

European association of endoscopic surgeons (EAES) consensus statement on the use of robotics in general surgery

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Robots are defined as “A machine capable of automatically carrying out a complex series of movements, especially one which is programmable” (Oxford Dictionary). Thomas Sheridan, the “Father of automation and robotics” from MIT used automation and robotics interchangeably: “Automation includes all those *things* that computers and machines can do to perform tasks for people faster, more accurately, and more efficiently (in terms of time, resources, and human labor) than if they were done directly by people”.

Robots have been used in industry for many decades. We trust robots to build our cars, land our planes and produce the computer this manuscript was written with. Robots do not tire and operate at a level of precision and accuracy with dedicated motions scalable in speed and force unreachable for human beings.

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The use of robots to assist in performing surgical tasks has been developed over the past 20 years, and current robotic systems are quickly penetrating the surgical realm. Thus, well-engineered systems have been designed to improve surgeons' performance when completing complex tasks. The robots currently used in surgery follow a master–slave configuration, with their activity fully controlled by a surgeon at a console, which can be more accurately described as telerobotic or telemanipulator as opposed to truly robotic. Due to the robots lack of autonomy in this model, they fall into a somewhat low category.

The introduction of robotic surgery has been slow and has followed a rather convoluted path. Initially introduced for cardiac surgery, robotic surgery later had a brief introduction into general surgery. However, it was the urological community that truly adopted the current robotic systems, using it to revolutionize prostatectomy moving from open radical prostatectomy to the new minimally invasive technique. In recent years robots are increasingly

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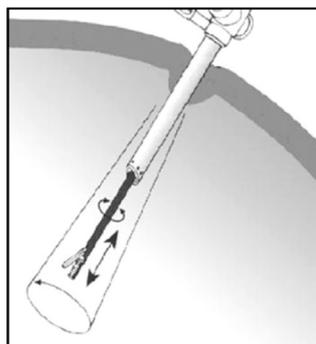
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Fig. 1 Reach of a laparoscopic tool in a space using 4 degrees and 6 degrees of freedom

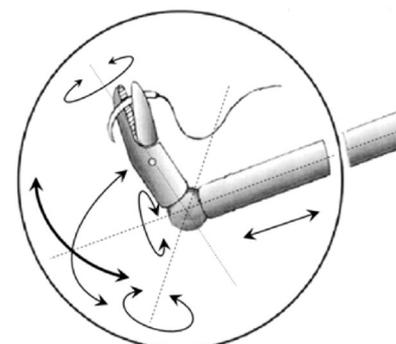
Manipulation

Limited to 4 degrees of freedom DOF.

- Rotation
- Translation,
- two axis in fulcrum



4 dof plus 2 endo-DOF
Articulation and rotation of the tip



Melzer et al 1992

being used more in gynecological surgical procedures, and are slowly penetrating some areas of general surgery.

While technology is not new to the operating room, there are several factors that differentiate the adoption process of current robots and their use from the other surgical technologies. Currently there is only one dominant company that produces and sells a surgical robot. Both purchasing and operation of these robots is expensive, making the robotic platform unaffordable for most hospitals. Furthermore, their high cost creates strong financial pressures that may bias stakeholder's decision making, potentially leading to over use of robotic procedures, as in the case of robotic prostatectomy. The surgical users and their societies have to make sure that patients are made aware of the alternative treatments available, including the non-surgical ones. Robotic surgery should only be applied based on solid evidence.

Creative marketing and direct patient education has made it difficult to produce significant high-level evidence

that makes a scientifically solid based case for the use of robots in general surgery. The EAES Technology Committee, therefore, decided to initiate a consensus process that although may not be based on high quality data, has analyzed the current literature, highlighted potential areas where there is merit in using a robot and outlined the necessary research in specific fields that will allow a more rational, scientific-based decision making process on the use of robots in general surgery.

In preparation of the manuscript it was decided to focus only on robotic systems used for endoscopic surgery. References to other robots used to manipulate laparoscopic cameras or hold retractors, and mechanical manipulators that are being introduced to the market are not commented on for lack of data and the limited impact they have on current surgical practice. As a result, if other configurations of robots emerge in the near future, this manuscript will not relate to any of them.

Methods

An expert panel was selected by the EAES technology committee to draft the consensus paper. The panel was composed of 13 members: 9 general surgeons, of which six are active robotic surgeons in various fields, one surgeon with expertise in technology assessment on a national level, a physician directing a large academic biotechnology research center, two engineers with vast experience in robotics and three active laparoscopic surgeons with extensive experience in surgical technologies.

An extensive literature search using Pubmed and Cochrane databases was conducted in all fields that involve robotics and general surgery procedures: Solid organs

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including donor nephrectomy, thyroid and parathyroid, hepatobiliary surgery, pancreatic surgery, upper gastrointestinal surgery for benign and malignant diseases, colorectal diseases, abdominal wall, and bariatric surgery. In addition we searched data on basic performance metrics that may have impact on general surgery: dexterity, precision, ergonomics, and training. Finally, we searched all data analyzing cost-effectiveness of the use of robots in general surgery. A total of 1,818 abstracts were extracted and used to screen the literature and to categorize all papers to different categories.

Each two members of the group with expertise in specific fields were assigned to analyze and write a draft on these fields. Drafts were based on full manuscripts that were analyzed and assessed for quality of data. The drafts were centralized and edited for content, style and data quality, and re-sent to the individual authors of each section. In April 2014 the group met for a 3-day workshop during which all texts were discussed in depth and statements were finalized with detailed data quality assessment. An additional round of editing was then made, and the final draft was compiled from all sections. The draft was presented in a dedicated session during the World Congress of Endoscopic Surgery, June 2014 in Paris, France. The audience was allowed to question and comment about all statements in the document, and the comments were recorded. An additional round of editing was performed taking the comments into account.

The document was then posted publicly on the EAES website for a period of 1 month, and a personal letter to all members of the society encouraged them to read it and send comments and suggestions to the first author (AS). The comments were discussed by the panel and the appropriate ones were incorporated into the document.

In addition, a questionnaire was sent to all EAES membership using an online survey tool, with responses from over 400 surgeons. It was decided to include the survey results in a separate document.

Since the level of evidence of the vast majority of data we found was poor, it was categorized according to the Oxford classification, without writing recommendations based on the evidence. In the future, when the scientific gap is filled, a second version of this document may be written with evidence-based recommendations.

The manuscript is divided into two parts; the first analyzes the technology and laboratory data on task performance with robots. The second analyzes the clinical evidence on the use of robots in general surgery.

Part 1

Technology: Design and history of current robotic systems, and laboratory evidence on performance with robots.

Dexterity, precision, speed, and surgeons' ergonomics

Before discussing the clinical significance of using a robot it is important to understand the technological basis and laboratory data that resulted from investigating the use of surgical tools with multiple degrees of freedom, and their effect on task performance in minimally invasive surgery.

The important technical parameters that need to be addressed to try and quantify potential benefits of this type of technology and may have strong impact on clinical outcomes are dexterity, precision, speed, and surgeons' ergonomics. In this section the level of evidence cannot be compared to the categories used to grade clinical data, as some of the data describe technological principles with absolute evidence that does not necessarily correlate with clinical evidence.

Dexterity

Statement: Robotics can enhance dexterity compared to manual laparoscopic surgery if 6 degrees of freedom are provided (LE 2B)

The term dexterity refers to human motor skills of hands and fingers and the ability to use these for manual tasks. Dexterity measures hand-eye coordination, agility, reflexes, and balance. It is important to note that in **clinical practice** there is no data on the degrees of freedom required to perform a specific task well. Clearly, there is a lot of data showing that very good clinical outcomes may be achieved with limited degrees of freedom, like in conventional laparoscopy.

The manipulation needed for surgical tasks includes a certain degree of freedom to operate the instrument's active tip; in robotics terminology this is referred to as end effector. There are at least six degrees of freedom required to reach a certain point in a given space from any direction, comparable to a human hand-arm kinematic system. A surgical robotic system has to mimic the human hand-arm kinematic with two degrees of freedom in the shoulder joint, two degrees of freedom in the elbow joint and two degrees of freedom in the wrist joint. The seventh degrees of freedom can be considered the opening and closing of jaws of forceps or scissors (see Fig. 1).

There is a differentiation between the external motions required to operate the instrument while inserted through the abdominal wall through an invariant point of insertion [1]. This point of insertion mirrors the motion of an instrument vice versa, so movement to the right becomes intra-abdominally movement to the left, while in-out

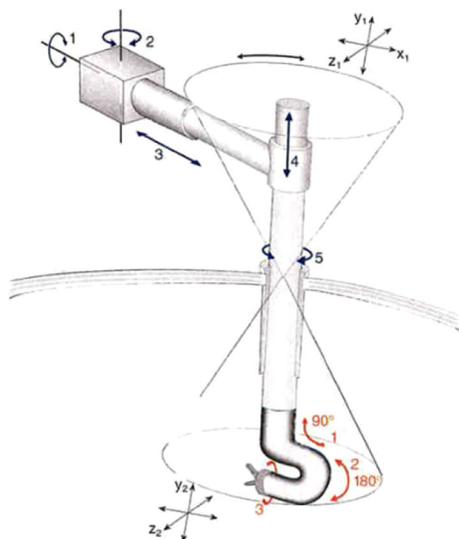
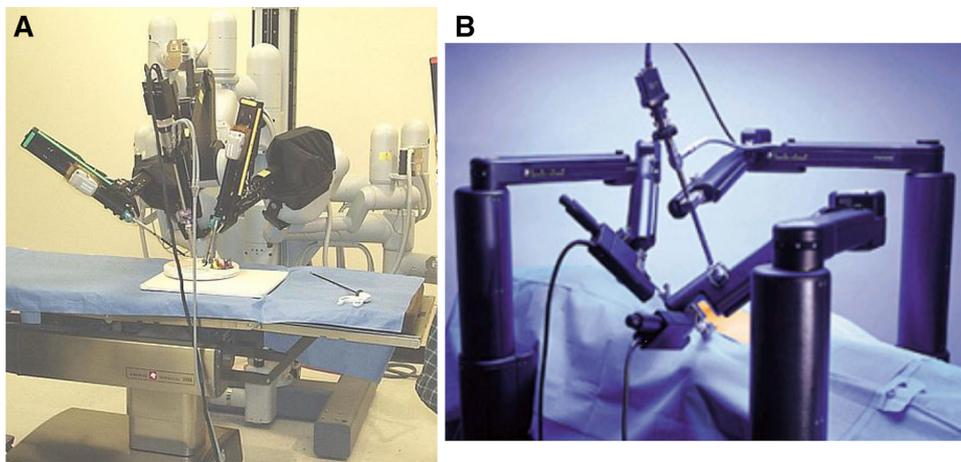


Fig. 2 Reach of a laparoscopic tool in a space using 4 degrees and 6 degrees of freedom

movements remain the same. Around this invariant point of insertion two degrees of freedom are required to reach with the instrument shaft in the abdominal cavity and two degrees of freedom are required to angulate the wrist the end effector which is very important to position the jaws according to the optimal tissue handling orientation for cutting, passing a well-placed suture or making a precise cut using scissors.

One problem in these orientations is that the ability to reach further out may become hampered so theoretically additional degrees of freedom and extension of the laparoscopic tool inside the abdominal cavity are required. This laparoscopic Intelligent Instrument System ISIS has been first proposed by Melzer et al. [2] (Fig. 2) and preliminary results on surgery in the phantom model were published later [3].

Fig. 3 Added reach of a laparoscopic tool with 7 degrees of freedom. **A** da Vinci[®] by Intuitive. **B** ZEUS by computer motion



Currently, only the da Vinci[®] system (Intuitive Surgical, Sunnyvale, CA, USA) mimics the previously described required degrees of freedom, and the existing literature confirms that these degrees of freedom are deemed suitable for the surgical task and provide adequate dexterity for complex tasks. If correct nomenclature is applied, the robotic system should be named as Master Slave Manipulator.

A laparoscopic robotic system was introduced in 1998 prior to da Vinci[®] (ZEUS by Computer motion Santa Barbara, CA, USA). ZEUS provided only 4 degrees of freedom similar to conventional laparoscopic surgery. It was not as successful as da Vinci, possibly due to the lack of 2 degrees of freedom required for optimal position of the jaws of the instruments intracorporally (Fig. 3).

Additional flexible kinematics with multiple degrees of freedom are currently under development. One example is the STIFFLOPP, an EU project with E.A.E.S. Partnership which would carry the potential to further extend manipulation of tools inside the operative space and may resolve problems of difficult to reach and narrow operative fields.

The use of robotic technology was shown to result in enhanced dexterity and a shorter learning curve for robotic surgery than that needed for laparoscopic surgery [4, 5].

The incorporation of Wrist-like joints, e.g., EndoWrist (da Vinci[®]), in telemanipulator/robotic systems contributes to increasing the four degrees of freedom available with laparoscopic instruments to seven degrees of freedom. The presence of the wrist is particularly useful in procedures that require a great amount of instrument maneuverability and flexibility, such as in endoscopic suturing. Tremor filtering and motion scaling technologies enhance surgical manipulation even further in robotic surgery. Motion scaling is the ability of the system to scale down large movements made by the surgeon on the master console to smaller movements made by the slave arms. This feature

adds to the precision of task execution. In addition, the da Vinci[®] system has oriented the hand-eye axis to be intuitive such that the surgeon has the impression that the instrument-hand axis is similar to open surgery.

Several papers have investigated dexterity enhancement from robotics. Moorthy et al. [6] showed that the presence of wristed instrumentation, tremor abolition, and motion scaling enhance dexterity by nearly 50 % as compared to laparoscopic surgery.

