

Fundamentals of Robotic Surgery: Outcomes Measures and Curriculum Development

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Abstract

Background. The growth of the use of robotic assistance in minimally invasive surgery has created a need for standardized curriculum for training and certifying surgeons in the specialized skills necessary to use these devices successfully.

Methods. To standardize the curriculum and certification of robotic surgeons, a series of consensus conferences have been used to compile the outcomes measures and curriculum that should form the basis for a Fundamentals of Robotic Surgery (FRS) program.

Results. This has resulted in the definition of 25 specific outcomes measures and the creation of curriculum for teaching those via didactic lecture, psychomotor skills labs, and team training activities. This work has been supported and/or reviewed by representatives of the leading surgical societies that are involved in the use of robotic surgery.

Conclusions. The participation by expert robotic surgeons and the support of leading surgical societies has led to the initial definition of outcomes measures and a curriculum in robotic surgery which can become an accepted standard for training and certification.

Background

In 2004, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) launched the validated Fundamentals of Laparoscopic Surgery (FLS) curriculum and, together with the American College of Surgeons (ACS), promoted the FLS as a minimum standard before a surgeon should be allowed to perform laparoscopic procedures independently [1]. In 2009, The American Board of Surgery (ABS) mandated that in addition to Advanced Cardiac Life Support (ACLS) and Advanced Trauma Life Support (ATLS) a certificate documenting the successful passing of the FLS exam be included in the application in order to be eligible to sit the examination for certification in General Surgery [2].

During the last decade, robotic surgery has transitioned through a similar evolution to laparoscopic surgery and is being recognized as an important surgical approach by multiple surgical specialties. The type and number of procedures being performed by robotic surgery has been constantly rising in urology, gynecology, colorectal, and pediatric surgery and numerous other specialties with an estimated 350,000 robotic procedures being performed in 2011 (Figure 1). Expert robotic surgeons and numerous surgical societies and certifying organizations have advocated the need for the creation of a unified approach and standardized curriculum for basic training and

certification in robotic surgery skills [3]. There have been efforts to develop a core curriculum for certifying robotic surgeons [4,5]; however, these have been fragmented, with different approaches and outcomes measures emerging from each. This has resulted in conflicting, competing and redundant curricula for training and assessment tools for robotic surgery. In addition, these curricula have generally lacked the human and financial resources necessary to complete the most comprehensive, multi-institutional validation that is necessary to gain acceptance at a national level.

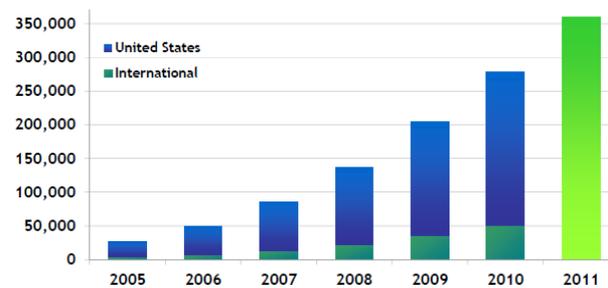


Figure 1. Growing number of robotic surgical procedures

Source: Intuitive Surgical, Inc Investor Prospectus, Feb, 2012

Through the combined support of two grants, one to the Minimally Invasive Robotics Association and the other to Florida Hospital Nicholson Center, we have created a process and a group of participants which unify the previous attempts to develop a robotic curriculum and have expanded to a much larger foundation of surgical societies with a stake in this new technology. These grants provide the necessary funding to carry the effort through multi-institutional validation with the support of participants from all surgical specialties that are currently performing robotic surgery.

Methods

Participation in this effort was invited from multiple certifying boards, professional surgical societies, and associations that represent international practitioners and regulators of various surgical specialties as well as the United States Department of Defense (DoD) and Veterans Health Administration (VHA) (Table 1). The conference participants are members of these organizations or agencies and are selected to be able to provide insight into the needs of their organizations, but they do not necessarily represent an endorsement or acceptance of the results, and participation does not imply acceptance by the societies, boards or agencies. However, the AUA, AAGL, and SAGES elected to appoint and send representatives who could officially speak for their organizations’ needs for a robotic curriculum and officially accept the results of the consensus conferences. This project is an effort to provide the stakeholders with the best scientific evidence upon which to base their decisions regarding implementation of a fundamental curriculum to meet their needs while reducing redundancy, competition and duplication of effort.

