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11 Robotic surgery training, simulation, and data collection

11.1 History and progress of training in minimally invasive surgery

Minimally invasive surgery, done either robotically or laparoscopically, has many advantages over traditional open surgery when performed successfully. These include fewer or smaller incisions, decreased blood loss, less pain, reduced infection, reduced scarring, and potentially shorter hospitalizations with faster recovery times for patients.

Among minimally invasive surgery types, laparoscopy is by far the most common. The term *laparoscopy* refers to procedures performed inside the abdomen and pelvis, using special surgical tools and a camera. These are placed into the patient through small incisions where trocars are placed. The trocars serve as pivots and points of reference for the laparoscopic instruments. The body cavity is usually insufflated with CO_2 gas, to allow more room for manipulations. Laparoscopic techniques feature prominently in general surgery, gynecology, and urology. Examples of laparoscopic procedures done by general surgeons include appendectomy, cholecystectomy, esophageal surgery, gastric surgery, colorectal surgery, liver surgery, adrenalectomy, pancreatectomy, splenectomy, and hernia repair, to name a few.

To facilitate surgeon training in laparoscopy, the American Board of Surgery (ABS) implemented the Fundamentals of Laparoscopic Surgery (FLS) training course in 2008 as a mandatory prerequisite for the ABS certifying exam. The FLS curriculum was implemented by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) in 1999, designed to teach the fundamental knowledge and technical skills required for basic laparoscopy in a standardized and systematic manner [1]. The cognitive component consists of preoperative considerations, intraoperative considerations, basic laparoscopic procedures, and postoperative considerations, which are presented in the way of didactic modules. Meanwhile, the hands-on component consists of exercises that teach bimanual dexterity through tasks involving the manipulation of objects inside a training box physical simulation environment. The FLS manual tasks are peg transfer, precision cutting, ligating loop placement, suture with extracorporeal knot, and suture with intracorporeal knot. Each task has objective benchmarks of efficiency and precision, obtained from experts, as well as defined errors with penalties, which trainees should learn to avoid [1]. Upon completion of the FLS skills-based training curriculum, which on average takes about 10 hours of distributed learning through numerous repetitions of each task, surgeon candidates

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then complete a high-stakes examination where they must demonstrate standardized levels of proficiency to obtain FLS certification [2].

Robotic surgery, also known as robot-assisted surgery, differs from laparoscopy in a number of ways. First of all, it restores some of the visuospatial deficit that is lost in laparoscopy, through 3D stereoscopic visualization. Second, there are additional features that can be desirable for the surgeon, including tremor filtering, eye tracking, and navigation, which can enable the surgeon to be more precise, while potentially saving valuable time intraoperatively in the operating room (OR). One downside to robotic surgery, besides the much higher cost of purchase and maintenance, is the longer set up time, also known as docking time, when compared with laparoscopy. Readers should also recognize that the number of FDA-approved surgical robotic devices available on the market is very limited thus far, when compared with the ubiquitous number of FDA-approved laparoscopic tools and instruments, which are readily available on the market for surgeons or healthcare facilities to purchase and use (Figs. 11.1 and 11.2).

Fig. 11.1: da Vinci Surgical Robot. Left image credit: Creative Commons 3.0 Unported License, Photo taken by: cmglee, WikiMedia Commons. https://commons.wikimedia.org/wiki/File:Cmglee_Cambridge_Science_ Festival_2015_da_Vinci.jpg. Right image credit: US Army, taken by: Jeff L Troth https://www.army.mil/article/152941/robotic_da_vinci_arrives_at_evans.

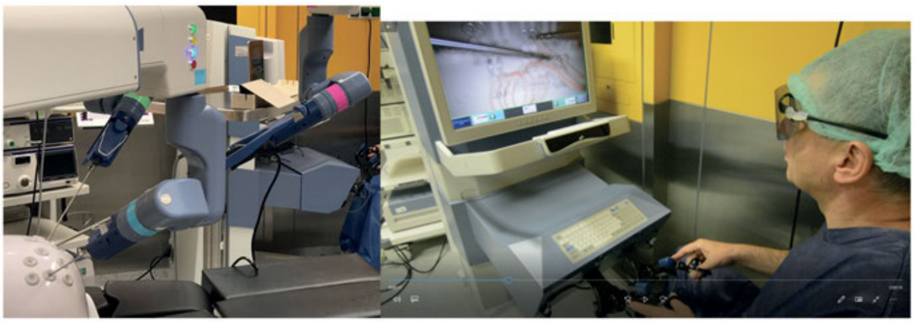

Fig. 11.2: Senhance Surgical Robot. Photo credit: own work.

The best known, most widely used, and most mature surgical robotic device on the world market is the da Vinci surgical robotic system from Intuitive Surgical Inc. Approved by the FDA in 2000, it held a monopoly share of the robotic surgery market and had virtually no competitor until the Senhance surgical robotic system from TransEnterix, formerly known as the Telelap ALF-X, which obtained FDA approval in 2017. Although other surgical robots with FDA approval exist, besides the da Vinci and the Senhance, they are not used for the purposes of general surgery. Specialized surgical domains with FDA-approved surgical robots include colonoscopy, catheter insertion, transoral surgery, and bronchoscopy. A review of current and emerging surgical robotic systems can be found in the 2019 review by Peters et al. [3] (Tab. 11.1).

