Simulation in Urological Training and Education (SIMULATE): Protocol and curriculum development of the first multicentre international randomized controlled trial assessing the transferability of simulation-based surgical training

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Objectives
To report the study protocol for the first international multicentre randomized controlled trial investigating the effectiveness of simulation-based surgical training and the development process for an evidence-based training curriculum, to be delivered as an educational intervention.

Participants and Methods
This prospective, international, multicentre randomized controlled clinical and educational trial will recruit urology surgical trainees who must not have performed ≥10 of the selected index procedure, ureterorenoscopy (URS). Participants will be randomized to simulation-based training (SBT) or non-simulation-based training (NSBT), the latter of which is the current sole standard of training globally. The primary outcome is the number of procedures required to achieve proficiency, where proficiency is defined as achieving a learning curve plateau of 28 or more on an Objective Structured Assessment of Technical Skills (OSATS) assessment scale, for three consecutive operations, without any complications. All participants will be followed up either until they complete 25 procedures or for 18 months. Development of the URS SBT curriculum took place through a two-round Delphi process.

Results
A total of 47 respondents, consisting of trainees (n = 24) with URS experience and urolithiasis specialists (n = 23), participated in round 1 of the Delphi process. Specialists (n = 10) finalized the content of the curriculum in round 2. The developed interventional curriculum consists of initial theoretic knowledge through didactic lectures followed by select tasks and cases on the URO-Mentor (Simbionix, Lod, Israel) VR Simulator, Uro-Scopic Trainer (Limbs & Things, Bristol, UK) and Scope Trainer (Mediskills, Manchester, UK) models for both semi-rigid and flexible URS. Respondents also selected relevant non-technical skills scenarios and cadaveric simulation tasks as additional components, with delivery subject to local availability.

Conclusions
SIMULATE is the first multicentre trial investigating the effect and transferability of supplementary SBT on operating performance and patient outcomes. An evidence-based training curriculum is presented, developed with expert and trainee input. Participants will be followed and the primary outcome, number of procedures required to proficiency, will be reported alongside key clinical secondary outcomes, (ISCRN 12260261).

Keywords
simulation, training, surgery, urology, randomised controlled trial, ISCRN 12260261
**Introduction**

Surgery, as a craft, has traditionally been learnt through an apprenticeship model, most famously recalled by the slogan ‘see one, do one, teach one’ [1]. This method of training produced highly skilled surgeons for many generations. However, over the last few decades, there has been a momentous rise in the adoption of minimally invasive procedures, which are often associated with steep learning curves and, thus, require a greater number of training hours to develop the required skill sets for proficiency [2]. Furthermore, with transformations in contemporary employment legislation significantly reducing working hours, and financial constraints in healthcare organizations, this Halstedian model has proved to be challenging for trainees to obtain the required levels of competency [3].

For a profession such as surgery, which is dependent on the development, acquisition and application of psychomotor skills such as fine manual dexterity and visuospatial awareness [4,5], such limitations in opportunities to train in the operating room (OR) may have negative consequences on overall training [6]. In recent years, surgical educators have been much influenced by the military and aviation industries, both of which rely heavily on intensive simulation training prior to real exposure [7,8]. The rising complexity of surgical cases and the changing attitudes of the medico-legal aspects in a surgeon’s training, as well as ethical concerns regarding training on patients, have led to the widespread adoption of surgical simulation as an adjunct to traditional OR-based learning [2].

Effective simulation can provide safe and controlled environments, outside of the OR, for trainees to acquire, maintain and enhance their surgical skill set through structured and perhaps repetitive self-practice, without endangering patient safety [9,10]. Moreover, simulation has been hypothesized to enhance progression along the initial phase of the surgical learning curve, with skills that are learnt via simulation being shown to be transferable to the OR [11]. Despite gathering momentum, simulation-based training (SBT) has remained predominantly unstructured, with a lack of high-quality scientific evaluation. The field of surgical education has been largely dominated by observational validation studies concerning particular training models, mostly conducted amongst medical students [12]. Little effort has been made (1) to identify strengths, weaknesses and suitability of training models described and/or validated in the literature, (2) to develop structured simulation-based curricula, and (3) to investigate the transferability of skills to the OR amongst training residents (as opposed to medical students who are complete novices).

