IS THERE A ROLE FOR VIRTUAL REALITY SIMULATORS IN TRAINING PROCEDURAL SKILLS?

A pilot study on flexible ureteroscopic stone extraction skills

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To Hoda

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Abstract

Introduction

The aim of this research is to assess the learning curve of flexible ureteroscopic stone extraction skill using the UroMentor™ simulator and transfer of this skill to the operating theatre.

Methods

After obtaining ethics approval, urology Post-Graduate Trainees (PGTs) from Post-Graduate Years (PGY) 1-4 participated in the study. The study was conducted in two phases. During phase I, participants completed three weekly one-hour training sessions on the UroMentor™ simulator practicing task 10. In this task, two stones from the left proximal ureter and renal pelvis were extracted using a basket under fluoroscopic guide. Objective assessments by the simulator and subjective assessments using the validated Ureteroscopy-Global Rating Scale (URS-GRS) were used to establish the learning curve. During phase II, the URS-GRS tool was used to assess performance of participants in the operating theatre.

Results

In phase I, ten urology PGTs (PGY1-4) with mean age of 27.6±1.9 (25-31) years participated in the study. PGTs practiced a total of 62 times, with a mean operative time of 13.8±7.3 minutes and a mean fluoroscopy time of 9.7±16.4 seconds. Competency in task 10 was achieved after seven trials on the UroMentor™ simulator. In phase II, seven PGTs were assessed during 60 consecutive flexible ureteroscopic stone extraction procedures in the operating theatre.

The mean operative time was 55.6±14.6 minutes and the mean fluoroscopy time was 28.6±6.4 seconds. There was a significant positive correlation between URS-GRS scores obtained on the simulator and in the operating theatre ($r=0.76$, $p=0.044$), thus establishing predictive validity of performance on the UroMentor™ simulator. Moreover, URS-GRS scores of all participants increased both on the simulator and in the operating theatre ($p<0.05$).

Conclusion

In conclusion, competency in flexible ureteroscopic stone-extraction (task 10) on the UroMentor™ simulator was achieved after seven trials. Since there was a strong positive correlation between URS-GRS scores on the simulator and in the operating theatre, the skill obtained on the simulator could be transferred to the operating theatre.

Resume

Introduction

Le but de ce projet de recherche est d'évaluer la courbe d'apprentissage des compétences en urétéroscopie souple pour l’extraction de calculs en utilisant le simulateur UroMentor^{TM}, ainsi que d’évaluer le transfert de ces compétences en salle opératoire.

Méthodes

Après avoir obtenu l'approbation éthique, des stagiaires postdoctoraux en urologie de la 1^{ere} à la 4^{e} année de résidence ont participé à l'étude. L'étude a été réalisée en deux phases. Pendant la phase I, les participants ont complété trois sessions de formation d'une heure par semaine sur le simulateur UroMentor^{TM} pour s’entraîner à la Tâche 10. Dans cette tâche, deux pierres de l'uretère proximal gauche et du bassinet rénal étaient extraites à l'aide d'un panier à calculs sous fluoroscopie. Des évaluations objectives, faites par le simulateur, et des évaluations subjectives, complétées en utilisant la Ureteroscopy Global Rating Scale (URS-GRS), une échelle éprouvée, ont été employées pour établir la courbe d'apprentissage. Pendant la phase II, l’échelle URS-GRS a aussi été utilisée pour évaluer la performance des participants dans la salle d'opération.

Résultats

Dans la phase I, dix stagiaires postdoctoraux en urologie (R1 à R4), avec un âge moyen de 27.6±1.9 (25-31) ans, ont participé à l'étude. Les stagiaires ont effectué la tâche un total de 62 fois, avec une durée opératoire moyenne de 13.8±7.3 minutes et un temps de fluoroscopie moyen de 9.7±16.4 secondes. Une compétence optimale pour effectuer la Tâche 10 a été obtenue après sept essais sur le simulateur UroMentor™. Dans la phase II, sept stagiaires postdoctoraux ont été évalués au cours de 60 extractions par urétéroscopie souple consécutives en salle opératoire. La durée opératoire moyenne était de 55.6±14.6 minutes et le temps de fluoroscopie moyen était de 28.6±6.4 secondes. Il y avait une corrélation positive significative entre les scores URS-GRS obtenus sur le simulateur et ceux obtenus en salle opératoire (r=0.76, p=0.044), établissant ainsi la validité prédictive de la performance sur le simulateur UroMentor™. De plus, les scores URS-GRS de tous les participants se sont améliorés, à la fois en salle opératoire et sur le simulateur (p <0.05).

Conclusion

En conclusion, la compétence à l'extraction de calculs par urétéroscopie souple (Tâche 10) sur le simulateur UroMentor™ a été atteinte de façon optimale après sept essais. Comme il y avait une forte corrélation positive entre les scores URS-GRS sur le simulateur et ceux en salle opératoire, l'habileté acquise sur le simulateur pourrait être transférée en salle opératoire.

Abbreviations

OR: Operating Room

PGTs: Post-Graduate Trainees

PGY: Post-Graduate Year

SD: Standard Deviation

URS: Ureteroscopy

URS-GRS: Ureteroscopy Global Raring Scale

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Conflict of Interest

I have no conflict of interests. The UroMentor^{TM} simulator was purchased by funds from the Montreal General Hospital Foundation.

