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Complementary routes towards precision urologic surgery: image guidance technologies and standardized training programmes

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CHAPTER 8

DEFINITION OF A STRUCTURED TRAINING CURRICULUM FOR ROBOT-ASSISTED RADICAL CYSTECTOMY WITH INTRACORPOREAL ILEAL CONDUIT IN MALE PATIENTS: A DELPHI-CONSENSUS STUDY LED BY THE ERUS EDUCATIONAL BOARD

On behalf of the ERUS Educational Working Group and the YAU working group on robot-assisted surgery

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ABSTRACT

Background: Robot-assisted radical cystectomy (RARC) continues to expand and several surgeons start training for this complex procedure. This calls for the development of a structured training program, with the aim to improve patient safety during RARC learning curve.

Objective: To define the structure of a curriculum for RARC with intracorporeal ileal conduit in male patients.

Methods: A modified Delphi consensus process was started to develop the curriculum structure. An on-line survey based on the available evidence was delivered to a panel of 28 experts in the field of RARC, selected according to surgical and research experience, and expertise in running training courses. Consensus was defined as $\geq 80\%$ agreement between the responders.

Results: Overall, 96.4% experts completed the survey. The structure of the RARC curriculum was defined as follows: 1) theoretical training; 2) preclinical simulation-based training: 5-day simulation-based activity, using models with increasing complexity (i.e virtual reality, dry- and wet-laboratory exercises), and non-technical skills training session; 3) clinical training: modular console activity of at least 6 months at the host centre. A RARC case was divided into 11 steps and steps of similar complexity were grouped into 5 modules; 4) final evaluation: blind review of a video-recorded RARC case.

Conclusions: RARC is a complex procedure. The first structured training program for RARC was developed with the goal of guiding starting surgeons from the first steps of RARC toward independent completion of a full procedure, improving patient's safety at the same time. Clinical implementation is urgently needed.

Radical cystectomy (RC) represents the gold standard for surgical management of organ-confined muscle-invasive bladder cancer and refractory non-muscle-invasive disease [1]. Owing to the surgical morbidity related to the open RC approach [2], the minimally invasive technique has been introduced in an attempt to improve patient outcomes. In the last decades, robot-assisted RC (RARC) increased exponentially, overtaking open RC [3]. Despite RARC being probably the most complex urological procedure with a non-negligible learning curve [4] and high complication rate, no training program is currently available to assist surgeons during their learning process. To overcome this issue, we developed the first structured training program for RARC, with the ultimate goal of improving patient's safety during the learning phase of the surgeon.