Vision

2D versus 3D

High quality 3D visualization is required to provide the best possible visual feedback during surgical operations. Studies evaluating the advantages of 3D over 2D vision have yielded conflicting results. Some studies cite a steep learning curve with 2D imaging obviating any improvement that may have been observed with 3D vision [5, 7–9]. Others criticize the quality of the 3D technology [7–9]; however, this might be due to the limitations of the technology available in the past. Byrn et al. [10] confirm a significant advantage using 3D vision over 2D on performance and error rates for both novices and experienced operators using the da Vinci. Moorthy [6] showed that 3D vision enhances dexterity with an additional 10–15 %. In addition, the presence of 3D vision results in a 93 % reduction in skills-based errors.

Single-incision robotic laparoscopy (SILS)

Statement: Robotics did not show added value in single-incision laparoscopic surgery (LE 4)

There is continued focus on reducing the number of incisions to further reduce the potential for morbidity, bleeding, and incisional hernias, while also improving cosmetic results. This has led to an increased interest in single-incision laparoscopic surgery. [11] The concept is comparable to the TEM system (Richard Wolf, Knittlingen Germany) developed by Buess et al. in the early 80s. It was used for a combination of single port and Notes procedures i.e., Rectopexy [1]. Dexterity problems were improved through the use of curved instruments. Although these are extending the reach within the operative field their dexterity is still limited to 4 degrees of freedom.

The triangulation limitations in single-incision laparoscopic surgery are currently being addressed with articulating tools

such as RealHand (Novare Surgical Systems, Inc., Cupertino, CA, USA) and Autonomy Laparo-Angle (Cambridge Endoscopic Devices, Inc., Framingham, MA, USA). These devices provide the seventh degree of freedom maneuverability to better enable tissue manipulation. The da Vinci[®] System (Intuitive Surgical, Sunnyvale, CA, USA) has also been used to improve surgical dexterity for performing transumbilical single-port radical prostatectomy, dismembered pyeloplasty, and right-side radical nephrectomy procedures [12].

According to Laparoendoscopic Single-site Surgery Consortium for Assessment and Research's (LESSCAR) [13] [whitepaper], the main technical challenge of single incision surgery is limited triangulation and retraction of tissues due to the crowding of optics and working instruments to a single axis. In order to prevent instrument handle interaction/collisions and to increase the working area in the abdominal cavity—articulating, or motorized instruments can be used [13]. While a single-curved tip manipulation requires a crossed configuration, double curved hand-instruments eliminate the crossed configuration thereby permitting more natural eye-hand coordination. However, the limited degrees of freedom and instrument collisions remain.

Since the endoscope enters through the same incision, the view of the operating field is hampered as well. Often a rigid scope with 30 % vision angle is used to create some sideways distance between camera tip and instrument shafts [13].

Another approach to address the visualization and tissue manipulation limitations with applications for both single-incision laparoscopic surgery and NOTES is the use of in vivo robots and devices that can be completely inserted into the peritoneal cavity through a single-transabdominal incision or a natural orifice. Once inserted, these devices can provide visualization or tissue manipulation capabilities without being constrained by the entrance incision.

Magnetic Anchoring and Guidance System (MAGS), including an intra-abdominal camera and various instruments such as retractors and cautery, that can be introduced into the peritoneal cavity through a single trocar [14] or natural orifice [15], is under development.

Natural orifice, trans-luminal endoscopic surgery (NOTES) robotic approach

NOTES surgery utilizes a flexible shaft carrying all the mechanics down to the point of surgery, which is then comparable to the required dexterity in open surgery. Therefore, instruments are required to reach out and then articulate further inward to achieve the appropriate triangulation of instrument tip position. This is not only a

challenge mechanically it is also a challenge due to the space restriction hindering the optimal positioning of any robotic devices. Semm et al. have identified early on, the appropriate position of instruments to each other with a laparoscopic optic in the center (triangulation) that exactly mimics the eye-hand co-ordination axis of a surgeon performing open surgery. Optimal triangulation is approximately 45 degrees of both wrists holding either a pincer in the other hand and a scissor in one hand with the stereoscopic 3D vision of the human eye looking directly into the operative space and direction.

In summary, robotic systems for SILS and or Notes should provide an appropriate dexterity and ergonomics with eye-hand co-ordination the surgeon is used to. Optimal performance of precise manipulation is mandatory and any compromise in this regard may reduce the accuracy and speed of the procedures and can become a safety issue.

Set-up, dexterity, complexity, and consequences for OR team

The robotic cart is relatively large and in combination with the rest of the system, it takes significant space in the operating theater. Ideally, the system is best employed in a dedicated robotics theater although with care it can be transported between theaters as required [16]. In addition, robot system set up and port placement are crucial to prevent collisions of the external robotic arms [16, 17].

Dedicated team with special training

Robotic systems need a dedicated team with special training. Robotic surgery requires familiarity with a unique surgical interface, requiring special training for robotic systems based competencies [18]. Ideally, a specially trained team should be organized, and include an experienced assistant who is able to perform instrument changes within the confined space between robotic arms, a task which can be inconvenient during critical portions of the operation. Unlike laparoscopic or open cases, the surgeon is isolated from the rest of the team which may create communication problems, as the surgeon's next moves may be difficult to anticipate due to lack of clues from facial expressions and body language [16]. Task delegation and team training is necessary to aid in system start-up, camera setting, cart docking, technical troubleshooting, and preparation for rapid conversion if necessary [19]. Integration of robotic surgery with the other operating room technologies and human beings in particular requires a system analysis and design approach [20], well known in industry and applied for over 50 years.

Lack of force feedback

Statement: Current robotic systems lack haptic feedback making tissue manipulation more difficult (LE5)

A major concern in robotic surgery has been the lack of haptic/force feedback. It has been shown that despite the change in the quality of tactile sensation, minimally invasive surgery provides limited force feedback that allows the interpretation of texture, shape, and consistency of objects [21–24]. This force feedback is significantly hampered by the friction in the instrument and of the instrument within the trocar, which can lead to higher forces applied than necessary to prevent slip [23, 25, 26]. In robotic surgery, the surgeon has to rely almost exclusively on visual cues to determine the nature of tissue-instrument interaction, in order to prevent iatrogenic tissue injury [27]. Suture damage in robot-assisted minimally invasive surgery is an operative mishap commonly attributed to a haptic feedback deprived sensory state [28, 29] and Anderberg [30] concluded that the lack of force feedback influenced outcome in dedicated tasks. Nonhaptic perceptual substitutes that compensate for lack of discriminatory force, tactile cognizance, and mechanical arm proprioception are reported [27]. Lack of haptic feedback may be replaced by new types of feedback such as enhanced visual cues [31] or vibrations in the handle [32]. Haptic feedback is of less importance in refined work, but is an issue to deal with, in case larger forces are exerted [28].

Force feedback or tactile sense [33] are very complex technologies and in order to duplicate the required soft and hardware control, to include haptics would significantly increase the cost of the robotic system. Calibration of sensors is one of the most critical issues mandatory for a reliable force feedback that would support the safety of surgical tasks.

Precision and speed

Statement: There is a trade-off between speed and precision. The higher the speed the lower the precision, this holds true for robotics and humans (LE 5)

Precision, accuracy, and speed are linked technical features. Particularly in precision and accuracy there is a buy-out by speed of reducing accuracy. In technical applications of robotics, huge robots with traditional hand-arm kinematics are used to precisely and quickly position

tools, as in the automotive industry. In surgical and medical applications this would require also very large sized and powerful robots because there is an estimate of one to ten translations of the robot maximum driving force and speed to the optimal accuracy working operation. This is comparable to the human arm-hand system; We are able to lift 20–50 kilos depending on training, but the precise motion of, for example writing with a pencil, is at maximum 50–100 g level appropriately to perform. The more weight the hand-arm system has to cope with, the lower the precision and accuracy becomes. This can, to some extent, be translated to a robot arm serial kinematic. In view of the low forces (1–10 N) applied during surgery, the current systems are appropriately powered and speed and accuracy seem to be in balance. In technical terms there are different kinematic solutions, some of them are very precise but slow, for example the Stewart Platform, which has been tried in Neurosurgery URM, Karlsruhe, Germany. There are also different ways to mechanically transmit the motion; via electric motors with wires, pneumatics, and hydraulics, which involve different characteristics for speed, accuracy and precision.

In summary, the slower the motion of the robot, the higher the force its drives can apply, and usually the higher the accuracy. For high-speed motion, high force and torque of robot arms are required, and the higher the speed of the end effector, the lower the precision becomes.

Statement: Complex tasks in endoscopic surgery are performed better and faster with robotics in an experimental setting (LE1B)

The da Vinci[®] system has been compared to standard endoscopic surgery in *ex vivo* experiments in an experimental setting Table 1 in [28]. Box trainers, the Promis trainer, animal intestine and live porcine models have been used to explore speed and precision. A variety of tasks were performed, but suturing and knot tying was the most often explored. In the vast majority of studies, performance with the robotic system was faster and better, although tearing of tissues and sutures remains an important risk factor [28].

Chien et al. [34] demonstrate the existence of speed-accuracy trade-off during robotic surgical task performance. This trade-off appears to be influenced by task difficulty. During robotic surgical task performance, surgeons may compensate for speed in order to maintain surgical accuracy between both novice and expert surgeons to a different degree. The speed-accuracy trade-off plays a substantial role in robot-assisted surgical proficiency.

Future studies are required to examine whether the trade-off phenomenon exists in more complex surgical tasks.

In the current literature there is some evidence that variability of movements determines stability of movement [35]. Less variability represents stable movement; whereas large variability suggests unstable movement. Variation could be reduced via repeated training because of the generation of internal models in the motor cortex [36]. This study found significantly larger variations in movement time among novice subjects compared to experts at all levels of task difficulty. The conclusion can be drawn that the more experienced surgeon can learn to cope faster with complex task at a higher speed with greater accuracy compared to the novice [37]. There is also an inter-individual difference in psychomotor skills that has been studied by Cuschieri et al.

Ergonomics

Statement: Surgeon ergonomics of robot-assisted surgery are better than ergonomics of standard endoscopic techniques, and can be improved further with optimal design of the workstation (LE 2B)

Robotics may reduce workload and physical- or mental strain in endoscopic surgery because ergonomics are favorable. This especially applies to pelvic surgery, where the surgeon is forced to stand aside the central working axis. Schatte Olivier [38] found less mental stress, better ergonomics and better performance in an experimental setup among 16 interns. Hubert et al. [39] recently confirmed higher workload and physical strain for standard techniques in an experimental model, including the use of electromyography.

Better ergonomics and less physical strain in the OR was also demonstrated by Lee et al. [40], using the validated JSL and RULA upper extremity scores. Rasweiler et al. [41] compared standard techniques, the Ethos ergonomic chair and robotic techniques in pelvic surgery and documented workload scores of 32, 14 and 5 respectively.

Improved body posture may result in less pain as was demonstrated by Bagrodia et al. [42] in a survey among urologic endoscopic surgeons. They reported pain after performing pelvic surgery in 50 % of surgeons after laparotomy, in 56 % after endoscopic techniques and in 23 % after working from behind a robotic workstation.

The currently available workstation may require adaptations to reach ideal ergonomics. This is supported by results from a small study from Lawson et al. comparing standard endoscopic to robot-assisted gastric bypass

surgery. The interesting aspect of this study is the fact that bypass surgery is performed from between the legs, which provides a much better body posture for the surgeon compared to that in pelvic surgery. They found improvement in strain for arms and thorax when using the robot, but better ergonomics for neck and trunk when standing at the OR table.

Future adaptations to the surgical console will further improve ergonomics, mainly by reducing the bending of back and neck, and by optimizing settings in relation to the physics of the surgeon [28]

The ergonomics of the *assistant surgeon* using the da Vinci system are compromised. Some publications (41) even indicate that the ergonomics for the assisting surgeon using the da Vinci system are even worse than in standard laparoscopy, because the robotic arms interfere significantly and reduce the dexterity of the assistant. Further research and development is required to improve this situation. [NOTE: Because of the recent introduction of the da Vinci Xi, there is no evidence regarding the ergonomics of the da Vinci Xi; however, one of the main goals with the new system is that the smaller, suspended arms may lead to less compromise of the first assistant than current systems].

Robotic surgery training

Statement: Robotic surgery is a specific surgical field that requires a new set of skills. Training for robotic surgery should be done using a formal curriculum for basic skills and for specific procedures (LE5)

Education, training, assessment, and certification for robotic surgery has not been as rigorously pursued as other surgical technologies, perhaps because it is still in its infancy and remains somewhat controversial how it should be accepted by the surgical community as a whole. In addition, the complexity of the robotic systems is such that the company(ies) that manufacture the systems are required by the Food and Drug Administration (FDA), as part of the approval process for the device, to develop technical instructional training in order for the surgeons to be able to utilize the robotic systems. Though not intentional, this instructional system includes the use of a set of skills and tasks which are used to demonstrate how the robotic system functions.

This instructional set has been mistakenly viewed as a training system for the surgeon to be able to perform robotic surgery, as opposed to the original design, which was for familiarization with the functioning of the robotic surgical system. Until very recently, this training has been conducted by the company's (ies') employees and not by surgical educators. Lately, attention has been directed to correcting this deficiency, partly due to pending litigation

due to a significant number of errors, primarily a result the lack of proper training as opposed to a few due to malfunction of the robot. This shortcoming is further compounded by the certifying bodies (the "boards" of the various surgical specialties) hesitancy to mandate training and provide certification because of uncertainty of the true necessity to train *all* their surgeons in robotic surgery.