Preface and Contribution

Mehdi Aloosh, Yasser Noureldin and Sero Andonian have contributed in designing this study. Data was gathered by Mehdi Aloosh. Mehdi Aloosh and Yasser Noureldin have analyzed the data. Mehdi Aloosh has also written the manuscript and all of the authors have contributed in editing of the manuscript.

Chapter 1: Introduction

1.1. Background

Traditionally, surgical training has been based on the apprenticeship model which was first introduced by William S. Halsted in 1904 (1). The apprenticeship model later developed into the current surgical residency system in the North America (2) and most parts of the world. In this model, Post Graduate Trainees (PGTs) learn surgical skills in the operating theatre by observing an expert surgeon perform a surgery and receive training from the expert. This model was based on the "See one, do one" concept. However, it has been criticized as a training model for learning complex technical skills because of several concerns, such as patient safety, diminishing learning opportunities for PGTs due to reduced work-hours and increasing complexity of procedures being performed in various specialties (3).

Flexible ureteroscopy is one such complex minimally invasive surgery with a steep learning curve. Therefore, Halstedian training model does not seem satisfy the training needs of PGTs. A better training alternative would be to use simulators to train and assess competency of PGTs in performing flexible ureteroscopy. The current body of work focuses on this aspect using a high fidelity virtual reality simulator.

1.2. Paradigm shift in surgical education

Halstedian training model as the cornerstone of current postgraduate surgical training is a time-based model of apprenticeship (4). Based on this model, it is expected that PGTs would find a chance to become competent in core surgical competencies within a predetermined period of time. However, recent changes in the medical field and expectations of the society have made it clear that the time-based surgical education is no longer sufficient to train competent surgeons. The changes in the medical field include rapid development in surgical technologies and techniques, which require PGTs spend more time to become experts in these technologies and techniques. Moreover, since patients are older with more co-morbidities, there is a higher chance of encountering more complex cases in practice. Therefore, more training is required. In addition, restriction on PGTs' duty hours, and a focus on efficiency in using operating theatre time and expensive instruments (5) have limited surgical training opportunities for PGTs (6). Furthermore, societal accountability has pushed medical education institutions to make sure that PGTs are competent and ready for independent practice. Another important ethical issue is consideration of training of novice post-graduate medical trainees on the patients, where there is higher risk of complication. These are some of the most important concerns that have driven a paradigm shift in medical education from a time-based surgical education to a competency-based medical education (CBME). For instance, the Royal College of Physicians and Surgeons of Canada (RCPSC) has developed CanMEDS framework, which outlines core competencies required for medical students and PGTs that should be obtained before graduation.

CBME focuses on learning outcomes instead of the time that a trainee should spend in the learning environment (7). Accordingly, institutions and training programs are moving towards designing curricula and programs that ensure PGTs gain required competencies. These new programs use teaching methods and assessment tools (8) that align with the desired outcomes. Correspondingly, simulation, as a teaching tool and most importantly as an assessment tool, has found an important role in the paradigm shift. Simulation has several desirable specification to be used in CBME. For instance, it is adjustable to the PGTs' learning needs and learning speed. As PGTs are different in acquisition of competency in performing new skills, simulation training is a suitable method to ensure achieving competencies in a stress-free and radiation-free environment for PGTs.

1.3. Competency in surgical procedures

Competency in performing a procedural skill is recognised by precise and efficient movements to accomplish the task without any error (9). To be competent in performing a surgical skill, a surgeon should be able to combine motor skills with theoretical knowledge and cognitive skills to perform a procedure at an acceptable level (10, 11). These skills include communication, leadership, decision-making and adaptability, etc. (12, 13). These qualities have been addressed as core competencies required for surgeons in the CanMEDS framework (14).

As expected, research done at McGill University (15) showed that PGTs' level of performance in procedural skills did not correlate with the theoretical knowledge (16, 17). Other authors emphasised on the importance of surgical strategy, which is based on theoretical knowledge and cognitive skills (18, 19). In fact, the latest perspective does not decrease importance of competence in performing procedural skills, which without it the surgeon would not be able to provide an acceptable level of care (20). Therefore, motor skills require important attention during procedural skill training.

Most surgeries are complex procedures composed of basic components (21). Improving performance in these basic components may improve performance of the whole complex procedure (22). It has been shown that in learning a complex procedure, deconstruction of the complex task into its components and learning each component separately is more effective than learning the whole task at once (23). In fact, learning increases when training takes place in multiple shorter sessions rather than a long complex training session (24). Moreover, if PGTs begin to learn complex surgeries by learning basic procedural skills, their focus of attention on each component will be higher. Therefore, this would enhance their learning; furthermore, automatically the time needed to perform the whole procedure would be reduced.

It has been shown that PGTs pass through three phases of learning surgical skills (6, 25). The first phase is cognitive phase. In this phase PGTs understand the task and its steps. The second phase is associative phase, in which the skill is practiced with huge cognitive effort until competency gained. Finally, during the autonomous phase, the skill can be performed automatically with the least cognitive effort. In the first and second phase, PGTs should focus on performing the procedure with all of their attentional capacity (26). Therefore, if PGTs receive training in the operating theatre in a real-time surgery with all of its complexities, their attention requirement may exceed their capacity. Consequently, this may affect learning negatively. In other word, if PGTs perform different parts of a procedural task in different training sessions, and if they receive real-time feedback, and have the chance to practice deliberately, their learning would be maximised (27). These circumstances could be achieved in simulated environments.