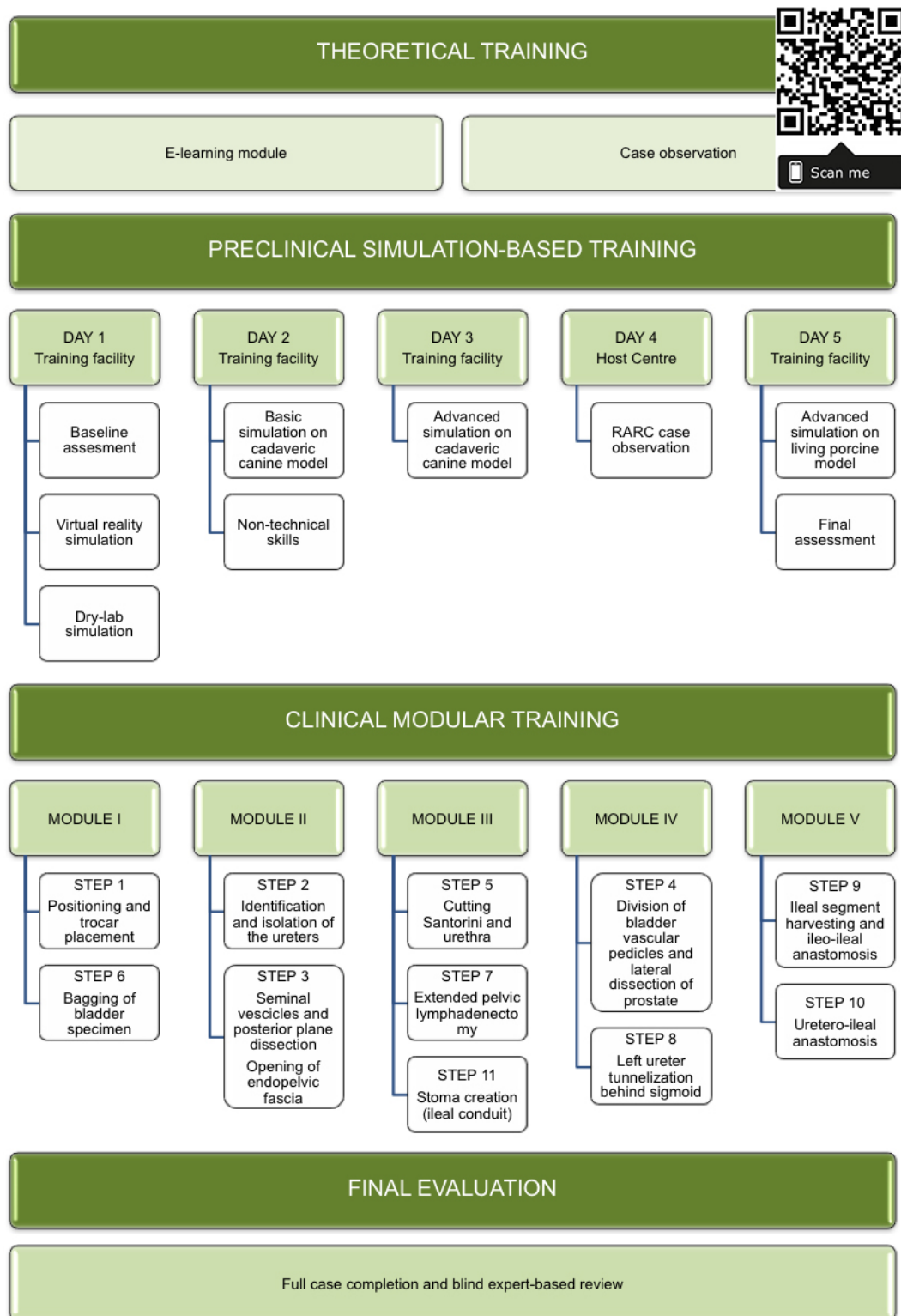
The structure of the curriculum was defined relying on a modified Delphi consensus process [5]. Using Google Forms (<https://www.google.com/intl/it/forms/about/>) a web-based survey (Supplementary material) based on the available evidence was generated and delivered to a panel of 28 experts in the field of RARC. Experts were selected according to their extensive experience in robotic surgery, the impact and number of their publications on robotic surgery and surgical training and their expertise in running training courses in the field of RARC. For simplicity, the web-based survey focused exclusively on RARC for male patients with intracorporeal ileal conduit. Consensus was defined as $\geq 80\%$ agreement between responders. Frequency and proportions were used to describe the outcomes of the survey.

The response rate in the first Delphi round was 96.4% (27/28). Consensus was reached in several areas assessed (Table 1). Unanimous agreement was reached on the statement that the adoption of a standardized curriculum for training can improve clinical outcomes during RARC learning curve and the established structure of the robot-assisted radical prostatectomy (RARP) curriculum [6] should be applied to the RARC curriculum. The panel agreed on the eligibility criteria for a trainee who should have previous experience with RARP, defined as full surgical autonomy in performing RARP, regardless of the number of procedures performed. Moreover, the trainee should have a minimum table-side assistance experience of 10 RARCs before beginning the curriculum. The structure of the RARC curriculum was divided into four main phases (Figure 1).

Table 1: Key statements of the modified Delphi consensus process for the definition of a structured training curriculum for robot-assisted radical cystectomy