A review of the literature reveals only two different curricula that describe and validate a robotic surgery course: Lyons et al. [43] chose 11 of the tasks designed by the commercial company Intuitive Surgical (Sunnyvale, CA, USA) for the da Vinci[®] robotic system to validate face, content and construct validity (EL5). While Dulan G et al. [44–47], over the course of 4 publications, used a few tasks of the Fundamentals of Laparoscopic Surgery (FLS) and some novel tasks which they created through task deconstruction to validate their curriculum (EL3). While excellently conducted studies, the curricula are derived from single institutions and only the latter were performed to proficiency levels. In addition the focus was only on psychomotor skills. There is also the perception that because robotic surgery is a minimally invasive surgery (MIS) procedure, the use of the FLS is adequate to train a surgeon to perform robotic surgery, and while Dulan et al. did select some FLS tasks, there are other skills inherent in robotic surgery (but not available to laparoscopic surgery) which must be taught and evaluated.

During a pilot study before beginning the Fundamentals of Robotic Surgery (FRS) curriculum, the FLS curriculum was used for training in robotic surgery. However, the FLS curriculum was abandoned as it was not able to demonstrate construct validity, wherein the novices performed equally as well as the expert surgeons on the FLS tasks (unpublished data from the FRS Curriculum Initiative and the author of this section RS). Thus a new device and curriculum was needed and subsequently developed by modifying three of the original FLS tasks and creating four new novel tasks that trained and assessed 26 basic skills. This curriculum, the Fundamentals of Robotic Surgery (FRS), is freely available online at <http://FRsurgery.org> as development was in conjunction with the US Department of Defense and an unrestricted educational grant from Industry (Intuitive Surgical, Inc, Sunnyvale, CA, USA), although industry was non participatory in the curriculum development. Additional information regarding the FRS follows.

The fundamentals of robotic surgery (FRS) curriculum

The FRS was developed in the U.S based upon an adaptation of a number of curriculum development processes that have been conceived and refined over more than 90 years of simulation and training by the military (Department of Defense—DoD), aviation (Federal

Aviation Administration—FAA), astronaut training (National Aeronautics and Space Administration—NASA), nuclear surety (Department of Energy—DoE), maritime (Federal Maritime Commission—FMC), Department of Transportation (DoT) and other major high-risk professions [48–51]. Beginning from ‘first principles’ the full spectrum of the FRS was developed through the use of consensus conferences (conducted by the Delphi Method) that included official representatives of 14 surgical societies, the DoD and the Veterans Administration (VA), which represent the civilian and federal sectors currently responsible for medical training using simulation. The result is a curriculum (course) of basic skills that all surgical specialties can use to train and assess the performance of surgeons desiring to engage in the practice of robotic surgery. At this time, the FRS curriculum is complete (see above reference) and a pilot study of the FRS is being conducted while the multi-institutional (15 institutions) multi-specialty validation trial is being developed and conducted.

The curriculum consists of a “curriculum full life-cycle development” process, developed as indicated above, and is a “course”, which addresses all the technical skills (cognitive, psychomotor and team-training-and-communication—TT&C) needed to be proficient in the most basic of skills in robotic surgery. The curriculum ‘begins as the patient enters the operating room, and ends as the patient leaves the operating room’—it is exclusively a technical skills course and does not include the essential knowledge-based portion of a curriculum: The peri-operative components of needs assessment, indications/contraindications, pre-operative and post-operative care. It does cover all of the three above technical areas and addresses the three phases: pre-procedure, intra-operative and post-procedure skills. The pre- and post-procedure phases have heavy emphasis on TT&C and some psychomotor skills, while the intra-operative phase (from when the surgeon sits down at the console until the completion of the psychomotor skills and leaves the console) focuses mainly on communication and hand-eye technical skills. There is an online didactic lecture series at <http://FRsurgery.org> (cognitive component of technical skills), which must be completed, and a test passed before moving onto the psychomotor skills. Assessment tools have been created to monitor performance. The validation trial will test experienced and expert robotic surgeons and use their performance scores to determine the benchmark values which the learners must reach. This is a training-to-proficiency curriculum, not a time-based curriculum, and the learner must reach the benchmark value before being allowed to continue further training in robotic surgery. The above listed participating organizations in the development of the FRS, have agreed to develop surgery-specialty-specific ‘fundamentals’ courses based upon the FRS foundation process, to continue the

completion (within a specialty) of the robotic skills unique to each specialty. Since the skills and tasks are abstract, they are valid representations of the skills needed in robotic surgery. However, successful completion does not qualify the learner to perform robotic surgery rather the FRS warrants proficiency in the utilization of the robot. An analogy would be a driver’s license which guarantees that the learner has the most basic knowledge and performance of technical skills on how to safely drive a vehicle. It does not, however, warrant that the learner is able to drive from one city to another, nor to drive a very complex vehicle like a transport trailer truck.

Once the FRS has been validated, it will act as one objective measurement tool in determining if the surgeon has the basic technical skills to perform robotic surgery. The results of this course must be combined with the other components as indicated above (which are not included in the FRS). In addition, there is a yet to be determined clinical monitoring period (proctoring) which is needed to provide a comprehensive assessment of safe robotic surgery.

Importance of the FRS curriculum

The FRS is intended to provide an objective assessment of the performance of a surgeon in the most basic skills. It is not, however, intended to provide final approval of comprehensive robotic surgery knowledge (see above). To date, there is no training or assessment tool that determines whether the surgeon is technically prepared to undertake complex robotic surgery procedures. Just as laparoscopic surgery began with practicing on patients resulting in numerous errors and poor outcomes, with robotic surgery the initial errors, complications, and prolonged operative cases, may be the result of the lack of a rigorous training program. Until the validation trial is complete, and there is acceptance by societies and surgical specialty boards for training and certification respectively, there is no benchmark to determine the proficiency of a surgeon in robotic surgery.

The relevance of this comprehensive approach to robotic skills training with these guidelines is that the evidence that is currently being assessed does not include data about the level of proficiency of the robotic surgeons reporting their experience. The data currently includes only the clinical outcomes in terms of patient safety (errors, complications, etc.), efficacy (operative time, length of hospital stay, etc.) and patient satisfaction (level of pain, return to work, etc.). With the exception of urologic robotic surgery, the majority of the reports in the literature on robotic surgery include surgeons who began robotic surgery less than 4 years ago and therefore are still in their ‘learning curve’. Thus the analysis and comparative effectiveness of robotic

surgery as compared to laparoscopic or open surgery, is subject to the inadvertent bias of comparing novices in robotic surgery (i.e., have not completed a formal training program nor enough surgical procedures to be outside of their learning curve) to expert laparoscopic or open procedure surgeons (i.e., experienced and/or expert surgeons). More rigorous (and valid) comparative effectiveness studies can be conducted for outcomes of robotic surgical procedures as the surgeons experience broadens taking them beyond their learning curves, and as the current FRS is validated, as well as the other more advanced critical components of robotic surgery education, such as training and assessment of full procedures are all completed.

Safety of current robotic systems

Reports of patient injuries during robotic surgery and malfunctions of the system were published since the system was released to the market. Recalls of needle holders for tip detachment, monopolar devices for arc generated through defected cover, and warnings that friction between the robotic arms may cause injuries to patients were issued in the past several years and published by the FDA.

The majority of the reported injuries were not clearly device-specific, but rather a result of human error, possibly from lack of proper training of the safe use of the device. The vast majority of device failures was not associated with patient injury, and was estimated at .38 % [52, 53].

The panel suggests that safety issue should be an important part of formal training of the use of the robot. In addition, device manufacturers are encouraged to add safety features to the device.

Clinical applications of robotic surgery

The following are all clinical applications of robotic surgery that have published data in the English literature.

Cholecystectomy

Statement: Robotic cholecystectomy has comparable clinical outcomes to standard laparoscopic cholecystectomy (LE3B)

Cholecystectomy is commonly the starting procedure for most robotic general surgeons. The current evidence to validate the benefits of robotic cholecystectomy is rather limited, partly due to the simple procedural steps but also the higher operative cost. A number of small and non-comparative series of robotic cholecystectomy have

demonstrated the safety and feasibility of the procedure. However, the main consideration particularly for a simple operation like cholecystectomy is cost-effectiveness [54–57]. (LE4) Cost requirements can only be justified provided that it is reasonable and a significant benefit is demonstrated.

Two early studies consisting of 10 and 20 patients respectively, failed to provide any convincing evidence of advantages of robotic cholecystectomy over laparoscopy in terms of patient outcomes and costs [58, 59] (LE3B). A more structured case-matched controlled study, consisting of 50 patients in each group, conducted by Breitenstein et al. [60] could not identify any difference in perioperative outcomes including operative time, conversion rate, morbidity and postoperative length of stay. Despite these similarities, higher cost was noted in robotic cholecystectomy which is largely due to amortization and consumables of the robotic system [60] (LE3B).

In a recently published Cochrane review on robot assistant vs. human or another robot assistance in patients undergoing laparoscopic cholecystectomy, four clinical trials with 431 patients (robot assistant 212 vs. human assistant 219) were identified. Despite all the trials being high risk of bias, no significant difference was identified for robot assistance over human-assisted laparoscopic cholecystectomy [61] (LE2A).

Single-site cholecystectomy

Robotic single-site cholecystectomy

In the past 20 years laparoscopic cholecystectomy became the standard of care. In an effort to further minimize the number of incisions two new techniques were developed recently: Single-incision laparoscopy and Natural Orifice Transluminal Endoscopic Surgery (NOTES). Both suffer from technical difficulties preventing a widespread use. The da Vinci[®] Si robotic platform enables robotic single-site surgery overcoming some of the technical difficulties encountered in single-site laparoscopy and therefore is considered by some the new evolution of cholecystectomy. Robotic Single-Site Cholecystectomy (RSSC) is a new technique and the first case series was published online on June 2011.

A literature search using the keywords: robotic single-site cholecystectomy, robotic single-port cholecystectomy, robotic single-incision cholecystectomy Of the 60 articles that were found only 16 met the criteria for assessment. Articles dealing with non-human research or technical robotics were excluded. The level of evidence is low due to the recent use of the technique and the nature of the articles, which were mostly non-controlled case series or cohorts, compared to matching historical groups. Due to

the technical nature of the articles describing this new technologic capability, the assessment herein is concentrated mostly on technical issues rather than clinical outcomes.

Statement: Robotic single-site cholecystectomy has comparable outcomes to laparoscopic single-incision cholecystectomy in selected cases of uncomplicated gallbladder disease (LE 3B). There are reports of device malfunction and technique related complications (LE4)

Since RSSC utilizes a new platform developed by Intuitive Surgical and there is limited experience with it, most studies were performed on selected patients with uncomplicated disease. Overall, the mean operative time, complication rate, and outcomes were comparable to SILC (LE 3B). This technology, however, enables overcoming the difficulties of SILC and reduces the manual skills required [62]. It is thought that this technique is an efficient alternative to SILC and may in time prove to be a safer procedure [62, 63].

Gonzalez et al. [64] retrospectively compared their results of RSSC to SILC and reported a similar complication rate of 1.8 % for both. Three patients out of 131 RSSC suffered from post-op complications. One patient had a wound infection while two patients had intra-abdominal abscesses requiring percutaneous drainage and prolonged hospital stay (LE 3B). Morel et al. [65] published a prospective review on 82 patients and reported a 4.9 % postoperative complication rate including one bile leak following conversion to open surgery. Another serious complication reported was a duodenal laceration requiring reoperation (LE 4). Buzad et al. [63] also reported a cystic duct leak in one patient out of 20 which was treated by ERCP (LE 3B). Konstantinidis et al. [66] reported that in their first 45 RSSC cases they had nine gallbladder perforations (20 %), one postoperative bleeding requiring reoperation and one wound infection (LE 4).

Two studies [67, 68] reported of device malfunctions. Wren et al. [68] operated 10 RSSC cases and reported of two intraoperative device malfunctions related to the access port which was torn while inserting the extraction bag. After modifying their technique this problem was resolved (LE 4). Uras et al. [67] reported one case out of 36 that the clip applier stuck and technical support was necessary to remove the robotic instrument (LE 4).

Of note, some of the studies reported herein were published very early in the experience of this new platform. The device and technique related complications attributed here therefore were appropriately dealt with.

The mean operating time of RSSC is quite diverse in the different publications. This diversity is probably due to the

different number of cases reported and the difference in the experience of the surgeons. Spinoglio et al. [69] compared their first 25 cases of RSSC to their historical first 25 SILC cases and found that the OR time was significantly shorter in RSSC. While this comparison maybe biased due to the experience gained by the group in single-site surgery prior to starting RSSC, they concluded that the robotic platform in RSSC may shorten the learning curve for single-site cholecystectomy for inexperienced surgeons.

Angus et al. [70] reported that in their first 55 cases the OR time was similar to the data published on OR time for SILS. They also concluded that a short learning curve is necessary to reach adequate acceptable OR time.

Studies which included morbidly obese patients [65, 66] state that the robotic platform facilitates the operation in this subset of patients and concluded that those patients that were not eligible for SILC due to high BMI may be candidates for RSSC.

There are significant differences between standard robotic instruments and the single-site instruments, which influence the surgeons' capabilities. The instruments are 5 mm in diameter and semi flexible unlike the standard rigid 8 mm instruments. The most significant difference, however, is the fact that these instruments do not have articulating tips. As a result, the instruments have limited range of motion which is further limited due to docking configuration that limits the surgical area. In order to expand the field of operation, re-docking may be necessary [64, 66, 67]. Moving the robotic working field from one quadrant to another is difficult as is due to the positioning of the side cart and at times re-docking is required. In single-site surgery there is an additional challenge due to the need for moving of the entire complex of instruments at once, hence re-docking is more probable in these situations.