There are several surgical procedures that have been simulated within the past 20 years. Endourologic procedures, including flexible ureteroscopy, are one of these procedures, which has been simulated with various models. Endourologic procedures take place in a closed-cavity (genitourinary system) to manage various urologic problems, such as, urothelial tumors and renal and ureteral stones. Because of this nature of these procedures, they are suitable for simulation training.

1.4. Importance of flexible ureteroscopy training

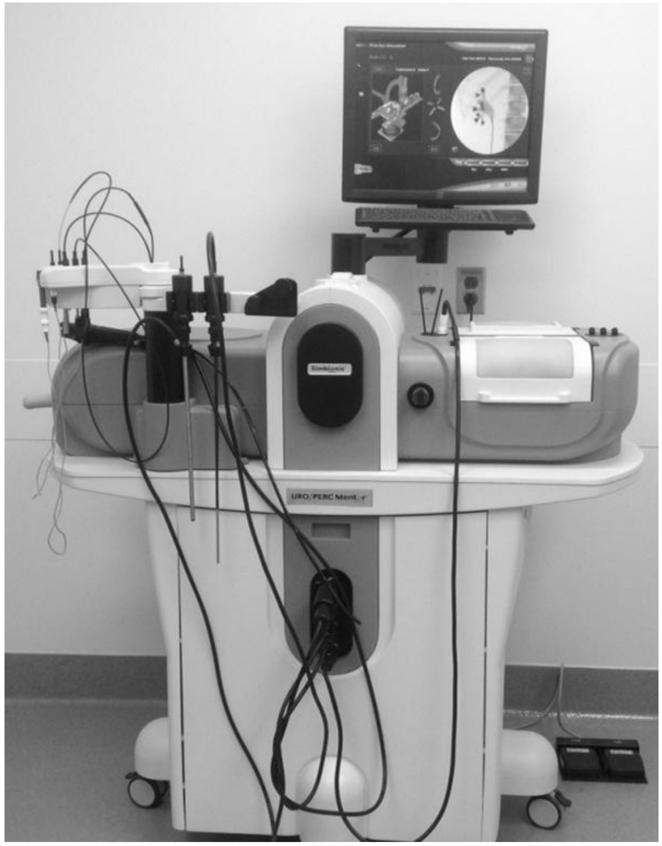
Despite being minimally invasive, without sufficient training, flexible ureteroscopy may result in catastrophic complications, such as, ureteral perforation and avulsion and loss of a kidney (28). Moreover, the fact that nephrolithiasis is a prevalent medical problem, which affects around 10% of population (29), demonetsrates the importance of training and achieveing competency in performing procedures required to treat a huge number of patients. Importantly, the latest American Urological Association guidelines recommends ureteroscopic lithotripsy as the gold standard for management of most ureteral and some renal stones among all different minimally-invasive options for management of nephrolithiasis (30). Furthermore, flexible ureteroscopy is also used in the management of upper tract urothelial carcinomas and uretero-pelvic junction obstruction (31, 32).

Fluoroscopy is used intra-operatively as a vital component of the procedure to guide surgeons in performing ureteroscopy. Thus, there is risk of excessive X-ray exposure to patients and operating theatre personnel. Finally, flexible ureteroscopy has a steep learning curve (33) requiring more than sixty procedures in the operating theatre to achieve competency, accordingly to the Accreditation Council for Graduate Medical Education (34). However, considering the latest reductions in work hours of PGTs, there are concerns regarding whether performing this number of ureteroscopic cases in the operating theatre could be a realistic expectation (35). In fact, it is difficult to rely exclusively on the operating theatre for teaching technical skills. Therefore, virtual reality simulators were introduced for training PGTs of technical skills, including flexible ureteroscopy. These simulators give the opportunity to PGTs to obtain the early phases of the learning curve before performing them in the operating theatre on the patients. Thus, these simulators could compensate for the deficiency in training hours for PGTs and improve patient safety.

1.5. UroMentor™ simulator

UroMentor ™ simulator (Simbionix, Cleveland, OH, USA) is a high-fidelity virtual-reality simulator that incorporates a physical model (pelvic box) and a computer interface (Figure 1). In this simulator, rigid cystoscope and semi-rigid and flexible ureteroscopes can be used in simulation training with a library of virtual cases. The simulator reacts, records and keeps tracking of objective parameters of the procedure, such as, operating time, fluoroscopy time, and number of traumas. Besides a real time feedback while performing the task on the simulator, a formative feedback is available at the end of each procedure. This feedback could be used to improve PGTs' performance.

Figure 1. UroMentor™ simulator (Simbionix, Cleveland, Ohio, USA)



1.6. Gaps in training flexible ureteroscopy using UroMentor™ simulator

Educational usefulness and validity of UroMentor™ simulator in performing endourologic tasks has been shown (28, 36-41). However, there is no data on how many times ureteroscopic stone extraction should be performed on the UroMentor™ simulator prior to performing this procedure in the operating theatre. In addition, there is no research whether skills acquired from practicing flexible ureteroscopic stone extraction on the UroMentor™ simulator are transferable to the operating theatre in the post-graduation level. In fact, there is lack of studies demonstrating the predictive validity of performance on the UroMentor™ simulator to performance in the operating theatre among PGTs. These uncertainties prevent optimal usage of the simulator and its incorporation into the urology training program. Therefore, the aim of the present study was to assess the learning curve of flexible ureteroscopic stone extraction using the UroMentor^{TM} simulator. Moreover, I aimed to assess the transfer of flexible ureteroscopy skills to the operating theatre (or predictive validity of performance on the UroMentor^{TM} simulator). These findings are important for incorporation of simulation training in the residency program designing which would ultimately result in an optimal educational program at the PGT level.