Another significant difference between laparoscopy and robotic surgery is the fact that a standardized and accredited education curriculum for robotic surgery is still lacking. The most developed training program so far is the Fundamentals of Robotic Surgery (FRS) curriculum. The FRS was created with the goal of teaching the common set of skills to operate with robotic surgery devices [4]. However, it is worth noting that the curriculum was mainly built around the da Vinci surgical system because of its pioneer role in the introduction of robotic surgery, being the only FDA-approved robotic device for general surgical procedures and holding a monopoly share of the market

Tab. 11.1: Selected list of FDA-approved robotic surgery systems [3]

Device Name	Manufacturer	Surgery Types	Notable Features
da Vinci surgical robotic system	Intuitive Surgical	Laparoscopy, urology, gynecology, thoracoscopy	Tremor filtering
Senhance surgical robotic system	TransEnterix	Laparoscopy, gynecology	Haptic feedback, eye tracking, fully reusable instruments
FLEX robotic system	Medrobotics Corp	Transoral, pharyngeal, laryngeal	Telescopic instruments
SPIDER—single port instrument delivery	TransEnterix	Laparoscopy	Triangulation of instruments from port
NeoGuide Colonoscope	Intuitive Surgical	Colonoscopy	3D mapping
Invendoscopy E200 for colonoscopy	Invendo Medical GmbH	Colonoscopy	Sterile, single-use
FreeHand camera control system for laparoscopy	Freehand 2010 Ltd.	Laparoscopy	Laser guided
Sensei X surgical robot for cardiac catheter placement	Hansen Medical	Cardiac catheterization	Navigation, haptic feedback
Monarch Platform for bronchoscopy	Auris Health	Bronchoscopy	Navigation, user-friendly controller

since its release in 2000. The FRS curriculum is described in detail in Chapter 11.2. For the Senhance surgical system, a specific training program or simulation platform does not yet exist, although it was made to mimic traditional laparoscopy, unlike the da Vinci robot. This raises the very interesting research question of whether laparoscopic skills will be transferable to the newly FDA-approved Senhance robot, and how that might affect the learning curve for trainees. Our group is presently conducting a research study to answer this question.

The lack of a nonstandardized and nonaccredited curriculum raises concerns for patients, and regulatory bodies about whether surgeons are sufficiently trained to perform surgeries with these emerging technologies. The regulatory body responsible for the manufacturing, performance, and safety of medical devices is the FDA. According to the FDA, robotically assisted surgery is both safe and effective, when used by surgeons who have adequate training [5]. However, the FDA does not regulate or standardize the practice of medicine and physician training. Instead, the FDA views training, development, and implementation of medical devices as a responsibility of manufacturers, physicians, and health care facilities. It also argues for the role of professional bodies and specialty board organizations, such as the ABS, in regulating the training of physicians. The FDA further advises physicians and workplaces to ensure that all staff have adequate training and credentialing so that robotically assisted surgical devices (RASD) can be used safely and efficaciously. The concerns of the FDA regarding training and credentialing were recently made public, in a 2019 press release, cautioning patients and healthcare providers on the safe use of surgical robotic systems in breast cancer surgery [6]. In the article, the FDA clearly states that the RASD were approved for general use on the grounds of safety and efficacy, citing that insufficient evidence currently exists on whether these devices influence survival outcomes for patients undergoing oncologic surgeries such as mastectomy. The FDA therefore recommends that a common sense approach be taken when adopting this new technology, where adequate discussion with the patient must take place, with respect to the benefits, risks, and alternatives to doing such a surgery robotically.

Our aim in writing this book chapter was to review the current state of the art in robotic surgery simulation and training and to give readers the viewpoint of the surgeon, so that readers can explore and work on robotic surgery problems without losing sight of the needs of the surgeon, who after all is the end user for these exciting, new technologies. Readers are encouraged to further explore other recent reviews on the topic of robotic surgery devices, training, and simulation [3, 7–11]. In addition, readers may obtain the summary report from the Institution for Surgical Excellence: Robotic Registry consensus Conference from September 2016, which provides a comprehensive analysis of the state of robotic surgery, with lists of expert recommendations toward implementing systemwide quality improvement measures and data collection frameworks to facilitate future progress in robotic surgery [12].

11.2 Simulation and training with respect to robotic surgery

11.2.1 Training

Training in robotic surgery is a natural progression. Starting from basic or rather simple tasks, the trainee must learn to manipulate objects purposefully through increasingly difficult and novel ways, while using only their eyes, hands, and other unnatural modes of computer guidance for feedback. For this reason, completing a basic task from open surgery, such as making one suture or one knot, can require significantly greater levels of concentration, dexterity, and experience to perform successfully using a surgical robotic system. From our experience, trainees in robotic surgery also start at different baselines and report different levels of subjective stress during the training process. Psychological demand, physical demand, time pressure, performance anxiety, effort, and frustration all contribute to the overall learning experience and robotic education of the trainees.

