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Computer-assisted surgery in children

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Lund 2010
To Krisztina, Rebecca, Isolde and Sebastian
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Abstract

Although positive in terms of patient trauma and recovery time, minimally invasive surgery has several technical drawbacks compared with open surgery. The new da Vinci® Surgical System from Intuitive Surgical® offers technical innovations aiming at overcoming these drawbacks and at improving the surgeon’s operating skills, such as the improved 3-D vision, tremor reduction and flexible instruments with a more natural and intuitive range of motion. In this thesis, the computer-assisted surgical instruments, and their application in paediatric surgery and paediatric urology, were investigated.

In a prospective study of the first six fundoplications using the da Vinci® Surgical System, retrospective data from the open surgical procedure and the conventional laparoscopic technique were used as controls. Computer-assisted laparoscopic surgery (CALS) was safe and feasible. The operating time for the computer-assisted procedure was longer than the open one, but comparable to the laparoscopic procedure, and the need for postoperative morphine analgesics and the length of hospital stay were reduced with the two minimally invasive methods. The short-term clinical outcome did not differ, the symptoms of gastroesophageal reflux disease disappeared in all the children.

The costs for CALS were compared with the costs for open and laparoscopic surgery in children. The total costs of CAL fundoplication amounted to EUR 9584. The costs for laparoscopic and open fundoplication amounted to EUR 8982 and EUR 10521, respectively. The cost of the CALS instruments per procedure (EUR 2081) accounted for the extra expense compared with laparoscopy. The increased costs for CALS due to longer operating time, were offset by the shorter hospital stay compared with open surgery, 3.8 and 7.9 days, respectively.

An experimental study of students with no prior surgical experience and divided by gender was performed to test the hypothesis that maiden users master surgical tasks more quickly with computer-assisted than with standard laparoscopic instruments. Each surgical task was performed four times with one of the techniques before changing to the other. Speed and accuracy were measured. A cross-over technique was used to eliminate gender bias and the experience gained from carrying out the first part of the study. The more advanced task of tying a knot was performed faster with the computer-assisted than with the laparoscopic technique. Shorter time was observed when the change was made from laparoscopy to the computer-assisted technique. Gender did not influence the results. The lack of tactile feedback in computer-assisted laparoscopy seemed to matter.
A case-control study of ten consecutive children undergoing computer-assisted retroperitoneoscopic nephrectomy due to a non- or malfunctioning kidney was performed. This prospectively gathered consecutive group of children was compared with a retrospectively collected group of all other children who had undergone open nephrectomy for benign renal disease at our centre between 2005 and 2009. All nephrectomies were performed with the retroperitoneal approach. Endpoints of this study were safety, the operating time, the number of postoperative doses of morphine, the length of hospital stay and the number of complications. Four out of ten patients in the CALS group had a total operating time within the range of the operating time for an open procedure but it was longer for the CALS procedure. The number of postoperative doses of morphine did not differ, but the hospital stay was shorter for the CALS group.

The patient benefit from CALS, in the form of low morbidity, improved cosmetics and shorter hospitalisation was associated with the minimally invasive approach. Whether computer-assistance leads to better long-term results and fewer postoperative complications is too early to determine. However, considering all the potential benefits of the CALS instruments, the future will favour its use in paediatric surgery.

Disclosure statement

In performing this work there were no conflicts of interest or competing financial interests. The author has not received any financial support from any of the manufacturers mentioned in this thesis.
List of original papers

This thesis is based on the following papers, referred to by their Roman numerals:


IV: **Anderberg M**, Clementson Kockum C, Arnbjörnsson E. Paediatric computer-assisted retroperitoneoscopic nephrectomy compared with open surgery. Submitted.

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### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AESOP</td>
<td>Automated Endoscopic System for Optimum Position</td>
</tr>
<tr>
<td>ARTEMIS</td>
<td>Advanced Robotic Telemanipulator for Minimally Invasive Surgery</td>
</tr>
<tr>
<td>CAL</td>
<td>Computer-assisted laparoscopy/laparoscopic</td>
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<td>CALS</td>
<td>Computer-assisted laparoscopic surgery/surgical</td>
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<tr>
<td>CDH</td>
<td>Congenital Diaphragmatic Hernia</td>
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<td>CWS</td>
<td>Cooperative Weichteilsarkom Studie</td>
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<tr>
<td>ENT</td>
<td>Ear, Nose and Throat</td>
</tr>
<tr>
<td>ESPGHAN</td>
<td>European Society for Paediatric Gastroenterology, Hepatology and Nutrition</td>
</tr>
<tr>
<td>FDA</td>
<td>United States Food and Drug Administration</td>
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<tr>
<td>GER</td>
<td>Gastroesophageal reflux</td>
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<td>GERD</td>
<td>Gastroesophageal reflux disease</td>
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<tr>
<td>HD</td>
<td>High Definition</td>
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<td>IRS</td>
<td>Intergroup Rhabdomyosarcoma Study</td>
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<tr>
<td>MIS</td>
<td>Minimally Invasive Surgery</td>
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<tr>
<td>NASA</td>
<td>National Aeronautics and Space Administration</td>
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<tr>
<td>OR</td>
<td>Operating Room</td>
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<tr>
<td>OSATS</td>
<td>Objective Structured Assessment of Technical Skill</td>
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<td>SD</td>
<td>Standard Deviation</td>
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<td>SL</td>
<td>Standard laparoscopy/laparoscopic</td>
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<td>SRI</td>
<td>Stanford Research Institute</td>
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<td>RMS</td>
<td>Rhabdomyosarcoma</td>
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<tr>
<td>VAS</td>
<td>Visual Analogue Scale</td>
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<tr>
<td>3-D</td>
<td>Three-dimensional</td>
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Introduction

‘The art of surgery is not yet perfect and advances now unimaginable are still to come. May you have the wisdom to live with them with grace and humanity’

(William Stewart Halsted 1852-1922)

Background

In the ever-evolving field of surgery, the open technique in which large incisions were needed for gaining access to and manipulating the surgical field, has dominated. These large incisions inevitably cause significant patient trauma in the form of pain and suffering, prolonged need for analgesics, and extended recovery time. Since the 1990s, small cameras and small surgical instruments, called laparoscopes and laparoscopic instruments inserted in the patient through small ports or holes, have been an option when performing surgery. This method of using laparoscopic instruments is called minimally invasive surgery (MIS) or “key-hole” surgery. Thanks to the improvement for patients in terms of cosmetics, shorter hospital stay and less pain, laparoscopy is now considered the gold standard worldwide for many surgical procedures.

However, the introduction of MIS in the paediatric surgery field has been somewhat slower than in adult surgery. The reasons for this are probably the diversity in diagnoses and size of the paediatric patients, the early lack of smaller instruments adapted for use in children, and the relatively long learning curve, which all complicate the introduction of a new technique.

There have been many reports in the literature on the use of laparoscopy for relatively simple procedures in children, such as appendectomy, in diagnosing and treating impalpable, undescended testis, for cholecystectomy and hernia repairs. The clinical comparative studies show that this procedure is safe and valuable also for children [1]. Even if most paediatric surgical procedures are probably still performed with the open technique, minimally invasive surgery is well established in the paediatric population today. However, for laparoscopic nephrectomy and more complex paediatric laparoscopic procedures such as partial nephrectomy, pyeloplasty and ureteral reimplantation, there are fewer comparative clinical reports, and these contain smaller series of patients. The success rate seems similar to that of open
surgery but the low number of reports might indicate that this technique remains a challenge to perform and teach [2,3].

Although positive in terms of patient trauma and recovery time, MIS has several technical drawbacks compared with open surgery. The surgeon uses wrist-rigid instruments implying not only decreased mobility due to the invariant point of insertion in the abdominal wall, but also only five degrees of motion including grip, thus limiting surgical dexterity. This can be compared with seven degrees of motion for open surgery. The movement of laparoscopic instruments is counter-intuitive since you have to move your hand to the right when you want the instrument to move to the left. Instead of looking directly at the hands, a standard two-dimensional (2-D) monitor is used for image projection which results in the loss of the natural depth perception. Furthermore, the ergonomic design is poor, with long instruments handled under tension from the abdominal wall in a standing position and sometimes for long periods of time. Due to the technical drawbacks involved, extensive surgical laparoscopic training is therefore required before the patient can benefit from this technique for surgical procedures and before it can be considered the new gold standard.

Laparoscopy was introduced at our department of paediatric surgery in the early 1990s and has been used as a diagnostic tool for appendectomy, cholecystectomy, for treating undescended testis and for placing gastrostomomas [4]. Reconstructive procedures include mainly Nissen fundoplications due to gastroesophageal reflux disease (GERD) and the creation of enterocutaneous stomas. In 2005, after extensive training, we performed our first laparoscopic urologic procedures in the form of pyeloplasties due to an obstructed pelvoureteral junction in two patients. Minimally invasive surgery in paediatric surgery is well-established but the advanced laparoscopic skills needed, at least for reconstructive surgery in children, may have limited its widespread application among paediatric surgeons, as it has at our department.

In 1997, a decade after the first laparoscopic cholecystectomy, the first laparoscopic procedure with so-called robotic assistance was performed by Cadieré et al. in Brussels, Belgium, where they performed a cholecystectomy. A year later the same team performed the first Nissen fundoplication with robotic assistance [5]. In recent years, robot-assisted laparoscopic surgery with the da Vinci® Surgical System from Intuitive Surgical® (Sunnyvale CA, USA) has been available outside the pilot centres and has been increasingly used. The surgical system offers technical innovations aiming at improving the surgeon’s operating skills, such as the improved 3-D vision, tremor reduction and flexible instruments with a more natural and intuitive range of motion than conventional laparoscopic instruments. It is a master-slave system where the surgeon, at a manoeuvre console in perfect ergonomics, uses a computer to translate his hand movements into instrument movements at the surgical cart placed beside the patient. If the da Vinci® Surgical System used for performing
MIS can be found to be easier than conventional laparoscopy, it can offer some very interesting possibilities for surgeons.

The simpler surgical procedures performed today using standard laparoscopic instruments might be carried out more quickly and easily with the assistance of the surgical system. The more complex laparoscopic procedures, today performed only by a very select group of highly skilled surgeons, could perhaps become routine surgery for more surgeons who would previously not have chosen the minimally invasive approach for such special procedures. Finally, with the da Vinci® Surgical System instruments some procedures that could hardly be performed using traditional MIS technologies are perhaps made possible.

The term robot was originally coined by the Czech play writer Karel Capek in 1921 in his play “Rossum’s Universal robots”. The Czech word “robota” means forced labour and a robot is a machine that performs autonomous repetitive movements [6]. Although often referred to as robotic surgery, as by me, the da Vinci® Surgical System cannot be pre-programmed to make decisions or run on its own. On the contrary, it is designed to replicate a surgeon’s hand movements after direct input. As others have pointed out, the term robotic surgery, often also used in the literature, can give the false impression that it is a robot that performs the surgery and this is strictly not correct [6-8]. However, the term robot and robotic surgery is still more frequent in the literature, probably for historic reasons or perhaps because of the futuristic touch to the word. Since the term robot should be reserved for automated pre-programmed movements, the term computer-assistance is preferred by the present author for this surgical system and will be used throughout this thesis.

Computer-assisted laparoscopic surgery (CALS) has proved to be safe and efficient with results comparable to those of the conventional laparoscopic and open surgical procedures in adults [9]. Adult urologists were early to start using this new technique and are still the most frequent users around the world, but in the last couple of years, reports from other surgical specialties, such as General Surgery, Ear-Nose-Throat (ENT) and Gynaecology have become more common. The literature on paediatric CALS is very limited and consists mainly of either reports of a surgical team’s initial experiences of performing different procedures with computer-assistance, or case reports of more unusual procedures performed for the very first time in children [10-12]. Even though the number of reports on paediatric CALS are few and the experience limited, the initial reports seem to demonstrate that it is a safe and feasible procedure with encouraging results also in children [6,8,13-24]. The role of CALS in children and its full potential, however promising, remains unclear.

When introducing a new technique or new instruments into clinical practice, safety and feasibility are matters that have to be addressed. Other aspects, such as costs of new technology, how to implement new techniques, defining benefits and drawbacks and evaluating its usefulness in the existing surgical field are equally important. The overall ambition for us when starting to use the da Vinci® Surgical
System was from the very beginning to evaluate all the above-mentioned factors in a research project and the result of our work is presented in this thesis.

In order to address the two questions of safety and feasibility and compare CALS with the earlier surgical methods, we carried out what, to our knowledge was the first clinical comparative study of CALS performed on children (Paper I). A recent review from 2009 by van Haasteren et al. found a total of eight case series and five comparative studies of children, where CALS was compared with either conventional laparoscopy, open surgery or both [25]. In Paper II, the cost involved for introducing CALS into clinical practice was addressed and compared with the costs for standard laparoscopic or open approaches. No similar reports exist in paediatric surgery.

The potential of CALS in children is, furthermore, demonstrated by some surgeons who have managed to perform procedures with these new instruments that they have never done before with the standard laparoscopic instruments [18]. Our team has performed a Morgagni Hernia repair in a small child, and a radical cystoprostatectomy due to a rhabdomyosarcoma in the bladder in a young boy with computer-assisted surgery; we have never done this laparoscopically before, thus converting an open procedure to a minimally invasive one with excellent results [26,27].

The question of training is, and has always been, central in surgery and for surgeons. With reduced working hours, more doctors, and shifting demands on surgeons leading to less time spent in the operating room (OR), the discussion on training has become even more important in the last decade. Conventional laparoscopic surgery may offer great advantages for patients but can be demanding for the surgeon because of several technical drawbacks. These factors might attribute to the relatively long training period required before reaching a professional level [28,29]. One stated consequence of the improved features of the computer-assisted surgical system is that laparoscopic surgical skills are more easily mastered and the learning curve is shortened [28,30,31].

A definition of the learning curve can be the amount of practice, in terms of time or number of repetitions, needed to reach a certain level of proficiency for completing a specific task. Parameters used when analysing learning curves are time to complete the task, the number of errors made and actions required. Learning curves in daily practice are often defined by operating time, blood loss, morbidity and length of hospital stay [30]. There is only very scant literature on the comparison of learning curves for CALS and standard laparoscopy [30,32]. It is also a challenge to interpret the results of earlier studies, one reason being the different levels of previous experience among the participants.

To know more about the learning curve in minimally invasive surgery, and preferably, as a consequence, to be able to shorten the time needed for operative training before reaching a consistent level, is desirable. We therefore decided to test the hypothesis that surgically novice subjects perform surgical tasks faster with the
computer-assisted laparoscopy (CAL) technique than with the standard laparoscopy (SL) technique; this is presented in the third paper (III).

For paediatric urology the open approach has been our method of surgery, with two exceptions, until we started with CALS. Today, more than 50% of our CALS patients have a urological disease. In the fourth paper we decided to analyse the initial experience with CAL for performing nephrectomies in children compared with controls undergoing open surgery, in terms of safety, operative time, blood loss, opioid requirements, the duration of hospital stay and complications (IV). To our knowledge, there are no similar reports concerning children.

**Evolution of robotic devices in surgery**

The first robot used in the brief history of robotics in surgery was the Puma 560, used by Kwoh et al. in 1985 [33]. It was a standard industrial robot employed as a stereotactic fixture for neurosurgical biopsies which, contrary to conventional frames, could position itself automatically and accurately. The Puma was later also used in a feasibility study for transurethral resection of the prostate which led to the development of a second-generation robot for prostate resections, called the Probot, at the Imperial College of London. The Probot consisted of two units, one larger positioning and support unit, and one smaller movable unit with limited motions and forces, better adapted for the specific surgical tasks, and making it safer than its industrial predecessor. In the US, the Robodoc® was designed for hip replacement surgery and used for the first time on humans in 1992. It assists the surgeon in the preoperative planning and intra-operative femoral canal drilling for the replacement of femoral heads and could result in increased prosthesis-to-bone contact [34]. After clinical studies it became the only active robotic system for orthopaedic surgery on the market cleared by the United States Food and Drug Administration (FDA) in 2008.