Simulation in Urological Training and Education (SIMULATE) [13] is the first international multi-institutional randomized controlled trial (RCT) to investigate the direct transferability of supplementary structured SBT amongst urology trainees, using an index procedure, compared with the current standard of training in the OR. In the present paper, we report the trial protocol and development process of a training curriculum to be utilised as an intervention.

**Trial Protocol**

This protocol has been reported in accordance with the Standard Protocol Items: Recommendations for Intervventional Trials (SPIRIT) statement [14] and the WHO Trial registration dataset (Table 1). All amendments to the protocol have been listed since formulation (Table 2).

**Objectives**

The primary objective of this RCT is to assess whether supplementary SBT is superior to the current standard of exclusive OR-based learning in helping surgical trainees reach a level of proficiency sooner than current standards. Key secondary objectives are: (1) to assess whether supplementary simulation training also leads to better clinical outcomes; and (2) to assess the feasibility, acceptability and educational value of the developed training curriculum for intervention.

**Trial Design**

This is a prospective, international, multicentre, parallel-group, pragmatic, superiority randomized controlled clinical and educational trial, in which surgical urology residents will be randomized to SBT or non-simulation-based training (NSBT) groups (Fig. 1), the latter of which was selected as a comparator since it is the current sole standard of training globally. As the first such RCT to determine the effects of supplementary SBT on training and clinical outcomes, the proposed study will train one group of urological trainees through a simulation curriculum of a selected index procedure and compare these with the arm of trainees who will only receive standard OR training, as is current practice.

**Index Procedure**

After extensive discussions within the Surgical Advisory Committee of the BAUS, TURP, ureterorenoscopy (URS) and laparoscopic nephrectomy were identified as potential index procedures that are commonly performed. However, given the variation in approach to laparoscopic nephrectomy [15] and the increasingly emerging widespread use of medical therapy and competitor technologies for TURP [16], URS was selected as the most suitable procedure for newly appointed novice trainees.

**Study Setting**

Newly appointed surgical trainees, enrolled onto a suitable training programme, will be approached for recruitment by
local co-investigators, as per suggestions from training programme directors. Alongside UK Deaneries, centres from Austria, Canada, China, Germany, Greece, Japan, Switzerland, Turkey and the USA will participate in this novel study (Fig. 2) [13]. Participants in the SBT group will be provided with training in a simulation environment as well as the standard OR training.

Eligibility Criteria

This trial will recruit urology trainees who must not have independently performed more than 10 full URS procedures and should have no prior experience with structured simulation training in URS. Opportunistic simulation encounters, of no more than 1 h, will not be an exclusion criterion.

Outcomes

The primary outcome of this study is the number of procedures required to achieve proficiency, where proficiency is defined as achieving a learning curve plateau of 28 or more on an OSATS assessment scale (i.e. 4/5 on each domain), for three consecutive operations, without postoperative complications.

| Data category                           | Information                                                                                                                                                                                                 |
|-----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Primary registry and trial identifying number | International Standard Registered Clinical/Social Study Number (ISRCTN) - ISRCTN12260261                                                                                                                    |
| Date of registration in primary registry  | 21 October, 2016                                                                                                                                                                                            |
| Secondary identifying numbers            | N/A                                                                                                                                                                                                        |
| Source(s) of monetary or material support | Urology Foundation                                                                                                                                                                                          |
| Primary sponsor                         | King’s College London                                                                                                                                                                                       |
| Secondary sponsor(s)                    | N/A                                                                                                                                                                                                        |
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| Public title                            | Simulation in urological training and education (SIMULATE): Transfer of skills from the simulation laboratory to the operating room                                                                            |
| Scientific title                        | SIMULATION in urological Training and Education (SIMULATE): a randomized controlled clinical and educational trial to determine the effect of structured simulation-based surgical training |
| Acronym                                 | SIMULATE                                                                                                                                                                                                  |
| Countries of recruitment                | Austria, Canada, China, Germany, Greece, Japan, Switzerland, Turkey, UK and USA                                                                                                                               |
| Health condition(s) or problem(s) studied | Role of surgical simulation in training                                                                                                                                                                     |
| Intervention(s)                         | Randomized arm: expert-led simulation curriculum for selected index procedure                                                                                                                               |
| Key inclusion and exclusion criteria     | Urology residents/ trainees                                                                                                                                                                                  |
|                                        | Inclusion criteria: performed < 10 of index procedure                                                                                                                                                       |
|                                        | Exclusion criteria: structured simulation-based training experience in index procedure of > 1 h                                                                                                             |
| Study type                              | Intervention                                                                                                                                                                                               |
|                                        | Allocation: randomized                                                                                                                                                                                      |
|                                        | Intervention model: parallel assignment                                                                                                                                                                     |
|                                        | Masking: outcomes assessor (assessing supervisor)                                                                                                                                                           |
|                                        | Primary purpose: educational                                                                                                                                                                                |
|                                        | Block randomization                                                                                                                                                                                          |
| Date of first enrolment                 | 24 October 2016                                                                                                                                                                                             |
| Target sample size                      | 48 calculated, 94 recruited                                                                                                                                                                                 |
| Recruitment status                      | Complete                                                                                                                                                                                                    |
| Primary outcome(s)                      | Number of procedures required to achieve proficiency, where proficiency is defined as achieving a learning curve plateau of 28 or more on an OSATS assessment scale (i.e. 4/5 on each domain), for three consecutive operations, without postoperative complications |
| Key secondary outcomes                  | ● Number of intra- and postoperative (48-h) complications                                                                                                                                                |
|                                        | ● Postoperative stone-free status at the point of discharge                                                                                                                                                |
|                                        | ● Feasibility, acceptability and educational value of SBT                                                                                                                                                |