To master any surgical skill, the trainee must be present and persistent for regular training to take place. In addition, the learner must have access through the institution to a conducive learning environment where they can practice tasks without distraction, and with enough time allocated to dedicated learning until a desired level of competence and proficiency can be reached.

In reality, the progression in training starts with acquiring basic knowledge about robotic surgery (for example, through e-learning from the Internet), and with assistance in set up during a robotic surgery operation (this is referred to as a bedside assistant) [11]. Learning is supplemented by the observation of robotic surgeries in the OR or behind the surgeon on the console, although observation can also take the form of virtual reality (VR) learning platforms such as GIBLIB, or emerging augmented reality technologies such as the Microsoft HoloLens 2.

Simulation is the next logical step in learning, which starts with console controls and the completion of basic motor tasks. Beyond this stage, the trainee moves on to complete a series of simulator modules, of increasing difficulty and requiring increasing levels of dexterity and coordination. This stage is thought to assume a classical learning curve, where early gains are achieved relatively quickly, but mastery requires exponential amounts of time spent training.

As the trainee becomes more competent on simulator tasks requiring increased levels of mastery and demonstrates increased proficiency with reference to the expert, they can progress safely to clinical tasks, which require substantially more responsibility than simulators. The training then takes place on patients, either through dual-console trainers, or through assisting on cases with the console with the help of an expert robotic surgeon, who is stationed physically in the OR or who provides telementoring off-site.

Altogether, training follows evidence-based simulation methods, synthesized into standardized robotic surgery training programs, such as the FRS, made by expert robotic surgeon groups who have a stake in educating medical students, residents, fellows, colleagues, and successors. Currently, there does not exist any learning modules whose completion and credentialing is regulated or required by the ABS, which oversees surgeon training.

11.2.2 Simulation

Simulation is an essential educational learning ground that allows for interactive training to take place in an environment that recreates or mimics real-world scenarios. The goals of this type of training can vary, but most simulators aim to teach specific skills that can be taught in clinical or preclinical simulation environments. No matter how realistic a simulator can be, it is not identical to real clinical cases with real patients [13]. Therefore, most simulator training takes place in the initial "preclinical" learning phase because the simulation purpose is to ensure that a sufficient amount of practice has taken place before trainees can use the technology to perform similar tasks on real patients. Therefore, simulators are used to improve surgeon performance within a safe and controlled training environment where the critical steps of any surgical operation may be recreated and practiced without requiring a patient.

There are several simulators available on the market for robotic surgery training [14]. Training products are generally classified into two categories: mechanical simulators and VR simulators. The former group consists of a physical training box, whereas the latter group provides a virtual training environment that is specially designed to mimic real-world tasks.

11.2.3 VR simulators

A summary of VR simulator platforms, which are presently used for robotic surgery training, can be found in Tab. 11.2. Readers wishing to read at length the detailed features of each simulation system should refer to Peters et al. [3]. The usefulness of a simulator depends on its capability to test the criteria that it is designed to evaluate, which is called *validity* [18]. The simulators mentioned in the table have demonstrated evidence of face validity (has real-life resemblance), content validity (mimics testing conditions), and construct validity (can differentiate novices from experts) [17, 19–24]. The da Vinci Skills Simulator (dVSS) and the ProMIS simulator require the application of the da Vinci robot to train, whereas the other simulators are stand-alone systems and do not require the da Vinci robot system to train. It is worth mentioning that the ProMIS system is a unique, hybrid VR and physical simulation training box system. ProMIS is attached to the da Vinci and presents the trainee with a more familiar, laparoscopic user interface.

Tab. 11.2: List of simulators and training features [3, 10, 15–17]

VR Simulator Platform	Company and Year of Release	Description of Training Exercises	Scoring Criteria
da Vinci Skills Simulator (dVSS)	Intuitive Surgical, 2011	Console controls training, EndoWrist manipulations, clutch use, camera control, electrosurgery (coagulation, dissection, cutting), needle exercises, suturing exercises, knot tying, games, complete surgical procedures	Task completion time, economy of motion, object drops, instrument out-of-view, use of excess force, radius of sphere centered on instrument tip, instrument collisions, and overall composite score
dV-Trainer (dVT)	Mimic, 2007	Console controls training, EndoWrist manipulations, clutch use, camera control, electrosurgery (coagulation, dissection, cutting), needle exercises, suturing exercises, knot tying, games	Task completion time, economy of motion, object drops, instrument out-of-view, use of excess force, radius of sphere centered on instrument tip, instrument collisions, and overall composite score
Robotic Surgery Simulator	Simulated Surgical Systems, 2010	Console controls training, visuospatial manipulation, needle exercises, electrosurgery, fourth arm control, tissue and vessel dissection, video-guided surgical training assisted by haptic feedback, complete surgical procedures	Task completion time, object drops, bimanual reporting of instruments out-of-view, bimanual reporting of grasps, camera movement optimization, object drops, use of excess force on tissue, instrument collisions, and overall composite score
RobotiX Mentor	3D Systems, 2014	Similar to dVSS training but with on-screen step-by-step coaching, FRS physical dome exercises with increasing difficulty, RTN and FLS-based skills training, single-site instrument suturing, stapler training, complete surgical procedures	Task completion time, bimanual reporting of instruments out-of-view, bimanual movement counts and path length, bimanual reporting of collisions, camera movement optimization, number of clutch uses
ProMIS	Haptica, 2003	Laparoscopic manipulations, needle handling, suturing	Completion time, path length, smoothness of motion

11.2.4 Physical training

In addition to VR simulator training, trainees can improve their robotic surgery skills using physical simulators, which can be further split into dry lab and wet lab flavors.