The first endoscopic guidance system on the market was the AESOP (Automated Endoscopic System for Optimum Position) approved by the FDA in 1995. This was a robotic arm mounted on the operating table that held and positioned the optic camera used in conventional laparoscopy under direct command and control of the surgeon. After several upgrades in the form of a second joint in the robotic arm, reducing space requirements for the robot, and a voice control system, the AESOP could hold a 5 to 11 mm endoscope of any angle. It was guided with voice–activated commands, which gave the surgeon complete control of the visual field, eliminated the need for an assistant surgeon holding the camera, saved time and made solo surgery possible. The AESOP has been used in thousands of procedures throughout the world [34]. However, not until the parallel advances in computer technology made it possible to transmit information through telecommunication lines in milliseconds, was the next step in the evolution of robotics taken. In “telemanipulative” surgery the surgeon directly controls the motion of instruments
from a master input unit, whose signals are transferred in real time to an output
device, where the instruments are placed. By adding a computer between the surgeon
and the instruments, the awkward motions of conventional minimally invasive
instruments could be translated into more natural hand motions and tremor could be
eliminated. It also opened up for the possibility to perform surgery from a distance if
the signals could be transferred via satellite. Unlike Robodoc® and Probot, which
used pre-programmed automated motorised movements, and were real robots, these
master-servant surgical systems under direct control of the surgeon, should more
correctly be called computer-assisted or telemanipulator surgical systems.

The next important step in the development of master-servant surgical systems
was the improvement of surgical instruments with active movement properties similar
to the human elbow and wrist. Conventional laparoscopic instruments have only five
degrees of freedom including grip, as compared to the human wrist that has seven.
The ARTEMIS (Advanced Robotic Telemanipulator for Minimally Invasive Surgery)
developed in Karlsruhe, Germany in 1992 and available for experimental use in 1996,
was the first master and servant manipulator system with six degrees of freedom [34].
More degrees of freedom meant that the instruments of the surgical system could be
moved in a fashion more similar to open surgery, thus overcoming some of the
limitations of conventional laparoscopic instruments.

Further improvement of telemanipulator systems was offered by the Zeus
Microwrist surgical system, developed by Computer Motion Inc. (Goleta CA, USA).
The Zeus Microwrist surgical system consisted of three arms mounted on the
operating table, one for the integrated AESOP camera holder and two for holding the
instruments. The surgeon sat and performed the surgery in front of a display but also
had some peripheral vision of the operating room. If the AESOP used an 11 mm,
endoscope, 3-D vision was possible. Since the arms were mounted directly on to the
operating table and the last two joints of the arms were fixed, the system allowed
normal adjustment of the table position throughout the operation [7,8,34,35].

The Microwrist instruments had wrists allowing surgery with movements
mimicking those in open surgery and by motion-scaling, the surgical system could
translate large movements of the surgeon into small movements of the instrument,
useful in surgery in small operating fields. There were articulated Zeus instruments in
a size of 5 mm and non-articulated in 3 mm, and the distance from the wrist of the
instrument to the tip was short. Thus, well suited for surgery in children, the Zeus
surgical system was used in some of the very first clinical reports of robotic assistance
in paediatric surgery, even after the introduction of the da Vinci® Surgical System
[7,15,35].
The history of Intuitive Surgical® and the da Vinci system

The original prototype for the da Vinci system was developed in the late 1980s at the former Stanford Research Institute (SRI) under contract to the U. S. Army. SRI was founded by the trustees of Stanford University in California, USA in 1946 after several decades of cooperation between the U.S. West Coast business executives and members of the Stanford community. SRI separated from the university in 1970 and changed its name to SRI International in 1977. It is an independent, non-profit scientific research institute working with government agencies, commercial businesses, foundations and other organisations to bring innovations from the laboratory to the market. Among innovations from the SRI are the automatic check processing in banking in 1955, the invention of the mouse for computers in 1968, the creation of the predecessor of Internet in 1969 and the technique for wireless network communication in 1977 [36].

Spanning many different fields of research, SRI was well suited for construction of the first telerobotic surgical system. The project interested not only the U.S. Army but also NASA (National Aeronautics and Space Administration) with its potential to make remote surgery possible. With a robotic device mounted on a battlefield vehicle or in a spaceship under direct control of a remote surgeon, soldiers and astronauts would have access to emergency minimally invasive surgery without having to move the surgeon to the patient.

In 1995, Intuitive Surgical® was founded by SRI International to continue the development of the robotic prototype, and in 1999 the da Vinci® Surgical System was launched. It became the first telerobotic surgical system to receive approval for general surgery from the FDA in 2000 and has later been approved also for urological, cardiothoracic and gynaecological surgery both in the US and in Europe. In 2003 Intuitive Surgical® purchased their only competitor Computer Motion Inc. The Zeus Microwrist surgical system became no longer available for new customers, but existing systems could be traded in for the da Vinci® Surgical System, making it the only surgical system currently on the market.

The da Vinci® Surgical System

The da Vinci® Surgical System has been well described in the literature and is a computer-enhanced telemanipulator system consisting of three main components: the master surgeon’s console, the surgical cart and the vision cart. In contrast to standard laparoscopic techniques, the system restores stereoscopic 3-D vision and the surgeon’s intuitive hand-eye coordination, provides tremor reduction and motion scaling, and features instruments capable of seven degrees of motion including grip, compared with the five degrees of motion provided by standard laparoscopic instruments [17,21,35].
Intuitive Surgical® named this surgical system da Vinci, after the inventor of the first robot, Leonardo da Vinci. In the same way as Leonardo da Vinci used unparalleled anatomical accuracy and three dimensional details to bring his masterpieces to life, the surgical system provides surgeons with enhanced details of the operating field [37]. The da Vinci cannot run on its own, nor can it be programmed or make any decisions on its own. Three versions of the da Vinci® Surgical System exist, the da Vinci from 1999, the da Vinci S (2006) and the da Vinci Si (2009). The Endowrist® instruments with seven degrees of freedom, 180 degrees of articulation and 540 degrees of rotation have the same qualities in all three versions, but the newer versions feature some improvements. The S version includes 3-D high definition (HD) vision (720p), extended reach of instruments, slimmer overall appearance and interactive video displays. The Si version features, among others, enhanced 3-D HD vision (1080i), comprehensive ergonomics settings and an upgraded console.

Master surgeon’s console

The surgeon is seated at the ergonomically designed surgeon’s console, which is connected to the patient-side surgical cart with electric cables. Through these cables video information is transmitted without delay from the dual channel endoscope to the console viewer, where two separate monitors, one for each eye, provide the surgeon with a tenfold magnified, 3-D HD vision of the operative field. With overlay mirrored optics, the image of the surgical field is projected directly atop the surgeon’s hands, serving to restore true hand-eye coordination, a natural correspondence of movements and an immersive operating environment in which the surgeon feels as if his or her hands are actually in the surgical field. Only when the head of the surgeon is placed within the viewer, can the instrument arms be manipulated, thanks to sensors on the side of the viewer.

In addition to receiving video input, the instrument arms as well as the endoscope are controlled from the master surgeon’s console through dual master controls. The movements of the surgeon’s thumbs and index fingers, attached to the master controls with strips of Velcro, are directly translated by the system computer into corresponding movements of the tips of the instruments. If the surgeon squeezes his thumb and index finger together, the corresponding tips of a needle driver or forceps are closed. Similarly, wrist movements of the surgeon’s hands are directly translated into wrist movements of the unique wristed instruments in a fashion very similar to open surgery. When translating the movements from the surgeon to the instruments, the system filters all tremors and allows up or downscaling of the movements. By pressing one of five foot pedals at the base of the console, the surgeon disengages the instruments from the master controls, which instead are used for control of the endoscope. Moving the grips to the right, adjusting the depth or rotating them, results in a corresponding movement of the endoscope and allows the
surgeon to alter the field of view. The remaining four pedals are used for camera focus, clutching and for bi- and monopolar diathermia. Some gross force feedback is sent to the surgeon via the master controls.

The user interface control panel and the user switch control panel, placed at the console on either side of the surgeon, are used for adjusting motion scaling, to calibrate the 0 or 30 degree endoscope, select the camera angle, place the system on standby or to completely disengage the system.

![Image of da Vinci surgical system](https://via.placeholder.com/156x464.png)

**FIGURE 1 Master surgeon’s console. © 2010 Intuitive Surgical, Inc**

**Patient-side surgical cart**

The patient-side surgical cart is the component of the system that actually handles the patient’s tissues. The cart consists of three or four motor-driven, cable-actuated arms mounted on a movable chassis, and for the da Vinci S and Si, even the chassis is motorised. One arm holds and manipulates the endoscope and two of the three instrument arms correspond to the surgeon’s right and left hands. By pressing a foot pedal, the surgeon can control which two of the three instrument arms are active. When arm number two is activated, arm three becomes inactivated and vice versa. Instruments in the two active arms are used for surgery, but the inactivated arm can be used for holding tissue since it stays in a fixed position when inactivated. The arms are covered with sterile drapes before the operation. The patient-side cart is moved to the correct position adjacent to the operating table, depending on the procedure, after trocar placement. After attaching the arms to the trocars, ‘docking’ of the da Vinci,
the arms are manoeuvred precisely into position using the setup joint buttons and clutch buttons on the arms.

In contrast to the camera arm, that uses simple mechanical adaptors to hold the endoscope, the instrument arms utilise sterile, reusable adaptors that serve as an electrical and mechanical interface between the arms and the articulating instruments. These adaptors feature four notched wheels that correspond to wheels on the instruments and on the arms. Within the instruments, the notched wheels are attached to a series of cables travelling the length of the instrument to the tip. By manipulating these wheels, the mechanical force produced by the arms is precisely transmitted through the cables to the tips of the surgical instruments. The electrical interface in the adaptors tells the system which particular instrument is being attached and records the number of times that instrument has been used. More than 40 different instrument tips are available, most in 8 mm size and some in 5 mm size, including a variety of energy-delivering instruments, and they are all reusable 10 to 20 times. Mounted on the cart is a draped, sterile monitor (da Vinci S) that allows the assistant to communicate with the surgeon visually. If the assistant demonstrates or draws with his finger on the monitor, those drawings appear on the screen in the master’s console, which can be useful in an educational setting.

FIGURE 2 Patient-side surgical cart. © 2010 Intuitive Surgical, Inc
Vision cart

The vision cart is a movable tower housing the dual light sources, camera control equipment, the insufflation device and a standard laparoscopic 2-D monitor for the patient-side assistant. A DVD recorder is also available, enabling the recording of all procedures. To achieve stereoscopic vision, the system uses a unique dual channel, 12 mm endoscope with two separate 5 mm telescopes, attached to two cameras. These three-chip cameras, attach to two separate camera control units on the vision cart that allow for colour balancing and processes the camera signals that provide the 3-D image at the master surgeon’s console. The endoscope is available in 0 and 30 degree versions and the most commonly used wide-angle camera configuration give a 10x magnified 60 degree field of view. A 5 mm endoscope exists but does not provide 3-D vision.

FIGURE 3 Dual channel endoscope and 8 mm Endowrist instruments. © 2010 Intuitive Surgical, Inc
Operative technique – paediatric considerations

System setup:

The surgical system is started and a system check is always performed before each procedure. The optic system is then calibrated for a zero or thirty degree endoscope depending on the procedure and white balanced. In these studies, a thirty degree endoscope was used for the fundoplications and the cholecystectomy and the zero endoscope for the urological procedures (I, II, IV). The patient-side cart is always positioned in the same corner of the operating room at setup. Instead the operating table and the anaesthesia equipment are rotated depending on the procedure so that the heavy patient-side cart only needs to be moved forward in a straight line to reach the operating table. Compared with conventional laparoscopy, an extra table for the system equipment is needed, and the three tables are placed around the operating table. Finally, the arms of the patient-side cart are dressed in a sterile draping.

Anaesthesia:

The patient-side cart of the da Vinci® Surgical System limits, to a greater or lesser extent, the anaesthesiologist’s direct access to the patient during surgery, depending on which procedure is performed and where the patient-side cart is positioned [38]. All the patients, therefore, routinely receive an extra peripheral intravenous line and an arterial line on extra long extensions. Besides a total of four intravenous access points the method of anaesthesia does not differ from the method used for conventional laparoscopy.

Patient positioning:

The placement of the patient is extremely important since it is not possible to make adjustments once the system is docked. The patient position must allow proper port placement and not interfere with the positioning of the patient-side cart. The padding under the patient needs to be extra thorough to prevent pressure damage during long procedures. Small patients (<15 kg) placed on their back and every patient placed on their side for retroperitoneal access, need an extra cushion under them and under the hip, respectively, to be lifted enough to avoid collisions between the arms of the patient-side cart and the operating table [39,40].
Port placement:

To place the ports with the recommended 10 cm distance from each other, to avoid external collisions of the patient-side cart arms, is almost never possible for a child. This has to be compensated for and is achievable if the angles are adjusted. The space for intra abdominal surgery is, in our experience, always sufficient but placing the ports for retroperitoneal access is a great challenge and must be very distinct [13,22]. If the ports are sub optimally placed, the procedure might not be possible to complete minimally invasively and could be a reason for conversion to open surgery.

A disadvantage of the current da Vinci instruments is the long distance between the articulating wrist and the tip of the instrument. For the da Vinci system software to allow the instruments to function, the instrument and the articulating wrist of the instrument must exit the trocar. There is a thick black marking on each da Vinci trocar, 2.90 cm from the distal end, where the so-called pivot point is located, i.e. the point around which the trocar moves. This mark should be placed just inside the patient according to the manufacturer. Using the mark to aid the placement of the trocars is often not possible in children since the trocars then enter the body cavity too much to allow the free movement of instruments. By adjusting and keeping the depth of the trocars in the skin to a minimum, the limited space in a child is used efficiently [40]. The risk of trocars being accidentally displaced, with subsequent air leakage, loss of pressure and vision, thus interrupting the procedure, might therefore be increased in children.

Surgical cart positioning and docking:

When the trocars are properly placed, the patient-side cart is moved to the operating table and the trocars are docked to the patient-side cart arms. The arms are positioned in the best starting angles, allowing maximum range of motion. Instruments are chosen and attached according to the surgeon’s preference.

Console surgery:

The console surgeon, stripped of his sterile clothing, and placed at the ergonomically master surgeon’s console, uses the five foot pedals (clutch, camera, camera focus, bi- and monopolar energy) and two hand controls to perform the actual surgery. The surgeon’s assistant stays beside the patient and assists when needed with changing of instruments, suction, cutting and the passing of sutures and drains in and out of the patient. The added fourth arm on later versions of the standard da Vinci® Surgical System rendered the assistant superfluous for holding and made solo surgery possible and some of the assistant’s tasks could very well be performed by the OR nurse. We
have, however, always used another paediatric surgeon, well experienced in gastrointestinal or urological surgery depending on the procedure, as the assistant. This is valuable not only when some parts of the procedure need to be performed with instruments not yet available for the da Vinci system, for example the use of LigaSure™ (Valleylab™, Covidien, Boulder CO, USA) or the Harmonic Scalpel (Ethicon® Harmonic Scalpel, Soma Technology, Blomfield CT, USA) but also for safety reasons, if rapid conversion is called for. When introducing new console surgeons, prior assistant training is mandatory. In the literature there is some evidence that assisting shortens the learning curve for performing computer-assisted surgery [41].

Undocking and closure:

At the end of the surgery the patient-side cart is undocked from the trocars and moved away from the operating table back to its starting position. The trocars are removed under direct visual control making sure no port bleeding occurs. The muscular fascias are then closed with absorbable, braided sutures, often Polysorb (Covidien, Norwalk CT, USA) 3-0 or 4-0 depending on the size of the patient. The skin is closed with absorbable, monofilament sutures, often Caprosyn 4-0 (Covidien, Norwalk CT, USA).
Surgical procedures

GERD – Fundoplication

Gastroesophageal reflux disease (GERD) is a common disorder in children, and both medical and surgical treatments have shown outstanding results. Whereas proton pump inhibitors are the mainstay of the treatment, laparoscopic or open surgical fundoplication is an alternative. Fundoplication is performed when spontaneous improvement or improvement with medication could no longer be expected.