Chapter 2: Review of literature

In this section, first training of procedural skills will be reviewed, considering various theories and frameworks. Then, basic concepts in learning surgical procedures, such as learning curve, assessment tools, and the challenges in those fields will be briefly acknowledged. Moreover, simulation based education and virtual reality simulators will be discussed, besides the gaps in using these simulators. Finally, literature will be reviewed to examine the role of UroMentor simulator in training flexible ureteroscopic stone extraction procedure.

2.1. Training in procedural skills

There are several reports that suggest how to perform training in medical procedural skills (42). One of the best training methodologies has been defined by Kovacs (43). This is a four stage learning model, which includes four consequent stages: “learn, see, practice and do”. In the first stage, a learner acquires cognitive knowledge related to the procedure. In the next stage, he/she sees an expert when performing the task. Then, he/she practices the procedure and finally, the trainee performs the procedure on the patients, in the real world. According to Kovacs learning a procedural skill has two phases. First phase is cognitive phase, which contains two sub-phases: conceptualization and visualization. The second phase is psychomotor phase, which follows the cognitive phase (43).

Recently, Sawyer and colleagues presented an evidence-based framework (42), which has critical application in training procedural skills in medicine. This framework is based on adult learning theory. It goes further than Kovacs’ framework by adding two stages to it. Sawyer et al. borrowed the definition of a procedural skill from Foley, who defined procedural skill as "mental and motor activities required to execute a manual task" (44). The framework is based on a five-stage developmental model of learning in medicine, which has been described by Dreyfus et al. Dreyfus et al believed that the development of medical capabilities takes place through a continuum of five levels: novice, advanced beginner, competent, proficient and finally expert level (45).

Another basis of Sawyer's framework is Simpson and Harrow's taxonomy (46), which defines psychomotor development. According to Simpson and Harrow, this development happens along five consequent stages. First stage is guided response, which includes trial and error and imitation in performing a task. Second stage is mechanism, which is performing the task habitual, skillful and confident. The next stage is considered competency level, which in procedure is performed quickly, accurately and coordinated. The fourth stage is adaptation, in which the performer is able to modify pattern of the movement to handle complex cases. The last stage is organization. This is mastery level. In this level, the performer creates new pattern of movement when required (46).

Considering these learning phases, Sawyer and colleagues' framework for procedural skill training includes six consequent stages: "learn, see, practice, prove, do, and maintain" (42). The first stage, "learn", is mainly dedicated to conceptualization. This includes understanding of concepts, such as, indications of a procedure. Accordingly, learning strategies, such as, reading or web-based multimedia programs are recommended in this phase to improve learning. It has been also suggested that cognitive knowledge can be verified by performing a standard test, such as, a multiple choice question test. The second stage of Sawyer's framework is "see", which is visualization of the task. It may be accompanied by verbal instruction of the trainer of each step of the procedure. Here the goal is deconstruction of the procedure. It may also include the learners' explanations of each step while the trainers perform the procedure (47).

In the psychomotor phase of training, the trainee performs the complete task in the real world, after several practices and corrections. Therefore, the next stage in training a procedural skill is "practice", which followed by "prove", in which the trainee should show his/her competency in performing the procedure. Subsequently, the trainee will do the procedure on a patient for the first time in the fifth stage of training, which is "do".

Back to "practice" phase, learner deliberately practices the task in a safe environment, such as, practising on a simulator. This practice contains an effortful mental and physical activity, which has been defined by Ericsson and colleagues (48, 49). Deliberate practice has these characteristics: 1. Learners are motivated; 2. There are clear learning outcomes; 3. The task is practiced repetitively; 4. Performance of learners is measured, continuously; 5. Constructive formative feedback is provided (42). In the "practice" phase, development in the acquisition of the skill should be accompanied by constructive formative feedback in a learning environment to maximize learning.

In a meta-analysis performed by McGaghie and colleagues, superiority of simulation in achieving a clinical skill has been shown (50). Simulation has several benefits if used for "practice" step. It can simulate various cases with a range of difficulty, from simple to complex, as well as, clinical variations. Moreover, it can provide individualized learning and the use of different strategies of learning (34), and longer periods of practice, if required.

The purpose of the next step, "prove" is to ensure that the trainee is competent to perform the procedure in the real world. Simulation could have a central role in this step (42). Similar to “practice” step, it is expected to have defined learning goals and reliable assessment tools in this level. Learner boosts deliberate practice until achieving the mastery level in performing the procedure. In fact, further practice and feedback improves insight to one’s own performance (51). The assessment tools should be valid and reliable. In the surgical field, there are several assessment tools, such as, global rating scales that have been used in this research.

“Do” stage in learning procedural skills is a transitional step from training on the simulator to performing the procedure on the patients. PGTs, who have showed their competency in performing the task in “prove” stage, now would be able to practice on patients, under direct supervision of an expert. If assessments showed that the trainee could be trusted, he/she performs the task independently without direct supervision.