Prospective randomized trials are necessary to establish possible benefits of this technique. It is obvious, however, that RSSC serves as the preliminary experience for this new platform and that this may facilitate completion of more complex procedures via single-incision surgery.

Statement: Robotic Single-Site Cholecystectomy may potentially overcome some of the technical limitations encountered in Single-Site Laparoscopic Cholecystectomy (LE 4)

Single-incision laparoscopic cholecystectomy (SILC) has many limitations which include: lack of triangulation; Instrument collision causing difficulty in dissection and retraction and limited range of motion; Poor visualization that demands expertise in order to achieve a non-compromised view; and Poor surgeon ergonomics causing physical, and mental stress.

All publications stress the fact that the benefit of the new da Vinci[®] Si platform for RSSC is its ability to overcome the technical difficulties encountered in SILC (LE 3). The use of semi flexible instruments which cross each other at the entrance point eliminate the phenomenon of coaxiality, therefore avoiding external collisions of the robotic arms and restoring triangulation. [68, 71–73] (LE 3) The system then allows for swapping the control of the crossed instruments thereby restoring the intuitive movements of standard robotic surgery. The 8.5 mm 3D laparoscope provides a better three-dimensional image that is significantly helpful in single-incision surgery, and operating through the robotic console reinstates the robotic type ergonomics [64, 66, 69] (LE 3).

Although the robotic system configuration may overcome some technical limitations of SILC this new platform introduces new limitations and new challenges.

Statement: Additional dedicated training and education are necessary prior to using the robotic single-site access port and system (LE 4)

The single incision dedicated access port and special robotic arm configuration is different from standard robotic surgery and non-robotic single-port surgery. These facts demand special attention during surgery and influence the time and outcome of the procedure.

The access port of the robotic platform includes a silicon port with four tunnels and an insufflation tube. The four tunnels accommodate an 8.5 mm camera, a 5 mm assistant trocar and 2-curved cannula for the flexible robotic instruments. This design dictates the robotic arms configuration and the single-site incision length.

The docking time in RSSC ranges from 5.2 to 15 min. Several studies emphasize the need for specific education and training of the operating team due to the complexity of attaching the three arms on a shared small area. Another point stressed is the safety of insertion of the semi flexible instruments. Due to the nature of the curved cannula these instruments are not intuitively brought into position and should be inserted under strict visual guidance to avoid organ injury [66, 67] (LE 4). A new challenge encountered using the single access port system is loss of pneumoperitoneum at times necessitating undocking and re-docking [62, 67, 71, 73]. The supposed reason of pneumoperitoneum loss is the dislodgment of the access port in thicker abdominal walls and significant Trendelenberg position (LE4). Undocking the robot and re-docking is also necessary for performing intra-operative cholangiogram when indicated, which prolongs the operation time [66, 68, 72, 73] (LE 4). One study that aimed specifically to address the docking time reported that the overall mean docking time in 64 cases was 6.4 min, which represented 8 % of the

operating time. They concluded that the docking process for RSSC is learned rapidly and does not significantly increase the overall OR time [74] (LE 4).

Another new issue related to the robotic platform in RSSC that should be mentioned is the higher than expected VAS pain scores encountered in some patients undergoing this procedure. Some studies reported excessive abdominal pain in a few patients that mandated readmissions and prolonged hospital stays [63, 65, 67]. The authors of these studies believe that the reason for the excessive pain is in the configuration of the instrument setup. The movements of the robotic arms can produce extensive traction of the umbilical wound, thereby producing increased postoperative pain. Although the remote center technology should create pivot points at the level of the abdominal wall to avoid traction of the wound, precise placement of the cannulas may not be achieved at all times leading to this kind of excessive wound traction (LE 3).

Future directions

The da Vinci[®] Si robotic platform enables performing RSSC; however, data are lacking regarding the performance and benefits of this technique. Following three years of introduction there is now a need for randomized comparative studies of RSSC and SSC in order to evaluate the true benefits of this novel technique. RSSC served as a learning operation for robotic single-site surgery and further applications are now expected to follow to benefit from this technique. It is obvious though that the da Vinci[®] Si platform was recruited for this technique but was not designed for it. If robotic single-site surgery is a significant part of the future of surgery, a dedicated robotic platform should be designed for this task.

RSSC and multi-modal imaging

Two studies were published specifically on RSSC using intraoperative fluorescent cholangiography (IOFC). The safety and efficacy of this technique was discussed in previous publications of standard and robotic operations. Adding a new component of RSSC to the equation reiterates the disadvantages the gold standard intraoperative cholangiogram. These include increased operative time, the need for a multidisciplinary team, exposing the patient and staff to radiation, the need for undocking and re-docking and the risk of bile duct injury during cannulation of the cystic duct especially in single-site cholecystectomy [75] (LE 4). While IOFC overcomes these disadvantages with no additional personnel, no exposure to radiation, no need to undock the robot and no risk of bile duct injury, there are still limitations to this technology that need to be taken into consideration. The near infrared penetration capability is

limited to 5–10 mm and therefore in patients who are obese or have significant inflammation there may be decreased visibility of the biliary structures. IOFC by itself cannot rule out common bile duct stones and it is not clear if IOFC alone can detect a biliary leak or injury intraoperatively [76] (LE 4). Overall the two publications conclude that IOFC is safe and contributes to a safe and quick dissection of the biliary structures, which is more important in single-site surgery.

Hepatobiliary surgery

Exploration of common bile duct, choledochoduodenostomy/hepaticojejunostomy

Statement: Robotic assistance may facilitate complex biliary surgery, particularly bilio-enteric bypass (LE3B)

While a number of small cohorts of robot-assisted laparoscopic common bile duct exploration have been reported, robotic bilio-enteric bypass for biliary stones is rarely described [77–79]. (LE4) Allkhamesi et al. [80] conducted a retrospective study comparing robot-assisted laparoscopic ($n = 18$) versus open exploration of common bile duct ($n = 19$) which did not identify any notable advantages. Of note the open conversion rate was unacceptably high in the robotic arm (4/19), and the result could probably be improved with better patient selection [80] (LE3B).

Mirizzi syndrome is often considered an absolute contraindication for laparoscopy as a result of dense fibrotic adhesions around Calot's triangle resulting in unclear anatomy. However, it could still be successfully managed with promising outcome in a small series of 5 patients by the robot-assisted laparoscopic approach [81]. (LE4) Apart from expertise with extensive laparoscopic experience, improved dexterity and enhanced 3-dimensional magnification conferred by the robotic system are the crucial elements for the success of such an operation.

The two common bilio-enteric bypasses are choledochoduodenostomy (CD) and hepaticojejunostomy (HJ). CD is indicated to relieve biliary obstruction mainly for recurrent biliary stones or other benign obstruction at the distal biliary tree. Either laparoscopic end-to-side or side-to-side constructions could be employed and reported postoperative outcomes are promising. Robotic CD is, however, not frequently performed.

Conventional laparoscopic HJ requires advanced skills and many limitations have to be overcome, such as reduced degree of freedom of movement in confined subhepatic space, 2D imaging and poor ergonomics. These limitations translate into a steep learning curve. On the contrary, robotic assistance provides a stable operative view as a

result of reliable retraction, enhanced dexterity, 3D imaging and improved ergonomics. All of which are important pre-requisites for the construction of a demanding HJ anastomosis.

Most robotic HJs were performed in pediatric patients following excision of choledochal cysts, while another relatively small group of patients had an HJ for palliation of malignant biliary obstruction or as a conversion of CD to HJ for the management of sump syndrome [82–87]. (LE4) The construction is usually in a roux-en-y fashion, with either an intracorporeal or extracorporeal approach, for a better functional outcome. Despite the use of robotic assistance, surgeons have to work in different quadrants for the creation of a roux-en-y anastomosis, which explains why various techniques/approaches have been attempted.

Partial hepatectomy

Statement: Robotic hepatectomy shows comparable clinical outcomes to laparoscopic hepatectomy (LE3A). The use of robotic assistance may increase the rate of minimally invasive major hepatic resections (LE4)

Laparoscopic liver resection is increasingly performed particularly after the Louisville International Consensus Conference held in 2008, although the development is still slower than other gastrointestinal surgery [88] (LE5) With the enhanced capabilities of the robotic surgical system, it is expected that robotic hepatectomy can overcome some of the limitations of conventional laparoscopy [89]. (LE5) After almost a decade of development, robotic hepatectomy is still often challenged not only by open but also laparoscopic liver surgeons regarding any additional benefits to justify the higher operation cost.

The initial development of robotic liver resections is similar to that of the development of laparoscopic liver surgery as demonstrated by the number of small cohorts reported in the past decades, with a few retrospective comparative studies [90–95]. (LE4; LE4; LE3B; LE4; LE4; LE4) Berber et al. compared 7 robotic versus 23 laparoscopic hepatectomies for peripherally located pathologies measuring <5 cm and concluded that both approaches resulted in similar perioperative outcomes [96]. (LE3B) However, Packiam et al. compared the clinical and economic outcomes of robotic ($n = 11$) versus laparoscopic lateral sectionectomy ($n = 8$) in which they identified no differences in operative outcomes and length of operation. Patients undergoing the robotic approach had more admissions to the intensive care unit (45 vs. 6 %), an increased rate of complications (27 vs. 0 %) and a longer length of stay (4vs. 3 days) resulting in a higher cost (including indirect cost like purchase and maintenance of

the robotic system) [97] (LE3B) The higher complication rate and frequent admission to the intensive care unit could be attributed to the learning curve effect.

Major hepatectomy poses a real challenge to even the most enthusiastic laparoscopic liver surgeons. Laparoscopy has limitations which include: difficulty to suture bleeding liver parenchyma laparoscopically, the need to perform complex hilar dissection for inflow control, unstable laparoscopic platform as a result of frequent instrument exchange, and potential shakiness of the camera system. Nguyen et al. reviewed a total of 127 published articles on laparoscopic liver resections with 2,804 minimally invasive liver resections and found that major hepatectomy rate was about 17 % (9 % right hepatectomy, 7 % left hepatectomy and 1 % extended hepatectomy) [98]. (LE2C) Studies have shown that in experienced hands, conventional laparoscopic major hepatectomies achieved similar patient and economic outcomes compared to open liver resections in selected patients in terms of intraoperative blood loss, blood transfusion rates and postoperative length of stay [99–101]. (LE3; LE4; LE3B) Recent papers from both Hong Kong and Pittsburgh confirmed the application of robotic assistance could probably confer more confidence to the operating team and result in a higher major hepatectomy rate [102, 103]. (LE4; LE3B) The higher rate of major hepatectomy could be explained by the enhanced visualization and dexterity of the robotic system in facilitating meticulous hilar dissection during inflow control, and also the reliable retraction of the third robotic arm to allow better exposure during hepatocaval dissection. Tsung et al. reported the biggest comparative series for laparoscopic ($n = 114$) and robotic hepatectomy ($n = 57$). No significant difference was noted in perioperative outcomes such as total complication rate, mortality rate, margin negativity rate and conversion rate. However, this was at the expense of an increased operative time. It is clearly demonstrated that the robotic approach allowed for an increased rate of major hepatectomy (81 vs. 7.1 %, $P < .05$). When comparing early versus late robotic cases, a clear learning curve effect was also identified [103] (LE3B).

The Iwate group attempted the first systematic review of 19 series of a total 217 patients undergoing 236 robotic liver resections, of which the major hepatectomy rate was 36.4 % ($n = 84$), conversion rate 4.6 % ($n = 10$), morbidity rate 20.35 % ($n = 48$) and zero mortality rate [104] (LE3A).

Apart from safety, oncological outcome is an important parameter to evaluate the effectiveness of this novel approach. However, available survival data about robotic hepatectomy for malignancy is still very limited. Lai and Tang et al. reported the largest number single-center study of 42 robotic hepatectomies for hepatocellular carcinoma

achieving an R0 resection rate of 93 %, and 2-year overall and disease-free survival rates of 94 and 74 % respectively [105]. (LE4) Choi et al. also reported no recurrence in 17 patients with HCC during a median follow-up of 11 months [93]. (LE4) Giulianotti et al. reported 17 patients with malignant tumors (HCC, $n = 1$, CRLM, $n = 11$, non-colorectal liver metastasis, $n = 4$, hepatoblastoma, $n = 1$). Among the patients with CRLM, 9 of 11 were alive and disease-free at a mean follow-up duration of 36 months, whereas the patient with HCC was alive and disease free for 6 months after surgery [106] (LE4).

Two exciting areas to be further explored in robotic liver surgery are augmented reality and the advancement of instrumentation. Augmented reality with 3D volume rendered images directly displayed in the console screen can allow operating surgeons to have a better appreciation of liver pathology in relation to surrounding biliary and vascular structures, which is crucial information for a more accurate anatomical dissection. With regards to instrumentation, the ultrasonic dissector is a useful instrument currently employed by many robotic surgeons. However, the versatility is limited by the loss of freedom of motion in comparison to other endowrist instruments. The ultrasonic aspirator would be another useful tool for parenchymal transactions if it is available to be used through the robotic arm.

Distal pancreatectomy

Statement: Spleen-preserving distal pancreatectomy may be facilitated by robotic assistance (LE3) and conversion to open surgery may be reduced (LE3B)

The relatively simple anatomy and the absence of the need to create a pancreatic anastomosis make it more acceptable for pancreatic surgeons to adopt minimally invasive distal pancreatectomy. Nevertheless, laparoscopic spleen-preserving distal pancreatectomy is still a challenging procedure, which requires ligation and division of individual splenic tributaries. Two systematic reviews by Jusoh and Ammori et al. (11 comparative trials) and Venkat et al. (18 comparative trials) confirmed lower operative blood loss, lower morbidity rate and faster recovery for laparoscopic over open distal pancreatectomy [107, 108]. (LE2A; LE2A) It can be concluded that laparoscopic distal pancreatectomy is both feasible and safe in selected patients; however, the larger issue lies in spleen preservation as the procedure requires fine and delicate techniques.