The surgical procedure was originally described by Nissen in 1961 and includes dissection of the diaphragmatic crura, the division of the small gastric vessels, the passing of fundus behind the oesophagus from left to right and finally the creation of a floppy wrap by suturing the fundus to the stomach including the oesophageal serosa in the sutures [42]. In our open procedures and later also our laparoscopic procedures, we have adopted the method described by Nissen but with the exception of dividing the small vessels of the gastric ventricle since this was not necessary to achieve an adequate wrap of the fundus. For our CALS procedures the surgical procedure is principally the same, as described in Paper I.

With the patient under general endotracheal anaesthesia and in a semi-lithotomy position, a 12 mm port for the camera was introduced through a mini-laparotomy below the umbilicus, and pneumoperitoneum was induced. The left and right upper quadrant ports were placed subcostally for the two robotic arms, a right upper quadrant port for liver retraction and an assistant port in the left lower quadrant below the umbilicus. Trocar placement differed somewhat from the laparoscopic procedure, in that trocars must be placed more laterally (page 35). The second assistant port was optional depending on the anatomy of the patient and the subsequent access to the area of interest for the operation. The presence of a per-operative gastrostomy affected the placement of assistant ports, but was of no other consequence for the surgery and taking it down seemed completely unnecessary.

Eight mm da Vinci instruments and VersaStep® trocars from Auto Suture™ (Covidien, Norwalk CT, USA) were used. Da Vinci hook tip or scissors and electrocautery were used for dissection of the crura. The short gastric vessels were not divided and the left liver lobe was not mobilised. The crura were sutured in most patients and a floppy fundoplication was performed. Four or five 2-0 nonabsorbable sutures (Gore-Tex®, W. L. Gore & Associates, Inc., Medical Products Division, Flagstaff AZ, USA) were used. The floppiness of the wrap was tested at the end of the procedure with a laparoscopic instrument to have tactical feedback. Fascia sutures were used in all holes and continuous, monofilament, absorbable sutures were used to close the skin.
Malfunctioning kidney – Nephrectomy and partial nephrectomy

The indications for nephrectomy in children are mainly to remove a non- or malfunctioning kidney primarily or secondary to complicated congenital anomalies. A malfunctioning kidney might increase the risk for the child to suffer from recurrent urinary tract infections or elevated blood pressure, and the theoretical risk of developing malignancy. In most cases, however, no symptoms are apparent at the time of surgery. In duplex kidneys the reason for performing a partial nephrectomy is the same as for nephrectomy if the system is non-functioning. If the system is non-functioning with an ectopic ureter ending distally to the bladder neck sphincter, a continuous urinary leakage will appear. The partial nephrectomy is then performed to treat the incontinence. If the system with the ectopic ureter has remaining function, a reimplantation of the ureter is, of course, performed instead. This procedure has been performed with CALS in children by others but not yet by us [16]. Prior to surgery, ultrasound and repeated scintigraphic investigations are performed to make sure that the kidney function or the partial kidney function is permanently low [43].

The open nephrectomy or partial nephrectomy was performed with the patient in the flank position and through a sub costal, transverse incision. After the mobilization of the ureter and vascular control with braided, absorbable 4-0 ligatures the kidney was removed. If partial nephrectomy was performed the kidney was divided with either the Harmonic Scalpel or electrocautery. The ureter was transected and tied as distally as possible. The fascia and skin were closed as previously described. The open procedure is often performed via a retroperitoneal approach and the minimally invasive procedure is either performed trans- or retroperitoneally. Previous reports comparing standard laparoscopic and open nephrectomy in children state that also the minimally invasive approach is safe and feasible [44]. Laparoscopy was never tried for nephrectomies or partial nephrectomies before we started to perform CALS.

The method to gain access to the retroperitoneal space for computer-assisted surgery previously described by Olsen et al. was used [45]. In brief: with the patient in the flank position and slight hip flexion with a gel cushion under the contralateral iliac crest, a 15 mm incision was made approximately 10 mm above the iliac crest in the anterior axillary line. After blunt splitting of the muscles, the lumbodorsal fascia was opened and the retroperitoneal space digitally created. The retroperitoneal working space was then fully developed with a home-made balloon inflated to 150 – 350 ml depending on the size of the patient. The two 8 mm instrument ports were placed under digital guidance, the lateral port just medial to the latissimus dorsi, two fingers above the iliac crest and the medial port just below the costal margin off the anterior axillary line. The renal trocar placements and the slight modification of trocar sites with the da Vinci S are shown on page 35.

An assistance port can be used depending on the complexity of the procedure and has been our preference for partial nephrectomies and pyeloplasties. A 12 mm balloon tipped trocar was inserted through the 15 mm incision and then secured by
inflating the balloon, tethering of the trocar, and by 2.0 sutures in the fascia and skin. The insufflation pressure of CO$_2$ was maintained below 12 mm Hg and the flow rate was initially set at 1 L/min and progressively increased to 5 L/min if necessary. The surgical system was docked from behind at an angle of 45 – 60 degrees to the mid-axillary line and a 0-degree telescope camera was used. A DeBakey grasper and a monopolar cautery hook or scissors were used for dissection.

The kidney was approached from behind and the hilum was primarily exposed. The vessels were identified and divided with LigaSure™, the Harmonic Scalpel or the cautery hook with subsequent dissection, division and tying of the ureter as far distally as possible. For the partial nephrectomy either the LigaSure™ or the Harmonic Scalpel has been used for resecting the nonfunctioning part of the kidney. The specimen was removed through the 15 mm incision. The fascia and skin were closed as previously described.

**Pelvoureteral junction obstruction – dismembered pyeloplasty**

An obstruction in the pelvoureteral junction needs to be treated before the kidney function deteriorates, if the patient suffers from pain caused by the obstruction or if the dilatation of the kidney increases on repeated investigations. The dismembered pyeloplasty is performed openly through a sub costal, flank incision into the retroperitoneum. The pelvoureteral junction is dissected and the obstruction removed. If a crossing polar vessel is the cause of the obstruction, a transposition is performed before the ureter is sutured with a wide anastomosis to the renal pelvis. A transanastomotic stent is always used, either a double J-stent (Rüsch, Teleflex Medical, Co Westmeath, Ireland) from the pelvis to the bladder or a percutaneous Pippi Salle stent (Cook, Limerick, Ireland). The first requires removal under general anaesthesia, whereas the latter can be removed as an out-patient clinic procedure.

The open procedure is normally performed via a retroperitoneal approach but the minimally invasive procedure is either performed trans- or retroperitoneally. The method to gain access to the retroperitoneal space for computer-assisted surgery previously described was used for all our pyeloplasties except in one case, where a very large renal pelvis made us choose the transabdominal approach in order to have enough space. Trocar sites are shown on page 35. An assistant port is useful for passing sutures, applying suction, cutting and assisting in visualizing the operating field. One or two hitch stitches, threads passed percutaneously and into the renal pelvis and proximal ureter, to aid holding the structures stable while suturing is performed. The stent is passed through the assistant port or via a needle directly through the skin. If a double J-stent was used, fluoroscopy was used to make sure the distal end of the stent entered the bladder. The method of the surgical procedure did not differ between the approaches, except that two running sutures of 5-0 or 6-0
Polysorb were used, whereas in open surgery single sutures are often used on the ureter.

**CDH – Repair of Congenital Diaphragmatic Hernia**

A Congenital Diaphragmatic Hernia (CDH) is a defect in the diaphragm often detected antenatally on routine ultrasound investigations or immediately after birth due to respiratory symptoms in the baby. It can contain abdominal organs present in the thorax, have a hernia sac or not and the grade of concomitant lung hypoplasia varies from almost none to directly lethal. A CDH in the posterolateral part of the diaphragm is often referred to as a Bochdalek hernia and a retrosternal CDH, which is much less common, is often called a Morgagni Hernia. In some cases a CDH can remain unnoticed, and be diagnosed later in the older child, who typically is seeking medical care for recurrent pneumonias.

The treatment for CDH is surgical, which traditionally has been performed through open surgery, either from the abdomen or from the thorax. The closure of the hernia can be accomplished with or without a patch, depending on the size of the defect and with or without resection of a hernia sac [43]. The first MIS repair of a CDH in a child was reported in 1997 [46] and the first MIS repair in a child without a patch was reported a year later [47]. The first report of a Morgagni Hernia repair with the da Vinci® Surgical System was reported in 2003 [17] and the first report of a Morgagni Hernia repair with the same system in a small child was reported by our team in 2008 [27]. Suturing of the defect was performed with interrupted, absorbable 2-0 sutures and port placements are shown on page 36. We have never performed any laparoscopic repair of a CDH but others report that suturing can be difficult with standard instruments [48]. Others report that reducing the viscera from thorax is easier with standard MIS instruments but that the suturing is facilitated with CALS [40].

**Rhabdomyosarcoma – Cystoprostatectomy**

Rhabdomyosarcoma (RMS) is the single most common type of soft-tissue sarcoma in children and can arise at virtually any site within the body because of its origin from immature mesenchymal cells. In Sweden, approximately 12 new cases of RMS occur annually, making it the third most common childhood extra-cranial solid tumour after neuroblastoma and Wilms’ tumour. Thanks to prospective multi-centre clinical studies, for example Intergroup Rhabdomyosarcoma Study (IRS) I–IV, overall survival with RMS has increased from 25% three decades ago to more than 70% today [49]. Although oncological paediatric surgery traditionally has been performed with open surgery, this surgical procedure in the pelvis in children can be very
challenging because of the limited space, minimal access and visibility. Together with an adult urologist, our team has performed the first reported case of a computer-assisted laparoscopic radical cystoprostatectomy in a 22-month-old boy with embryonal rhabdomyosarcoma in his urinary bladder [26]. We could thus combine the experience gathered at our hospital of performing radical CALS in the pelvic region with the experience from performing surgery in small children in a safe way.

The child was treated according to the Cooperative Weichteilsarkom Studie (CWS) 2002-P protocol. A four port transperitoneal approach and the zero degree lens were used (page 36). Because the ports were placed in the abdomen, it was relatively easy to obtain enough distance between the instruments to be able to perform this procedure even in a small child. Total operative time was 345 min; 40 min for placing ports and docking of the patient-side cart, 185 min at the console, and 120 min for creating the ureterostoma and closure. Vision was excellent throughout the procedure, which is very important during dissection and not always the case during open surgery inside the pelvis. The blood loss was minimal and radicality was never compromised. The boy was on his feet the day after surgery, had little need of opioid analgesics, and started to eat. He was transferred to the oncology department after six days for chemotherapy and left the hospital for home three days later.

Rare Genitourinary Malformation – Hemihysterectomy

Complex non-communicating Müllerian/Wolffian malformations are rare and a strict classification from an embryological point of view is sometimes difficult [50,51]. Diagnosis is often delayed due to the rarity of the condition but symptoms typically include increasingly severe dysmenorrhoea. A thorough preoperative investigation is mandatory to rule out other anomalies and to plan a correct surgical approach. Major venous anomalies associated with complex Müllerian/Wolffian malformations are very rare and we have only been able to identify two other case reports [52,53].

A fifteen year old girl was referred to the Department of Paediatric Surgery at Skåne University Hospital, for increasing dysmenorrhoea, constant abdominal pain and an extended abdomen. Investigations identified a left sided non-communicating hemiuterus, a 15 x 13 x 8 cm haemato-oophorosalpinx, ipsilateral renal agenesis and associated inferior vena cava duplication with a high division and aberrant courses of the external iliac and hypogastric veins. Working together with gynaecological surgeons trained in anatomic dissection of the pelvic side wall, a CALS procedure was performed. To facilitate surgery in the upper abdomen in relation to the large cystic mass, the trocars were placed higher but equally distributed, as used for standard computer-assisted surgery in the pelvis [54]. All four instrument arms of the da Vinci S system and one 12 mm assistant trocar (Excel® Ethicon Inc, Somerville NJ, USA) were used (page 36). The grossly enlarged haemato-oophorosalpinx was drained
followed by a retroperitoneal dissection and mapping of the aberrant blood vessels, enabling a safe left-sided hemi hysterectomy and salpingo-ophorectomy with minimal blood loss.

A hemi hysterectomy performed by traditional laparoscopy to treat rudimentary horns or a didelphic uterus has been previously described from larger centres [55,56]. The rarity of the condition and the lack of centralisation in Sweden offer little opportunity to gain experience with this procedure. Moreover, the associated vessel anomalies and the dense retroperitoneal tissue would have made a laparoscopic procedure even more technically challenging and hazardous. Compared with traditional laparoscopy, the main disadvantages of a computer-assisted approach are the high cost of investment and maintenance and the need for more and larger ports. However, we believe that the da Vinci system facilitates minimally invasive surgery even in rare and complex conditions, as demonstrated in our case by the meticulous retroperitoneal vessel dissection and subsequent step-by-step mapping and coagulation of the atypical blood vessels supplying the hemiuterus and adnexa.
Port placements used in the computer-assisted procedures

**Fundoplication trocar setup (one assistant port is optional)**

<table>
<thead>
<tr>
<th>Alternative 1</th>
<th>Alternative 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Diagram of port placements for Fundoplication" /></td>
<td></td>
</tr>
</tbody>
</table>

- **Optic port 12 mm**
- **Da Vinci working port 8 mm**
- **Assistant port 5 mm**
- **Assistant port 12 mm**
- **Gastrostomy**
- **Umbilicus**

**Renal surgery: retro and transperitoneal trocar setup (left side). © 2010 LH Olsen**

<table>
<thead>
<tr>
<th>Retroperitoneal</th>
<th>Retroperitoneal</th>
<th>Transperitoneal</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Diagram of port placements for Renal surgery" /></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Retroperitoneal Standard da Vinci**
- **Retroperitoneal Da Vinci S**
- **Transperitoneal**
CDH repair trocar setup

- Optic port 12 mm
- Da Vinci working port 8 mm
- Assistant port 5 mm
- Assistant port 12 mm
- Gastrostomy
- Umbilicus

Rhabdomyosarcoma trocar setup

Hemihysterectomy trocar setup
Aims of the thesis

The major aim of this thesis was to investigate the new computer-assisted surgical instruments and their application in paediatric surgery and paediatric urology. The specific aims of the respective papers were:

- To investigate the feasibility and safety of computer-assisted laparoscopic surgery in children in comparison with open and conventional laparoscopic surgery when performing fundoplications. (I)

- To investigate the in-hospital costs for computer-assisted laparoscopic surgery in children compared with open and conventional laparoscopic surgery when performing fundoplications. (II)

- To investigate the first part of the learning curve for computer-assisted laparoscopic surgery compared with standard laparoscopic surgery and how gender of the subject or earlier experience influenced the results. (III)

- To study the short-term results of computer-assisted retroperitoneoscopic nephrectomy with open nephrectomy in children and to discuss the further use of this new technique. (IV)
Subjects and Methods

The Department of Paediatric Surgery, Children’s Hospital Lund, Skåne University Hospital is a tertiary paediatric surgery centre serving the most southern parts of Sweden with almost two million inhabitants. In addition to our normal catchment area, some patients are received from other parts of Sweden, if they also have a serious cardiac disorder, since Lund is one of two centres where paediatric cardiothoracic surgery is performed in Sweden. We describe a single centre experience and all our CALS patients were operated on between January 2006 and June 2010. Included in the papers that constitute this thesis are patients operated on up to March 2010.

The author of this thesis was the console surgeon for the first 50 procedures, after which a second console surgeon was introduced. One laparoscopically trained gastrointestinal paediatric surgeon and/or one paediatric urologist has assisted in all our CALS procedures. The paediatric surgical experience for all surgeons involved ranges from 10 to 30 years. The inclusion criteria in the study group of CALS patients were that all were included prospectively. The control patients, our last patients operated on with the open and/or standard laparoscopy technique, were retrospectively included. Due to limited access to the surgical system, the studied CALS patients were operated on consecutively after medical priority and not consecutively according to diagnosis, except for our first six patients where a fundoplication was performed consecutively. The only exclusion criteria were reoperations, which were performed with open surgery. The da Vinci® Surgical System was used from 2005 to 2007 and the da Vinci® S Surgical System from 2007 and onwards.