Domain	Item	Consensus
Overview	Clinical outcomes during RARC learning curve can be improved by the adoption of a standardized curriculum for training	100% (27/27)
	The established structure of the robot-assisted radical prostatectomy curriculum should be applied to the RARC curriculum	100% (27/27)
Eligibility	Before beginning the RARC Curriculum, the candidate should have previous experience with robot-assisted radical prostatectomy	81.5% (22/27)
	Before beginning the RARC Curriculum, the candidate should have a minimum table-side assistance experience of 10 RARCs	81.5% (22/27)
	To be eligible, a centre should already have an ERUS Host center certification	81.5% (22/27)
	A total of 30 annual RARC cases is the minimum volume for a center to be eligible as RARC Curriculum host centre	81.5% (22/27)
Pre-clinical simulation-based training	Preclinical simulation-based training will have the structure presented in Figure 1	89% (24/27)
	The baseline assessment and virtual reality simulation-exercises already established for the robot-assisted radical prostatectomy curriculum should be applied to the RARC curriculum	89% (24/27)
	The dry-lab exercises with synthetic hydrogel models should include the following: Ureteroileal anastomosis	96.3% (26/27)
	Bowel anastomosis	85.2% (23/27)
	The animal model for the wet-lab exercises should be a cadaveric canine model and a living porcine model	81.5% (22/27)
	The wet-lab exercises should include the following: Case simulation on animal model	92.6% (25/27)
	Vascular injury	81.5% (22/27)
	Bowel injury	81.5% (22/27)
	Bowel stapling	92.6% (25/27)
	Vessel sealer management	81.5% (22/27)
Clinical Modular training	Non-technical skills training should include the following: Decision making	92.6% (25/27)
	Emergency scenario	96.3% (26/27)
	Team training	85.2% (23/27)
	RARC steps were defined as follows: I. Patient positioning and trocar placement II. Identification and isolation of the ureters III. Incision of the Douglas pouch, freeing of the seminal vesicles, transection of vasa deferentia, opening of Denonvilliers and preparation of the space between prostate and rectum. Opening of the endopelvic fascia IV. Dissection and division of the bladder vascular pedicles. Lateral dissection of prostate (with or without nerve sparing) V. Cutting of puboprostatic ligaments, cutting of Santorini plexus with oversewing, and cutting of the urethra (avoiding tumor spillage by placing a clip on proximal urethra) VI. Bagging of bladder specimen VII. Extended pelvic lymph node dissection (can be performed after step II and before step III) VIII. Tunnelization of the left ureter behind the sigmoid IX. Harvesting of the bowel segment and ileoileal anastomosis X. Ureteroileal anastomosis XI. Stoma creation (RARC with ileal conduit)	100% (27/27)
	RARC was divided into five modules according to the complexity of each step using a scale from I (easy) to V (complex): Module I: step I and VI Module II: step II and III Module III: step V, VII and XI Module IV: step IV and VIII Module V: step IX and X	100% (27/27)
	The progression of the trainee through the different steps must follow a modular pattern according to the level of complexity of each step	96.3% (26/27)
	The duration of the modular training activity should be 6-12 months	100% (27/27)
Final assessment	The final assessment should be based on the evaluation of an index video by certified independent examiners in a blind-review process	92.6% (25/27)
	A new procedure-specific scoring system should be developed for the RARC curriculum, based on objective metrics defining the steps to be completed and the errors to be avoided	89% (24/27)
	The final assessment should be based on a procedure-specific scale focusing on the following steps: 1) Dissection of bladder pedicles; 2) Harvesting of the ileal segment and ileoileal anastomosis 3) Uretero-ileal anastomosis	81.5% (22/27)

Figure 1: Structure of the European Association of Urology Robotic Urology Section curriculum for robot-assisted radical cystectomy (RARC) defined by the modified Delphi consensus process.



The first phase consisted of *theoretical training*, including e-learning and case observation. The second phase consisted of 5-day *preclinical simulation-based training*, including simulation-based activity using models with increasing complexity

(i.e virtual reality, dry- and wet-laboratory exercises), and non-technical skills training session. In the dry laboratory, synthetic hydrogel models are used to improve suturing skills and simulate ureteroileal and bowel anastomosis. In the wet laboratory, cadaveric canine and living porcine models are used for simulation of the full case procedure and of vascular and bowel injury. Each trainee's performance is assessed in an objective fashion relying on a set of 5 Da Vinci skills simulators exercises [7] before (baseline assessment) and after the training session (final assessment). The third phase consisted of *clinical modular training* of at least 6 months at the host centre. A RARC case was divided into 11 steps, defined as discrete segmental units of the surgery in chronological order. There was high agreement regarding the progression of the trainee through the different steps that must follow a modular pattern according to the level of complexity of each step. Therefore, each step's complexity was ranked using a scale from 1 (easy) to 5 (complex) and steps with similar complexity were grouped together into 5 modules, defined as unit of the same complexity regardless of chronological order. The fourth phase consisted of the *final evaluation*, based on the blind review of a video-recorded RARC case.