OSATS, Objective Structured Assessment of Technical Skills; SBT, simulation-based training.
outcomes include: (1) number of intra- and postoperative (48-h) complications; (2) postoperative stone-free status at the point of discharge; and (3) feasibility, acceptability and educational value of SBT.

Participant Timeline
Following recruitment (and intervention for the SBT arm), participants will be followed up either until they complete 25 procedures or for 18 months (Fig. 1). The end of follow-up is defined as the completion of a maximum of 25 semi-rigid and flexible URS procedures or 18 months, per trainee, in the OR. Data acquisition for the primary outcomes will be via the most widely used and well-validated assessment scale [18], OSATS [19]. Secondary outcomes will be collected using a newly produced tool, the ureteroscopy assessment score (URSAS), and via evaluation surveys, which will be distributed to all participants in the SBT group following the intervention.

Sample Size
To date, there are currently no published data with respect to the number of procedures that trainees require to achieve proficiency under the current practice, but experts agree that it is reasonable to assume that trainees will perform between five and 25 procedures, with an average of 15. Using the range rule, it can then be assumed that the standard deviation approximates 5. With a fixed-sample size design, assuming that these assumptions are true, the present study would need 44 trainees to achieve the primary outcome, to show a reduction in the number of procedures in the SBT arm of at least one-third (mean of 10 procedures or less), with 90% power and 5% type I error. Numbers recruited will need to be inflated to 48 to allow for a 10% drop-out rate.

Recruitment, Allocation and Blinding
Recruitment of participants and randomization will take place on five separate occasions at: (1) UK Deaneries, (2) European Centres, (3) Japanese Centre, (4) Chinese Centre and (5) North American Centres. All co-investigating sites will be visited and potential trainees will be informed and consent sought from them. Randomization will be executed per centre or UK Deanery. Sequence generation will be by web-based computer randomization (www.randomizer.org), where groups are to be allocated in a 1:1 ratio, stratified according to recruitment site or UK Deanery. Participants will be instructed to conceal their allocation from supervising teams to avoid any bias during assessments. Due to the nature of the study, blinding of participants is not possible.

Data Collection and Management
Each site and/or local collaborators will be met and informed of all materials required prior to data collection. Participants

| Protocol version and date | Reason for amendment |
|--------------------------|----------------------|
| V1.0, 01/06/2015         | Original protocol    |
| V2.0, 01/04/2016         | Main reasons for amendment: |
|                         | • The addition of European sites and respective co-investigators/principal investigators participating in the trial. |
|                         | • International Standard Registered Clinical/Social Study Number (ISRCTN) number - ISRCTN12260261 |
| V3.0, 01/09/2016         | Main reasons for amendment: |
|                         | • The addition of further sites from Japan, China and North America and respective co-investigators, participating in the trial |
|                         | • Upon discussions within trial steering committee, the following amendments were made: |
|                         | • Due to higher level of evidence and validity status, primary outcome measure limited to OSATS |
|                         | • The term ‘proficiency’ in primary outcome clearly defined to avoid all ambiguities |
|                         | • Due to variability in healthcare systems across the international participating centres, the removal of cost analysis from secondary outcomes |
|                         | • Sample size calculation re-afﬁrmed and odd numbers corrected to even numbers (43 to 44 and 47 to 48) |