Paper I

This was a prospective study of the first six fundoplications using the da Vinci® Surgical System during the period January to June 2006. Retrospective data from the latest six patients operated on at our centre using the open surgical procedure and the conventional laparoscopic technique were used as controls. The work-up for all patients was the same and included clinical findings at endoscopy, oesophageal biopsy, preoperative 24 h pH measurements and an upper gastrointestinal X-ray series searching for anomalies, hiatus hernia or partial outlet obstruction. Impedance measurements were not performed in any of the patients. For 24 h pH measurements in the CALS group, the BRAVO® (Medtronic, Shoreview MN, USA) was used and
for the patients in the open surgery and the laparoscopy group, a Synectics 24® antimony electrode and the Digitrapper® recording device (Medtronic, Salt Lake City UT, USA) was used. The electrodes were placed fluoroscopically two vertebrae above the diaphragm in accordance with ESPGHAN criteria. The reflux was considered pathological if the duration of pH < 4 in the oesophagus exceeded 10% over a 24 h period, threatened the child’s health or resulted in failure to thrive. A DeMeester score below 14.72 (95th percentile) was considered normal [57,58].

Fundoplication was performed when spontaneous improvement or improvement with medication could no longer be expected. The fundoplication was performed by the same team and in the same way in all three groups, only the instruments differed. No gastric drainage procedure was performed. Operating time was recorded as skin to skin in all groups, including docking time but not preoperative setup time for the surgical system in the CALS group, as this was done simultaneously with induction of anaesthesia and positioning of the patient. The length of hospital stay was recorded in days and determined by the computerized hospital admission and discharge records for all the patients. For the control group, all information was obtained from charts or the surgery planning database Provisio® (Provisio AB, TietoEnator Healthcare & Welfare, Sweden) but in the study group, the operating time was recorded prospectively.

All patients received paracetamol (15 mg/kg) every sixth hour postoperatively. Epidural anaesthesia was never used. Postoperative morphine was ordered by the surgeon on call after evaluation of the patient’s pain. Postoperative pain was evaluated for each patient by the registered nurse on duty according to the visual analogue scale (VAS). The administration of morphine was stopped when the patient was on the lowest third of the scale. The reliability and validity of the VAS as a measure of pain has been established previously [59,60]. All patients were discharged from the hospital when fully mobilised to their habitual state and full pain control without morphine was achieved. The criteria for discharge did not differ between the groups.

Follow-up included personal interviews after 1 month. The patients were scheduled for personal interviews after six months and endoscopy and oesophageal 24 h pH measurement one year after surgery. The patients were questioned specifically about heartburn, regurgitation, retrosternal pain, dysphagia and vomiting. The outcome was compared with the patient’s preoperative situation. The analyzed variables were: patient age and sex, body weight, pre-operative 24 h pH data and DeMeester score, operating time skin-to-skin, the number of days morphine was needed, length of postoperative hospital stay, postoperative complications and functional results one month after surgery. No patient was lost to follow-up. All were analysed.
In this study, the first 14 consecutive children undergoing minimally invasive Nissen fundoplications using the da Vinci® Surgical System between January 2006 and April 2008 were prospectively included. For comparison, retrospective data from the years 2000 to 2005 from the latest ten patients operated on using the open surgical procedure and the latest ten patients using the conventional laparoscopic technique were used. All patients requiring fundoplication after January 2006 were operated on with CALS. The three groups were comparable with regard to age. The patients in the open surgery group weighed less (Table 1).

### TABLE 1 Demographic data: age and weight

<table>
<thead>
<tr>
<th>Surgical methods</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CALS</td>
</tr>
<tr>
<td>Number of patients (female/male)</td>
<td>14 (3/11)</td>
</tr>
<tr>
<td>Age at operation, years</td>
<td></td>
</tr>
<tr>
<td>MEAN ± SD</td>
<td>8 ± 4.2</td>
</tr>
<tr>
<td>(Range)</td>
<td>(1 – 15)</td>
</tr>
<tr>
<td>Weight at operation, kg</td>
<td></td>
</tr>
<tr>
<td>MEAN ± SD</td>
<td>22 ± 11.7</td>
</tr>
<tr>
<td>(Range)</td>
<td>(6 – 46)</td>
</tr>
</tbody>
</table>

Statistical analysis was performed using the Kruskal-Wallis test.

No patient was excluded from the retrospective data or the CALS data. The patient’s weight was not an impediment to using CALS, and the smallest patient in the CALS group weighed only 6 kg. There were no differences in preoperative symptoms (Table 2) or in the DeMeester score (Table 3).

### TABLE 2 Demographic data: symptoms and concomitant diseases

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Surgical methods</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CALS (14)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>14</td>
</tr>
<tr>
<td>Vomiting blood</td>
<td>9</td>
</tr>
<tr>
<td>Pulmonary infections</td>
<td>11</td>
</tr>
<tr>
<td>Concomitant diseases:</td>
<td></td>
</tr>
<tr>
<td>Cerebral paresis</td>
<td>8</td>
</tr>
<tr>
<td>Cerebral malformations</td>
<td>3</td>
</tr>
<tr>
<td>Gastrointestinal malformation</td>
<td>2</td>
</tr>
<tr>
<td>GERD only</td>
<td>1</td>
</tr>
</tbody>
</table>
All 34 patients vomited excessively and 26 (76 %) suffered from repeated pulmonary infections. Out of a total of 34 children, 27 (80 %) had a neurological handicap, and 4 (12 %) a gastrointestinal malformation in the form of a diaphragmatic hernia or oesophageal atresia, one child with each diagnosis in the CALS and open group, and only 3 (9 %) children had GERD alone.

**TABLE 3 Demographic data: work-up and DeMeester score**

<table>
<thead>
<tr>
<th>Surgical methods</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALS (14)</td>
<td>Laparoscopic (10)</td>
</tr>
<tr>
<td><strong>Endoscopy:</strong></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>2</td>
</tr>
<tr>
<td>Oesophagitis</td>
<td>12</td>
</tr>
<tr>
<td><strong>Histology:</strong></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>1</td>
</tr>
<tr>
<td>Oesophagitis</td>
<td>7</td>
</tr>
<tr>
<td>Barret's</td>
<td>6</td>
</tr>
<tr>
<td><strong>24 h pH measurement:</strong></td>
<td></td>
</tr>
<tr>
<td>duration of pH &lt; 4 (in % of 24 h*)</td>
<td></td>
</tr>
<tr>
<td>MEAN ± SD</td>
<td>16 ± 14</td>
</tr>
<tr>
<td>(Range)</td>
<td>1 – 39</td>
</tr>
<tr>
<td><strong>DeMeester score</strong></td>
<td></td>
</tr>
<tr>
<td>MEAN ± SD</td>
<td>46 ± 43</td>
</tr>
<tr>
<td>(Range)</td>
<td>3 – 137</td>
</tr>
</tbody>
</table>

* Total time is used since some of the patients do not walk and some feed via a gastrostomy. Statistical analysis was performed using the Kruskal-Wallis test.

The work-up for all 34 patients in the three groups, the indication for and the surgical procedure itself, the postoperative analgesia regimen and the criteria for discharge, were the same as previously described in Paper I. The operating time, the duration of hospital stay and the use of morphine were also recorded as previously described in Paper I (Table 4).

The economic assessment consisted of a cost minimisation evaluation comparing the CALS, laparoscopic and open surgical procedures. Only the direct in-hospital medical cost was evaluated. The cost of the preoperative work up with endoscopy, oesophageal biopsies and 24 h pH measurements, and outpatient visits as well as the cost of ambulatory medical treatment were not included as they were the same for all three groups. The costs for the procedure and hospital stay included staff, medical care, operating room and house rent, interest and overhead costs. The prices for the procedure were calculated per minute of operating time and the prices for the hospital stay per day (Table 5).
### TABLE 4 Operating time, use of morphine and length of hospital stay

<table>
<thead>
<tr>
<th>Surgical methods</th>
<th>Operating time, minutes</th>
<th>Use of morphine, days</th>
<th>Hospital stay, days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN ± SD</td>
<td>MEAN ± SD</td>
<td>MEAN ± SD</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>Range</td>
<td>Range</td>
</tr>
<tr>
<td>CALS (14)</td>
<td>207 ± 47</td>
<td>1.1 ± 0.9</td>
<td>3.8 ± 1.9</td>
</tr>
<tr>
<td>Laparoscopic (10)</td>
<td>207 ± 52</td>
<td>1.6 ± 0.7</td>
<td>5.2 ± 3.0</td>
</tr>
<tr>
<td>Open (10)</td>
<td>129 ± 43</td>
<td>3.3 ± 0.9</td>
<td>7.9 ± 2.8</td>
</tr>
<tr>
<td></td>
<td>(145 – 285)</td>
<td>(1 – 3)</td>
<td>(1 – 8)</td>
</tr>
<tr>
<td></td>
<td>(140 – 285)</td>
<td>(1 – 3)</td>
<td>(3 – 12)</td>
</tr>
<tr>
<td></td>
<td>(73 – 215)</td>
<td>(2 – 5)</td>
<td>(5 – 13)</td>
</tr>
</tbody>
</table>

Statistics was performed using the Kruskal-Wallis test.

### TABLE 5 Cost for each minute in the operating room and in-hospital care per day

<table>
<thead>
<tr>
<th>Costs</th>
<th>Anaesthesia 17 €/minute</th>
<th>Hospital stay 1057 €/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs for staff</td>
<td>51 %</td>
<td>67 %</td>
</tr>
<tr>
<td>Care related costs</td>
<td>25 %</td>
<td>11 %</td>
</tr>
<tr>
<td>House rent and interest</td>
<td>10 %</td>
<td>15 %</td>
</tr>
<tr>
<td>Overheads</td>
<td>14 %</td>
<td>7 %</td>
</tr>
<tr>
<td>Sum</td>
<td>100 %</td>
<td>100 %</td>
</tr>
</tbody>
</table>

All prices according to the regional hospital price list from 2007. All prices are according to the regional hospital price list from 2007. The hospital budget for the da Vinci® Surgical System is described in Table 6. The cost of CALS operations was divided into fixed overhead costs and variable procedure-related costs.

### TABLE 6 Hospital budget for computer-assisted laparoscopic surgery

<table>
<thead>
<tr>
<th>Fixed overhead costs</th>
<th>Cost per year</th>
<th>Cost per operation</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Material investment</td>
<td>196 655</td>
<td>596</td>
<td>959</td>
</tr>
<tr>
<td>▪ Service agreement</td>
<td>119 883</td>
<td>363</td>
<td></td>
</tr>
<tr>
<td>Variable costs per procedure</td>
<td></td>
<td></td>
<td>2081</td>
</tr>
<tr>
<td>▪ Draping, trocars, instruments</td>
<td></td>
<td></td>
<td>2081</td>
</tr>
<tr>
<td>Fixed and variable costs per procedure</td>
<td></td>
<td></td>
<td>3040</td>
</tr>
</tbody>
</table>

All prices are according to the regional hospital price list from 2007 and based on the scheduled number of 330 CALS procedures per year. All prices in EUR (1 EUR = 9.20 SEK).
The fixed costs included investment in the da Vinci® Surgical system and costs of servicing. The variable costs included specific instruments, draping and trocars for the surgical system. In addition, the da Vinci material investments were discounted using a discounted cash flow technique, a net present value method, with a marginal cost of capital of 5% per year and a depreciation period of five years.

Paper III

From a cohort of approximately 500 medical students at Lund University, volunteers were invited to participate in this project and from these, 20 subjects (10 men and 10 women), were randomly selected. The subjects were between 23 and 30 years old and had no prior practical experience of open surgery, standard laparoscopy (SL) or computer-assisted laparoscopy (CAL). There were no drop-outs or excluded participants.

All the subjects were given the same standardised oral and written information by the trial instructor (Appendix 1). The tasks the subjects were supposed to perform were also demonstrated once for each of the methods CAL and SL before the trial started. One instructor and three evaluators, all working at the Department of Paediatric Surgery were used. The evaluators registered the subjects’ performances in accordance with a predetermined template. The subjects were allowed to ask for guidance and the instructor gave them standardised advice along the way. The subjects were not allowed to observe or communicate with each other and were therefore isolated during the study. The primary and secondary end points were time and accuracy when performing the simulated surgical tasks using computer-assisted and conventional laparoscopic instruments.

The workstation was prepared in a standardised way and the participants were allowed to familiarise themselves with the instruments for two minutes before starting the trial. The thread was 20 cm long for both suturing and tying a knot. Each of the 20 students carried out three tasks, grab the needle in a correct way, place three continuous sutures over a rift in the Skin Pad in Jig® and tie a surgical knot. These tasks were done four times with each of CAL and SL.

For each set, time and quality indicators (1-6 below) were recorded.

1. Grab the needle  
2. Continuous suturing (3 stitches)  
3. Tie a knot (double)  
4. Damage to the Skin Pad in Jig®?  
5. Dropped needle?  
6. Tearing of the thread?  

   time in seconds  
   time in seconds  
   time in seconds  
   yes/no  
   number of times/set  
   number of times/set.
The subjects were divided according to gender and half the males and half the females began with CAL and SL, respectively. Each subject’s results from the CAL and the SL, respectively, were recorded and mean values were calculated for the groups: CAL first, SL first, CAL last and SL last.

Paper IV

A case-control study of ten consecutive children undergoing computer-assisted retroperitoneoscopic nephrectomy with the da Vinci® Surgical System between September 2007 and February 2010 due to a non- or malfunctioning kidney was performed. This prospectively gathered consecutive group of children was compared with a retrospectively collected group of all other children who had undergone open nephrectomy for benign renal disease at our centre between 2005 and 2009. Nine out of the 21 children (10 of 23 nephrectomies) in the control group were operated on during the time period when also CALS was used for nephrectomies. In the open control group two children underwent bilateral nephrectomy, one of which was performed in a single surgical procedure, but all CALS were unilateral. All 33 nephrectomies were performed with the retroperitoneal approach. The patients’ demographics and diagnoses are listed in Table 7.

**TABLE 7 The patients’ demographics and diagnoses**

<table>
<thead>
<tr>
<th>Surgical methods</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CALS</strong></td>
<td><strong>Open</strong></td>
</tr>
<tr>
<td>Number of patients</td>
<td>10</td>
</tr>
<tr>
<td>Female/male</td>
<td>4/6</td>
</tr>
<tr>
<td>Number of kidneys</td>
<td>10</td>
</tr>
<tr>
<td>Side left/right</td>
<td>8/2</td>
</tr>
<tr>
<td>Age at surgery, years</td>
<td>7.0 (1.2 – 13.7)</td>
</tr>
<tr>
<td>Weight at surgery, kg</td>
<td>24.0 (8.6 – 61.0)</td>
</tr>
<tr>
<td>Length at surgery, cm</td>
<td>120 (55 – 155)</td>
</tr>
</tbody>
</table>

**Diagnoses**

- Hydronephrosis | 1 | 4 |
- Renal dysplasia | 5 | 4 |
- Multicystic dysplasia | 2 | 3 |
- Renal hypoplasia | 1 | 2 |
- Vesicoureteral reflux | 1 | 2 |
- Nephrotic syndrome | 8 |  |

Data were presented as median (range). Statistical analysis was performed using the Mann-Whitney U test.

The endpoints of this study were safety, the operating time, the number of postoperative doses of morphine, the length of hospital stay and the number of complications. Operating time, length of hospital stay and the discharge criteria were determined and recorded as previously described in Papers I and II. All postoperative
doses of morphine were collected from the computerised chart system Melior® v.1.5 (Siemens Medical Solutions, Siemens, Germany) and counted manually. No randomisation was done. Data were presented as median (range) unless otherwise stated.

Statistical methods

Statistical analysis in Papers I and II was performed using the Kruskal-Wallis test, which is a non-parametric test for three or more small groups of data. Since the test is used for analysing three or more groups, the significance found is applicable on the analysed groups and not on subgroups. To analyse two out of three groups at a time would not be consistent with good statistical practice and is something we have been advised against. Furthermore, all the groups in Paper II were compared using a Student’s t-test for independent symbols.