Until recently, only three retrospective comparative studies have been conducted to validate the outcomes of robotic distal pancreatectomy compared to open procedures. Waters et al. from the US reported similar cost for

robotic distal pancreatectomy when compared to both laparoscopic and open distal pancreatectomy (robotic \$10588, laparoscopic \$12986, open \$16059). They also noted a tendency of a higher rate of splenic preservation (robotic 65 %, laparoscopic 19 %, open 12 %) at the expense of a longer operative time (robotic 298 min, laparoscopic 222 min, open 245 min) [109]. (LE3B) Kang et al. from Korea reported a similar advantage of spleen preservation (robotic 95 % vs. laparoscopic 64 %) with longer operative time (robotic 348.7 vs. 258.2 min) but the cost was much lower in the laparoscopic group (robotic \$8300 vs. laparoscopic 3861.7) [110]. (LE3B) The last comparative study reported by Daoudai et al. from the US also showed a similar spleen preservation rate (robotic 7 % vs. laparoscopic 18 %) but shorter operative time for the robotic approach (robotic 293 min vs. laparoscopic 372 min) [111] (LE3B).

Pancreaticoduodenectomy

Statement: Robotic pancreatico-duodenectomy shows comparable results to both open and laparoscopic equivalents in selected patients, with a tendency of reduced operative blood loss. (LE3B)

Although there is limited evidence of conventional laparoscopic pancreatico-duodenectomy (PD) in the literature, this is an important foundation for the future development of robotic PD. In the four non-randomized studies comparing open versus laparoscopic PD, there is a tendency of increased operative time and reduced blood loss for the laparoscopic arm but none of them addressed survival benefits compared to the open gold standard [112–115]. (LE3B) It should also be noted that all these procedures were performed by experienced laparoscopic pancreatic surgeons, making it quite difficult to reproduce and generalize in other surgical centers.

Robotic surgical systems can enhance dexterity, restore hand-eye coordination, and improve ergonomic posture as well as visualization of the operative field. These are all essential factors to overcome many of the obstacles encountered in laparoscopic PD. Giulianotti et al. performed the first robotic PD in 2003 in which he employed various techniques for the eight cases ranging from hybrid to full robotic procedure and from resection to reconstruction [55]. (LE4) Among the 134 robotic pancreatic procedures reported by Grosetto and Chicago in 2011, there were 60 PDs with a morbidity rate of 26 % and a pancreatic fistula rate of 31.3 % [116]. (LE4) Zureikat et al. from Pittsburgh reported 24 PD among their 30 robotic pancreatic procedures with an overall pancreatic fistula rate of 27 % [117] (LE4).

There are four non-randomized trials comparing open versus robotic PD. All the studies showed reduced blood loss in the robotic arm, but other parameters like morbidity, mortality and oncological outcome surrogates are comparable [118–121] (LE3B).

Upper gastrointestinal surgery for benign diseases

Statement: Robot-assisted fundoplication provides comparable clinical outcomes to laparoscopic fundoplication in the treatment of reflux disease (LE1B)

When robotic surgery was introduced in general and abdominal surgery, surgeons were looking for opportunities to prove superiority. Robotic systems are made to support complex endoscopic surgery, but there are not that many procedures that are performed at a scale that allows randomization to be performed in a reasonable time frame.

Laparoscopic fundoplication in type 1 hiatal hernia is a procedure of medium complexity for experienced surgeons, and ergonomics are good when standing between the patient's legs. It is performed frequently, and is an ideal procedure to learn using robotic systems because it includes both careful dissection and extensive suturing. But what are expectations when one tries to prove superiority of the robot in early results? Laparoscopic surgery for reflux disease has very few serious complications in experienced hands. Hospital stay is short already, and there is no argument to find why return to work should be faster when operating on patients with a robot.

Reflux disease was chosen for randomized trials in the early days of robotics, because of available volume. Six randomized studies have been performed; all small, all without clear expectations or decent power calculation. These trials have been summarized repetitively in meta-analysis, and the conclusions are uniform. No superiority was demonstrated in complications or hospital stay. Operative times were longer, and procedures were more expensive. The only study that showed shorter operative times was that by Gutt et al. These conclusions could be expected upfront, due to the lack of serious issues in routine endoscopic fundoplication, and excellent results with standard techniques.

In four of the six mentioned randomized studies, 6–12 month objective results on outcome of reflux treatment were studied. Draaisma et al. [122], Muller-Stich et al. [123] and Morino et al. [124] found no difference. Melvin et al. [125] only found less use of anti-secretory drug in the robotics group. Frazzioni et al. [126] compared objective reflux parameters of a robotics cohort with an earlier cohort operated by standard techniques. They found significantly less acid exposure in the distal esophagus at midterm in the robotics group.

Statement: Robotic repair of large hiatal hernias appears to be safe. Comparative studies are not currently available (LE5)

Hiatal hernia repair with use of robotics is documented only in case reports or as a part of mixed initial surgical case studies. There is one prospective study which found 40 consecutive documented cases of type 3 and 4 hernias. The authors concluded that the technology can be applied safely with a relatively low recurrence rate at 1 year. Robot-assisted redo repair of hiatal hernia and anti-reflux disease may be superior to standard laparoscopic techniques. Broeders et al. [127] compared 30 cases of endoscopic redo surgery (2008–2011) to 43 cases of robotic redo surgery (2011–2013) with more patients operated initially by laparotomy in the robotics group. Conversions, major complications and hospital stay were significantly lower in the robotics group. This data was presented at the 2014 meeting of the Dutch Society of Endoscopic Surgery, but await publication at the time of this consensus.

Statement: Robot-assisted Heller myotomy for achalasia may result in less perioperative perforations and better quality of life compared to standard endoscopic techniques (LE 2B)

Horgan et al. [128] analyzed prospectively gathered data on robot assisted ($n = 59$) and standard ($n = 62$) patients. They found 0 % perforations in the robot group, as compared to 16 % perforations in the endoscopic group. Huffmann et al. [129] also found 0 % in the robotic group ($n = 24$) versus 8 % in the endoscopic group ($n = 37$) in a comparable study design. They also found better quality of life mid-term results in the robotic group. The papers have some confounding factors including comparison of data from a single robotic surgeon with data from multiple surgeons performing the operation occasionally, and the presence of an exceptionally high perforation rate in the laparoscopic group.

Upper gastrointestinal surgery for malignancies

Minimally invasive surgery (MIS) for upper gastrointestinal (UGI) malignant diseases has become widely performed since the first laparoscopic gastrectomy (LG) for cancer was reported in 1994 [130]. However, it is widely accepted that laparoscopic surgery for this disease is time consuming and has certain limitations, such as two-dimensional imaging, restricted range of motion of the instruments, and poor ergonomic positioning of the surgeon. Computer aided surgery and robotic surgical systems potentially improve further on currently available MIS technology and overcome these limitations. Robotic surgery can potentially provide

technical advantages over conventional laparoscopy, but its role for UGI malignant diseases is still unclear.

A Medline search was performed until December 2013, using the following terms: computer assisted surgery, robotic, partial gastrectomy, esophagectomy, esophagus and upper gastrointestinal surgery. A number of papers were excluded from analysis because they did not match the main objective of the study. Thirty papers with data on gastric cancer were identified. No papers were found with level of evidence (LE) 1, four papers with LE 2A [131–134], six papers with LE 2B [132, 135–140], four papers with LE 3A [141–145], two papers with LE 3B [146, 147] and 14 papers with LE 4 [148–161].

For esophageal resection, 13 papers were identified. No papers were found with LE 1 and 2A, two papers with LE 2B [162, 163], although one of them compared to robotic system [163], only one study with LE 3A [145] and 10 papers with LE 4 [164–173].

Gastric cancer

Statement: Robotic gastric resection has comparable clinical outcomes to standard laparoscopic gastrectomy for cancer. It may reduce intraoperative blood loss and postoperative length of stay as compared with laparoscopic gastrectomy, but is associated with longer operative time and higher cost (LE2A)

Robotic surgery for gastric carcinoma seems to be an interesting field with great potential for development, since the laparoscopic approach is known to be time consuming and complex. The need for a proper lymphadenectomy in difficult to reach areas, together with the advantages that the robot offers to perform hand-sewn anastomosis, particularly after total gastrectomy, makes surgeons believe that robots may play an important role in this surgical field.

Robotic surgery for gastric carcinoma has been described in the literature for both total and subtotal gastrectomies [132, 133]. The oncological results, in terms of lymph nodes harvested and R0 resections together with the survival rates, offers similar results to open and laparoscopic surgery; however, the long-term results of this technique need to be further studied. In terms of morbidity both laparoscopic and robotic techniques, seem to be similar, although robotic gastrectomy may reduce intraoperative blood loss and the postoperative hospital length of stay compared with laparoscopic gastrectomy and open gastrectomy [133, 139], however the total cost of robotic-assisted surgery seems to be higher [133]. One study [146] (LE3B) compared laparoscopic, robotic and open gastrectomy, demonstrated a higher risk of anastomotic leaks after both minimally invasive techniques.

Robotic gastrectomy for the treatment of gastric cancer may facilitate lymphadenectomy and alimentary tract reconstruction [148] with the possible exception of obese patients [136], although this still has to be demonstrated in prospective randomized series (LE4).

The potential advantages of robotic surgery compared to laparoscopic approach include many different important aspects. These advantages are observed when performing a full hand-sewn anastomosis for reconstruction [150], especially after total gastrectomy which can be facilitated by using a robot-sewing technique, since esophago-jejunal anastomosis is one of the most difficult steps in performing the total gastrectomy. The potential to reproduce D2-lymphadenectomy, large resections, and complex reconstructions provides an important role in the therapeutic strategy of advanced gastric cancer [152], particularly since robot-assisted surgery fulfills oncologic criteria for D2 dissection and has an oncologic outcome comparable with that of open gastrectomy. It has been also demonstrated that gastrectomy with lymphadenectomy performed by a robotic-assisted system can be performed safely using electric cautery devices alone without ultrasonic-activated instruments [135]. Another advantage of robotic surgery that was demonstrated included a reduced learning curve in particular for this procedure.

Although some groups have shown a significant learning curve effect in the initial 25 cases of the robotic group [137], it was shown that experienced laparoscopic surgeons could perform a robotic gastrectomy with an acceptable level of skill, even in initial series [147]. Nonetheless tele-robotic surgical systems offer distinct advantages to surgeons and may facilitate an increase in the number of surgeons performing advanced laparoscopic gastrointestinal operations [141] with an apparent reduction of the learning curve as compared with laparoscopic surgery [155].

Esophageal cancer

Statement: Robot-assisted thoracoscopic esophagectomy with total mediastinal lymphadenectomy has comparable clinical results to standard minimally invasive techniques. There may be a reduced rate of recurrent laryngeal nerve palsy (LE2B)

Minimally invasive esophagectomy has emerged as an important procedure for disease management in esophageal cancer with clear margin status, lower morbidity, and shorter hospital stays compared with open procedures.

Robotic surgical systems are most effective for operations in areas that are confined and difficult to reach, such

as esophageal and rectal resections. In this sense, the esophagus possesses attributes that are interesting for general thoracic robotic surgeons [166], being an ideal organ for a robotic approach. There is limited data published in the literature, although robot-assisted esophagectomy with total mediastinal lymphadenectomy has been reported for esophageal cancer [162], but no improvement in oncological outcomes could be identified with the use of the robot. In terms of short-term oncological outcomes, these were equivalent to the open approach for esophageal cancer. Operative benefits appear to be encouragingly similar to the laparoscopic approach with some demonstration of improvement over the open technique despite a prolonged operative time. However, the level of evidence is poor and more randomized controlled trials and long-term survival studies within a framework of measured and comparable outcomes are required [145]. One potential benefit of a robotic approach is in preventing recurrent laryngeal nerve palsy. Suda et al. have demonstrated in a nonrandomized prospective study that robot assistance significantly reduced the incidence of vocal cord palsy and hoarseness and time on the ventilator [162]. Other potential advantages of robotic approach seems to be that it affords R0 resection, thorough thoracic lymph node dissection and low blood loss [169, 171], as well as allowing the sewing of a 2-layered chest anastomosis with good early results [165].

Transhiatal esophageal resection is considered an alternative to thoracoscopic esophagectomy. The benefits include minimally invasive mediastinal dissection without thoracotomy or thoracoscopy. A reasonable operative time with minimal blood loss and postoperative morbidity can be achieved, in spite of the technically demanding nature of the procedure, which may be improved by the use of the robotic system. Robotic transhiatal esophagectomy with the elimination of a thoracic approach may be considered an option for the appropriate patient population in a comprehensive esophageal program [166].

Gastrointestinal stromal tumor (GIST)

There is lack of sufficient evidence regarding robotic gastric resection of gastrointestinal stromal tumors (GIST) since only series with small numbers were published in the literature [174, 175]. Surgical robotic approach for GIST was reported to be safe [174] although better evidence is needed to clarify the effective role of different surgical strategies. There seems to be a potential for robotic surgery to be especially advantageous for oncologically safe resection of esophago-gastric or duodeno-gastric junction or other unfavorably located gastric GIST. Potentially, some of the features of robotic surgery may facilitate performing a safe, large atypical gastrectomy, close to the pylorus or cardia [175].