The increasing adoption of robot-assisted surgery in urological field also for RC calls for the development of standardized and validated training programmes in order to improve patient's outcomes during the learning process of this complex surgical procedure. The increasing focus towards patient's safety is bringing surgical robotic training more and more out of the operating room and has forced mentors to move away from the Halstedian surgical training program of "see one, do one, teach one" where patients are inevitably exposed to an increased risk of suboptimal outcomes. Under these premises, we developed the first available structured curriculum for RARC with intracorporeal ileal conduit. This structured training program is in line with those proposed by the European Association of Urology Robotic Urology Section (ERUS) for RARP [6] and robot-assisted partial nephrectomy [5]. *Theoretical and preclinical simulation-based training* are key elements. The latter allows replacement of a real patient with virtual, synthetic and animal models in order to improve technical skills of trainees and shorten their learning curve for a specific procedure. It is required before clinical training in the operating theatre because it was shown to significantly improve surgical performance [7]. It is of note that high agreement was reached by the panel regarding the importance to include non-technical skills training into the preclinical simulation-based phase, underlying that appropriate communication/confirmatory

feedback with bed-side assistant, anaesthetist and theatre staff are mandatory to ensure safe robotic surgical performance [8]. The core of all ERUS curricula is the *modular console training*, where the interaction between mentor and trainee is mandatory to allow the progression through modules of increasing complexity. The role of the mentor is pivotal to the success of this process, and appropriate experience and skills are vital: the ability to share expertise often is not innate, and the increasing need for training of mentors is being recognized [9]. Another key element is the *final evaluation*. Measurement of outcomes and performance level verification become imperative. The panel reached agreement that a new specific scoring system should be developed for the RARC curriculum, based on objective and validated performance metrics, defining the steps to be completed and the errors to be avoided, to track progression of the trainee and ensure that defined benchmarks of skills will be reached before the trainee progresses to the next level of difficulty (proficiency-based progression training) [10].

Despite its novelty, this study is not devoid of limitations. First, it was developed for men candidate to RARC with intracorporeal ileal conduit. Consequently, this curriculum is not applicable to female candidates to RC and cannot be used to assist surgeons during their learning process for RARC with neobladder. Second, no pilot clinical validation was provided that will ultimately show whether this ERUS curriculum will allow progression through the learning curve without a detrimental effect on the patient's clinical outcomes [5].

The first structured training pathway for RARC was developed based on an international consensus between experts. This curriculum will drive a surgeon from the first steps of RARC toward independent completion of a full procedure. Clinical implementation of this curriculum is urgently needed.

SUPPLEMENTARY MATERIALS

SUPPLEMENTARY METHODS

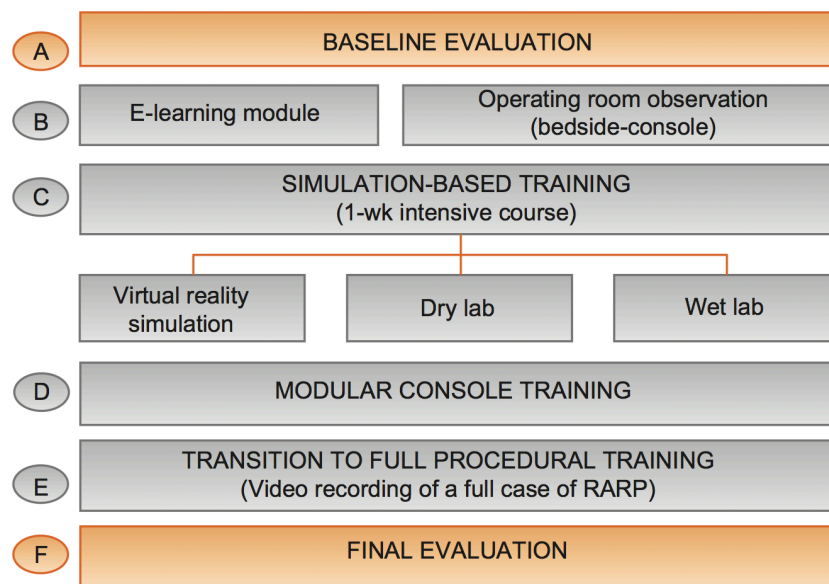
The purpose of the following survey questionnaire is to provide a shared training pathway for robot-assisted radical cystectomy [RARC] utilising the Delphi process to reach a consensus view. All answers/comments from the questionnaire will be anonymised both in evaluation and reporting.

Section 1 - Overview

1. Clinical outcomes during RARC learning curve can be improved by the adoption of a standardized curriculum for training

- ☐ I agree
☐ I do not agree

2. The established structure of the robot-assisted radical prostatectomy curriculum should be applied to the RARC curriculum



- ☐ I agree
☐ I do not agree

Section 2 – Eligibility

1. To be eligible for the modular console training the candidate should have a minimum table-side assistance experience of 10 RARCs

- ☐ I agree
- ☐ I do not agree - Less are sufficient
- ☐ I do not agree - More are required

2. Should previous experience with robot-assisted radical prostatectomy be required before beginning the RARC Curriculum?