For Paper III, mean values of the four repeated trials for each participant were computed. Non-parametric analyses were then carried out, i.e. Wilcoxon’s signed rank test was performed for paired samples and the Mann-Whitney test of two independent samples was performed for data assessments before and after the cross-over. The chosen non-parametric test methods are conservative in the sense that they require a larger sample size than corresponding parametric tests (e.g. Student’s t-test) to confer results with equivalent statistical power. However, we do not have any knowledge about statistical distribution and other population characteristics of the included variables. In the light of this, we believe that non-parametric statistics is preferable for an adequate interpretation of the p-values obtained in the analyses. The study design of Paper III is described in Table 8.

**TABLE 8 Study design; every subject repeated each of the three tasks four times, starting with either CAL or SL, then changed method and repeated the four sets of three tasks. Mean values of the four repeated CAL and SL trials for each participant were computed and analysed.**

<table>
<thead>
<tr>
<th>Method</th>
<th>Group</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Cross-over</th>
<th>Group</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAL</td>
<td>A</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>←</td>
<td>C</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>CAL</td>
</tr>
<tr>
<td>CAL</td>
<td>B</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>←</td>
<td>D</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>CAL</td>
</tr>
<tr>
<td>SL</td>
<td>C</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>←</td>
<td>A</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>SL</td>
</tr>
<tr>
<td>SL</td>
<td>D</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>←</td>
<td>B</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>→</td>
<td>SL</td>
</tr>
</tbody>
</table>

Statistical analysis was performed using the Mann-Whitney test of two independent samples before and after the cross-over and the Wilcoxon’s signed rank test for paired samples.
The students were randomly divided into groups, five female students in each of groups A and C, and five male students in each of groups B and D. Every student repeated each of the three tasks four times, starting with either computer-assisted laparoscopy (CAL) or standard laparoscopy (SL), then they changed method and repeated the four sets (1 – 4) of three tasks. The transfer effect of difference in experience based on the CAL users’ prior SL experience and vice versa, was tested regarding the three surgical tasks using the Mann-Whitney test of two independent samples. Friedman’s and Wilcoxon’s signed rank test were used for analysis of tries of knot tying and suturing. Male and female participants were compared using the Mann-Whitney signed rank-test for paired samples. In Paper IV the non-parametric Mann-Whitney U test was used for analysing the data.

The collected data were stored in an Excel 2003 database (Microsoft Corporation, Redmond VA, USA). SPSS statistical software (SPSS Inc., Chicago IL, USA), version 15.0, was used for analysing the data. A p-value lower than 0.05 was considered significant.

Ethical considerations

The introduction of new techniques and instruments in clinical surgical practice always raises ethical questions. The potential benefit for the patient must be balanced against any risks and drawbacks. There is an undeniable learning curve when taking up a new technique, no matter how much training there is before, and training in a simulated environment is not always possible. Even where simulations exist, they cannot fully make up for the lack of experience at start. Therefore, a thorough analysis of the initial results is important also from an ethical standpoint. Intention to treat was the main analysis strategy and encompassed all the patients. We strongly believed that the patients in this study would benefit from the use of the new instruments, but our ambition with the project was also to set the base for further studies for the benefit for patients in the future.

The da Vinci® Surgical System was approved by the FDA in 2000 and by the Institutional Review Board at Skåne University Hospital before our start. Verbal, informed consent from all the children’s guardians was obtained prior to surgery. The use of CALS instruments when performing paediatric surgery and performing scientific studies comparing CALS and controls was approved by the Regional Committee for Research Ethics in Lund (D nr 2009/59 and D nr 2010/49).
Results

Paper I

There was no difference between the three compared groups of patients regarding age and sex, body weight and preoperative work-up including DeMeester score. Only three out of the 18 children were healthy besides the GERD and 12 out of 18 had a serious neurological disorder. All had a pathological DeMeester score as a sign of severe gastroesophageal reflux and the mean values ± SD (range) were 73 ± 33 (31 – 137), 52 ± 37 (27 – 86), 48 ± 37 (24 – 48) for the CALS, laparoscopic and open groups, respectively. The operating time, the need for postoperative morphine analgesics and the length of hospital stay differed (Table 9).

The mean time for the CALS was longer than for the standard laparoscopic or open procedure. However, the operating time for the four latest CALS operations was the same as the operating time for the laparoscopic operations. The use of morphine showed a more than 50% reduction and the postoperative hospital stay was reduced from six to four days with the two minimally invasive methods. All the operations were performed without complications or procedure related mortality. Neither of the two minimally invasive methods required conversions to open surgery. Blood loss was minimal for all the patients. There was no difference in the short-term clinical outcome between the groups; the symptoms of GERD disappeared in all the children.

### TABLE 9 Operating time, use of morphine and length of hospital stay

<table>
<thead>
<tr>
<th></th>
<th>Surgical methods</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CALS (6)</td>
<td>Laparoscopic (6)</td>
</tr>
<tr>
<td>Operating time, minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEAN ± SD</td>
<td>213 ± 81</td>
<td>189 ± 13</td>
</tr>
<tr>
<td>(Range)</td>
<td>(150 – 285)</td>
<td>(140 – 257)</td>
</tr>
<tr>
<td>Use of morphine, days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEAN ± SD</td>
<td>1.3 ± 0</td>
<td>1.5 ± 0.7</td>
</tr>
<tr>
<td>(Range)</td>
<td>(1 – 3)</td>
<td>(1 – 2)</td>
</tr>
<tr>
<td>Hospital stay, days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEAN ± SD</td>
<td>4 ± 1.4</td>
<td>3.5 ± 0.7</td>
</tr>
<tr>
<td>(Range)</td>
<td>(1 – 7)</td>
<td>(3 – 4)</td>
</tr>
</tbody>
</table>

Statistical analysis was performed using the Kruskal-Wallis test.
Paper II

The total costs of CAL fundoplication amounted to EUR 9584. The costs for laparoscopic and open fundoplication amounted to EUR 8982 and EUR 10521, respectively (Table 10). Anaesthesia, operation and immediate postoperative care were calculated to EUR 3488, EUR 3488 and EUR 2174 for CAL, laparoscopic and open surgery, respectively. This corresponds to a similar operating time for CAL and laparoscopic surgery while open surgery was faster (Table 4). The cost of the CALS instruments per procedure (EUR 2081) accounted for the extra expense compared to laparoscopy. CAL fundoplication resulted in the shortest hospital stay, 3.8 days compared with 5.2 for laparoscopic and 7.9 for open surgery. Thus, the costs of in-hospital care were EUR 4015, EUR 5494 and EUR 8347 for the CALS, laparoscopic and open procedures, respectively.

TABLE 10 Cost of each fundoplication

<table>
<thead>
<tr>
<th></th>
<th>Anaesthesia</th>
<th>CALS instruments</th>
<th>In-hospital care</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALS</td>
<td>3488</td>
<td>2081</td>
<td>4015</td>
<td>9584</td>
</tr>
<tr>
<td>Laparoscopy</td>
<td>3488</td>
<td></td>
<td>5494</td>
<td>8982</td>
</tr>
<tr>
<td>Open surgery</td>
<td>2174</td>
<td></td>
<td>8347</td>
<td>10521</td>
</tr>
</tbody>
</table>

All prices according to the regional hospital price list from 2007. All prices in EUR (1 EUR = 9.20 SEK).

Paper III

The tasks of “grabbing the needle” and “sutting continuously” were carried out at equal speeds with CAL and SL (Table 11). The transfer effect was seen when performing the continuous suturing for CAL but not for SL (Table 12). The same transfer effect was seen for CAL in tying a knot but not for SL. The task of tying a knot was performed faster with CAL than with SL regardless of whether CAL was performed first or second. A difference was observed in tying the knot when changing to the other operating technique, regardless of which technique the subjects started with. The difference favoured CAL and was negative for SL (Tables 11, 13).

Dropping the needle happened more often during the CAL part of the study and tearing the thread only occurred with the CAL technique. Damage to the Skin Pad in Jig® was equally frequent (Table 11). Learning curves could be seen for continuous suturing (Figure 5) and tying a knot (Figure 6) for both CAL and SL when comparing trials 1 and 4. There was no difference between the male and female subjects’ performances regarding any of the three tasks or the three quality indicators included in the study.
**TABLE 11** Time and accuracy for all 20 participants. Time in seconds and qualitative parameters for all 20 participants after four repeats with CAL and SL expressed as the number of times they occurred (n)

<table>
<thead>
<tr>
<th>Time in seconds</th>
<th>Computer-Assisted Laparoscopy</th>
<th>Standard Laparoscopy</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grab the needle</td>
<td>8 ± 6 (1 – 28)</td>
<td>6 ± 4 (2 – 25)</td>
<td>0.064</td>
</tr>
<tr>
<td>Continuous sutureing</td>
<td>180 ± 106 (57 – 663)</td>
<td>205 ± 89 (86 – 472)</td>
<td>0.117</td>
</tr>
<tr>
<td>Tie a knot</td>
<td>121 ± 77 (45 – 560)</td>
<td>266 ± 178 (68 – 1027)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Accuracy times/set**

<table>
<thead>
<tr>
<th></th>
<th>CAL</th>
<th>SL</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Damage</td>
<td>8</td>
<td>2</td>
<td>0.058</td>
</tr>
<tr>
<td>Dropped needle</td>
<td>79</td>
<td>18</td>
<td>0.001</td>
</tr>
<tr>
<td>Torn thread</td>
<td>5</td>
<td>0</td>
<td>0.059</td>
</tr>
</tbody>
</table>

Mean, standard deviation (SD) and range obtained from each trial performed by each participant (× a total of 80 trials). Statistical analysis was performed using Wilcoxon paired-sample test for 20 participants, with mean values over the four trials per participant of time-in-seconds and accuracy variables.

**TABLE 12** Continuous sutureing for each group of 10 participants and transfer effect

<table>
<thead>
<tr>
<th></th>
<th>MEAN ± SD (RANGE)</th>
<th>MEAN ± SD (RANGE)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAL first vs SL first</td>
<td>216 ± 123 (76 – 663)</td>
<td>198 ± 82 (108 – 472)</td>
<td>0.545</td>
</tr>
<tr>
<td>CAL last vs SL last</td>
<td>144 ±70 (57 – 346)</td>
<td>209 ± 96 (86 – 438)</td>
<td>0.019</td>
</tr>
<tr>
<td><strong>CAL first vs CAL last</strong></td>
<td>0.049</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SL first vs SL last</strong></td>
<td>0.364</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CAL first vs SL last</strong></td>
<td>0.004</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SL first vs CAL last</strong></td>
<td>0.059</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Statistical analysis was performed using the Mann-Whitney test of two independent samples before and after the cross-over and the Wilcoxon’s signed rank test for paired samples (i.e. for CAL first vs. SL last and SL first vs. CAL last, respectively). The four repeated trials for each participant were aggregated into a mean value for each participant, subsequently the total sample size was 20 participants.

**TABLE 13** Tying a knot for each group of 10 participants and transfer effect

<table>
<thead>
<tr>
<th></th>
<th>MEAN ± SD (RANGE)</th>
<th>MEAN ± SD (RANGE)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAL first vs SL first</td>
<td>152 ± 94 (48 – 560)</td>
<td>266 ± 173 (68 – 935)</td>
<td>0.005</td>
</tr>
<tr>
<td>CAL last vs SL last</td>
<td>91 ± 35 (45 – 195)</td>
<td>267 ± 186 (70 – 1027)</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>CAL first vs CAL last</strong></td>
<td>0.004</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SL first vs SL last</strong></td>
<td>0.762</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CAL first vs SL last</strong></td>
<td>0.037</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SL first vs CAL last</strong></td>
<td>0.005</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Statistical analysis was performed using the Mann-Whitney test of two independent samples before and after the cross-over and the Wilcoxon’s signed rank test for paired samples (i.e. for CAL first vs. SL last and SL first vs. CAL last respectively). The four repeated trials for each participant were aggregated into a mean value for each participant, subsequently the total sample size was 20 participants.
FIGURE 5 The mean time for each try of continuous suturing for the 20 subjects with SL and CAL in seconds. Statistical analysis was performed using the Friedman’s test for comparing trials 1 - 4 (p = 0.001 for SL and p = 0.001 for CAL) and the Wilcoxon Signed Rank test for comparing trials 1 and 4 (p = 0.001 for SL and p = 0.002 for CAL).

FIGURE 6 The mean time for each try to tie a knot for the 20 subjects with SL and CAL in seconds. Statistical analysis was performed using the Friedman’s test for comparing trials 1 - 4 (p < 0.001 for SL and p = 0.3 for CAL) and the Wilcoxon Signed Rank test for comparing trials 1 and 4 (p < 0.001 for SL and p = 0.009 for CAL).
Paper IV

There was no difference in age, weight or length of the patients in the two groups (Table 7). All the operations were performed without peroperative complications and in the CALS group without conversion to open surgery. The operating time in the console was 100 (65 – 180) minutes. The total operating time was longer for the CALS group, 202.5 (128 – 325) minutes than for the open group, 72 (44 – 160) minutes (Table 14). The mean console operating time was 118 (SD ± 48) minutes and the mean open operating time was 87 (SD ± 32) minutes. The time for placing trocars for the surgical system, positioning, docking and undocking of the da Vinci and finishing the procedure was 71 (60 – 145) minutes. Four out of ten patients in the CALS group had total operating times within the range of the operating time for an open procedure (Figure 3). The blood loss was minimal (< 20 mL) in both groups.

The number of postoperative doses of morphine did not differ, 0 (0 – 2) for the CALS group and 0 (0 – 7) for the open group but the hospital stay was shorter for the CALS group, 1 (1 – 4) day compared with 2 (1 – 7) days for the open group (Table 14). The only complication seen at follow-up was a retroperitoneal urinoma that appeared on the fifth postoperative day in the first patient operated on with computer-assistance.

<table>
<thead>
<tr>
<th>Surgical methods</th>
<th>Operating time, minutes</th>
<th>Console time</th>
<th>Pre- and post console time</th>
<th>Morphine doses</th>
<th>Hospital stay, days</th>
<th>Complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALS (10)</td>
<td>202.5 (128 – 325)</td>
<td>100 (65 – 180)</td>
<td>71 (60 – 145)</td>
<td>0 (0 – 2)</td>
<td>1 (1 – 4)</td>
<td>1</td>
</tr>
<tr>
<td>Open (23)</td>
<td>72 (44 – 160)</td>
<td></td>
<td></td>
<td>0 (0 – 7)</td>
<td>2 (1 – 7)</td>
<td></td>
</tr>
</tbody>
</table>

Data were presented as median (range). Statistical analysis was performed using the Mann-Whitney U test.
This thesis addresses different aspects of great importance to the surgeon when a new technique or method is introduced in the evolving field of surgery. In the four papers we have looked at the feasibility and safety (I), costs (II), initial learning curve (III) of computer assisted surgery in children and finally compared it with our previous treatment of choice for nephrectomies (IV). Three of the papers are clinical works and one is an experimental study.

When we first started, the use of computer-assisted surgery was slowly diffusing out from the pilot centres around the world where the first cases had been performed, but very few publications existed. A group from Frankfurt in Germany had demonstrated that CALS was feasible even in children, when they reported in 2001 the first fundoplication with the da Vinci® Surgical System in a child and their initial experience of eleven fundoplications, two cholecystectomies and one salpingooophorectomy [10,14,61]. However promising, the role of CALS in paediatric surgery was unclear and global experience very limited. From the handful of centres in the paediatric world where it was used, some case series had emerged but there were no comparative studies and to this date no randomised controlled trials.

Our hospital obtained its first da Vinci® Surgical System in 2005 and the da Vinci® Si Surgical System in 2007. In 2010, the da Vinci® Si Surgical System replaced the standard system, which was moved to the clinical skills centre Practicum at Skåne University Hospital in Lund. The two robotic systems are shared by five departments: Paediatric Surgery, Gynaecology, Urology, General Surgery and ENT and more than 300 procedures are performed per system per year. Since the systems are shared and their application in adult surgery more established, we have access to one system just one day every two weeks. Without the capacity to use it during the summer months June, July and August, it gives us roughly 15 operating days per year.