Dry lab trainers typically make use of synthetic materials which can be as simple as spherical beads or shoelaces, to highly detailed and realistic organlike phantoms from materials that are designer made to mimic biological tissue. These trainers can teach real-life surgical skills such as grasping, cutting, and suturing and robot-specific skills such as camera control and clutch use.

Wet lab, on the other hand, typically uses cadaveric human or animal tissues (fresh or frozen) for a more realistic simulation experience. In addition to all of the skills that can be practiced upon in dry lab, wet lab simulations can be used to teach electrocautery with energy devices, in an environment where interaction of surgical robot instruments with biological tissues is nearly identical to what the surgeon would experience during a real case. Animal tissues are generally favored over cadaveric tissues. Although performing operations on live animals is occasionally done, it is rather uncommon unless there is a very good reason to anesthetize and euthanize such an animal for the purposes of surgical training.

Lastly, box trainers that are available for laparoscopy can be adapted for use in robotic surgery. Examples of box trainers from laparoscopy that have been adapted to robotic surgery include the FLS trainer, which is the gold standard across the United States [25], and the Laparo trainer, which is a popular and cost-effective option, particularly in the European Union. The reason for this modification is that the laparoscopic box ports likely will not readily accommodate the robotic surgery instrument arms.

11.3 Robotic courses

Although many simulators were released and have been implemented in training surgeons on robotic surgery, proper training courses, criteria, and credentialing guidelines are still in the early phase of development. Currently, the leading robotic surgery training program is the FRS.

11.3.1 Fundamentals of robotic surgery

FRS is an educational, training, and assessment robotic surgical skill program [26], available online at frsurgery.org. The consensus conference began the development of FRS program [4, 27] funded by the Department of Defense and Intuitive Surgical System [26]. Professionals of different areas including behavioral psychologists, medical educators, statisticians, psychometricians, and over 80 national/international robotic surgery experts were involved in establishing the FRS curriculum through the use of the full life cycle development process [28]. Essentially, FRS was developed to be generalized to any robotic surgical systems and not limited to da Vinci surgical system [27]. Pioneers in robotic surgery cooperated together during four consensus conferences to produce the final FRS curriculum, which is composed of four modules with seven psychomotor skills tasks [8] that would be assessed based on the agreed upon 25 criteria of robotic surgery, listed in Tab. 11.3. FRS validation was completed in 2016 through a multi-institutional, multispecialty, randomized controlled trial [27].

The FRS curriculum consists of four online modules, listed in Tab. 11.4. Each module consists of short narrated video lectures with a quiz at the end of each module [29].

Tab. 11.3: Consensus criteria for the evaluation of FRS trainees [7, 4, 12]

Preoperative	Intraoperative	Postoperative
1. Situation awareness	9. Closed loop communication	24. Undocking
2. Instrument-hand-eye coordination	10. Docking	25. Transition to bedside assist
	11. Knot tying	
3. Needle driving	12. Instrument exchange	
4. Atraumatic handling	13. Suture handling	
5. Safety of operating field	14. Energy sources	
6. Camera controls	15. Cutting	
7. Clutch use	16. Foreign body management	
8. Blunt and sharp dissection	17. Ergonomic position	
	18. Wrist articulation	
	19. Robotic trocars	
	20. System setting	
	21. Multiarm control	
	22. Operating room setup	
	23. Respond to robot system error	

Tab. 11.4: FRS modules

Module 1: Introduction to Surgical Robotic Systems	Introduction to minimally invasive surgery, components of robotic system, and system functionality
Module 2: Didactic Instruction for Robotic Surgery Systems	Instructions for safe and effective use of robotic procedures in the preoperative, intraoperative, and postoperative phases [8]
Module 3: Psychomotor Skills Curriculum	Description of the physical model of the FRS dome (fig of the dome), description and scoring guidelines for the seven tasks
Module 4: Team Training and Communication Skills	Communication training for surgical teams, consisting checklists during preop, docking, intraop and postop phases, as well as modules on situational awareness, teamwork, and mutual support

11.3.2 Robotics Training Network (RTN)

'The Robotics Training Network is a multi-center training network, formed in 2010, which oversees the structured training of surgeons in robotic surgery, requiring the completion of a validation tool to assess robot-assisted surgery proficiency [30]. It consists of three phases: bedside assistance, surgeon console training, and maintenance of learning skills. In 2011, the RTN had settled an accredited curriculum of best practices in robot-assisted surgery among its academic institution partners. The RTN curriculum has three phases, detailed in Tab. 11.5 [30].