Table 2 Revision chronology for amendments to protocol.
and/or supervisors will be requested to complete the required assessment materials, namely OSATS alongside URSAS, for each URS procedure performed, up to 25 procedures or up until 18 months. Because UK trainees are often assigned to multiple different supervisors and/or hospital sites, they will be primarily responsible for returning the completed data. Local collaborators will be collecting and/or returning the completed materials at participating international sites. Regular communication will be made with participants to enquire about their progress and request completed assessment sheets – on paper or electronically. Data will be stored on a secure computer at the primary investigating site (Guy’s Hospital). All electronic data will be received by a safe and secure server and anonymized before analysis.

Statistical Methods

All demographic data will be analysed using a chi-squared test to ensure a successful randomization has taken place. Similarly, the number of baseline procedures will be compared using a t-test or equivalent non-parametric tests. The primary outcome analysis will be based on the intention-to-treat sample as well as per protocol. A logistic regression model will be employed to assess and compare the number of participants who have reached proficiency in both arms. The number of procedures required to achieve proficiency will be assessed using a time-to-event analysis with a Cox regression model, whereby proficiency is defined as three consecutive procedures with an OSATS score of 28 or above (i.e. 4/5 on each domain) and the timescale defined by the number of procedures. Secondary outcomes of complications and stone-free status will be assessed using descriptive analyses.
Ethics and Consent

Full ethics approval was obtained from the host institute, King’s College London, on 28 April 2015 (Ref: BDM/14/15-68). A detailed information sheet for participants and consent form was produced and approved as part of the ethics approval. Consent will be sought from all identified and agreeable participants by the primary team (A.A., K.A.) at each site, including consent for video recording and anonymised use of training data. All confidential data will be stored at a secure point and computer at Guy’s Hospital, with access limited to the primary team of investigators (A.A., K.A., P.D.).

Intervention

Curriculum Development

A two-round Delphi study was conducted for development of a simulation-based curriculum for URS (Fig. 3), to be delivered as part of the educational intervention [17]. The most highly validated and evidence-based models were identified from the available literature [12]. An online survey was developed (www.surveymonkey.com) for dissemination to trainees and urolithiasis specialists in the UK. The survey enquired about the demographics and experience of respondents followed by describing features of each method and asked respondents to rate the extent of their inclusion and of the relevant basic tasks and cases on a five-point Likert scale. Finally, respondents were asked to rate the order in which each method should be utilised in the curriculum. In Round 2, specialists were invited to confirm the outline of the curriculum and make suggestions where necessary. A final training curriculum was devised in accordance with all received feedback, for delivery to the SBT group. All delivered interventions will be standardized across sites, in line with the developed curriculum. Didactic lectures and supervision will take place in multiple languages, according to site of delivery.

Survey Demographics

In round 1, a total of 47 respondents consisting of trainees (n = 24) with URS experience, and urolithiasis specialists (n = 23) participated in the survey. The mean (range) age of the specialist group was 44 (36–59) years with a mean (range) experience level of 836 (100–2000) procedures for semi-rigid URS and 671 (17–2000) procedures for flexible URS. Trainees were aged between 28 and 40 years (mean: 33 years) with a 4:1 male:female ratio and their experience ranged between 0 and 250 semi-rigid URS (mean: 129) and 0–200 flexible URS (mean: 93) procedures. In round 2, 10 specialists responded to review and re-affirm the suggested curriculum (Fig. 3).

Curriculum Outline

Available training models with the highest level of evidence for semi-rigid and flexible URS were identified as: URO-Mentor (Simbionix, Lod, Israel) VR simulator, Uro-Scopic Trainer (Limbs and Things, Bristol, UK) and Scope Trainer (Mediskills, Northampton, UK) [12]. Invited survey participants were requested to suggest and/or select the most suitable tasks and/or cases to perform on each of the listed models, as well as enquiring about the inclusion of full immersion simulation [20] and human cadaveric simulation [21]. The responses indicated that, following lectures, the curriculum should begin with VR (52%) followed by ‘dry-lab’ (48%), then full immersion (53%), and should conclude with cadaveric simulation (55%). The majority of respondents (84%) expressed that the curriculum should teach semi-rigid URS first, followed by flexible URS.