Each consensus conference was conducted over a two-day period using a modified Delphi method [6]. This methodology consisted of a facilitator who captured the input and guidance of the participants. This input was then analyzed for common concepts to create a list of critical items in robotic surgery. Previously published material from the University of Texas Southwestern curriculum was used as a template for initial idea generation [7,8]. The individual outcomes measures and curriculum materials were itemized and votes taken on their importance according to each participant. This method led to a composite ranking which was captured in a draft report. The report containing the first group ratings was then sent to each participant for their private deliberation. Each participant then submitted a second set of scores which were informed by the first composite scores, but anonymous to other group members. This modified Delphi Method led to a higher level of consensus around the measures and the curriculum. It also identified those items for which there was little group support. Those items were removed from the list of outcomes measures and from the outline of the curriculum.

Table 1. Invited Organizational Representation in Fundamentals of Robotic Surgery.

American Assoc of Gynecologic Laparoscopy (AAGL) * American College of Surgeons (ACS) American Congress of Obstetrics and Gynecology (ACOG) American Urologic Association (AUA) * American Academy of Orthopedic Surgeons (AAOA) American Association of Thoracic Surgeons (AATS) American Association of Colorectal Surgeons (ASCRS) Minimally Invasive Robotic Association (MIRA) † Society for Robotic Surgery (SRS) Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) * American Board of Surgery (ABS) Accreditation Council of Graduate Medical Education (ACGME) Association for Surgical Education (ASE) Residency Review Committee (RRC) – Surgery Royal College of Surgeons-Ireland (RCSI) Royal College of Surgeons-London (RCSL) Royal College of Surgeons-Australia (RCSA) U.S. Department of Defense (DoD) † U.S. Department of Veterans Health Affairs (VHA)
† : Funding Organizations * : Executive Committee

The first conference on outcomes measures was attended by 20 participants that included surgeons, scientists, educators, and facilitators. The ranking of the tasks identified was done by a subset of nine experienced surgeons. Participants who were not surgeons abstained from the scoring process.

The second conference on curriculum development was attended by 38 surgeons, scientists, educators, and facilitators. This group reviewed and became familiar with the material from the first conference. Thereupon, they were divided into three working groups to develop curriculum that focused on didactic and knowledge-based information, psychomotor skills, and team training and communications. Similarly, the actual ranking of the material developed was limited to experienced surgeons within the group.

The curriculum was further defined at a third conference of 18 participants in which participants added significant detail to the outline that came from the second conference. The edited and revised product of this event provided a detailed curriculum in all three areas.

Results

The first consensus conference resulted in a mission statement for the effort and a list of 25 outcomes measures which the group agreed should be mastered by a surgeon seeking privileges in robotics.

FRS Mission Statement

“Create and develop a validated multi-specialty, technical skills competency based curriculum for surgeons to safely and efficiently perform basic robotic-assisted surgery.”

The outcomes measures included 8 pre-operative, 15 intraoperative and 2 post-operative outcomes measures which are shown in Figure 2. The resulting report provides detailed definitions, descriptions, errors, outcomes and metrics for each of these [9].

Pre-Operative	Intra-Operative	Post-Operative
System Settings	Energy Sources	Transition to Bedside Asst
Ergonomic Positioning	Camera Control	Undocking
Docking	Clutching	
Robotic Trocars	Instrument Exchange	
OR Set-up	Foreign Body Management	
Situation Awareness	Multi-arm Control	
Closed Loop Comms	Eye-hand Instrument Coord	
Respond to System Errors	Wrist Articulation	
	Atraumatic Tissue Handling	
	Dissection – Fine & Blunt	
	Cutting	
	Needle Driving	
	Suture Handling	
	Knot Tying	
	Safety of Operative Field	

Figure 2. FRS Outcomes Measures.

The second consensus conference on curriculum development resulted in outlines and principles for the creation of a curriculum to teach the previously identified list of outcomes measures (Figure 3).

Didactic & Cognitive	Psychomotor Skills	Team Training
Lecture-based	Principle-based	Checklist-based
Intro to Robotic System	Based on Physical Models (Virtual Models are Derivative)	#1: WHO Pre-Op
Pre-Operative Activity	3D Exam Tools	#2: Robotic Specific
Intra-Operative Activity	Use Tasks that have Evidence of Validity	#3: Undocking & Debriefing
Post-Operative Activity	Multiple Outcomes Measured per Exercise	#4 Crisis Scenarios
Each Activity includes: Goals, Conditions, Metrics, Errors, Standards	Cost Effective Solution	
	High Fidelity for Testing, Lower Fidelity for Training	
	IRR Requires Ease of Administration	

Figure 3. FRS Curriculum Outline and Principles.