- ☐ Yes
- ☐ No

3. To be eligible, a centre should already have a ERUS host centre certification

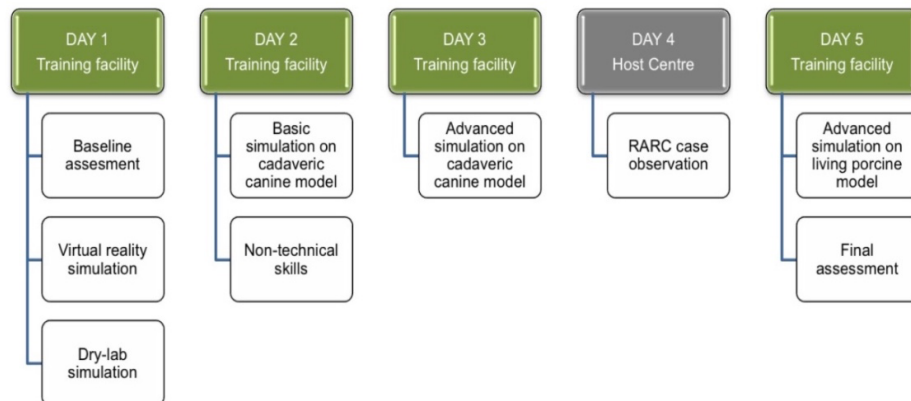
- ☐ I agree
- ☐ I do not agree

4. Select the minimum annual RARC volume for a centre to be eligible as RARC Curriculum host centre

- ☐ 20
- ☐ 30
- ☐ 40
- ☐ 50
- ☐ 100

Section 3 - Pre-clinical simulation-based training

1. The pre-clinical simulation-based training should have the following structure:



- ☐ I agree
- ☐ I do not agree - less simulation time is required
- ☐ I do not agree - more simulation time is sufficient
- ☐ Other (please specify)

2. The baseline assessment and virtual reality simulation-exercises already established for the robot-assisted radical prostatectomy curriculum should be applied to the RARC curriculum

- ☐ I agree
- ☐ I do not agree

3. The dry-lab exercises should include (can tick multiple answers)

- ☐ Ureteroileal anastomosis
- ☐ Bowel anastomosis
- ☐ Other (please specify)

4. The animal models for the wet-lab exercises should be a cadaveric canine model and a living porcine model

- ☐ I agree
- ☐ I do not agree
- ☐ Other (please specify)

5. The wet-lab exercises should include (can tick multiple answers)

- ☐ Case simulation on animal model
- ☐ Vascular injury
- ☐ Bowel injury
- ☐ ICG view management
- ☐ Vessel sealer management
- ☐ Bowel stapling
- ☐ Other (please specify)

6. Which of the following non-technical skills should be included in the RARC Curriculum (can tick multiple answers)?

- ☐ Communication
- ☐ Leadership
- ☐ Decision making
- ☐ Team training
- ☐ Emergency scenarios
- ☐ Other (please specify)

Section 4 – Clinical modular training

1. To provide a standardized and reproducible program, RARC steps were defined as follows:

- I. Patient positioning and trocar placement
- II. Identification and isolation of the ureters
- III. Incision of the Douglas pouch, freeing of the seminal vesicles, transection of vasa deferentia, opening of Denonvilliers and preparation of the space between prostate and rectum. Opening of the endopelvic fascia
- IV. Dissection and division of the bladder vascular pedicles. Lateral dissection of prostate (with or without nerve sparing)
- V. Cutting of puboprostatic ligaments, cutting of Santorini plexus with oversewing, and cutting of the urethra (avoiding tumour spillage by placing a clip on proximal urethra)
- VI. Bagging of bladder specimen
- VII. Extended pelvic lymph node dissection (can be performed after step II and before step III)

- VIII. Tunnelization of the left ureter behind the sigmoid
- IX. Harvesting of the bowel segment and ileoileal anastomosis
- X. Ureteroileal anastomosis
- XI. Stoma creation (RARC with ileal conduit)