When introducing high technology equipment into clinical practice it is important to initially keep the new technique on as few hands as possible [18]. Dedication in your team members is another key to success. It is important to train thoroughly, to select a suitable procedure and patients to start with [18] and preferably perform the first cases with a proctor at your side for advice. Our team of three nurse-assistants, three scrub nurses and three surgeons trained for six months in the da Vinci dry lab, set up at the Skåne University Hospital in Lund, and in Aarhus, Denmark, where the paediatric urologist Dr Henning Olsen began to use the da Vinci in 2003. The decision to include all CALS patients prospectively in a database,
as well as to record all procedures from the start, was made with the intention to evaluate our experience after a certain time and compare with controls.

We considered a fundoplication suitable as a first CALS case for many reasons. It is relatively simple with some meticulous dissection and only a few sutures, but does not involve many reconstructive steps that are difficult to perform laparoscopically. It was a procedure that we had performed both with standard laparoscopic instruments and with open surgery, giving us controls for comparison with two previous methods of surgery. The operative field is perhaps more readily accessible with MIS, than through the open approach, and CALS could therefore be beneficial for the patient. The medical therapy for GERD is efficient enough to make consecutive surgery possible, even in a specialty such as paediatric surgery, where large volumes of patients with similar diagnoses hardly exist.

Advantages and limitations of computer-assisted surgery

Previous studies have reported the safety and feasibility of computer-assisted anti-reflux surgery in children [12,14,15,62,63]. The comparative study by Morino et al. in adults showed no significant differences in terms of feasibility and outcome, but higher costs owing to a longer operating time and the use of more expensive instruments for the computer-assisted laparoscopic fundoplication compared with the standard laparoscopic procedure [64]. Costi et al. noted technical advantages of the da Vinci system over conventional laparoscopy in dissection, passage around the oesophagus, increased effectiveness in suturing, improved image quality, but longer operating time and no proven benefit for Nissen fundoplication in adults [65].

Our report was the first comparative study on computer-assisted laparoscopic Nissen fundoplications in children and the results suggest that CALS in children, already for the first six patients, was safe and comparable with conventional laparoscopic surgery with regard to operating time, postoperative pain and length of the postoperative hospital stay (I). The operating times between the three groups differed; the long operating time for computer-assisted fundoplications at the beginning of the learning curve of a new technique, was expected.

In a case-controlled study of 20 patients, Lehnert et al. found similar operating times for computer-assisted and standard laparoscopic Thal semi-fundoplications in children. They concluded that the computer-assisted surgical system was superior to the established standard laparoscopic techniques requiring tissue preparation, but that the potential benefit in operating time was counterbalanced by the increased complexity of setting up the system [66]. Albassam et al. matched and retrospectively compared 25 + 25 children undergoing a Nissen fundoplication with CALS and standard laparoscopy. Their operating time and length of hospital stay were similar.
for the two groups and in agreement with our reported findings [67]. Furthermore, these authors noted that studies on children reported comparable operating times for Nissen procedures with CALS and standard laparoscopy, but longer operating times and no added benefit for studies in adults [31,64-66,68,69]. Copeland et al. case-matched and selected 50+50+50 children and compared Nissen Fundoplications with the open, laparoscopic and computer-assisted approach. They conclude that computer-assisted surgery is equivalent to standard laparoscopic surgery in terms of complications and length of stay and found that both these methods had longer operating times, but reduced lengths of hospital stay compared with open surgery. These conclusions are supported by our study [70].

Margaron et al. concluded, in their case series of 15 children, that computer-assisted laparoscopic Nissen fundoplications were feasible also in children with a gastrostomy [71]. We have made no distinction between the children with or without a gastrostomy, since we share the experience of Margaron et al. that a gastrostomy is not a limiting factor for CALS.

In the study on computer-assisted retroperitoneoscopic nephrectomy (IV) safety and feasibility were demonstrated, as no perioperative complication occurred in either group, and this is supported by others [13,20]. One complication was noted at follow-up in our first CALS patient, a one-year-old boy with a non-functioning kidney due to vesicoureteral reflux grade IV, but the complication was not considered to be related to the use of the surgical system.

We have not found any other studies comparing computer-assisted retroperitoneoscopic with open nephrectomy in children. Najmaldin and Antao report a series of four computer-assisted laparoscopic nephrectomies, console time 103 (55–110), total operating time 162 (114–170) minutes, length of hospital stay 2 (1–2) days and four nephroureterectomies, console time 96 (58–180), total operating time 172 (132–235) minutes and length of hospital stay 1 (1–2) days [20]. Passerotti and Peters describe how to perform a computer-assisted nephrectomy but do not report any results from their series [22,23]. In a recent publication by Lee et al., computer-assisted laparoscopic nephrectomy with contralateral ureteral reimplantation was performed in four patients and this combined procedure had a mean total operating time of 291 (243–380) minutes and a mean length of hospital stay 2.3 (1.9–2.9) days [16]. Rogers et al. report the largest series of 42 adult computer-assisted nephrectomies for the treatment of benign and malignant disease. Their console time was 158 (69–300) minutes, the operating time 294 (129–483) minutes and the length of hospital stay 2.4 (1–8) days [72].

Our study showed a significantly longer operating time for the computer-assisted retroperitoneoscopic nephrectomy, 202.5 (128–325) minutes, compared with the open procedure, 72 (44–160) minutes, but also a shorter length of hospital stay. The operating time in the console was 100 (65–180) minutes. The median and mean number of doses of morphine, 0 (0–2), 0.2 (SD ± 0.6) and 0 (0–7), 1.4 (SD ± 2) in the CALS and open group, respectively, were lower in the CALS group but
not significantly so. Only one out of 10 patients in the CALS group received morphine postoperatively as compared with nine out of 21 patients in the open group. Previous reports comparing standard laparoscopic and open nephrectomy in children state that also the minimally invasive approach is safe and feasible. Ku et al. included 10 + 13 children undergoing nephrectomy and had a similar median operating time, 150 (120 – 200) and 145 (90 – 200) minutes, but a shorter median hospital stay, 2.5 (2 – 6) and 4 (3 – 14) days, in the laparoscopic and open group, respectively [44]. Lee et al. reported 9 + 9 children younger than two years undergoing laparoscopic and open retroperitoneal partial nephrectomy with similar mean operating times, 162 (116 – 244) and 175 (150 – 226) minutes, but a shorter mean hospital stay, 1.8 (1 – 3.9) and 4.6 (3.8 – 7) days, in the laparoscopic and open groups, respectively [73]. Their shorter hospital stay was supported by our study, but the operating time for CALS was significantly longer than for the open procedure. However, our operating times are not that different from those of others but show less consistency with some very long procedures (Figure 7).

![Figure 7 Operating time for each CALS and open nephrectomy and CALS console time in minutes](image)

Partly, this is because we are still in a learning phase. The longest operating times were mainly caused by various technical problems such as conflicts of working arms on the outside, and a large kidney in cases four and five, added time for instructing a new console surgeon and scrub nurse for case six, and bleeding from one port hole, seriously impairing visibility in case seven. Our tenth CALS patient weighed only 8.6 kg, which made retroperitoneal port placement more challenging and limited the
operative field. However, we expect the operating time to decrease with the number of cases performed, as reported for computer-assisted laparoscopic partial nephrectomies by Lee et al. [74], and consider a total of 120 minutes to be reasonable. Two of our last three cases come close to that time.

Introducing new instruments in surgery often prolongs the operating time initially, as seen in these studies (I, IV). However, the learning curve for CALS is steep, perhaps partly due to the 3-D vision [75,76]. The operating time for the four last patients in Paper I, still representing the learning curve, was similar to the mean operating time in the laparoscopic group, representing the late routinely operated patients (Figure 8). Learning curves in paediatric operations are, however, difficult to analyse since the number of patients is relatively small and the difference between each child in general is greater than between adults. A weight factor of five is not rare in children. Children undergoing fundoplications often have concomitant diseases with scoliosis, gastrostomies and have had previous surgery which can complicate the procedure. With limited access to the da Vinci system, patients with similar diagnoses are not operated on consecutively, which of course also affects the learning curve. Since the total operating time, reflects the learning curve of the entire team of surgeons, nurses, anaesthesiologists and assistant nurses, and not only the surgeons’ performance, console time could be a better end-point when learning curves for a CALS procedure are analysed.

![Figure 8](image)

**FIGURE 8** The console time in hours for the first six CALS fundoplications demonstrating the learning curve
The 3-D vision, the advanced instruments and improved ergonomics for the surgeon with the computer-assisted surgical system compared with standard laparoscopy, has been perceived to enhance surgical precision, but the technique was limited because the size of the system was not adapted for children [12,14,15]. These advantages could lead to shorter operating time for CALS compared with conventional laparoscopy, as was reported by Müller-Stich et al., in contrast to other studies in adults [69] and previously, when the AESOP was used instead of a human camera holder [63]. The increased dexterity of the CAL instruments, the tremor reduction and the excellent 3-D vision similar to the view in open surgery, is most advantageous in complex procedures where delicate dissection or advanced suturing skills are needed [22]. In reports, as well as according to our own experience, some laparoscopic procedures could be accomplished minimally invasively for the first time with the surgical system [11,18,26,27]. Hemal et al. report having used the da Vinci for pyeloplasty in patients with pelvoureteral junction obstruction with previously failed open repair. These authors concluded that the surgical system was especially beneficial in the management of this very technically challenging procedure and reported excellent success rates and reduced operating times compared to standard laparoscopy [77]. The technical advantages of the surgical system are perceived to facilitate surgery also in simpler cases, and surgeons who reserved the da Vinci for their most complex cases consider this a mistake [18]. By performing easier cases, the entire team of surgeons and nurses gains experience that is needed later for complex operations. Even if there are no technical or patient advantages in performing a cholecystectomy with computer-assistance, it could be an ideal teaching case.

Computer-assisted laparoscopic pyeloplasty is the most common procedure performed in paediatric urology and has shown outcome and complication rates similar to the open and laparoscopic procedure [19,39,78]. Chan et al., reported five CAL pyeloplasty patients with a mean operating time of 224 (160 – 255) minutes [79]. The largest reported paediatric series is from Olsen et al., with 67 computer-assisted retroperitoneoscopic pyeloplasty patients over a five-year period, with shorter mean operating time, 146 (92 – 300) minutes compared with previous reports [39]. Lee et al. and Yee et al., compared transperitoneal CAL pyeloplasties with the open procedure and found longer operating times, decreased use of opioids and a shorter length of hospital stay [80,81] for the CALS procedure.

The retroperitoneal approach offers an access comparable with standard renal surgery and has been our preferred approach for all computer-assisted renal surgery. The main theoretical advantages are a direct and rapid exposure of the kidney, minimization of the risk for injury of peritoneal viscera and for postoperative obstructive adhesions, and the confinement of a postoperative haematoma or urinoma to the retroperitoneum in the case of a complication. Comparative studies on the trans- and retroperitoneal approach are only performed for conventional laparoscopy.

As Passerotti and Peters and Casale and Kojima have pointed out, port placement with the retroperitoneal approach must be distinct [13,22] but operating
times for conventional laparoscopy in children become shorter, with times approaching those for the open procedure and the learning curve is considered reasonable [82]. Castellan et al. report their experience with laparoscopic partial nephrectomy in the paediatric age group and conclude that there are no significant differences between the transperitoneal and retroperitoneal approach with regard to operating time, complication rates or hospital stay. Since the transperitoneal approach offers more space than the retroperitoneal, it has been advocated for children younger than one year but the retroperitoneal approach is preferred in older patients [83]. McDougall et al. performed laparoscopic nephrectomies in adults with benign renal disease and small kidneys (< 100g) and reported that the retroperitoneal approach was associated with lower postoperative doses of morphine and quicker return to oral intake than the transperitoneal approach, but the total length of hospital stay was not affected [84]. Canon et al. reported no major differences between the retroperitoneoscopic and transperitoneal approaches to minimally invasive pyeloplasty in children, especially in terms of success. The transperitoneal approach showed a steeper learning curve, shorter operating time (184 minutes compared to 239 minutes for retroperitoneal pyeloplasty), and subjectively greater ease in suturing, thanks to more space [85]. To establish which approach is better for minimizing the risk for complications, further studies with larger series of patients are warranted.

In accordance with previous reports, the intuitive handling and the articulation of the instruments, and the 3-D vision of the surgical system have facilitated our MIS procedures and, as previously stated, made us attempt the minimally invasive approach for the very first time. The distribution of our CALS procedures is listed in Table 15. For pyeloplasties, fundoplications and for the repair of Morgagni hernias, the benefit of computer-assistance is obvious [27]. Even for the ablative procedures nephrectomy and partial nephrectomy, where no advanced suturing is involved, the procedure is perceived easier for dissecting and securing the vessels. The minimally invasive approach offered improved cosmetics and easier access to the surgical field for both the 15-year-old girl who had a CALS hemihysterectomy and the 22-month-old boy with rhabdomyosarcoma in his bladder compared with the alternative open approach [11,26].

Our main concern has been the size of the surgical system, which is not very well suited for children. The large 8 mm instruments and the 12 mm 3-D endoscope demand larger trocars and cause bigger scars than the 3 – 5 mm endoscopes and instruments used in standard paediatric MIS. Slightly paradoxically the existing 5 mm da Vinci instruments need more space inside the child patient to function due to a different construction than the 8 mm instruments. Since space is the limiting factor for instruments and arms to manoeuvre, we have never used those smaller instruments. Thakre et al. studied surgical performance in cubic boxes of different sizes and were able to identify the smallest workable volume with the da Vinci system, i.e., 125 cm$^3$ corresponding to a cube edge size of 50 mm. These authors concluded that workspace has a significant impact on performing a surgical procedure
successfully [86]. With careful planning and experience we have learnt to adjust the angles of the instrument arms, trocar placement and trocar depth to avoid collisions on the inside or the outside that would make surgery impossible [40]. Long operating time in our experience, is almost always caused by limited space and conflicts. Docking the system in CALS procedures adds some time compared to standard laparoscopy, but does not affect the total operating time significantly. The average docking time after 60 CALS procedures (Table 15) is \(8.8 \pm 2.9\) (4 – 15) minutes which corresponds well with the time reported for others, \(11.9 \pm 3.2\) (4 – 20) by Najmaldin et al. and four minutes by Meehan et al. [18,20]. Moreover, the time for docking decreases with experience.

### TABLE 15 Distribution of CALS procedures in our first 60 children

<table>
<thead>
<tr>
<th>Domain</th>
<th>Procedure</th>
<th>N</th>
<th>%</th>
<th>Completed</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal</td>
<td>Fundoplication</td>
<td>23</td>
<td>22</td>
<td>96</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CDH repair– Morgagni type</td>
<td>2</td>
<td>2</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cholecystectomy</td>
<td>1</td>
<td>1</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cystoprostatectomy Rhabdomyosarcoma</td>
<td>1</td>
<td>1</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hemihysterectomy Uterus didelphus</td>
<td>1</td>
<td>1</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Abdominal</td>
<td>subtotal</td>
<td>28</td>
<td>47</td>
<td>27</td>
<td>96</td>
</tr>
<tr>
<td>Retroperitoneal</td>
<td>Pyeloplasty</td>
<td>18</td>
<td>10</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nephrectomy</td>
<td>10</td>
<td>10</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Partial Nephrectomy</td>
<td>3</td>
<td>3</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kidney biopsy</td>
<td>1</td>
<td>1</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Retroperitoneal</td>
<td>subtotal</td>
<td>32</td>
<td>53</td>
<td>24</td>
<td>75</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>60</td>
<td>100</td>
<td>51</td>
<td>85</td>
</tr>
</tbody>
</table>

With experience the patient-side cart position, the patient position and the port placements have become more optimal, overcoming the limitations, but sometimes the surgical procedure had to be performed with less than ideal positions. To overcome the fact that children are too small for optimal distance between ports, you could shift to an alternative trocar placement than you would have chosen for standard MIS, such as the use of the transabdominal approach used by many paediatric surgeons instead of the retroperitoneoscopic approach. Converting an open retroperitoneal procedure to a transabdominal MIS procedure seems less advantageous than using the retroperitoneoscopic approach, which we have done for all but one of our renal surgical CALS procedures.

However, the limited space in the retroperitoneum has been the reason for our conversions to open surgery. The smallest patient operated on through the retroperitoneum weighed 9 kg and the smallest one operated on through the abdomen weighed 6 kg. Others have reported successful CALS repairs of congenital
anomalies in children weighing little over 2 kg [87,88]. Another drawback of the surgical system is the lack of tactile feedback, but this is well compensated for with improved vision, and not a great concern [18,21].