Tab. 11.5: Phases of training in robotic training network [30]

Phase I (bedside assistance)	Self-guided learning using online materials and quizzes, a dry lab and simulator, and an OR component. In addition, there are problem solving, professionalism, and communication components.
Phase II (surgeon console)	Dry labs must be completed before trainees can proceed to the OR.
Phase III (in development)	Ongoing maintenance of skills

As of 2013, the RTN has been introduced to 50 programs to develop or evaluate outcome measures, curricula, and validation studies and to improve patient safety and quality of care [30]. Robot-assisted skills are assessed using the Robotic-Objective Structured Assessment of Technical Skills, which measures performance on tasks based on depth perception and accuracy, force in tissue handling, dexterity, and efficiency. This assessment has demonstrated construct validity [26].

11.3.3 SAGES Robotics Masters Series

The Robotics Masters Series (RMS) is a training program from SAGES, which is a combination of e-learning modules and on-site learning, taking place at annual conferences for a fee. The curriculum features three stages of difficulty and achievement: competency, proficiency, and master [31]. RMS completion at the competency level of achievement is deemed to be approximately equal to what a graduating general surgery chief resident should be able to achieve. Proficiency achievement is the next level, which is approximately equivalent to what a junior surgeon, a few years out of training, should be able to achieve. Lastly, master level of achievement is the highest achievement in RMS and approximates to what an experienced surgeon should be able to achieve after many years of surgery practice [31]. Each training level incorporates didactics (recorded videos and lecture learning) and robotic surgery skill training (simulation and cadaver training) but also includes mentorship [31].

11.3.4 Fundamental skills of robot-assisted surgery (FSRS) training program

The FSRS is an on-site robotic surgery training program from the Applied Technology Lab for Advanced Surgery (ATLAS) in Roswell Park Comprehensive Cancer Center, established in 2007. What began as an initiative to improve safety and quality with respect to robotic surgery systems transformed into a validated learning program with on-site training center, employing collaboration of surgeon experts and developers of VR systems [32, 33].

The training program contains four modules spanning from basic to advanced (state of performance) levels of achievement and lasting between a few days to a few weeks. The VR simulator that is used is the dVSS, but in addition to exercises specific to this system, a combination of dry lab and wet lab simulations is also practiced by trainees. Lastly, the training program incorporates parts of the FLS curriculum, perhaps because ATLAS is a partner institution of SAGES.

To give trainees real-world practical experience, FSRS bridges simulation training with hands-on tutorial training by nonphysician experts on machine docking and troubleshooting. Lastly, FSRS trainees observe live cases in robotic surgery [33]. A full description of the training is beyond the scope of this book chapter, but it can be found on the FSRS Web site for interested readers.

11.3.5 da Vinci Technology Training Pathway

The da Vinci Technology Training Pathway is an online training course created by Intuitive Surgical Inc. that accompanies the da Vinci surgical robot system [34]. Surgical worksheets and guides are provided in this portal to assist the users with their training. There are four phases of the training program described in the Tab. 11.6 [35].

Tab. 11.6: da Vinci Technology Training Pathway [35]

Phase I: Introduction to da Vinci Technology	Test drive the da Vinci Surgical System Review procedure video relevant to your planned da Vinci procedures Complete live epicenter and/or standard case observation Complete live standard case observation
Phase II: da Vinci Technology Training	Complete da Vinci Technology online training (recommended) Complete da Vinci Technology In-Service with da Vinci representative Complete da Vinci Technology online assessment Perform da Vinci Technology Skills Drills – Skills Drills – Skills SimulatorTM (if available) Review two full-length procedure videos relevant to your planned da Vinci procedures on da Vinci Online Community Complete preparation for da Vinci Technology Training (all above prerequisites must be completed before attendance)

Tab.11.6 (Continued)

	Schedule and attend da Vinci Technology Training Important: da Vinci Technology Training is either 1 or 2 days, dependent on clinical specialty. Training times are dependent on the training center's hours of operation. Please contact your da Vinci representative for start and end times. – If an attendee is more than 30 minutes late, the training may be cancelled and no certificate awarded. – Leaving the training event before the completion of all tasks will result in no certificate being awarded. – The surgeon is responsible for all costs associated with rescheduling when the reschedule is due to tardiness or early departure. – If the surgeon is unable to complete the protocol within the scheduled time, no certificate will be awarded; however, rescheduling to complete another full da Vinci Technology Training will be permitted at no cost to the surgeon.
Phase III: Initial Case Series Plan	Complete initial case series Complete two da Vinci Technology skills activities per week, for example: – assist in a da Vinci procedure – perform a da Vinci procedure – complete a da Vinci Technology Skills Drills session – complete a da Vinci Skills Simulator session (if available) – review a da Vinci Surgery procedure video relevant to your planned da Vinci procedures
Phase IV: Continuing Development	Attend surgeon-led course(s) (Course details are available in the da Vinci Training Passport brochure and course catalog. If not available in your market, please check with your da Vinci representative for course details.) Complete at least two additional activities after initial case series: – Surgeon lecture program – Complex da Vinci procedure observation – Complex da Vinci procedure video review – da Vinci surgery webinar – Peer-to-peer consultation via Surgical Congress

11.4 Early clinical training in robotic surgery

Mentoring is a type of training whereby the learner is supervised and guided by a more experienced surgeon. It can be especially useful in the second part of the training process, after the trainee has acquired competence in basic skills and knowledge. Although simulators make up the majority of training time for residents and fellows, the content validity of simulators of current technologies still cannot represent all real-world possibilities. Actual physical limitations or unforeseen events can happen during any procedure in the OR. Hence, as the user gains competency, the next best step in training takes place during real, clinical procedures.