Didactic Lectures

Suggestions regarding lecture objectives and content were gathered in round 1 of the survey, placed into groups with five main titles and finalized by experts in round 2 (Fig. 4). All the suggested titles scored >3.5/5 on a Likert scale. The titles were as follows: (i) OR set-up, ureteric access and retrograde studies (score 4.13/5); (ii) A guide to guidewires, access sheaths, stents and baskets – which and when? (score 3.75/5); (iii) LASERs: types, size, settings and safety (score 3.63/5); (iv) semi-rigid URS: indications, techniques risks and complications (score 4.13/5); and (v) flexible URS (score 4/5).

VR Simulation

The URO-Mentor has an inherent number of simulated tasks and skills that are categorized as basic skills, stone manipulation and strictures treatment (Appendix S1). The tasks were assessed in full to allow appropriate selection into the curriculum. All 10 basic tasks relating to URS on the URO-Mentor scored a mean of ≥3/5. Three stone manipulation cases scored above ≥4/5 and all stricture cases were felt to be too advanced for a curriculum aimed at novices. In round 2, the top-scoring tasks and cases (score ≥4/5) were selected for the final curriculum and narrowed down to renal stone extraction (Task 10; score 4/5) and left distal ureteric stone (Case 2; score 4.3/5) for semi-rigid URS and kidney inspection (Task 8; score 4.13/5) and lower calyceal stone (Case 7; score 4.04/5) for flexible URS (Fig. 4).

‘Dry-lab’ Simulation

A number of semi-rigid URS tasks were suggested for dry-lab simulation to be performed on the Uro-Scopic Trainer, including ureteric orifice cannulation, guidewire placement,
Fig. 4 The SIMULATE ureteroscopy training curriculum, designed to be delivered as the educational intervention. The curriculum begins with introductory didactic lectures followed by virtual reality and dry-lab simulation for semi-rigid and flexible URS, respectively. If feasible, this is to be followed by full immersion simulation and cadaveric training, respectively. fURS, flexible ureterorenoscopy; NTS, non-technical skills; OR, operating room; UO, ureteric access; URS, ureteroscopy; VR, virtual reality.

Didactic Lectures

VR Simulation

Dry-lab Models

Full Immersion Simulation

Cadaveric Simulation

1. OR set-up, UO access & retrograde studies
2. Consumables—types, size, settings & safety
3. Semi-rigid URS
4. Flexible URS
5. NTS in Surgery

Semi-rigid URS tasks:
• Renal Stone Extraction (Task 10)
• Left distal ureteral stone (Case 2)
Flexible URS tasks:
• Kidney Inspection (Task 8)
• Lower calyceal stone (Case 7)
3 semi-rigid URS cases on the Uni-Scopic Trainer:
1. Lower ureteric stone
2. Mid-ureteric stone
3. Upper ureteric stone
fURS cases on the Advanced Scope Trainer:
1. Diagnostic fURS
2. Lower pole stone
Non-technical skills scenarios in “The Igloo”
1. Emergency OR Team Brief
2. Intra-operative Surgical Emergency
3. Inexperienced Member of Staff
4. Managing Faulty Instrumentation

Fresh Frozen Cadavers
• Bladder Visualisation
• Retrograde studies
• Insertion/Removal of Access Sheath
• UO Catheterisation
• Diagnostic Intrarenal Inspection
• C-arm Control
• Stent Insertion

basket extraction and laser fragmentation of stones. These were collated and presented for selection in round 2. Experts (n = 10) selected a final three cases. The cases were ordered and detailed as (i) Case 1 – distal/lower ureteric stone (87.5%), (ii) Case 2 – mid-ureteric stone (75%) and (iii) Case 3 – proximal/upper ureteric stone (87.5%). For flexible URS, diagnostic inspection of calyces, laser stone fragmentation and basket extraction were suggested in round 1 and adopted in two cases: (i) Case 1 – diagnostic flexible URS and (ii) Case 2 – lower pole/calyceal stone to be performed on the scope or advanced scope trainers.