The last phase in learning a procedural skill defined by Sawyer et al. is “maintain”. Maintenance of competencies required in performing procedural skills is a crucial requirement for clinical practice. As level of skill in a particular task will gradually decrease if the task is not practiced regularly, maintaining the skill with regular practice is a necessity. Accordingly, “maintenance” is a competency that has been defined by Accreditation Council for Graduate Medical Education (ACGME) and American Board of Medical Specialties (52). Simulation interventions have been suggested to be very useful for maintenance purposes (42). This is more important in the case of novices, as the speed of degradation in skill is higher in them compared with experts. Moreover, this is important for those practitioners who do not perform the task regularly or who have been out of practice for a long period of time. It is clear that simulation cannot substitute clinical practice completely. Thus, simulation training could be a supplement to clinical practice (53). In previous reports, maintenance training based on simulation has been described as “Just-in-time”, “rolling refresher”, a “booster” training, etc. (42).

2.2. Automatization in performing procedural tasks

To learn a new procedural task, a novice trainee is required to invest his/her full attention to perform the task. In deliberate practice, a trainee combines learning with performance, which requires full attention. However, when the task is performed repeatedly, its entire components is saved in the long-term memory (54). This makes the task very easy and faster to retrieve from memory. Therefore, less energy and attention are required to perform the task. This phenomenon has been shown in laparoscopic surgery studies (26). However, there is a steep learning curve to perform a procedure at the maximum level of expertise. The more the task is complicated the longer it takes to reach expertise. According to Ericsson et al., highly complex skill tasks, such as chess or professional sports believed that take 10 years on average to achieve mastery level of performance if an individual intensively practices performing the task (49).

2.3. Level of supervision in learning procedural skills

Supervision of a trainee and the level of supervision is a matter of entrustment in trainee's competencies in performing a task. As competency is task based and not universal, a trainee may require a direct supervision in performing a task, while he/she is able to perform other tasks, independently. The supervision should be provided by an expert (55), such as, an attending surgeon. Moreover, the supervision not only preserves patient safety, but also, satisfies real time formative feedback (42). Ten Cate has defined levels of supervision of a trainee. In the first stage, learner just observes a procedure performed by an expert. In the second stage, trainee performs the task under direct supervision of an expert. It is clear that expertise is particular to a special task and it is not universal. Therefore, the expert is an individual who is expert in that particular task. In the third stage, supervision is available, but it is not direct. It is available in minutes, if requested. Finally, the trainee who eventually becomes expert in performing the procedure would be able to offer supervision for novice trainees (56).

2.4. Assessment tools

The most commonly used assessment tools in simulation training are checklists and Global Rating Scales (GRS). Each one has its own pros and cons. Checklists are good, because of their objectivity and specificity. They are sequential and can be followed easily (57). The disadvantage of checklists is that they are not able to distinguish between more important and less important steps. Moreover, it is not necessary to complete all of the steps in performing a procedure (58). On the other hand, GRS provides a broader assessment of a procedural skill by assessing several parameters. GRS has been originally developed based on the Objective Structured Assessment of Technical Skill (OSATS) rating scale, which was in turn developed by Martin et al. in 1997 (59). In fact, OSATS was first developed for open surgery skills, and GRS developed and validated for minimally invasive surgeries, such as ureteroscopies (37, 39, 40, 60). Often in GRS, a score of 1 is considered novice performance, a score of 3 is competent and a score of 5 is considered as expert perf3ormance. The advantage of GRS is that it provides a comprehensive view of competency in a procedural skill without considering steps in performing the task. The disadvantage is its inability to diagnose incorrect steps in performing the procedure (58).

Ureteroscopy Global Raring Scale (URS-GRS), which is used in the current study, contains seven parameters, each scored on a Likert scale from 1 to 5 bringing the maximum score to 35. These parameters included respect for tissue, instrument handling, endoscope handling, time and motion, forward planning, use of assistants, and knowledge of the procedure (61). Please see table 1.

Table 1. Ureteroscopy-Global Rating Scale (URS-GRS); modified from Matsumoto et al. (61)

Variable	1	3	5
Respect for tissue	Scope frequently pushed into urothelial wall; Used unnecessary force with tools	Scope occasionally pushed into urothelial wall; Careful handling of tools for the most part	No trauma to urothelial wall with scope; Consistent and careful handling of tools
Time and motion	Many unnecessary moves	Made some unnecessary moves but time more efficient	No unnecessary moves and time is maximized
Instrument handling	Needed to repeatedly attempt	Able to success within first few tries; Occasional awkward maneuver	Able to success with lucid motion and no awkwardness
Handling of endoscope	Frequently had scope pointing away from the center of the ureter/calyx; Scope poorly aligned during procedure	Had scope centered for the most part; Guidewire in view for the most part; Better use of scope angle during procedure	Scope always centered and guidewire always in view; Scope always set at a good angle throughout procedure
Flow of procedure and forward planning	Frequently stopped or need advice or assistance from examiner	Demonstrated the ability to think forward with relatively steady progression of procedure	Obviously planned procedure from beginning to end with lucid motion
Use of assistants	Failed to have assistants help with marking tools	Appropriate use of assistants most of the time	Strategically used assistants to the best advantage at all times
Knowledge of procedure	Deficient knowledge; Needed specific instruction at most operative steps	Knew all important aspects of operation	Demonstrated familiarity with all aspects of operation