Didactic and Knowledge. The didactic and knowledge working group initially created an outline in bullet point format of the didactic FRS curriculum content. This outline was then expanded upon prior to and during the third conference by adding content to each bullet point. This content included a detailed narrative description of each bullet point and identification of all errors that a learner should be familiar with. In addition, the group

identified the best delivery method for the created content (i.e. lecture, slide presentation, images and video, multimedia, etc).

The major categories of the outline include:

1. Introduction to surgical robotic systems
2. Pre-operative set-up of equipment and positioning of staff.
3. Intra-operative use of a robot, surgeon ergonomics, visual field control, and necessary instruments and supplies.
4. Post-operative steps for surgeon transitioning to patient bedside and removing the robotic system from the operative field

In the introduction section, the general principles of robotic surgery are described, especially as they contrast with laparoscopy (i.e. 3D imaging, master-slave relationship, motion amplification, fulcrum elimination, etc.), followed by a description of the components and the functions of currently available systems (i.e. operating controllers, clutching, visualization capabilities, etc). The current state of the art and products in the field guide the descriptions of a robotic system, but an effort was made to keep these generalized and agnostic to existing products.

The preoperative section focuses on preparing the robotic system for surgery, as well as patient and staff positioning to minimize intraoperative conflicts. The intraoperative section describes appropriate operation of the robotic system during surgery and identifies potential problems that may be encountered and solutions that the learner should be familiar with. Operating the system in a way that ensures patient safety is central to this section. This section is subdivided in the phase before and after the transition of the surgeon to the robotic console. The postoperative phase focuses on safe removal of the robotic system from the patient once its assistance is no longer needed.

Central to all sections is the identification of potential errors in performance and solutions to prevent them or correct them once they occur.

The next step for this group will be to define the best methods for delivery of the curriculum content.

Psychomotor. The psychomotor skills working group prefaced their work with seven principles that should be applied in selecting or designing a skills device for robotic surgery. Those principles were:

1. The tasks should be 3 dimensional in nature.
2. The tasks designed for testing should be such that they have multiple learning objectives that incorporate multiple tasks from the first conference report. The tasks designed for

training will have more focused learning objectives.

3. Implementation of the tasks and the resultant method for teaching should be cost effective.
4. High fidelity models should be used for testing. Training can use lower fidelity devices or methods.
5. Tasks should be easy to administer to ensure Inter-Rater Reliability (IRR).
6. The tasks should be designed for implementation with physical objects and devices. Future implementation in VR with a simulator would be derivative of the physical model.
7. Preference should be given to tasks that have existing evidence of validity

The group then identified 16 of the 25 outcomes measures which contain psychomotor features. To address these, they proposed ten skills tasks which could be used to measure proficiency. Three of these tasks were drawn from FLS, others were selected from existing educational programs, and designs for new testing devices were proposed.

1. FLS peg transfer
2. FLS suturing
3. FLS pattern cutting
4. Running Suture
5. Dome with four towers
6. Vessel dissection and clipping
7. UTSW 4th arm retraction and cutting
8. Energy and mechanical cutting
9. Docking task (new design)
10. Trocar insertion task (new design)

For each of these, the group identified the associated task description, conditions, metrics, and errors.

In the third conference, this working group specifically designed multiple psychomotor devices that would be used to measure proficiency. The goal was to combine each of these into a single multi-function device which could be used for rehearsing or testing on all of the necessary skills. In keeping with their original principles, this is a physical device which must be operated upon by an actual robot. So the testing platform would include the robot and one instance of this multi-function device. This device contains the following subcomponents.

- Ring tower transfer
- Docking and instrument insertion
- Vessel energy dissection
- UTSW 4th arm cutting
- Cloverleaf dissection
- Railroad track suture

The multi-function device is being designed in CAD software before being fabricated (Figure 4). A detailed description of the device, its capabilities, and the methods used to evaluate student performance are included in the curriculum documentation. A computer generated video

showing the full psychomotor test with the device has been developed and is available for viewing.

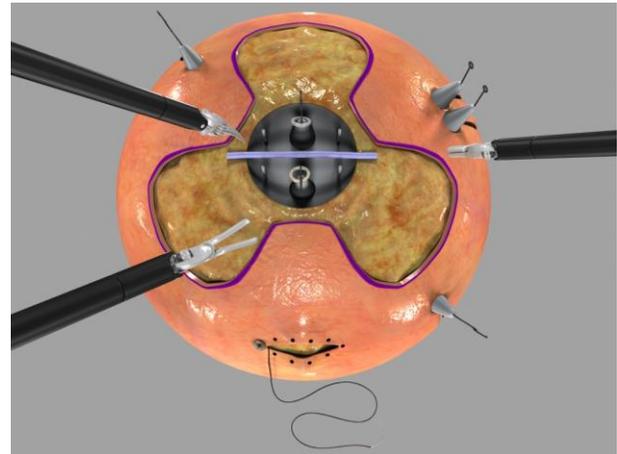


Figure 4. Psychomotor Testing Device

Team Training and Communications. The team training and communications working group prefaced their work by defining the importance of team training in a robotic environment. They identified the following principles as essential to successful team-based operations and training.