The da Vinci Model Si provides dual-console capability for junior and supervising surgeons to operate at the same time and transfer the control to and from each other during the operation [36]. This allows the mentoring surgeon to guide the trainee at specific points in each procedure, for example, during suturing. This controller-swap mode has improved the learning curve and lessened the anxiety of the trainee during the early stages of clinical training [37]. The term “telementoring” has been assigned to this way of supervision.

11.5 Global data collection for robotic surgery

The exponential increase in information that is now generated by RASD warrants the need to standardize data collection, storage, and sharing practices. A global robotic surgery registry that collects, stores, and facilitates high-quality information flow could have many potential benefits for surgeons, regulators, hospitals, and robotic device manufacturers. For example, surgeons or trainees could obtain real-time feedback on their operative performance, such as on the economy and efficiency of their movements. Regulators or licensing bodies could use the registry to improve existing training programs and for establishing benchmarks for certification, credentialing, and continuing education purposes. Hospitals could search for patient outcomes and develop processes that enhance the quality of care, optimize workflow, and reduce the costs associated with robotic surgery. Lastly, manufacturers could conduct pre- and postmarketing surveillance of their devices and identify areas for future innovation.

In 2016, the Robotic Registry Consensus Conference was organized, which brought together experts and decision makers from healthcare, government, and industry, with the goal of organizing a national robot-assisted surgery registry [12]. The consensus opinion was that a registry should be constructed, and that it should meet the following criteria: open to the collection of data from all RASD procedures across all specialties, analyze and process data in near real time, collect data that are crucial for distinguishing between device-related malfunctions versus non-device-related events, prevent duplicate data entry, and serve as a resource to participating institutions for evaluating patient safety, and for surgeons to use for self-assessment and self-improvement.

During the conference, three separate working groups created guidelines for data and reports, which ought to be collected from all robotic surgical devices [12]. A second goal of the meeting was to link device data with clinical outcomes obtained from partner institutions. Through this integration, it may be possible to tell in the future whether a poor outcome is linked to device malfunction or perhaps to surgeons and hospital teams who may not have had adequate training with the device. In either case, the goal of the registry is to generate evidence that can then be used to improve healthcare processes and patient outcomes. The consensus recommendations from these working groups are summarized in Tab. 11.7–11.9.

Tab. 11.7: Group 1 structure and metrics for current data repositories [12]

Device malfunction	– System error codes and faults – Loss of video – System transferred into a recoverable or nonrecoverable safety state – Display of blurry images at surgeon's console or assistant's touch screen – Burnt/broken parts and components – Fell into surgical field or body cavity
Generic surgeon errors	Visceral injury: – burn/puncture/avulsion/transection – number of reversible/nonreversible complications Device use errors: – collision of arms – pedal confusion – off-site injury/lack of device visualization
Case descriptors	– Time of surgery/time of day/faults – Level of surgeon experience – Demographics of team training – Approach (e.g., hybrid) – Emergency versus elective – Alerts (improper/not enough)
Team-based errors	– Inadequate experience with handling emergency situations – Lack of training with specific system features – Inadequate troubleshooting of technical problem/system/instrument checks before procedure – Incorrect port placements/docking errors/electrocautery settings

Tab. 11.8: Group 2 consensus on measurement data collection for RSDR [12]

Desirable data [38]	Categories of collected data: – Discharge with comorbidities and procedures – Cancer stage or some disease – Discharge disposition – Length of stay – Reoperation – Anesthesia time
Available databases	NSQIP STS SGO SAGES AHSQC NCDB
Limitations of data collection	– Patients do not come back to the same hospital – Linkage with claims can validate whether sicker patients return to the same or other hospital – MACRA will require return to same provider

Tab. 11.9: Group 3 consensus on the implementation of RSDR [12]

Data the robotic systems are capable of "reporting"	– System make/model – Time and date of procedure – Surgeon ID instruments selection – Time stamps of all reported events (automated) – Maintenance history – Accidental actuation – Deviation from plan (robot specific) – How often a feature is used (workflow) – Ergonomic indicators – Camera specification and manipulation – Surgeon engagement time at the console – Total OR time/case time/console time – Energy and setting of energy device – Energy use history – Insufflator time and amount of gas used – Inputs to the instruments – Power source errors – Robotic arm failure – Registration error (robot specific)
Data facilitated from sources outside the device	– Surgeon profile/experience/glove size – Cloud source of video and audio – Tissue condition – Procedure type – Inform verification spec – Was it used as intended – Automatically collected data – Manual time stamps
Future concerns	– Cloud sourcing data – Hardware/software malfunction – Robotic coordinator or industry rep entering data
Training issues	– FRS or FLS should be completed to validate the use of the device – Maintenance of certification on the device