Colorectal surgery

Statement: The definition of robotic-assisted surgery for rectal cancer is currently not standardized (LE5)

Most cases of robotic-assisted surgery for rectal cancer are performed as a laparoscopic-assisted procedure involving robotic proctectomy only (conventional hybrid) [176] (LE 3). Unlike conventional hybrid, the reverse hybrid is a modified procedure where robotic proctectomy is performed as first operative step [177] (LE 4). Other robotic-assisted surgery for rectal cancer has also been described including hand-assisted laparoscopy with robotic proctectomy [177] (LE4), totally robotic-assisted surgery for rectal cancer with single docking [178] (LE 4), as well as natural orifice specimen extraction with robotic hand sewn anastomosis [179] (LE4).

Statement: Robotic-assisted surgery for rectal cancer has comparable clinical outcomes compared to standard laparoscopic surgery (LE2A)

As previously published in a consensus conference [180] (LE5) the potential benefit of robotic proctectomy is its ability to achieve an increased rate of uninvolved circumferential resected margins. (CRM) [181–183] (LE3B) This is the result of the robot's wristed instruments ability to overcome the fulcrum effect created by the trocars in the confined space of the pelvis. Preoperative MRI pelvimetry data suggest that interspinous distance is a predictive factor for involved CRM [184] (LE 2B). However, obesity was not found to be associated with increased CRM involvement [185] (LE3B). Robotic proctectomy also holds the potential benefit of increasing the feasibility of robotic proctectomy in subgroups of patients with unfavorable anatomy [186] (LE5), thereby decreasing conversion to laparotomy [187–190] (LE2A). A recent large administrative database indicated that robotic proctectomy is most commonly used in male patients [191] (LE2c).

A potential disadvantage of robotic proctectomy is its possible negative impact on the quality of total mesorectal excision (TME) due to the absence of tactile feedback. While there is limited literature dedicated to assessing the quality of TME in robotic proctectomy, [192] (LE3) [183, 193, 194] (LE3B) MRI pelvimetry data suggest that interspinous distance and obstetric conjugate are predictive factors for TME quality [184] (LE2B). It is still controversial whether high body mass index (BMI) is a predictive factor for decreased TME quality [195, 196] (LE 2C; LE3).

Statement: Robotic and laparoscopic-assisted surgery for rectal cancer, are equally safe except for low-volume surgeons (LE4)

No differences in rates of intraoperative complications were found in both a meta-analysis and a systematic review comparing robotic to laparoscopic surgery for rectal cancer. [188, 197] (LE2A). Despite a lack of studies on the impact of high BMI upon complication rates of robotic-assisted surgery for rectal cancer, the open and laparoscopic surgery literature reported higher conversion to laparotomy [196] (LE3B), and longer operating time [185] (LE3B). A recent systematic review and a large administrative database concurred with three previous systematic reviews in that there are no significant differences in rates of postoperative complications when robotic-assisted proctectomy is compared to its laparoscopic counterpart [187–189, 197] (LE2A) [191] (LE 2C). However, another recent large administrative database has indicated that robotic-assisted proctectomy performed by low-volume surgeons may actually result in increased rates of post-operative complications when compared to the rates associated with high-volume expert surgeons performing the same operation [198] (LE 2C).

Statement: Studies on the learning curve for robotic proctectomy for rectal cancer are focused on operating time (LE5)

The few studies dedicated to the learning curve for robotic proctectomy have looked at operating time and its breakdown [199] (LE3B). Based on operating time, the learning curve for robotic proctectomy has been defined as 20 cases for experienced surgeons with limited laparoscopy experience [200] (LE4). Similarly, others have defined as 15–25 [201] and 21–23 cases both on the basis of operating time [202] (LE 4).

The potential impact of the surgeon's learning curve on histopathological metrics such as TME quality and CRM depth remains unknown. A study including the surgeon's learning curve reported a 31 % near complete TME quality after robotic proctectomy in 13 patients as opposed to 15 % after laparoscopic proctectomy [192] (LE3B). Dissimilarly, an earlier pilot RCT [203] (LE2B) found no significant difference in TME quality when comparing robotic proctectomy in 18 patients with 16 laparoscopic proctectomy cases.

Statement: Robotic-assisted proctectomy does not provide significant differences in postoperative recovery compared to laparoscopic-assisted surgery for rectal cancer (LE2A)

Three meta-analyses of non-randomized data from eight studies found no significant difference between the two approaches when analyzing timing for passage of flatus, time to resumption of solid diet, and length of hospital stay. [187–189] (LE 2A). According to a recent systematic review most studies showed longer operating time but several authors reported a significant decrease in estimated blood loss, a shorter length of stay and a shorter time to first flatus or diet [197].

Statement: Robotic-assisted proctectomy for rectal cancer shows no significant differences in quality of histopathology metrics and survival rates compared with the laparoscopic counterpart (LE4)

According to two meta-analyses [187, 189] (LE 2A), two prospective non-randomized studies [204, 205] (LE2b), five retrospective studies [181, 182, 192, 206, 207] (LE3B) and a systematic review [197] (LE2A) lymph node harvest did not differ between robotic and laparoscopic-assisted proctectomy for rectal cancer. No differences were found in distal resection margins based on two meta-analyses [187, 189] (LE 2A), two prospective non-randomized studies [204, 205] (LE2B), five retrospective studies [181, 182, 192, 206, 208] (LE 3) and a systematic review [197] (LE2A).

The impact of robotic-assisted proctectomy on circumferential resection margin (CRM) involvement, however, remains controversial. Several studies report no significant differences in CRM involvement as compared to laparoscopic-assisted proctectomy [187, 189, 192, 204–206, 208] (LE2A; LE2B, LE3). Nonetheless, a few retrospective case-matched studies found significantly decreased CRM involvement after robotic-assisted proctectomy [181–183] (LE3B). A confounder in the current literature on CRM is its reporting as a discrete variable defined as greater than 1 mm [204, 206] (LE2B, LE3B) or greater than 2 mm [181] (LE3) rather than continuous variable in mm. Currently, there is limited literature dedicated to assessing the quality of TME in robotic proctectomy [183, 184, 192, 194] (LE3B).

The potential benefit of robotic TAMIS is in overcoming the technical limitations of standard TAMIS involving improved dexterity in cases of difficult manipulation and suturing. The literature on robotic TAMIS is limited representing cadaver studies [209] (LE5) and case reports without comparisons [210, 211] (LE4).

Rectal prolapse

Statement: Robotic rectopexy for rectal prolapse shows comparable clinical outcomes to the standard laparoscopic counterpart (LE3B)

There is limited literature on robotic rectopexy for rectal prolapse. Several studies reported significantly longer operative times for robotic rectopexy as compared to laparoscopic rectopexy [212–214] (LE3B). Mean operative time ranged from 152 to 221 min as compared to a range from 113 to 163 min, respectively. However, a few other studies reported no such differences [215, 216] (LE3B). It is controversial whether the functional results of robotic rectopexy are any different from the laparoscopic counterpart [217] (LE 2A). While earlier reports showed similar functional outcomes [214, 218] (LE3B), more recent studies claim significantly improved obstructed defecation scores, improved digitation, and straining following robotic rectopexy [213] (LE3B). In terms of recurrence rates after surgery, one study reported significantly higher rates 2 years after robotic rectopexy [218] (LE3B). Nonetheless, all papers shared the limitations of small sample size and short-term follow up. A recent systematic review confirms the limited literature about robotic rectopexy with studies that showed longer operative times, less estimated blood loss and shorter length of stay [219] (LE2A).

The current literature reveals that there is a high prevalence of the use of mesh in robotic rectopexy. Currently, this practice is not evidence-based as a large pooled analysis suggested that the addition of mesh does not decrease recurrence rates when compared to suture rectopexy [220] (LE2C). The literature review [214, 216, 218] (LE3B) revealed that the suspension of the rectum was performed laparoscopically in most studies, whereas rectal mobilization was performed robotically. Mesh fixation to the promontory was accomplished with metal tacks [214, 216, 218] (LE3B), a technique that is not a substitute for suturing. In fact, laparoscopic suture rectopexy resulted in lower complication rates, improved continence and a 20 % recurrence rate at median follow-up of 13 years in patients with no pre-existing constipation [221] (LE4). A potential benefit for robotic rectopexy could be facilitating of suturing with intracorporeal knot tying [215] (LE3B). Preservation and improvement of function in pelvic floor disorder surgery requires meticulous dissection and preservation of the autonomic nerve supply by careful dissection. Robotic assistance can be advantageous particularly in the narrow pelvic space due to the high-definition three-dimensional stereoscopic and magnified vision, instruments with multiple degrees of freedom, improved ergonomics, motion scaling and tremor-free movements [214, 222] (LE2A, LE3B). Compared to classic laparoscopy,

robotic surgery could provide enhanced dexterity with decreased risk of nerve damage, safer and more precise movements in the pelvis, easier intracorporeal suturing, and less conversions [223] (LE4).

Colectomy

Statement: Robotic-assisted colectomy shows comparable clinical outcomes to standard laparoscopic colectomy (LE1B)

Potential benefits of robotic-assisted colectomy include lower conversion rates to laparotomy [219, 224, 225] (LE 2A) as compared to laparoscopic-assisted colectomy. It is noteworthy, robotic-assisted colectomy is currently still performed in most cases with laparoscopic assistance, which includes vessel sealing device, stapler, and suction/irrigation. An additional potential benefit of robotic-assisted colectomy consists of possibly increased feasibility of handsewn intracorporeal anastomosis in right colectomy [226, 227] (LE4). Intracorporeal ileocolic anastomoses offer advantages compared to their extracorporeal counterpart [228] (LE 2C). Moreover, handsewn intracorporeal ileocolic anastomoses have been shown to provide benefits when compared to stapled anastomoses [229] (LE 2C). However, unlike right colectomy, left colectomy may involve three abdominal quadrants and therefore require redocking leading to slightly increased operating time.

The literature includes one RCT [230] (LE 1B) and several retrospective comparative studies [225–227, 231–236] (LE 3) [235]. Nonetheless, a large administrative database reported significantly shorter hospital stay in patients undergoing robotic-assisted colectomy by high-volume surgeons and/or in high-volume hospitals as compared to low volume counterparts [198] (LE2C).

A higher incidence of venous thromboembolic events has been reported following robotic-assisted colectomy [237] (LE 2C) Although this association has been ascribed to longer operative times [219] (LE 2A), it is unclear to which extent docking and undocking time may contribute to increased operative time in low-volume hospitals. In fact, administrative databases do not include data on operating time and/or its breakdown [198, 237] (LE 2C).

Robotic single-port access may increase the feasibility of sub/total colectomy through the abdominal wall defect of pre-existing or anticipated ileostomy [238] (LE 5). The subgroup of patients benefitting from robotic single-port sub/total colectomy with ileostomy may include acute refractory colitis and/or indeterminate colitis [239] (LE4).

Statement: Robotic-assisted colectomy performed by low-volume surgeons may result in increased rates of postoperative complications when compared to the rates following high-volume expert surgeons (LE2C)

Low-average-and high-volume surgeons were defined as performing an annual volume of <5, 6–15, >15 cases. Postoperative complications increased among low-volume surgeons (<5 cases) and included bleeding, postoperative ileus, anastomotic leakage, and enterocutaneous fistula [198] (LE 2C).

Statement: There is limited literature assessing the histological extent of robotic-assisted segmental colectomy for colon cancer (LE1B)

Of the several available metrics [219] (LE 2A), the current literature has only addressed the lymph node harvest reporting no differences [225–227, 230–232, 234] (LE 1B). Overall and disease-free 3-year survival rates after robotic-assisted sigmoid resection for sigmoid cancer seem similar to those of laparoscopic sigmoid resection [236] (LE 3).

Future outcome measures of robotic colectomy should include detailed histological metrics.

Bariatric surgery

Obesity is a worldwide epidemic, and the only evidence-based, durable treatment of this disease is bariatric surgery. Bariatric surgery is an effective treatment to obtain durable weight loss in severely obese patients.

Statement: Robotic-assisted bariatric surgery shows comparable clinical outcomes to standard laparoscopic bariatric surgery (LE3A)

Robotic surgery has been applied in many different bariatric procedures including gastric banding, gastric bypass, sleeve gastrectomy, and biliopancreatic diversion/duodenal switch. It was also reported that robot-assisted RYGB could be performed safely for Super Obese patients (BMI > 50 kg/m²). (LE4) [240] Some author's have described the assistance of the robot during part of the procedure (robot-assisted) and others its use for the entire procedure (totally robotic). Many series and reviews show that bariatric surgery, when performed with the use of robotics, had similar or lower complication rates as compared with traditional laparoscopy (LE3A) [241]. A systematic review demonstrated that robotic-assisted bariatric surgery is both a safe and feasible option for severely obese patients. (LE3A) [242]. The major complication rates did

not differ significantly between robotic and laparoscopic RYGB in a recent review. Also, no significant difference was found in specific complications including anastomotic leak, bleeding, stricture, or reoperation. These outcomes represent EL3 for the same reasons as for the overall complications. The operative times reported in a review, found no significant difference in operative time between techniques, although a mean difference of 15.96 min favored laparoscopic RYGB [243].

Robotic surgery confers several theoretical technical advantages over traditional laparoscopy that may enable more precise manipulations and increased dexterity by downscaling the surgeon's movements. (LE3A) [241, 244] These technical advantages are expected to improve clinical outcome in more complex minimally invasive procedures like gastric bypass in particular with important steps of the procedure such as anastomotic suturing. (LE5) [244] However, this has not been translated to a real outcome in clinical practice.