2.5. Learning curve in surgical training

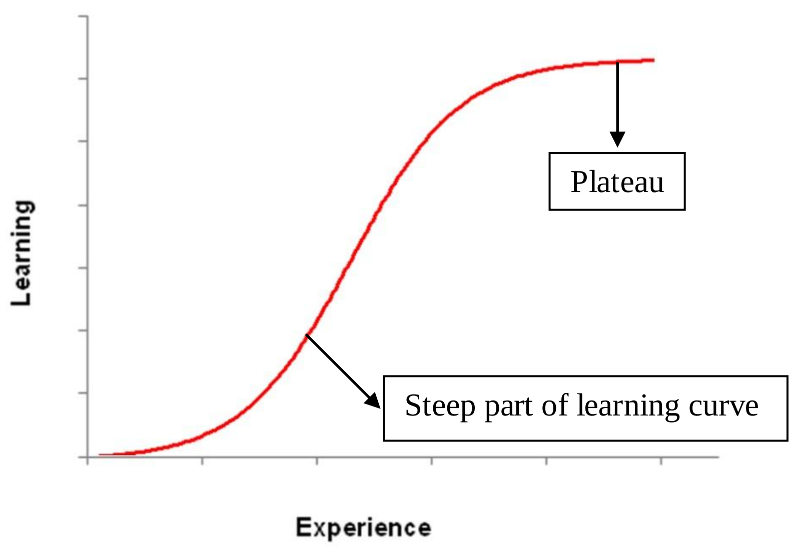
Learning curve can be thought of as an improvement in performance over time (62). Gaining motor skills could be visualized by a curve, where skills are measured during the period of learning. This curve which is called learning curve has following four phases (63):

1. Baseline performance
2. Rapid improvement in performance followed by a gradual improvement in the skill
3. Plateau, which is no improvement in the skill despite practice
4. Decline in the skill during time

Defining learning curve is important for training and assessment purposes and it provides information to design a training program. In fact, it helps to define how many cases a surgeon is required to perform to become competent in the new procedure. This is also important for patients' safety not only because it shows that PGTs are ready for independent practice, but also because it might help patients to make informed decisions at the time of preoperative counselling, and by knowing surgeon's level of performance. In fact, studies have shown that there is higher rate of complications because of being novice in performing a procedure (64). Therefore, learning curve has significant implications in training and adoption of new procedures in the field of surgery.

Moreover, defining learning curve is helpful for self-learning, by reflecting on own performance and learning needs. In the new paradigm shift in medical education, the learner has more space and responsibility for learning and defining his/her own learning needs. In addition, new procedures are constantly evolving, in the field of surgery. In this circumstance, there is a period in which inexperienced surgeons perform novel procedures with more difficultly, or longer operation time, and perhaps with more complications. This period is called "procedure development learning curve", which is different form learning curve of a novice PGT who is learning a standard procedure (62). But the same framework in learning procedural skills applies to these cases.

Figure 2. Learning curve of flexible ureteroscopy stone extraction skill



2.6. Factors affecting the learning curve

The learning curve is influenced by several factors. First, factors related to the PGT or the surgeon could affect a learning curve. For instance, experience in other procedures could change learning curve of a new procedure. Interestingly, now that minimally invasive procedures have superseded open techniques, large multicentre studies have shown that the learning curve of minimally invasive surgeries reached a plateau sooner for the new generation of surgeons compared with the previous generation (65). Moreover, for a procedure each individual has a separate learning curve, which will not necessarily follow the learning curve of the group of PGTs or surgeons (66).

Second, patient related factors, such as case-mix can influence the curve. Third, surgery-related factors, such as, operating time, estimated blood loss or oncological factors, such as, positive surgical margin are effective elements. Moreover, quality of life elements, such as, pain and incontinence are important (62). In fact, the learning curve of a procedural skill would be different depending on the definition of the expertise and the outcome measured (66). For example, if mean blood loss is considered as the desired outcome a PGTs would achieve it sooner than the one year mortality post-surgery (62).

2.7. Challenges in learning curve studies

A recent review noted that the majority of studies on learning curves have examined the latest surgical procedures and there is few data about basic urological procedures (66), such as, flexible ureteroscopic stone-extraction. Moreover, studies defining the learning curve lack a standardized method of calculating learning curve (66). As mentioned earlier, for a given procedure different endpoint outcomes could be considered (67). Therefore, different learning curves for the same procedure have been determined. For example, Gumus et al. (68) defined competency in robot-assisted laparoscopic prostatectomy by a positive surgical margin (PSM) rate of 6%. However, in other studies, the overall PSM rates was around 21% (69). This could cause variations in the defining one learning curves in various studies (66).

The complexity of cases may have a huge effect on outcomes, which is used to define learning curve. For instance, if a learning curve has defined based on complex cases it would be very different from curves based on simple cases. However, there is little data on these differences in the studies performed on learning curves. Moreover, from an educational perspective, the trainer is required to interfere when a PGT is not progressing or going to make an error during a case (66). Therefore, it is not easy to control the degree of participation of the expert in each procedure. Each surgery case is unique and different degree of intervention or participation of the expert is required. In addition, formative feedback has a crucial importance in the improvement of performance of trainees, thus it has a huge effect on the learning curve during deliberate practice on the simulator. Therefore, explicit statement about this feedback and its quality and quantity is required. As a result, comparisons between learning curve studies are confusing, considering the above-mentioned discrepancies.

2.8. Simulation-Based Medical Education (SBME)

Online Oxford English Dictionary (1989) describes simulation as a "The technique of imitating the behavior of some situation or process (whether economic, military, mechanical, etc.) by means of a suitably analogous situation or apparatus, especially for the purpose of study or personnel training" (70). In the medical field, simulation has been defined as a strategy or technique to imitate or amplify everyday clinical situations, interactively (71). Therefore, a simulator is a physical device or representation on which, during a simulation, a task or a part of a task is replicated (72). In fact, the purpose of using simulation as a training activity resembles a real situation that people should intervene.