In summary, data collection in robotic surgery is a work in progress. The Coordinated Registry Network (CRN) for RASD is currently under construction and will most likely be available for access through MDEpiNet in late 2020 [39]. In the future, this CRN and others like it will facilitate real-time data collection from RASD for marketing surveillance, evidence generation, and regulatory decision making. However, registry technologies are still in the early phase, and infrastructure differences between large and small healthcare institutions will likely remain an obstacle to the widespread adoption and use of this technology. The National Evaluation System for health Technology Coordinating Center is working closely with the FDA to accelerate the construction of registries that will link clinical data, billing records, and health records with device data [40]. The final proposal for integration and data flow is shown in Fig. 11.3, which

Fig. 11.3: Full cycle model of dataflow for robotic technologies.

depicts a cycle of continuous improvement in robotic surgery based on registry evidence and clinical outcomes.

11.6 References

[1] Tsuda S. "Fundamentals of laparoscopic surgery—a SAGES Wiki article." SAGES, www.sages.org/wiki/fundamentals-laparoscopic-surgery/ (accessed July 1, 2019).

[2] Ritter EM, Scott DJ. "Design of a proficiency-based skills training curriculum for the fundamentals of laparoscopic surgery." *Surgical Innovation* 14, no. 2 (2007): 107–2.

[3] Peters BS, Armijo PR, Krause C, et al. "Review of emerging surgical robotic technology." *Surgical Endoscopy* 32 (2018): 1636. https://doi.org/10.1007/s00464-018-6079-2.

[4] Smith R, Patel V, Satava R. "Fundamentals of robotic surgery: a course of basic robotic surgery skills based upon a 14-society consensus template of outcomes measures and curriculum development." *International Journal of Medical Robotics and Computer Assisted Surgery* 10, no. 3 (2013): 379–84. doi:10.1002/rcs.1559.

[5] Center for Devices and Radiological Health. *Computer-Assisted Surgical Systems*. U.S. Food and Drug Administration. https://www.fda.gov/medical-devices/surgery-devices/computer-assisted-surgical-systems (published March 13, 2019; accessed July 3, 2019).

[6] Center for Devices and Radiological Health. *Caution Using Robotically-Assisted Surgical Devices in Women's Health*. U.S. Food and Drug Administration. https://www.fda.gov/medical-devices/safety-communications/caution-when-using-robotically-assisted-surgical-devices-womens-health-including-mastectomy-and (published February 27, 2019; accessed July 3, 2019).

[7] Rogula T, Acquafresca PA, Bazan M. “Training and credentialing in robotic surgery.” In *Essentials of Robotic Surgery*, edited by Kroh M, Chalikonda S. Cham: Springer, 2015.
[8] George EI, Smith R, Levy JS, Brand TC. “Simulation in robotic surgery.” In *Comprehensive Healthcare Simulation: Surgery and Surgical Subspecialties*, edited by Stefanidis D, Korndorffer J Jr., Sweet R. Cham: Springer, 2019.
[9] Bric, JD, Lumbard DC, Frelich MJ, et al. “Current state of virtual reality simulation in robotic surgery training: a review.” *Surgical Endoscopy* 30 (2016): 2169. https://doi.org/10.1007/s00464-015-4517-y.
[10] MacCraith E, Forde JC, Davis NF. “Robotic simulation training for urological trainees: a comprehensive review on cost, merits and challenges.” *Journal of Robotic Surgery* (2019). doi:10.1007/s11701-019-00934-1.
[11] Sridhar AN, Briggs TP, Kelly JD, Nathan S. “Training in robotic surgery—an overview.” *Current Urology Reports* 18, no. 8 (2017). doi:10.1007/s11934-017-0710-y.
[12] Robotic Registry Consensus Conference Report, 2016. http://surgicalexcellence.org/wp-content/uploads/2017/04/ROBOTIC-REGISTRY-CONSENSUS-CONFERENCE-Summary-Report-10-23-16.pdf.
[13] Gaba DM. “The future vision of simulation in health care.” *Quality and Safety in Health Care* 13, no. 1 (2004): i2–10.
[14] Issenberg SB, McGaghie WC, Hart IR, et al. “Simulation technology for healthcare professional skills training and assessment.” *JAMA* 282, no. 9 (1999): 861–6.
[15] da Vinci® Skills Simulator (dVSS). Mimic Technologies Inc. Seattle, WA. https://mimicsimulation.com/da-vinci-skills-simulator/ (accessed July 7, 2019).
[16] RobotiX Mentor—3D Systems. Littleton, CO. https://simbionix.com/simulators/robotix-mentor/ (accessed July 7, 2019).
[17] McDonough PS, Tausch TJ, Peterson AC, Brand TC. “Initial validation of the ProMIS surgical simulator as an objective measure of robotic task performance.” *Journal of Robotic Surgery* 5, no. 3 (2011), 195–9. doi:10.1007/s11701-011-0256-9.
[18] Wass V, Van der Vleuten C, Shatzer J, Jones R. “Assessment of clinical competence.” *Lancet* 357 (2001): 945–9.
[19] Hung AJ, Zehnder P, Patil MB, Cai J, Ng CK, Aron M, Gill IS, Desai MM. “Face, content and construct validity of a novel robotic surgery simulator.” *Journal of Urology* 186, no. 3 (2011): 1019–24.
[20] Kelly DC, Margules AC, Kundavaram CR, et al. “Face, content, and construct validation of the da Vinci Skills Simulator.” *Urology* 79, no. 5 (2012): 1068–72.
[21] Hertz AM, George EI, Vaccaro CM, Brand TC. “‘Head to head’ comparison of three state of the art virtuality robotic surgery simulators.” *Military Surgical Symposium 2018*. Presentation MSS24, Seattle, WA.
[22] Liss MA, Abdelshehid C, Quach S, et al. “Validation, correlation, and comparison of the da Vinci Trainer™ and the da Vinci surgical skills simulator™ using the Mimic™ software for urologic robotic surgical education.” *Journal of Endourology* 26, no. 12 (2012): 1629–34.
[23] Tanaka A, Graddy C, Simpson K, et al. “Robotic surgery simulation validity and usability comparative analysis.” *Surgical Endoscopy* 30, no. 9 (2016): 3720–9.
[24] Whittaker G, Aydin A, Raison KN, et al. “Validation of the RobotiX Mentor robotic surgery simulator.” *Journal of Endourology* 30, no. 3 (2016): 338–46.
[25] Hutchins AR, Manson RJ, Lerebours R, Farjat AE, Cox ML, Mann BP, Zani S. “Objective assessment of the early stages of the learning curve for the senhance surgical robotic system.” *Journal of Surgical Education* (2018). doi:10.1016/j.jsurg.2018.06.026.
[26] Chen R, Rodrigues Armijo P, Krause C; SAGES Robotic Task Force, Siu KC, Oleynikov D. “A comprehensive review of robotic surgery curriculum and training for residents, fellows, and