1. Team alignment with common objectives
2. Inclusion
3. Empowerment
4. Shared ownership and responsibility
5. Person specific directives
6. Task management and completion
7. Reiterative/‘Just in time’
8. Risk management/ quality improvement

Their curriculum incorporates robotic-specific management tools including checklists, critical communication protocols, and debriefing. The following checklists were recommended:

1. Pre-Operative Checklist (WHO Checklist)
2. Robotic Docking Checklist
3. Intraoperative Checklist
4. Undocking (Post-op)
5. Debriefing

The following critical communication protocols were recommended:

1. Instrument Exchange Protocol
2. Specimen Management (if specimen involved)
3. Foreign Body Management (if foreign body is involved)
4. Handoffs
5. Intraoperative Checklist
6. Recognition and Management of Bad Events

The specific methods of testing/assessing team skills include test questions, video clips with embedded questions, and simulations. Some of the simulations that are being considered include urgent undocking, team

empowerment when problems are identified, and robot malfunctions.

Conclusions

A consensus-based curriculum for certifying surgeons in robotic skills is being developed through collaboration of leading robotic surgeons who represent multiple societies with a stake in qualifying robotic surgeons. The group's work is being supported by both a private and a government grant.

The development of FRS is multi-specialty, system agnostic and follows decades of experience in other industries at developing education and training programs. Using the curriculum for training and assessment should result in a surgeon who has proficiency in basic robotic surgical skills and who is capable of passing the requirements of high stakes testing and evaluation. At some future time, this testing and evaluation would be administered by an appropriate independent, objective and authoritative organization, which would adopt the materials developed through this consensus process.

Acknowledgments

The participants in the consensus conferences were invited or nominated based on their ability to represent a larger organization which is interested in the development, standardization, and certification of robotic surgery. These participants volunteer their time for this effort and their expertise is a major source of the material in the reports and publications.

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References

- [1] Peters JH, Fried GM, Swanstrom LL, Soper NJ, Sillin LF, Schirmer B, Hoffman K; SAGES FLS Committee. Development and validation of a comprehensive program of education and assessment of the basic fundamentals of laparoscopic surgery. *Surgery*. 2004 Jan;135(1):21-7.
- [2] ABS news release. ABS to Require ACLS, ATLS and FLS for General Surgery Certification. 2008 Aug 15; available online at http://www.absurgery.org/default.jsp?news_newreqs as accessed on 06/11/2012
- [3] Zorn KC, Gautam G, Shalhav AL et al. Training, credentialing, proctoring and medicolegal risks of robotic urological surgery: recommendations of the society of urologic robotic surgeons. *J Urol*. 2009 Sep;182(3):1126-32.
- [4] Goh AC, Goldfarb DW, Sander JC, Miles BJ, Dunkin BJ. Global evaluative assessment of robotic skills: validation of a clinical assessment tool to measure robotic surgical skills. *J Urol*. 2012 Jan;187(1):247-52
- [5] Hung AJ, Patil MB, Zehnder P, Cai J, Ng CK, Aron M, Gill IS, Desai MM. Concurrent and predictive validation of a novel robotic surgery simulator: a prospective, randomized study. *J Urol*. 2012 Feb;187(2):630-7.
- [6] Dalkey N. The Delphi Method: An experimental study of group opinion. RAND Corporation Memorandum (RM-5888-PR), 1969.
- [7] Dulan G, Rege RV, Hogg DC, Gilberg-Fisher KM, Arain NA, Tesfay ST, Scott DJ. Proficiency-based training for robotic surgery: construct validity, workload, and expert levels for nine inanimate exercises. *Surg Endosc*. 2012 Jun;26(6):1516-1521.
- [8] Dulan G, Rege RV, Hogg DC, Gilberg-Fisher KM, Tesfay ST, Scott DJ. Content and face validity of a comprehensive robotic skills training program for general surgery, urology, and gynecology. *Am J Surg* 2012 April;203(4):535-539.
- [9] Satava RM, et al. Fundamentals of Robotic Surgery Consensus Conference I: Outcomes Measures. *Surgery* (in press).