Simulation can be categorized into low-fidelity and high-fidelity, in terms of replicating the real situation. High-fidelity simulator simulates more aspects of real surgical procedures, including physiological responses. For instance, a high-fidelity simulator could be a full body mannequin, which responds physiologically to interventions of users. On the other hand, low fidelity simulators do not respond to users, such as, mannequins used for training suturing techniques. Moreover, simulators have various types, including bench models, animal models, cadaver, and virtual reality simulators. (73)

Using simulation in medical training satisfies several current concerns in achieving competency in surgical education. For instance, using simulation makes PGTs able to perform repetitive tasks with various levels of difficulty and clinical variations in a controlled environment. Simulation is also adaptable to multiple learning strategies and it gives opportunity for feedback. Moreover, using simulation could be integrated within overall curriculum (74). Therefore, there is a huge trend towards using simulation for both training and assessment of competencies in surgical education (75). Moreover, using simulation for training novice PGTs can satisfy the ethical concerns of practice on patients during the early phases of training, which the risk of error is high. Thus, use of simulation has been identified as an important mean to overcome shortage in learning opportunities that medical education currently faces (76).

2.9. Virtual reality simulators

Virtual reality could be defined as technologies, which allow producing and interacting with three dimensional computerized models in real time (63). Virtual reality simulators provide a platform for trainees to interact with the simulated environment, which in the current study is a surgical situation. Moreover, these simulators record PGTs' performance and provide real time feedback. This ability is very helpful to assist PGTs to track their learning and to define their educational needs. This ability of simulators makes them very useful for the assessment of procedural skills of PGTs (77).

2.10. Validation of virtual reality simulators

It has been shown that simulation shortens the length of the learning curve for procedures in the operating theatre compared with controls (78). However, virtual reality simulators should be validated based on different definitions for validity to be successful in shortening the learning curve in the real life. Validity includes (79, 80):

1. **Face validity:** This defines users' opinion including PGTs' about degree of realism experienced using the simulator.
2. **Content validity:** This shows experts' opinion about simulator and if the simulator is an appropriate tool for training purposes.
3. **Construct validity**: This is an ability of the simulator in distinguishing different levels of performance.
4. **Concurrent validity**: This compares the simulator with the gold standard method.
5. **Predictive validity**: This validity shows correlation of performance on the simulator and in the operating theatre.

2.11. Gaps in using simulators for training purposes

It has been shown that that simulation is effective. It means that SBME interventions have positive effects on learning including knowledge, skills, and behaviours besides patients' outcome (81). However, review of the literature have highlighted the lack of research on these instructions in using simulators (34). In fact, although simulation has been used extensively in surgical training and assessment (82), especially in minimally invasive surgeries, little work has been done to clarify the instructional use of the simulators in SBME (83). This includes flexible ureteroscopy lithotripsy.

Moreover, using high fidelity simulators may not necessarily results in better outcomes in training compared with low fidelity simulators. Some studies have shown that low fidelity simulators can be as effective as high fidelity simulator in improving technical skills of PGTs (84). In fact, low fidelity simulators, such as, ureteroscopy part-task model has been shown to have good face, content and construct validity (85). These models are less expensive than high fidelity simulators and could be very useful in low stakes situation (85). Indeed, learning does not just depend on the fidelity of the simulator, but accompanying teaching and real-time feedback has a paramount importance in shortening learning curve of technical skills. In addition, comparison of effectiveness between virtual reality simulator and wet and dry models have not yet been done. Therefore, it has been concluded that perhaps a combination of training methods would be best to train procedural skills (66).

Some studies have shown that defining the number of required laparoscopic procedures to achieve competency cannot be determined prior to achieving competency in the procedure (86). As mentioned before, some believe that there is no single number of surgeries for achieving competency (66). Achieving competency for very basic laparoscopic exercises was very different between trainees, in terms of number of practice trials (171-782 trials) and time spent for training (5.5-21 h) (87). Moreover, all aspects of a procedural technique are not similar. Challenging technical aspects of a procedural skill are more important than other aspects (66).

Therefore, in defining the learning curve these aspects will require more attention. Finally, non-technical factors are also important factors in the performance of a procedure.

2.12. Studies performed on UroMentor™ simulator

In total, 21 studies have examined educational utility of the UroMentor™ simulator. A summary of these studies, which assess various validities of the simulator, is available in table 2. Face validity of the simulator in performing ureteroscopy has been determined in previous studies (88-90). These studies have shown that the simulator can represent a real experience of ureteroscopy procedure. Dolmans et al. recruited experts and non-experts in ureteroscopy. They all were asked to perform a task on the simulator and fill a questionnaire about the degree of realism on their experience on the simulator. Out of a 5-point scale, mean score of realism was 3.16 and usefulness of UroMentor TM for educational purposes was scored 3.98 (88). Moreover, two other studies has examined the face validity of performing cystoscopy on the simulator (91, 92). Content validity of the UroMentorTM for ureteroscopy has been evaluated in two studies (88, 89). Michel et al. showed that seven training courses of the simulator had a high degree of realism and usefulness for education (89).