postgraduate surgical education." *Surgical Endoscopy* (2019 Apr 5). doi: 10.1007/s00464-019-06775-1.

[27] Satava RM, Stefanidis D, LevyJS, et al. "Proving the effectiveness of the fundamentals of robotic surgery (FRS) skills curriculum a single-blinded, multispecialty, multi-institutional randomized control trial." *Annals of Surgery* (2019).

[28] Smith R, Patel V, Satava R. "Fundamentals of robotic surgery: a course of basic robotic surgery skills based upon a 14-society consensus template of outcomes measures and curriculum development." *International Journal of Medical Robotics and Computer Assisted Surgery* 10, no. 3 (2014): 379–84.

[29] Welcome to FRS. (n.d.). http://frsurgery.org/ (accessed July 18, 2019).

[30] Robotics Training Network. (n.d.). https://robotictraining.org/ (accessed July 18, 2019).

[31] Jones DB, Stefanidis D, Korndorffer JR, Dimick JB, Jacob BP, Schultz L, Scott DJ. "SAGES University Masters program: a structured curriculum for deliberate, lifelong learning." *Surgical Endoscopy* 31 (2017): 3061–71.

[32] Fundamental Skills of Robot-Assisted Surgery (2018). https ://www.roswe llpar k.org/education/atlas-program/testingtraining/fundamental-skill s-robot-assisted surgery-FSRS (accessed July 18, 2019).

[33] Stegemann AP, Ahmed K, Syed JR, et al. "Fundamental skills of robotic surgery: a multi-institutional randomized controlled trial for validation of a simulation-based curriculum." *Urology* 81, no. 4 (2013): 767–4. doi:10.1016/j.urology.2012.12.033.

[34] *Intuitive Surgical da Vinci Training* (2017). https://www.intuitives surgical.com/training/ (accessed July 18, 2019).

[35] da Vinci® Training Passport Technology Training Pathway: Surgeon.

[36] Intuitive Surgical Inc. Skills Simulator for the da Vinci SI Surgical System; 2012; da Vinci Skills Simulator; 2016. http://www.intuitivesurgical.com/products/ skills_simulator/ (accessed July 12, 2019).

[37] Marengo F, Larrain D, Babilonti L, et al. "Learning experience using the double-console da Vinci surgical system in gynecology: a prospective cohort study in a university hospital." *Archives of Gynecology and Obstetrics* 285 (2012): 441–5.

[38] Alemzadeh H, Raman J, Leveson N, Kalbarczyk Z, Iyer RK. "Adverse events in robotic surgery: a retrospective study of 14 years of FDA data." *PLoS One* 11, no. 4 (2016): e0151470. doi:10.1371/journal.pone.0151470.

[39] Robotic-Assisted Surgical Devices (RASD) CRN—MDEpiNet. *Medical Device Epidemiology Network*. http://mdepinet.org/rasd/ (accessed July 18, 2019).

[40] Fleurence RL, Shuren J. "Advances in the use of real-world evidence for medical devices: an update from the national evaluation system for health technology." *Clinical Pharmacology and Therapeutics* 106 (2019): 30–3. doi:10.1002/cpt.1380.