mortem varkensdarmen werden het vervaardigen van een darmanastomose met en zonder robotassistentie vergeleken. Beide studies lieten een duidelijk voordeel van robotchirurgie zien. De vaatoperaties werden sneller verricht met minder fouten en minder bloedverlies. Een analyse van het vervaardigen van de darmnaden liet zien dat zelfs ervaren laparoscopisch chirurgen een betere prestatie leverden met robotassistentie, ondanks dat ze geen enkele eerdere ervaring hadden met robotchirurgie.

Concluderend werd in een experimenteel model aangetoond dat er een meerwaarde van robotchirurgie is tijdens endoscopische operaties. Ook werd een subjectief voordeel van robotchirurgie ervaren tijdens klinische ingrepen.

Is er een rol voor robotchirurgie in de dagelijkse praktijk?

Om robotchirurgie op dagelijkse basis te gaan gebruiken moet niet alleen de toepasbaarheid ervan worden aangetoond, ook dient er een duidelijke meerwaarde ten opzichte van standaard endoscopische chirurgie te zijn. Deze meerwaarde moet tot uiting komen in een verbeterde prestatie of in de mogelijkheid meer complexe chirurgie endoscopisch uit te voeren, resulterend in een verbetering van de kwaliteit van zorg.

Hoofdstukken 8 en 9 toonden reeds de meerwaarde van robotchirurgie aan in een experimentele setting. Zodra deze meerwaarde wordt aangetoond in de klinische situatie moeten er twee punten van aandacht worden besproken, die op dit moment de grootschalige integratie van robotchirurgie in de dagelijkse praktijk verhinderen.

Ten eerste zijn er aanzienlijke kosten verbonden aan het gebruik van robotsystemen, die gerelateerd moeten worden aan de eventuele meerwaarde. Op korte termijn zal er geen sprake kunnen zijn van kosten-effectiviteit, aangezien het prijsniveau van de robotsystemen nog hoog ligt. Waarschijnlijk zal de prijs zakken wanneer er meer systemen worden geïnstalleerd en kan kosten-effectiviteit in redelijker perspectief worden geplaatst. Op dit moment moet robotchirurgie echter alleen gezien worden als een investering in een instrument ter verbetering van de kwaliteit van zorg. Of de kwaliteit van zorg dusdanig toeneemt dat een dergelijke investering te rechtvaardigen is zal in de komende jaren moeten blijken.

Een tweede punt van aandacht is het tijdverlies dat optreedt tijdens het opstellen en steriel afdekken van het robotsysteem. Tijdverlies resulteert in hogere kosten, waardoor kosten-effectiviteit verder in het gedrang komt. Om die reden zal het tijdverlies, zoals beschreven in hoofdstuk 3, moeten afnemen, of er moet worden aangetoond dat procedures met robotassistentie sneller kunnen worden uitgevoerd dan zonder robot, zodat de totale tijd op de operatiekamer niet toeneemt. In experimenten werd dit al aangetoond, met kortere operatietijden voor robotgeassisteerde dan voor standaard endoscopische ingrepen, zoals beschreven in hoofdstuk 8 en 9. De haalbaarheid van het verkorten van het tijdverlies werd aangetoond met het verrichten van vijf laparoscopische cholecystectomieën op één dag, tussen 8 en 16.30 uur, waarbij met een permanente opstelling van de robotapparatuur werd gewerkt, resulterend in een tijd van 7 minuten, die nodig was tussen de ingrepen om de robot weer gebruiksklaar te maken.

Op basis van deze klinische en experimentele ervaringen kan worden geconcludeerd dat de toepassing van robotchirurgie weliswaar meerwaarde biedt maar dat hier een investering van tijd en geld tegenover staat die een grootschalige introductie op dit moment in de weg staat.

Toekomstperspectieven

Naast toepassing van robotchirurgie tijdens endoscopische chirurgie biedt het concept, met een computer tussen de handen van de chirurg en de eind-effector van de instrumenten, mogelijkheden om chirurgie en 'virtual reality' te integreren. Op dit moment wordt in de console alleen het beeld van de operatie geprojecteerd, net zoals bij standaard endoscopische chirurgie. Het is reeds mogelijk om naast deze gegevens ook anatomische informatie, verkregen uit pre- en peroperatieve beeldvorming te projecteren. Dit biedt de mogelijkheid om belangrijke structuren te accentueren en aan de oppervlakte onzichtbare structuren in beeld te brengen.

Een volgende mogelijkheid is het projecteren van de preoperatieve beeldvorming in de console voor de operatie en hierop de chirurgische handelingen te simuleren. Op deze manier kunnen procedures worden gepland en geoefend en kan er een rol ontstaan voor het gebruik van deze systemen tijdens de training van chirurgen in opleiding. De computersystemen van de robot kunnen precies het niveau van handelen bepalen en beoordelen of er voldoende gerepeteerd is en of de operatie veilig kan worden uitgevoerd.

Een andere optie voor training van chirurgen is de mogelijkheid om twee consoles te koppelen. Op deze manier hoeft de supervisor niet langer toe te kijken terwijl de pupil opereert, maar kan hij vanaf zijn eigen console direct de controle over de instrumenten overnemen. Deze 'rijles' opstelling kan chirurgie veiliger maken en de leercurve verkorten.

Conclusie

Dit proefschrift toont de uitvoerbaarheid en veiligheid van robotchirurgie aan voor standaard en meer complexe endoscopische procedures. Er werden duidelijke voordelen van robotassistentie aangetoond ten opzichte van standaard endoscopische chirurgie. Om robotchirurgie in de dagelijkse praktijk te implementeren, moet in de komende jaren worden aangetoond dat de voordelen opwegen tegen de toegenomen kosten en het tijdverlies.

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Curriculum vitae auctoris

The author of this thesis, Jelle Piet-Hein Ruurda, was born in Oss, the Netherlands on March 3, 1975. He graduated high-school (Gymnasium-ß) at the Titus Brandsma Lyceum in Oss in 1993, and matriculated to medical school at the University of Amsterdam. In 1997/98 Jelle worked as a Research Fellow in the field of Paediatric Molecular Oncology at the National Institutes of Health, National Cancer Institute in Bethesda, Maryland, USA under Dr. L.J. Helman. On September 27, 2000 Jelle obtained his medical degree from the University of Amsterdam.

Upon graduation, Jelle started working as a research resident at the Department of Surgery, University Medical Centre Utrecht under Prof. Dr. Th.J.M.V. van Vroonhoven and Prof. Dr. Chr. Van der Werken. Jelle got involved in the project 'Operating Room of the Future' headed by Dr. I.A.M.J. Broeders, which culminated in this thesis on robot-assisted endoscopic surgery.