The largest series of patients collected includes a total of 1100 Robotic-Assisted RYGBs from two centers. The patients had a mean preoperative age of 46.9 years, mean weight of 131.9 kg, and mean body mass index of 47.9 kg/m². In this review, the mean operative time was 155 min with no conversions reported. Complications described were few, and included two cases of pulmonary embolism (.19 %), three cases of deep venous thrombosis (.27 %), one case of gastrojejunal anastomotic leak (.09 %), and nine cases of staple line bleeding (.82 %). The mortality rate reported by the authors was zero. (LE4) [245].

In another published review including 22 series and a total of 1,253 patients who underwent Robotic-Assisted RYGB with a mean preoperative body mass index of 46.6 kg/m² were obtained from 13 included studies. Major complications of malabsorptive procedures included low rates of anastomotic leaks (2.4 %), bleeding (2 %) and strictures/stenosis (3 %). There were no reported deaths. (LE3) [242].

RSG is a safe alternative when used in bariatric surgery, showing similar results as the laparoscopic approach. Surgical time is longer in the robotic approach, while hospital length of stay is lower. No leaks or strictures were found in the robotic cases. However, further studies with larger sample size and randomization are warranted. (LE4) [243] Finally, robotic surgery in bariatrics is evolving in the revisional surgery and may confer some advantages when more complex procedures and suturing are required [246, 247, 248].

The learning curve of complex bariatric procedures appears to be shorter when robotic gastric bypass is compared with the traditional laparoscopic approach (LE3A)

[241]. The learning curve for the RA-LBPD/DS is estimated to be 50 cases. (LE4) [249] Robotic SG may be an initial procedure before performing more complex procedures. When considering the learning curve for the sleeve gastrectomy, nineteen cases is the number suggested. (LE4) [250] Cost issues and operative times will need to be more clearly estimated in the future [247].

Shorter operative times were demonstrated in a few studies using the robot for Roux-en-Y gastric bypass; however, many case series studies showed longer operative times in the robotic arm. (LE3A) [241] Expected costs, however, were greater for robotic RYGB. (LE3A) [243] While safe and intuitive, the robotic approach was burdened by a longer operative time and higher equipment costs. Moreover, it did not seem to provide a real advantage over standard laparoscopy in terms of hospital length of stay and complications rates. (LE3B) [251].

Despite the advantages related to robotic technology in the field of bariatric surgery, the procedures are associated with increased cost and operative time, which may limit its use in less complicated procedures such as gastric banding. (LE3) [244] There is limited data regarding use of the robot for gastric banding, as it seems that the procedure is too simple to be performed with this technology.

Future high-powered randomized controlled trials are required to accurately evaluate clinical outcome and cost-effectiveness of robotics both in gastric bypass and in sleeve gastrectomy and to further define the role of robotics within the field of bariatric surgery. Longitudinal studies would also help elucidate any long-term outcomes differences with the use of robotics versus traditional laparoscopy.

Splenectomy

A literature search was performed using key words "robotic splenectomy" and "robotic partial splenectomy" yielding seventy articles. After excluding articles, a total of twenty-one papers written between 2002 and 2013 were reviewed. Of the articles found those that were excluded were three non-English (one in Japanese and two in Romanian). From the 21 papers, 16 were case reviews (LE 4), 3 were retrospective comparative studies (LE 3B) and 2 were reviews (LE 5). Many papers came from the same group of authors, which causes one to wonder if some cases were reported more than once. In the case of multiple articles reported by the same group of authors, only the last paper published by the group was considered in order to calculate the total number of patients operated. We found a total of 117 patients reported in the literature.

Statement: Robotic splenectomy and partial splenectomy have comparable clinical outcomes to standard laparoscopic splenectomy (LE3B)

Minimally invasive splenectomy improves patient morbidity, reduces length of stay in hospital, reduces perioperative pain and provides enhanced cosmesis. However, the breadth of minimally invasive splenectomy procedures now includes hand-assisted LS (HALS), natural orifice transluminal endoscopic surgery (NOTES), robot-assisted splenectomy and single-port access (SPA) splenectomy. All the papers reviewed indicated that robotic splenectomy surgery was safe using the da Vinci[®] Robot. There was no statistically significant difference regarding intraoperative blood loss, conversion rate to laparotomy, food intake, drain removal, postoperative complications, and median time to discharge. [252–255].

Statement: Robotic splenectomy and subtotal splenectomy have longer operative time and higher costs compared to standard laparoscopic ones (LE3B)

In a retrospective study comparing 6 robotic versus 6 laparoscopic splenectomies mean operative time was statistically longer being 154 min in respect of 127 min. In another comparative study including a total of 32 cases of subtotal splenectomy the reported operative time was 107 min in the robotic group and 95 for the laparoscopic one.

In all the studies analyzed robotic splenectomies were always associated with higher costs [256, 257].

Adrenalectomy

Statement: Robotic adrenalectomy has comparable clinical outcomes compared to standard laparoscopic adrenalectomy (LE3B)

Since the first robotic adrenalectomy less than a decade ago, this modality has gained increased acceptance in the urologic community and has been employed with increased frequency in minimally invasive centers [258]. In a preliminary comparative study by Morino of 20 patients and reviews that followed, reported a slightly higher complication rate. (LE2B) [255], (LE3B) [259, 260].

Studies of robotic adrenalectomy and laparoscopic adrenalectomy show that the techniques are both safe and effective when compared to an open approach. (LE3B) [261]. Robotic technology is an acceptable option in high volume robotic centers from the standpoints of outcomes, feasibility, and cost. (LE3B) [261]. Robotic techniques for adrenalectomy may have potential advantages compared

with laparoscopic adrenalectomy, but no objective superiority has been demonstrated thus far. Surgical outcomes have been comparable with laparoscopic adrenalectomy, although there have been no randomized controlled studies. (LE5) [262].

Robotic surgery has proven to assess the surgical anatomy of the adrenal glands, its vascularization, and the surrounding structures, through a high definition and magnified three-dimensional view of the operating field provided by the da Vinci[®] surgical system. [263] Robotic surgery offers the potential for increased visualization and faster learning curve which may allow for both faster, and more precise dissection, as well as increased utilization of minimally invasive techniques. Robotic-assistance offers unique advantages in visualizing and dissecting the adrenal gland, especially considering its challenging vasculature. Success in these procedures depends on a firm understanding of adrenal anatomy as well as in careful patient selection. (LE3B) [261]. The learning curve for robotic adrenalectomy, the point after which conversion rates and operative times significantly decrease, is more than 20 cases even in surgeons with extensive laparoscopic experience. (LE3B) [261] Robotic adrenalectomy can be performed even in the pediatric population. [264] However, there is still a lack of clinical data demonstrating improved outcomes for robotic surgical applications for adrenalectomy (LE4) [254, 265, 266]. In order to elucidate the real benefit compared to the exorbitant costs associated with the use of these tools, more outcomes data for surgical robotics is required.

Other robot-assisted procedures reported include: robot assisted laparoscopic adrenalectomy for adrenocortical carcinoma, (LE4) [267] unilateral or synchronous bilateral adrenalectomy using the da Vinci[®] robot, (LE4) [254] and single and retroperitoneal adrenalectomy site robotic adrenalectomy. (LE4) [253, 268] (8).

Expert panel opinion: There seems to be a potential in using robotic surgery for large right-sided tumors. The panel outlines this area as a direction for study as there is enough evidence for an ethical basis for randomized trials.

Transaxillary thyroidectomy

From open to endoscopic to robotic-assisted minimal invasive thyroidectomy

Minimally invasive approaches for thyroid diseases are relatively new and not yet considered the standard of care. Since its introduction in 1997 various techniques of endoscopic thyroid lobectomy have been described in the literature [269–272]. Endoscopic thyroidectomy has been touted as having superior cosmetic results as compared

with open thyroidectomy, while providing similar surgical outcomes even for the treatment of selected malignant tumors. Currently there are no meta-analysis studies comparing open vs endoscopic approaches [273].

Endoscopic thyroidectomy is a technically challenging procedure. A limited 2 dimensional visualization within a small operative field combined with current standard instrumentation makes dissection very challenging. Due to the technical difficulty that endoscopic thyroidectomy entails, there are only a handful of surgeons performing this procedure worldwide. The da Vinci[®] robotic system with its increased dexterity has been shown to overcome many of these limitations and difficulties as noted above, and may prove to be as revolutionary in thyroid surgery as it did in urology with prostatectomy.

Robotic-assisted vs standard endoscopic thyroidectomy

A search was performed using the terms ‘robotic’, ‘thyroidectomy’ and ‘neck surgery’ yielding 165 abstracts, of which only 132 were considered eligible for review.

Statement: Robotic-assisted transaxillary thyroidectomy has comparative clinical outcome to endoscopic transaxillary thyroidectomy (LE3B)

Jackson et al. in a recent systematic review of the literature, 143 references were retrieved, of which 9 publications were analyzed [274]. Overall 2,881 patients are represented in this analysis, with distribution across open (794 patients), endoscopic (965 patients), and robotic (1,122 patients) approaches to thyroidectomy. Of the 1,122 patients undergoing robotic-assisted thyroidectomy, 69 patients underwent the bilateral axillo-breast approach (BABA) and 1,053 patients underwent the gasless, transaxillary approach. Four articles directly compared conventional open thyroidectomy with robotic thyroidectomy, four articles [275–278] compared endoscopic thyroidectomy with robotic thyroidectomy, and one article used BABA to compare with all three approaches [274]. Jackson et al. [274] concluded that when compared to endoscopic approach, the clinical outcomes were comparable in terms of length of stay, and postoperative complication rates. Cosmetic satisfaction, however, was higher in the robotic group and although not statistically significant, the length of operation was 20.99 min shorter in the robotics group versus the endoscopic group. They also found a decreased need for an additional surgical assistant in the robotics group, which may have an effect on the overall cost.

In a meta-analysis comparing robotic vs endoscopic thyroidectomy, six non-randomized comparative studies

were analyzed. Of 2,048 patients, 978 underwent robotic thyroidectomy while 1,070 underwent endoscopic thyroidectomy. There were no differences in conversion rates, operative time, length of post-operative hospital stay, or number of lymph nodes harvested between robotic and pure endoscopic approaches. The authors did note that robotic thyroidectomy was associated with a greater amount of post-operative fluid drainage [279].

Statement: Robotic and endoscopic thyroidectomy showed comparable operative time and postoperative outcomes with the exception of a higher risk of transient hypocalcemia in the robotic approach (LE 3B) [275–278]. In cases of central compartment neck dissection Robotic thyroidectomy had a shorter mean total operative time and a higher number of retrieved central lymph nodes (LE3B)

In a study by Lee et al. [276] comparing robotic to endoscopic thyroidectomy, the robotic approach was found to have a shorter operative time (110 vs. 142 min), improved lymph node retrieval (4.5 vs. 2.4), and a shorter learning curve (35–40 vs. 55–60). In Both approaches postoperative length of stays and complication rates were similar. Another study by Lee et al. [277] compared 580 patients undergoing robotic approach to 570 in the endoscopic approach. They found improved lymph node retrievals in the robotic group with a higher incidence of postoperative transient hypocalcemia (12.5 % vs 0) when compared to the endoscopic group. Lang et al. [275] found that compared to the endoscopic approach, the robotic approach afforded a higher rate of identification of the contralateral recurrent laryngeal nerve (100 vs. 42.9 %) with a slightly longer operative time initially that was attributed to the learning curve. However blood loss, hospital stay, and surgical complications were similar in both groups. These findings confirm that in difficult cases, specifically those requiring more complex dissection, robotic-assisted surgery is superior due to the available increased dexterity [276].

Statement: Robotic-assisted transaxillary thyroidectomy achieves same quality of histopathology metrics when compared to endoscopic approach (LE3B) [280]

In a study by Lee et al. [277], comparing endoscopic to robotic approaches mean tumor size was comparable; however, capsular invasion and central nodal metastasis were more common in robotic group then endoscopic group. Overall the number of retrieved central lymph nodes was statistically significant higher in the robotic group.

Hospital stay, operating time, intra-op complications and post-op outcome were similar between the two groups.

Two more issues worthwhile to be mentioned when dealing with robotic thyroidectomy: the learning curve and sensory changes of the skin flaps. The current literature on robotic-assisted transaxillary thyroidectomy suggests that the learning curve is 50 cases for total thyroidectomy and 40 cases for subtotal thyroidectomy.

In a prospective, controlled, multicenter study including 644 total or subtotal thyroidectomies, Lee et al. compared the outcomes in terms of operative time, blood loss, hospital stay, pathologic results, and postoperative complications between one experienced (ES) and three non experienced (NS) robotic surgeons. Mean operative time was longer and the complication rate was higher for the NS patient group compared with the ES patient group ($P < .001$ for each). The operative times and complications rates for the NS group were similar to those of the ES group once the NS had performed 50 cases for total thyroidectomies or 40 cases for subtotal thyroidectomies [281].

Concerns exist about potential sensory changes of the skin flaps after BABA (bilateral axillo-breast approach) especially of the breast area. In a prospective cohort study Kim et al. analyzed that sensation of the breast area on 19 patients at three points in time: prior to surgery, and 1 and 3 months postoperatively. Chest area sensation was assessed using Semmes–Weinstein monofilaments, a biothesiometer and an infrared thermometer. The testing showed sensation was affected at 1 month postoperatively as compared to preoperative baseline, but returned to baseline by 3 months postoperatively [282].

Donor nephrectomy

Statement: Robotic-assisted donor nephrectomy has comparable clinical outcomes when compared to standard laparoscopic donor nephrectomy (LE3B), even when a right nephrectomy is performed with a less favorable vascular anatomy (LE4)

Donor nephrectomy has been performed laparoscopically for more than a decade, and in many places transformed transplantation programs by increasing the numbers of potential donors significantly. The use of robotic assistance in these procedures may have two theoretical advantages. Firstly, the dexterity and enhanced imaging may help perform the procedure complex vascular anatomy is present. Secondly, the potential of the assistance of a robot may allow more surgeons to perform donor nephrectomy using minimally invasive techniques.