The da Vinci® Surgical System was developed for adults, yet has it been made to work for children. It is not perfectly adapted for paediatric surgery today but some modifications have been made to reduce its size and improve manoeuvrability. In contrast to adult surgeons, who often repeat a single procedure, paediatric surgeons perform many varying procedures, which can limit the ability to efficiently develop the skills of conventional laparoscopy. If MIS is made easier with computer-assistance this could be especially important in paediatric surgery [89,90]. To know when it is appropriate to assess a new developing technology could be difficult according to Peters [91]. That the technology will continue to evolve as long as there is interest in using it, seems likely.

Considerations on subjects and methods

There are, of course, several limitations in the comparison between prospectively followed CALS patients and historical controls in Papers I, II and IV. Selection bias with a tendency to include smaller children in the open group could be considered one. The risk for change in overall treatment regimen over the years affecting the outcome parameters, but not related to the methods we studied, could be another. Furthermore, surgical methods might change over the years, risking confounding comparisons.

In Papers I and II we did not select the included patients, since all patients in need of a fundoplication were operated on with CALS. All our CALS patients at the time were then compared with all the latest patients in the open and laparoscopic group. The patients in Papers I and IV did not differ in age or weight, but those in the open group in Paper II weighed less. In Paper IV, those nine children operated on with an open procedure during 2008 – 2009 were not different from the open group as a whole and more a reflection of limited access to the surgical system for laparoscopy. The smallest patient operated on with CALS in Paper IV weighed 8.6 kg and only five out of 21 patients in the open group weighed less. The students in Paper III were randomly selected, though matched for sex, but all fulfilled the criteria of having no prior experience of laparoscopy or CALS. The amount of previous experience among the subjects in computer gaming was not tested and could be considered a weakness since computer gaming has been shown to affect surgical performance in simulators [92,93].
The method for performing a fundoplication has not changed over the years at our department, except for the instruments used. All fundoplications have been performed by the same team of surgeons. The post-operative care has changed over the years at our department, especially considering pain management. The more frequent use of epidural analgesia and morphine pumps does, however, not apply to the patients studied in this thesis since all received only paracetamol with or without doses of intravenous morphine.

The use of morphine was calculated in postoperative days in Papers I and II, but more specifically in doses, in Paper IV. All doses of any medication are registered in the paper charts or, more recently, electronically. VAS scores for the measurement of pain were used to objectify our postoperative pain control and the discharge criteria. Length of hospital stay is an endpoint with many biases. Our hospital discharge system does not calculate the hours the patient is registered as an in-patient, but only the number of days. The number of days a patient is registered as an in-patient could be affected by the distance from home to the hospital. The surgeon might keep a patient in hospital an extra day if this distance is far, to make sure of any possible complications occurring, but this consideration is not different between the three groups of patients studied. If anything, there might be a tendency to prolong hospital stay when a new method is introduced. To calculate in-patient periods in hours would not avoid bias, since a patient is discharged from hospital when the nurse has the time to do so or when home transport becomes available.

A randomization of the children to either open, laparoscopic or CALS, was impossible for a number of reasons. First, we do not have unlimited access to the da Vinci® Surgical System and a randomization would be difficult to handle for organizational reasons. The fact that nine children were operated on with an open procedure even after we started using CALS is a result of this. Second, our catchment area of southern Sweden with two million inhabitants is not enough to include many patients in a study in a short time period. Furthermore, we cannot afford to exclude patients without counteracting the advantage of randomization by injecting bias into the study material in the form of historical data. However, with a larger number of patients and strictly prospective, age-matched cohorts, the statistical analysis would be more robust and the evidence stronger. In the absence of such a study, our report is an attempt to add to the current literature and to set the basis for further studies.

Aspects on costs of computer-assisted surgery in children

Calculating costs for health care is not an easy task since the economical systems are not focused on calculating costs per patient or per procedure, and traditionally, health care providers are unaware of the costs involved when caring for a patient. For the
surgeon, it is impossible to calculate the costs for the care provided. There is no registration of the material used per patient at our hospital, except for the use of some specific, very expensive equipment or for very expensive medical treatments. The input for the economists is therefore limited. To avoid wrong input as far as possible, all calculations in Paper II have been carried out by the hospital’s chief financial manager.

The costs for anaesthesia were EUR 17 (156 SEK) per minute and the costs for the staff accounted for 51% of that sum. Care related costs, such as medicine used during the procedure, instruments and disposables, accounted for 25%. House rent and interest, and overheads amounted to 10% and 14%, respectively. Compared with the cost for anaesthesia for adults at Skåne University Hospital, the cost per minute, in our calculation, is probably higher, mainly due to higher costs for staff. Since the cost was the average cost per minute, one could argue that the costs do not apply for the specific group of patients that was studied in Paper II. Whether or not the children undergoing fundoplications, require cost-wise average anaesthesia, is impossible to tell. Eighty% of the patients in Paper II had a neurological disorder but there is no definition of an average ill child. However, even if that was true, that bias would exist in all three groups. The fact that the children in the open group weighed less did not, in my opinion, have an impact on the costs for anaesthesia, but the data to support this opinion are lacking, since costs are not registered per kilo.

The costs for hospital stay were EUR 1057 (9724 SEK) per day. The number of staff per patient in a paediatric surgery ward is probably higher than in an adult ward and the costs for staff accounted for 67% of the total cost. As for anaesthesia, costs are calculated as average cost and the same concerns as mentioned above, might apply. The cost for the da Vinci® Surgical System was divided into fixed overhead costs and variable procedure-related costs. The fixed costs included investment in the surgical system and costs for servicing. The variable costs included specific instruments, draping and trocars for the surgical system. Costs per procedure were then calculated based on the annual number of CALS procedures at our hospital.

When calculating the cost of each CALS fundoplication the variable costs certainly must be taken into account, but this is less obvious for the fixed costs. Since the hospital investment of the surgical system and its service had already been made, we have chosen, in an attempt to provide the reader with a better interpretation of the actual cost of the CALS procedure, not to add the fixed cost to the cost of each procedure in our results and in Table 10. The cost of earlier investments in instruments for laparoscopic and open surgery were also already included in the standard cost for the operating unit and therefore not taken into account.

Our results show that the operative costs were higher for the CALS technique, due to the extra costs for consumables (variable costs) for the da Vinci® Surgical System. If the time required for the operations using the three different surgical methods were to be equal, as well as the duration of the hospital stay, then the costs of CALS would be 29% higher than those for open and laparoscopic surgery, because of
the cost of the da Vinci® system (fixed costs) and instruments (variable costs). If the fixed costs are excluded, the extra cost for CALS instruments is 22%, all else being equal. The use of laparoscopic instruments does not result in any extra cost. These instruments have been used at our centre since 1994 and are included in the cost for the operating unit at our hospital, as well as all other reusable or disposable items. The same may apply to CALS instruments in the near future. Our presented calculations do not include the total cost for the preoperative work-up of the patients or the outpatient costs before and after surgery. If these items were to be included in the calculations, the total cost would increase and the percentage difference between the three groups would decrease.

A 22% cost increase, when CALS is used, for a standard operative intervention such as a fundoplication, has to be justified by improved benefit for patients, or the cost has to be substantially reduced. In a case-control matched prospective study comparing the costs for CALS and laparoscopic cholecystectomies in adults, Breitenstein et al. found that the operating times and hospital stay were similar and the overall hospital costs were higher by USD 1730 for CALS (USD 7985 versus USD 6255) [94]. These authors concluded that this (22%) difference was mainly related to the amortisation and consumables of the surgical system, which was supported by our study. Smith et al. reported that CALS for radical cystectomy in adults was associated with increased overall cost by USD 1640 (USD 16248 versus USD 14608) compared to open cystectomy. The costs for the surgical system and instruments, accounted for all but 6 USD of the extra costs for CALS procedures, due to a shorter hospital stay than for open surgery [95].

Kam et al. compared CALS in mitral valve repair in adults and found no significant increase in mean hospital costs (AUD 18503 vs. AUD 17880) over conventional surgery, if capital costs were excluded. CALS operating time was 18% longer, intensive care unit stay 19% shorter and length of hospital stay was reduced by 26% [96]. At the 11th European Congress of Paediatric Surgery in Berne, Switzerland in June 2010, Professor David Diamond from the Children’s Hospital in Boston, USA presented their initial experience of CALS when performing reimplantations of ureters in children with vesicoureteral reflux and reported less or equal costs compared with the open procedure [97]. In Dr Azad Najmaldin’s experience at St James’s University Hospital, Leeds, United Kingdom, the costs for paediatric CALS were also very similar to the costs for open surgery [98].

Our first data were presented as Abstract No. 22 at the 8th European Congress of Paediatric Surgery in Turin, Italy, May 16th – 19th 2007. After six CAL funduplications and a total of 18 patients, the mean costs for CALS procedures, including the fixed costs, were 34% higher than the mean costs for laparoscopic and open procedures taken together. After 14 CAL funduplications, and calculated in the same way, the difference was 8%. The number of patients is small but there seems to be a relatively short learning curve in our material, affecting the cost analysis when
operating times decreases. Some authors report shorter operating time with CALS than with open and standard laparoscopy, favouring CALS also cost-wise [31,99].

The length of hospital stay is long in our study and may not be comparable with in-hospital stays elsewhere. The extent of concomitant disease in our patients and their serious symptoms, as shown in Tables 2 and 3, are probably the cause. As shown by our data in Tables 4-6 and 10, the shorter hospital stay compensates for the extra cost of the CALS. This makes CALS already viable for us compared with the open surgical technique but not when compared with laparoscopic surgery. The shorter hospital stay for CALS surgery compared with laparoscopy in our material can only be coincidental. However it affects the cost analysis.

New technology usually entails extra costs. Extra costs are acceptable if the patients benefit from this new technology. Since costs are easy to measure compared with patient benefit, a thorough analysis is necessary. In our opinion, CALS offers qualities that standard laparoscopy does not and the extra cost should not be a deterrent even at this early stage of CALS evolution. The development of new CALS instruments better adapted to paediatric surgery will probably lead to cost reductions in the future, since operating times can be shortened and more procedures performed per year. The operative costs of instruments may also be reduced if prices decrease due to increased competition between companies. In our department, prices for standard laparoscopic instruments have fallen since the time when this technology was new, fifteen years ago. Furthermore, a simple procedure might not necessarily have to be cost efficient; if the team gains sufficient experience to be able to perform more complex procedures, these, at least, will certainly prove to be cost efficient.

The pedagogical potential of computer-assisted surgery

Very few studies comparing the learning curves of CAL and SL have been published. In the experimental setting a diversity of parameters, not always well-defined, has been used for analysis of learning curves and only the very beginning of the learning curve is studied. In the clinical setting, an experience bias has been expected due to prior laparoscopic experience of the participating surgeons [28,32,68,100-103]. Both experimental and clinical studies show diverging learning curves for CALS. The results of previous studies are not conclusive and to objectively evaluate the learning curve of CALS is difficult.

The experimental study included participants without any prior experience of open surgery, CAL or SL, making the group homogeneous. The performed tasks, well-defined and described, closely mimicked some of the proper surgical procedures used every day in the operating theatre. The only surgical system currently on the
market and standard laparoscopic instruments were used. The number of participants and repetitions studied was decided after power calculation.

The task of tying a surgical knot was always faster with CAL than with SL, even when the participant had gained no experience by carrying out the first part of the study with SL. There are learning curves seen for tying a knot for both CAL and SL when comparing trials 1 and 4. The learning curve is steeper for SL but the curves never cross (Figure 6). These findings differ from most previous studies where the initial performance with CAL is often inferior to the performance with SL [104]. In the recent publication by Stefanidis et al. the authors reported that computer-assistance significantly improved intracorporeal suturing performance and shortened the learning curve. They also reported that performance of laparoscopic knot tying without computer-assistance did not improve after three repeats [105]. The first statement is supported by our study but the latter is not since we also saw a significant learning curve for SL. Performing more advanced tasks like tying a knot might be faster for maiden users due to the fact that CAL is more “intuitive” with instrument movements mimicking normal hand movements. This is supported by some authors [31]. The fact that CAL is performed with 3-D vision instead of the 2-D vision in SL might also improve the performance, as has been suggested by others [76,100].

The transfer effect, with a faster performance if the specific method was used as the second part of the study when the tasks had already been tried by the first method, was seen for continuous suturing and tying a knot with CAL, but not for SL. This might be interpreted as the CAL method being easier to adapt to once acquaintance had been made with the tasks themselves, at least for maiden users. The study by Blavier et al. showed worse performance when shifting from one method to the other in both directions. The shorter learning curve for CAL noted by the same authors is supported by our study [100].

The learning curve consists of an initial steep phase in which performance improves rapidly. When the change in improvement slows down, the learning curve reaches a plateau phase in which variability in performance is small. The number of repetitions reported here is too low to reach consistency, which characterizes the end of the learning curve. The learning curve for SL was steeper, but the number of repetitions too few to disclose a complete learning curve. This was not the aim of the study. We concentrated on the first phase of the learning curve in order to detect even small changes or differences between the two techniques used. From the data, we can therefore only conclude that it is initially easier for novice subjects to use computer-assistance for the specific tasks using the set performance parameters. Whether or not the curves for CAL and SL eventually cross after more repetitions, or when the plateau phase of the learning curve for each technique is reached, remains unclear. This could be the aim of another study in the future.

The objective structured assessment of technical skill (OSATS) described by Reznick et al. is a validated tool widely used in the education literature. The OSATS is feasible, reliable and can be used for testing technical competence with high clinical
relevance [106]. Focusing on comparing the different repeats and the transfer effect in all three tasks, we did not calculate a total score for the time and accuracy parameters. Dropping the needle was more common in the CAL group. Half of the subjects dropped the needle while performing SL and all but two while performing CAL. Furthermore, the thread was only torn when using CAL (Table 11). Tactile feedback is not yet possible with CAL, which is the most probable explanation for our findings. In spite of these differences, albeit significant, the performance when using CAL was not slower in the task “continuous suturing” compared with SL. Without the dropping of the needle in the task “continuous suturing”, CAL might have been faster. Learning curves are also seen for a continuous suture for both CAL and SL when comparing trials 1 and 4 (Figure 5). The two figures 1 and 2 express the mean time for each try for the specific task but do not take into account the order in which the task is performed. As already stated, no difference was noted between CAL and SL for “continuous suturing”. Clinical reports have indicated that the improved vision in CAL seems to make up for the lack of tactile feedback for more experienced surgeons [18]. The tearing of threads and dropping of needles is probably a greater challenge for the beginner.

The end points of our study, time and accuracy, may not be the best ones to measure. Length of pathway and economy of movement might be better predictors of learning curve and safe performance of laparoscopic surgery. A further possible limitation of our study is that error reduction, an important goal of training, was not measured. The study of Narazaki et al. suggests that both task completion time and distance travelled is shortened with training for novice users [102].

The suggested advantage of faster laparoscopy in the CAL group might not be relevant in clinical surgery, since inexperienced users are not supposed to perform advanced laparoscopic surgery. CAL surgeons today are often senior surgeons and already expert laparoscopists. However, the training to become an expert takes a lot of time and is costly, so learning curves are important also for the future education of young surgeons. If CAL is proven easier to master with equal or better results than SL, CALS could be an option for efficient surgical training. The many steps of a surgical intervention each have a learning curve and if learning curves are shorter for CAL it may have some clinical relevance even at later stages of training.