Full Immersion Simulation

In round 1, a range of scenarios were put forward to be carried out in the full immersion simulation environment, including management of inexperienced teams, use of complex sequences or equipment and management of complications. These qualitative suggestions were categorized under four titles and selected by experts in round 2, all scoring ≥3.8/5 (Fig. 4). A ureteric injury scenario was suggested in round 1 but rejected later because of limitations in simulation models to successfully replicate such a complicated injury. Furthermore, a separate lecture on non-technical skills in surgery was also suggested to be delivered prior to training.

Cadaveric Simulation

The use of cadavers was thought to be of value, ‘only if available and feasible’. The stated benefits were primarily to enhance training, use real-time fluoroscopy and explore variable anatomy. Tasks were suggested as of those similar for dry-lab models in round 1. These concepts were synthesized and a list of feasible tasks was produced and approved at round 2 (Fig. 4). An important warning from expert participants was to limit each participant to one kidney and ureter due to the fragile nature of ureters and possible strictures as a result of them being frozen prior to use.

Educational Value

Participants were questioned regarding the value of the curriculum; 93% expressed that the curriculum should be included in training programmes and that more efforts are needed to produce similar procedural curricula, aimed at trainees (90%). When asked about the feasibility of incorporating the curriculum within formal training programmes, respondents mean response was 3.75/5 on a Likert scale. Only 50% of respondents felt that it ought to be incorporated as part of accreditation.

Discussion

Surgical simulation has seen exponential growth in the last decade, with both increasing uptake and developments [2-3,22]. Numerous studies have been conducted on the perceived educational benefits of SBT and a handful have also reported transfer of skills to higher levels such as training on cadavers [12]. The significant majority of studies have assessed training models for face and content validity, as per the previously used taxonomy of validation [23], which are very subjective measures. The limited number of RCTs have all been conducted on a small scale. Thus, the primary hypothesis regarding surgical simulation training (that it can reduce the initial phase of the novice learning curve) has not been tested prior to this study. To our knowledge, SIMULATE is the first multicentre international RCT of such scale to investigate the effectiveness and transferability of SBT.
In conclusion, SIMULATE is the curriculum for robot-assisted radical prostatectomy [40]. The present study reports the RCT protocol and the development process and outcomes of the educational intervention for the selected index procedure: a simulation-based URS curriculum for novice trainees. Despite the development and evaluation of a large number of individual training models in surgical education [12,24-29], each model may have particular strengths and drawbacks. Thus, their combined use in a curricular fashion, addressing specific learning needs, has been suggested to be more effective [30].

In a preceding small-scale RCT [31], a similar curriculum was developed for medical students incorporating various platforms for URS and non-technical skills within a full immersion simulation environment. Medical students who were trained using the curriculum outperformed the control group. However, drawing conclusions from medical students as novices is a major limitation in simulation studies. Studies should therefore mainly recruit residents in-training, as they will ultimately be the first to receive such training. Soria et al. report such a curriculum for semi-rigid [32] and flexible URS [33], the selected index procedure for the present RCT. The authors demonstrate face, content and construct validity of a modular three-stage curriculum, which also begins with theoretical knowledge followed by simulation using the ETXY Uro-Adam (ProDelphus) model and a porcine reno-ureteric unit. Similarly, the European Association of Urology Urolithiasis Section (EULIS) has also developed a URS curriculum and examination for novice residents [34], and reports positive outcomes [35]. Such reports can also be found in the literature for other curricula such as the urological adaptations of the Fundamentals of Laparoscopic Surgery skills curriculum [36-39] and the European Association of Urology Section of Robotics training curriculum for robot-assisted radical prostatectomy [40].

In conclusion, SIMULATE is the first international multicentre RCT investigating the effect and transferability of supplementary SBT on operating performance and patient outcomes. An evidence-based training curriculum was developed with expert and trainee input for the selected index procedure, URS. Participants will be followed up for the length of 25 procedures or 18 months. The primary outcome, number of procedures required to attain proficiency, will be reported alongside key clinical secondary outcomes.

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Conflict of Interest

None declared.

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Abbreviations: NSBT, non-simulation-based training; OR, operating room; OSATS, Objective Structured Assessment of Technical Skills; RCT, randomized controlled trial; SBT, simulation-based training; SIMULATE, Simulation in Urological Training and Education; URS, ureterorenoscopy; URSAS, ureteroscopy assessment score.

Supporting Information

Additional Supporting Information may be found in the online version of this article:
Appendix S1. URO-Mentor (Simbionix).
Data S1. Statistical analysis plan.