There are a number of case series and case reports on robotic-assisted laparoscopic donor nephrectomy, most of

them are short case series and case reports finding the procedure to be safe, but not reporting any advantage over laparoscopic donor nephrectomy [283–285]. There are some comparative studies in the English literature, all of which compare historical results or cohorts. One such study by Renoult et al. compared robotic-assisted donor nephrectomy to historical results of open donor nephrectomy [286]. The study demonstrates very similar results except for a shorter hospital stay in the robotic group, which is consistent with comparisons between open and minimally invasive procedures. Another study by Xiaolong et al. [287] does not demonstrate a difference in complication rate or kidney function when comparing laparoscopic to robotic donor nephrectomies in which the right kidney is used even with potentially a more complex vascular anatomy. Interestingly, Oberholzer et al. [288] does not report a difference in surgery results but rather found an increase in the number of donor nephrectomies since the introduction of robotic assistance to the program.

Miscellaneous procedures

Although an extensive search in the literature was made, several procedures in general surgery had a very low number of significant publications. The following is a short summary of current data on these procedures:

Robotic hernia repair

Several case reports described the addition of laparoscopic inguinal hernia repair as part of robotic radical prostatectomy. The current literature describes the use of standard TAPP approach safely using a robot. There is no long-term efficacy data aside from reporting the technique. [289, 290] There are also some case reports that describe the use of suture fixation of the mesh in ventral hernia repair using robotic assistance, with potentially better outcomes than by tacking it. [291]

No comparative studies were found that prove such an advantage. Currently a randomized trial on incisional hernia is underway when it concludes it will be interesting to see what those findings will be.

Robotic Para-thyroidectomy

An extensive data search produced very few papers, dating from 2004 through January 2014. There were 16 abstracts found of which five reports were related to case series, the largest one including 11 patients.

One paper [292] describes robotic assistance for the resection of mediastinal parathyroid, which may have a value because it turns it into a minimally invasive procedure.

Cost effectiveness of robots in general surgery

Introduction

Cost effectiveness analysis in healthcare is defined as “an economic evaluation that examines both the costs and the health outcomes of alternative intervention strategies” [293]. This is not to be confused with business models put forward which suggest purchase of new technology is cost-effective for an organization because it may attract more patients and thereby generate more revenue. The majority of the evidence regarding cost effectiveness in robotic surgery has been generated in studies looking at prostatectomy and hysterectomy. Both Irish [294] and Canadian [295] Health Technology Assessments concentrated their analyses on urological and gynecological procedures, stating that for most other procedures there was not yet enough evidence to allow an assessment of efficacy or cost effectiveness. We have analyzed 677 papers searched for under the terms robotic surgery cost and robotic surgery cost effectiveness. A total of 42 papers addressed cost and/or cost effectiveness of robot-assisted surgery in general surgical procedures. There were four randomized controlled trials, four meta-analyses, two systematic reviews, with the rest of the papers made up of case series or case series with matched or historical controls. The procedures examined were gastrectomy (3 papers), Roux-Y-gastric bypass (5 papers), thyroidectomy (5 papers), benign esophageal surgery (6 papers), colonic surgery (11 papers), adrenal surgery (3 papers), liver surgery and cholecystectomy (2 papers each), pancreatic and splenic surgery (1 paper each) and finally all general surgery (3 papers).

The level of evidence for the costs of robotic surgery is poor. The randomized trials that have been undertaken are small and underpowered. Case series, matched with contemporaneous or historical controls are open to huge bias in terms of both case selection and learning curve and do little to help us assess the cost-effectiveness of robotic surgery. It is clear from the literature available that robotic-assisted surgery produces comparable outcomes across a range of general surgical procedures. Also, different authors measure the cost of using a robot differently. Some measure direct OR costs only, others, total hospital costs, and some, hospital bills (which includes the hospitals profit); there is no consistency. In addition to this, the cost of using a robot decreases as annual throughput of cases increases with many authors suggesting upwards of 300 cases per annum as the point at which such expensive equipment becomes potentially “cost effective”, or represents a valid business case for a hospital. Data on case throughput is not recorded in any of the papers studied.

Much of the work published to date is during the learning curve of the authors and there is some evidence that operating time may fall with time [296] with one

author reporting a set up time of just 7 min for their last 50 cases. The vast majority of trials and case series that have addressed cost or cost effectiveness of robotic surgery across general surgical procedures have found equivalent clinical outcomes at consistently higher OR and total costs. There is, however, very little level 1 evidence to allow the many confounding variables of case series to be excluded from these conclusions.

Statement

Robotic general surgery is more expensive than conventional laparoscopic surgery with comparable clinical outcomes (LE 1B)

General Surgery

Several American papers have studied robotic surgery with the aid of large national patient databases. Wormer et al. [297] looked at a nationwide sample of patients between October 2008 and December 2010 and found out of 297,335 general surgical procedures there were just 1,809 robotic cases. Dividing the data up further to examine the most prevalent procedures, they found overall cost for laparoscopic gastrojejunostomy was \$60,837 as compared to \$28,887 for a laparoscopic approach. For fundoplication the difference was smaller at \$37,638 as compared to \$32,947. In contrast Salman et al. [298] looked at a later series containing 1,389, 235 patients from which 37,270 (2.6 %) had robotic surgery and found robotic costs to be lower at \$30,540 as compared to \$34,537 for laparoscopic surgeries. Two further nationwide surveys [198, 237] looked at 744 and 2,583 robotic cases respectively. The robotic surgery cost \$5,272 more and took 39 min longer in the study by Keller et al. as compared to costing \$3,424 in the study by Tyler et al.

Colorectal surgery

Park et al. [230] performed a randomized trial of robotic versus standard laparoscopic right hemi-colectomy. With 35 patients in each group they detected no significant clinical differences in the outcomes of the two cohorts. The hospital costs for robotic surgery were \$ 12,235 for robotic surgery as compared to \$10,320 for standard laparoscopic surgery. The authors commented that the increased cost was mainly due to the consumables needed for the robotic cases. Mirnezami et al. [299] performed a systematic review, identifying 17 papers with 288 patients. The data was too heterogenous for a formal systematic review, nevertheless the authors found clinical outcomes to be similar while operating time was longer and cost greater for robotic surgery. A second systematic review in 2013 [300]

identified 351 patients in case series that had robotic colonic surgery and again clinical outcomes were similar, but robotic surgery took longer and cost more.

In further case series looking at rectal resection [208, 301] the cost of robotic surgery was \$ 14,647 as compared to \$ 9,978 for laparoscopic surgery in one series and stated as more expensive for the robot in the other. Three further series looking at colectomy and compared patients to in house historical controls [231, 233, 234] all stated the robot was equivalent in terms of clinical outcomes and more expensive with Rawlings et al. [233] estimating excess OR cost at \$1,484. A small series of robot assisted rectopexy [214] assessed excess cost at \$745 per case while another paper [302] highlighted the cost of special drapes at \$350 per case.

Benign esophageal disease

In a small RCT with 20 patients [303] Nakadi et al. found identical clinical outcomes but commented the robotic surgery was far more expensive. A meta-analysis by Markar et al. [304] identified 226 patients in 6 studies which again demonstrated clinical equivalence between laparoscopic surgery and robotic-assisted fundoplication, but operative time and cost were increased. A second meta-analysis with 221 patients had similar findings [305]. Another review [306] identified 91 cases of robotic-assisted fundoplication with an excess cost of 1883 Euros per case. One further small case series [307] with eleven patients found robotic surgery took 47 min longer than a laparoscopic approach and cost 987 Euros more per case. One study has looked at Heller's myotomy in a multicenter retrospective analysis [308] and found that 149 robotic cases cost on average \$9415 as compared to \$7441 for \$2116 laparoscopic cases.

Gastrectomy

In a meta-analysis of 7,200 patients in nine separate studies, Hyun et al. [132] found both that robotic gastrectomy was more costly and took on average 62 min longer per case than a traditional laparoscopic approach. In a series of 30 robotic gastrectomies, Park et al. [230] found equivalent clinical outcomes, but an excess cost of 3,189 Euros per case for robotic surgery. Similarly, Eom et al. [309] compared 30 robotic distal gastrectomies with 62 laparoscopic procedures from the same institution and found both operative time and costs were increased for the robotic surgery.

Bariatric surgery

The only randomized controlled trial to look at OR time and cost for robotic bariatric surgery studied the

performance of a new fellow who randomized his RYGB operations between robotic and laparoscopic approaches [310]. In this unique setting average operative time was 124 min for the robot as compared to 153 min for standard laparoscopy. These observations are of interest as they may suggest advantages in favor of the robot in those learning new procedures. In a meta-analysis covering ten studies with 2,557 patients undergoing robotic RYGB [311] robotic surgery took longer and cost on average \$15,447 per case as compared to \$11,956 for laparoscopic surgery. In a retrospective review of institutional performance, Hagen et al. [312] compared 524 open RYGB with 323 laparoscopic procedures and 143 robot assisted cases. Robotic surgery had fewer leaks than their laparoscopic cases and also cost less at \$19,363 as compared to \$21,697 for laparoscopic cases. In contrast Scozzari et al. [251] compared 423 laparoscopic RYGB with 110 robotic cases and found clinical equivalence but an excess cost of 11,20 Euros per robotic case. In another comparative study Hubens et al. [313] looked at 45 robotic and 45 laparoscopic RYGB and found that robotic surgery cost more and also that there were several small bowel injuries during their learning curve with the robot.

Thyroidectomy and adrenalectomy

Broome et al. [314] in an institutional review found that robotic thyroidectomy cost an average of \$5,795 as compared to \$2,668 for a laparoscopic case. Yoo et al. [138] undertook a similar institutional review of 165 laparoscopic thyroidectomies and compared them to 46 robotic cases. Their OR costs showed a laparoscopic case cost \$829 as compared to \$6,655 for a robotic case. A third comparison of 140 thyroidectomies in two institutions [315] found total hospital costs for open, laparoscopic and robotic surgery to be \$9028, \$12505 and \$13670 respectively. Other authors commented on the advantage of a favorable body habitus for robotic thyroidectomy raising the possibility of some selection bias in these series.

One small randomized trial of laparoscopic versus robotic adrenalectomy [255] compared two groups of 11 patients and found increased morbidity in the robotic group and increased cost of \$730 per case. Brunaud et al. [316] looked at 100 robotic adrenalectomies and found average cost per case was 4102 Euros as compared to 1799 Euros for laparoscopic cases. A small pilot series from Holland [317] cost the OR for robotic adrenalectomy at 1181 Euros per case which was stated as more expensive than a standard laparoscopic approach. One further series of 30 robotic adrenalectomies looked at hospital charges [318] and found that robotic surgery was \$1378 more per case.

Hepatopancreatobiliary surgery

One study has compared robotic surgery with laparoscopic cholecystectomy with 50 cases in each group [60]. Clinical outcomes were identical but robotic surgery cost \$7,985 per case as compared to \$6,255 for laparoscopic surgery. An institutional review of distal pancreatectomy [109] looked at 32 open cases, 28 laparoscopic cases and 17 robotic cases. With the caveat that there were fewer malignancies in the robotic group, the survey found that robotic surgery took longer in the OR but cost less (\$10,588 as compared to \$12,986 for laparoscopic and \$16,059 for open) largely because hospital stay was reduced in the robotic group. It is not clear whether this was because of case selection or an inherent advantage of robotic surgery. One study has looked at liver resection comparing 11 robotically assisted left lateral segmentectomies with 18 laparoscopic cases [97]. The authors found that there were more complications in the robotic group and equipment costs were \$6,553 per case as compared to \$4,408 for laparoscopic cases.

Summary

Following an extensive literature search and a consensus conference with subject matter experts the following conclusions can be drawn:

1. Robotic surgery is still at its infancy, and there is a great potential in sophisticated electromechanical systems to perform complex surgical tasks when these systems evolve.
2. To date, in the vast majority of clinical settings, there is little or no advantage in using robotic systems in general surgery in terms of clinical outcome. Dedicated parameters should be addressed, and high quality research should focus on quality of care instead of routine parameters, where a clear advantage is not to be expected.
3. Preliminary data demonstrates that robotic system have a clinical benefit in performing complex procedures in confined spaces, especially in those that are located in unfavorable anatomical locations.
4. There is a severe lack of high quality data on robotic surgery, and there is a great need for rigorously controlled, unbiased clinical trials. These trials should be urged to address the cost-effectiveness issues as well.
5. Specific areas of research should include complex hepatobiliary surgery, surgery for gastric and esophageal cancer, revisional surgery in bariatric and upper GI surgery, surgery for large adrenal masses, and rectal surgery. All these fields show some potential for a true benefit of using current robotic systems.
6. Robotic surgery requires a specific set of skills, and needs to be trained using a dedicated, structured training program that addresses the specific knowledge, safety issues and skills essential to perform this type of surgery safely and with good outcomes. It is the responsibility of the corresponding professional organizations, not the industry, to define the training and credentialing of robotic basic skills and specific procedures.
7. Due to the special economic environment in which robotic surgery is currently employed special care should be taken in the decision making process when deciding on the purchase, use and training of robotic systems in general surgery.
8. Professional organizations in the sub-specialties of general surgery should review these statements and issue detailed, specialty-specific guidelines on the use of specific robotic surgery procedures in addition to outlining the advanced robotic surgery training required to safely perform such procedures

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