- ☐ I agree
- ☐ I do not agree
- ☐ Free text for comments

2. Select a score [1 easy - 5 difficult] for the level of complexity of the following steps

- I. Patient positioning and trocar placement: 1-5
- II. Identification and isolation of the ureters: 1-5
- III. Incision of the Douglas pouch, freeing of the seminal vesicles, transection of vasa deferentia, opening of Denonvilliers and preparation of the space between prostate and rectum. Opening of the endopelvic fascia: 1-5
- IV. Dissection and division of the bladder vascular pedicles. Lateral dissection of prostate (with or without nerve sparing): 1-5
- V. Cutting of puboprostatic ligaments, cutting of Santorini plexus with oversewing, and cutting of the urethra (avoiding tumor spillage by placing a clip on proximal urethra): 1-5
- VI. Bagging of bladder specimen: 1-5
- VII. Extended pelvic lymph node dissection: 1-5
- VIII. Tunnelization of the left ureter behind the sigmoid: 1-5
- IX. Harvesting of the bowel segment and ileoileal anastomosis: 1-5
- X. Ureteroileal anastomosis: 1-5
- XI. Stoma creation (RARC with ileal conduit): 1-5

3. The progression of the trainee through the different steps must follow a modular-pattern according to the level of complexity of each step

- ☐ I agree
- ☐ I do not agree

4. The duration of the modular training activity should be 6-12 months

- ☐ I agree

- ☐ I do not agree – Less is sufficient
- ☐ I do not agree – More is required

Section 5 – Final assessment

1. Should the final assessment be based on the evaluation of an index video by certified independent examiners in blind-review process?

- ☐ I agree
- ☐ I do not agree

2. Should the final assessment be based on the GEARS scale?

Depth perception				
1	2	3	4	5
Constantly overshoots target, wide swings, slow to correct		Some overshooting or missing of target, but quick to correct		Accurately directs instruments in the correct plane to target
Bimanual dexterity				
1	2	3	4	5
Uses only one hand, ignores nondominant hand, poor coordination		Uses both hands, but does not optimize interaction between hands		Expertly uses both hands in a complementary way to provide best exposure
Efficiency				
1	2	3	4	5
Inefficient efforts; many uncertain movements; constantly changing focus or persisting without progress		Slow, but planned movements are reasonably organized		Confident, efficient and safe conduct, maintains focus on task, fluid progression
Force sensitivity				
1	2	3	4	5
Rough moves, tears tissue, injures nearby structures, poor control, frequent suture breakage		Handles tissues reasonably well, minor trauma to adjacent tissue, rare suture breakage		Applies appropriate tension, negligible injury to adjacent structures, no suture breakage
Autonomy				
1	2	3	4	5
Unable to complete entire task, even with verbal guidance		Able to complete task safely with moderate guidance		Able to complete task independently without prompting
Robotic control				
1	2	3	4	5
Consistently does not optimize view, hand position, or repeated collisions even with guidance		View is sometimes not optimal. Occasionally needs to relocate arms. Occasional collisions and obstruction of assistant.		Controls camera and hand position optimally and independently. Minimal collisions or obstruction of assistant

- ☐ I agree
- ☐ I do not agree

3. Should the procedure specific scoring system already established for the robot-assisted radical prostatectomy curriculum be applied to the RARC curriculum?

Parameter	Score	Meaning	Descriptive examples
Instrument use	1	Dangerous	Entering instruments blindly
	2	Incompetent	Several attempts
	3	Safe	Identifying anatomy
	4	Masterful	No bleeding, instruments in sight
Tissue handling	1	Traumatic	Uncontrolled movements
	2	Laborious	Repeated attempts
	3	Safe	Effective handling with some damage
	4	Masterful	Avoiding damage
Errors	1	Bleeding	Tissue avulsion, damage to organs

	2	Minor bleeding	Occasional bleeding, no damage
	3	Minimal bleeding	Minimal damage
	4	No bleeding	
End result	1	Damage to organs	Kidney, liver or spleen, bowel
	2	Inadequately performed	Proctor took over
	3	Sufficient	Ready for the next step
	4	Masterful	

☐ I agree

☐ I do not agree

4. Should the final assessment be based on a procedure-specific scale focusing on the following steps: 1) Dissection of bladder pedicles; 2) Harvesting of the ileal segment and ileoileal anastomosis 3) Ureteroileal anastomosis?

☐ I agree

☐ I do not agree - more steps must be included

☐ I do not agree - less steps must be included

5. Should a new procedure specific scoring system be developed for the RARC curriculum, that is based on objective metrics defining the steps to be completed and the errors to be avoided?

☐ I agree

☐ I do not agree

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