Further use of computer-assisted surgery in children

Animal studies demonstrate that computer-assistance can increase the applicability of MIS to complex procedures in children and neonates. Lorincz et al. performed oesophageal resection and end-to-end anastomosis in piglets weighing 2 – 3.5 kg, as a model for the repair of an oesophageal atresia and tracheoesophageal fistula. They
noted no leakage in the anastomosis but some stenosis requiring dilatations, and concluded that computer-assistance facilitated the MIS approach also in the limited space the size of an infant’s chest [107]. The same group performed a computer-assisted portoenterostomy in pigs simulating the treatment for biliary atresia and recorded no leakage or stricture at the sites of anastomosis [108]. Faust et al. performed surgery on 16 pigs to train and define the optimal approach for computer-assisted neck surgery and then used this porcine neck model to operate eight pigs with thyroidectomy. These authors concluded that computer-assisted MIS is feasible and especially advantageous in small spaces thanks to tremor filtration, motion scaling and the addition of the wrist to the endoscopic instruments [109]. Passerotti et al. performed ileocystoplasty augmentations in ten pigs to define the technique and discover potential pitfalls. They observed a rapid learning curve for the procedure and that intracorporeal suturing of bowel-bladder anastomosis was efficient but that bowel-bowel anastomosis was best performed extracorporeally to avoid leakage [110]. The laparoscopic procedure of intravesical reimplantation to cure vesicoureteral reflux was developed in an animal model and later successfully applied to children [111]. The same procedure has been performed with computer-assistance and the experience gained may permit the development of more complex bladder surgery procedures, such as bladder-neck or ureterocoele repairs [112]. The extravesical reimplantation via the transperitoneal approach could be an appealing alternative for anti reflux surgery if the bladder space is limited, as in smaller children [23].

Computer-assistance is used for a growing number of different procedures as the experience of this new technique increases among paediatric surgeons. The surgical system is perceived especially beneficial in small spaces, where precise surgery is called for and in remote areas, not easily accessible for open surgery. Passerotti et al. describe the use of CALS for resections of urological anomalies in the almost inaccessible retrovesical space and Storm et al. used CALS for bladder neck dissection and the placement of a bladder neck sling in two children with spinal dyspharism and sphincter deficieny [113,114]. Meehan et al. corrected a congenital duodenal atresia in a 2.4 kg newborn and performed two Kasai portoenterostomies and two choledochal cyst resections. They considered these procedures particularly suited for CALS rather than standard laparoscopy [115,116]. Gundeti et al. report the first case of computer-assisted laparoscopic ileocystoplasty augmentation in a ten-year-old girl with a neurogenic bladder and conclude that more research is needed to decide if this approach provides any significant advantage over the open procedure even if feasibility and excellent cosmetics were noted [117]. Nguyen et al. were encouraged by their experience of using CALS for performing appendicovesicostomies in a series of ten children and anticipated that, with experience, they would be able to perform more reconstructive surgeries in the future [118].

Although originally intended for making remote surgery possible, a feature successfully demonstrated in 2001 when a surgeon performed a cholecystectomy from New York, USA on a patient in Strasbourg, France [119], the telesurgical properties
of the da Vinci® Surgical System are currently not available. The future focus on remote surgery will probably be as a means to facilitate surgeon-to-surgeon coaching, but among others, legal and ethical issues have to be resolved first. The applications for this novel technique will continue to evolve with growing experience and as long as there is an interest among paediatric surgeons for using it. Only with further research in the field, will the potential of computer-assisted surgery in children be revealed.
Conclusion and future perspectives

Conclusion

When comparing CALS with open and laparoscopic surgery, the results show that CALS is safe, feasible, comparable to laparoscopic surgery and better than open surgery with regard to the use of morphine for postoperative analgesia and length of hospital stay. In the light of our gained experience, we suggest that CALS becomes the new standard for performing fundoplications in children.

The introduction of computer-assistance into surgical practice involves increased costs for in-hospital care, mainly due to the cost of the new instruments, education and training. The cost can, however, already today, be considered acceptable since it seems comparable to the cost for open surgery, which can be the alternative and is a procedure that has never been questioned.

When studying the educational potential of the da Vinci instruments compared with standard laparoscopic instruments, the hypothesis was supported that a surgical task, such as tying a knot, was performed faster using CAL than with SL, while easier surgical tasks could be performed equally fast with either technique. The lack of tactile feedback in CALS seems to be a factor to consider at least for maiden users. Experience from one technique was transferred to the other. The data do not support the suggestion that considerable SL experience is important for those starting to use CAL. On the other hand, previous experience did matter in the study. As expected, no difference between the performances of male and female subjects was noted.

The evaluation of CALS nephrectomies compared with open nephrectomies shows that retroperitoneal computer-assisted laparoscopic nephrectomy in children is an effective and safe procedure. In spite of longer operating times compared with open surgery, the computer-assisted procedure significantly shortens the length of hospital stay and adds cosmetic advantages.

The results support the future use of computer-assisted minimally invasive surgery in children. For reconstructive surgery, the benefit of computer-assistance in laparoscopy seems more obvious, but also in simpler tasks the better instruments and the 3-D vision facilitates the procedure. Computer-assistance can sometimes be the determining factor for whether a procedure can be performed as an open or MIS procedure. Whether computer-assistance leads to better long-term results and fewer postoperative complications is too early to decide. Considering all the potential
benefits of the CALS instruments, we have reason to believe that the future will favour its use in paediatric surgery.

**Future perspectives**

The technology of computer-assistance in performing MIS in children has been proven safe and feasible for a number of paediatric surgical interventions. In spite of limited worldwide experience it is already today comparable with the standard laparoscopic technique that has existed for twenty years. Especially for complex procedures, where delicate dissection is required, the surgical field is not easily accessible and in precise suturing, computer-assistance is advantageous. Computer-assisted surgery represents an alternative to conventional open or minimally invasive surgery and should be considered when patients are counseled. While working with this thesis, the author became increasingly convinced that the computer assisted technology in performing MIS is here to stay in some form and that it will develop during the years to come.

We have seen an enormous improvement in the field of conventional laparoscopic surgery over the last twenty years and something similar will surely evolve also in the field of computer-assisted surgical systems. Since the da Vinci was launched in 1999, three revised versions have reached the market and eventually the monopoly situation of today will disappear and the pace of development increase.

In the 1990s, paediatric surgeons had to use adult instruments when performing MIS, but subsequently, as the demand for instruments adapted for children increased, the 2, 3 and 5 mm instruments used in paediatric departments throughout the world were developed. If paediatric surgeons around the world start to call for CALS instruments well-adapted for use in children, their pressure on the industry to comply will increase. To have 5 mm instruments, with the same appearance and function, as the 8 mm have today, should not be too difficult and would be the first natural step. Eventually 3 mm instruments would be good for surgery in the newborns. The size of the system’s patient-side cart has to decrease substantially, minimizing the risks for external collisions that have been the main concern during procedures and in some cases made the MIS approach impossible for our youngest patients. Perhaps the future instruments will not only be smaller, but also more flexible and with applications that today only exist in conventional laparoscopic instruments. Maybe the instruments will be free floating, controlled through an electromagnetic field, totally reducing the need for clumsy arms with wires and wheels. The technique with wires and wheels was abandoned by the airplane industry years ago, and when replaced with computerised control systems, the arms in the future surgical systems will be less bulky and the risk for threads and tissue getting tangled up in the instruments avoided. Similarly, smaller endoscopes with 3-D vision will become available, as the technology for light emission,
computers and the camera continue to develop. The integration of diagnostic tools such as ultrasound, Doppler flow metrics and x-ray, will surely be available, as well the possibility to perform some form of automated, preprogrammed movements for the most routine tasks during a procedure.

The intense research on haptic feedback will continue. The force feedback, seen in the computer gaming industry today, will develop into something very close to reality, and eventually this haptic feedback will be integrated into the future surgical systems. Even though the lack of tactile feedback does not really pose a problem for many surgeons [18, 87], and is probably well-compensated by better vision, it will be a major improvement.

The role of computer-assisted surgery in surgical training has to be established. The use of simulators in surgical training is emphasised before starting to perform actual surgery on live patients and is in use for conventional MIS [120]. Residents entering a surgical program will, in the future, have access to computer-assistance when they start their MIS training. Simulators will be developed and improved for CALS but already today the system offers great potential not yet fully implemented in the education of surgeons [121]. The superior 3-D vision will enable the educating institutions to improve the quality of the surgical program with benefit for the children. Those who plan a career in paediatric surgery may learn MIS faster and safer than today, where training is performed at the operating table during open surgery or with the technology used for minimally invasive surgery in general.

The drawback of increased costs for CALS may be reduced in the future due to shorter operating times, shorter in-hospital stays and, with increased competition, cheaper instruments, as seen for standard laparoscopy. Reported operating times for CALS are often longer than those for standard MIS. The latter technology has been around for twenty years and operating times for MIS are often published by senior, expert laparoscopists. With greater experience of CALS, operating times will decrease, becoming closer to or superseding, the operating times for open surgery, as already seen in some hands [99]. Perhaps the initial investment cost forces us to concentrate its use to larger CALS centres, in order to gain an increased patient volume load and decrease the cost per procedure. On the other hand, if the length of stay and patient morbidity decrease, the CALS procedure might prove to be a very cost efficient invention. The evidence for superior clinical long-term outcomes with CALS in children is still lacking, but with growing experience among surgeons and continuous scientific evaluation, this might change in the future.

The introduction of computer assistance in the ever-evolving field of surgery has triggered a development that will continue. As with every new technology in surgery, it challenges the established routines and pledges for a different way of performing surgical interventions. By questioning the necessity for the operative invention and scrutinizing the way a procedure is performed, the quality of the surgeon’s work improves. The data on, and experience of, computer-assisted surgery in children are still limited, and this warrants further research. By playing an active
part in evaluating the technical innovations to come, paediatric surgeons can influence their development for the future benefit of children in need of surgery.
Populärvetenskaplig sammanfattning


Syftet med detta projekt är att skaffa erfarenheter av och utvärdera datorassisterad kirurgi på barn. Denna nya teknologi har jämförts med öppen kirurgi och konventionell laparoskopisk kirurgi. Metoden som används är kliniskt arbete med datorassisterade kirurgiska ingrepp på barn, varefter ingreppen utvärderas löpande och jämförts med samma typ av ingrepp tidigare genomförda med öppen eller laparoskopisk kirurgi. Målet är att ta reda på om tekniken även är säker på barn, om patientens situation förbättrats och om denna nya teknik innebär snabbare och säkrare inlärning för kirurgen.

Delarbete I

I undersökningen ingick arton barn, sex stycken i vardera gruppen, opererade med öppen, laparoskopisk respektive datorassisterad kirurgi. Samtliga barn hade svår gastroesofageal reflux (backflöde av magsyra upp i matstrupen) och kräkningssymptom. Barnen var jämförbara när det gällde vikt, ålder och sjukdomens allvarlighetsgrad. Operationstid, användandet av smärtstillande mediciner, sjukhuvudvistelns längd samt komplikationer under eller efter operationen jämfördes. Slutsatsen blev att datorassisterad laparoskopisk fundoplakin (operation för
gastroesofageal reflux) är jämförbar med konventionell laparoskopisk operation när det gäller operationstid, vårdtid och användandet av morfin. Jämfört med öppen kirurgi är operationstiden längre men vårdtiderna kortare och användandet av smärtstillande betydligt mindre.

Delarbete II


Analysen visade att kostnaden för den datorassisterade fundoplikationen var 17 % högre än kostnaden för motsvarande laparoskopiska ingrepp och densamma som kostnaden för den öppna kirurgin. Investeringen i det datorstyrda operationssystemet samt inköp och underhåll av nya instrument stod för merparten av kostnadsökningen. Om bara de rörliga kostnaderna medräknades var kostnaden för den datorassisterade fundoplikationen 7 % högre än kostnaden för motsvarande laparoskopiska ingrepp och 9 % billigare än kostnaden för den öppna kirurgin. För varje vårddag som sparades sjönk sjukvårdskostnaden. Den datorassisterade kirurgin förkortade vårdtiden med 3-4 dagar jämfört med öppen kirurgi vilket innebar att den samlade kostnaden blev jämförbar.

Delarbete III

För att undersöka den pedagogiska potentialen närmare genomfördes det tredje delarbetet som en experimentell studie. Syftet med undersökningen var att undersöka om det är enklare för en oerfaren användare att lära sig utföra kirurgiska uppgifter med datorassisterad operationsteknik än med konventionell laparoskopi. Läkarstudenter fick utföra enkla operativa ingrepp (plocka upp en nål, sy en fortlöpande sutur och knyta en dubbelknut) upprepade gånger dels med vanliga laparoskopiska instrument och dels med datorassisterade instrument. Studenterna hade ingen tidigare erfarenhet av varje av de ena eller den andra tekniken. Förutom tidsåtgången registrerades kvaliteten på arbetet i form av eventuella skador på underlaget, hur ofta en nål tappades och hur ofta en tråd slets sönder.

Försöken visade att det gick fortare att knyta en kirurgisk knut med datorassisterad än med konventionell laparoskopisk teknik. Uppgiften att fatta en nål och sätta tre fortlöpande suturer gick lika snabbt med båda teknikerna. Den
erfarenhet det innebar att ha använt konventionell laparoskopisk teknik före datorassisterad teknik överfördes och ledde till snabbare utförande av uppgifterna med den datorassisterade tekniken. Tappad nål var vanligare vid användandet av datorassistans liksom avsluten tråd, vilket endast förekom med denna teknik. Detta kan bero på att de datorassisterade instrumenten saknar känsel och att man därför inte känner hur hårt eller löst man håller i nålen eller tråden.

Vår slutsats var att mer avancerade operativa ingrepp var enklare att utföra med datorassistans än med konventionell laparoskopisk teknik för oerfarna operatörer och att ytterligare försök kan vara av intresse.

Delarbete IV

Barn födda med missbildad njure eller med förvärvad njurskada, där njuren saknar funktion, opererades med öppen eller datorassisterad laparoskopisk kirurgi. Säkerheten i samband med ingreppet, operationstiden, behovet av smärtstillande medicin, vårdtiden och eventuella komplikationer jämfördes mellan de båda operationsteknikerna. Säkerheten var god och antalet komplikationer låg med båda metoderna. Fyra av tio patienter som opererades med datorassistans hade jämförbar operationstid med några av de öppet opererade, men den genomsnittliga operationstiden var längre. Behovet av smärtstillande skiljde sig inte åt men vårdtiden var kortare för de barn som opererades med datorassisterad laparoskopisk kirurgi jämfört med de öppet opererade.


Förbättringarna för kirurgen i form av förstorad, tredimensionell bild av operationsområdet, enklare hantering av instrumenten och förbättrad arbetstillskning, bör i förväntningen leda till större kirurgisk precision, mindre risk för skador på patienten i samband med operationen och bättre resultat. Eftersom tekniken förefaller enklare att lära sig än vanlig laparoskopi, kommer tekniken att ingå som en naturlig del i utbildningen av framtidens kirurger. På sikt bör då stora, komplicerade ingrepp som idag inte kan utföras med titthålsteknik bli möjliga att med god säkerhet utföra med datorassistans, vilket sannolikt leder till mindre smärtor och kortare vårdtider för barnen.
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Appendix 1

Information to the participants in the project Robotics versus Laparoscopy

Thank you for choosing to participate in this research project. To try laparoscopic instruments and the da Vinci® Surgical System in a dry lab setting is not part of the normal Lund University Medical School curriculum. We are therefore pleased to give you the opportunity to try laparoscopy and robotic surgery for the first time.

You will receive a certificate of attendance at the end of the day to show your supervisor if questions are asked about your leave of absence from the normal class.

Your total participating time for the project is four hours, either in the morning or in the afternoon. Please bring a book, there will be some waiting.

Before starting, an instructor will give you standardized instructions, all at the same time, on what to do. You will then have some minutes to familiarize yourself with the laparoscopic instruments, the robotic system and the dry lab setting. You will then wait your turn in an adjacent room.

You will each perform three tasks, repeated four times consecutively, both with laparoscopic and robotic instruments. If you are in the half that starts with laparoscopic instruments you will use robotic instruments for the second part and vice versa. Your goal is to perform the tasks as quickly and as accurately as possible.

The three tasks are:

1: Grab and place the needle correctly in the needle holder (at 2/3 of the needle length from the tip of the needle) and lift it to a starting position for suturing.

2: Do continuous suturing with three stitches over a slit in the Skin Pad in Jig®.

3: Tie a surgical knot with two simple throws and secure it (direction irrelevant).

Time in seconds for the tasks, damage to the pad, dropping of the needle and tearing of the thread will be recorded. Between each repeated task 1-3, you will have some minutes to rest. After you have finished four sets you will change instruments.
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