Construct validity of UroMentor™ simulator, which demonstrates ability of the simulator to distinguish different levels of performances in cystoscopy (91-97) and ureteroscopy (90, 98-102), has been determined in the past. Schout et al. examined construct validity of the simulator in performing diagnostic cysto-ureteroscopy among a group of medical interns in a randomized control trial. Trained individuals on the simulator performed significantly better than the control group, without training on the simulator, using global rating scale (score of 3.8 vs. 3.0 and $p < 0.001$) (103).

Table 2. Summary of studies assessed different validities of UroMentor™ simulator in ureteroscopy procedure

	Types of validity				
Study	**Face**	**Content**	**Construct**	**Concurrent**	**Predictive**
Dolmas et al. 2009 (88)	*	*			
Michel et al. 2002 (89)	*	*			
Watterson et al. 2002 (90)	*		*		
Wilhelm et al. 2002 (98)			*		
Knoll et al. 2003, 2005 (99, 101)			*		
Jacomides et al. 2004 (100)			*		
Ogan et al. 2004 (102)			*		*
Chou et al. 2006 (104)				*	
Matsumoto et al. 2006 (105)					*

Watterson et al. (90) and Wilhelm et al. (98) randomized medical students into two groups: training group on the UroMentor™ simulator and control group without training on the simulator. These studies used global rating scales to assess competency of medical students in performing ureteroscopy. Both of the studies found a significant difference between trained and untrained students (global rating score of 23.6 vs. 14.7, $p < 0.001$ (90) and global rating score of 21.3 vs. 16.1, and $p < 0.001$ (98)). In another study, Jacomides and colleagues (100) recruited medical students and urology residents for their study. They trained both groups on the UroMentor and assessed their performance before and after training on the UroMentor simulator. However, medical students experienced a significant improvement in operating time (17.4-8.7 min, $p < 0.05$). There was a significant difference between PGTs and students in operating time (8.7 vs. 6.7 min, $p < 0.01$). In another study, Knoll et al. assessed experienced urologists' performance on the UroMentor simulator. There was a good correlation between the urologists' previous experience and outcomes on the simulator. For instance, total operating time was 12.3 minutes in the group that had performed more than 40 surgeries in the past, while operating time was 18.5 minutes in those with less than forty surgeries. This was considered a significant difference in operating time between the two groups (101).

Concurrent validity, which compares the simulator with the gold standard method, has also been examined for ureteroscopy (104). Chou and colleagues recruited sixteen first year medical students in a study. They divided the participants into two groups. Then, they trained one group on the UroMentor simulator for cysto-ureteroscopy, laser lithotripsy and stone extraction. They trained the other group on ureteroscopy training model (from Limbs and Things) for the same procedure. Both groups were trained until competency level, meaning being able to independently perform the procedure. Two months later, participants were assessed for their performance during an ureteroscopic procedure on a pig model, using an objective structured assessment of technical skills (OSATS). The objective assessment tool assesses competency by evaluation of several elements, including handling of tissue, flow of operation, instrument handling, knowledge of instruments, use of assistants, and knowledge of procedure. Chou et al. found that both groups were able to perform the steps of the procedure correctly, without a significant difference ($p = 0.38$). (104)

Finally, predictive validity of the UroMentor simulator in performing ureteroscopy has been evaluated. Ogan et al. and Matsumoto et al. showed that there is a good positive correlation of performance on the simulator and in the operating theatre (102, 105). Ogan and colleagues recruited a group of medical students and a group of PGTs. They trained only medical students on the UroMentor simulator, then compared medical students' and PGTs' performance on a cadaveric model. Performance of the medical students on the simulator was correlated with their performance on the cadaver, using global rating scale (Pearson correlation coefficient was 0.62 and $p < 0.01$). Interestingly, PGTs, who did not receive training on the simulator performed significantly better on the cadaveric model, using GRS (global score of 3.8 vs. 4.8 and $p < 0.01$) (102), means that clinical experience is superior to simulator training in the real practice.

In fact, both of abovementioned studies assessed medical students group for training on the simulator. They trained medical students on the UroMentor™ simulator, and then compared their performance on a male cadaver with a group of urology residents. They found that the performance of medical students on the simulator correlates their performance on the cadaver in several parameters, including total operating time and global rating scores. Moreover, the researchers found a correlation between the training level of the PGTs and their performance on the cadaver. In addition, Ogan et al. showed that training on the simulator could not make medical students able to override the performance of PGTs who did not practice on the simulator (102).

Chapter 3: Material and Methods

This study was conducted at McGill University Health Center after obtaining McGill University ethics approval (No. A05-E38-15A) and informed consents from all participants. Urology residency training in Canada is five years. At McGill University Health Center, there are 3 urology PGTs (one PGY1-2, one PGY3-4, and one PGY-5) at a given time rotating on the endourology service. Prior to implementation of this training program on the UroMentor™ simulator, flexible ureteroscopic stone extraction was performed by PGTs in the PGY4 level. Regardless of their PGY lever, PGTs who wanted to participate in this study were recruited to be trained on the simulator immediately prior to starting their clinical endourology rotation and thus prior to performing ureteroscopic stone-extraction in the operating theatre. Since each endourology rotation is twelve weeks, consecutive PGTs from PGY one to four rotating on the endourology service were recruited for the study between September 2015 and August 2016. Each participant filled out a questionnaire regarding age, gender, handedness, PGY level, previous practice on virtual reality simulators, and previous experience in performing endourologic procedures, such as cystoscopy, semirigid and flexible ureteroscopy.

This study was conducted in two phases. The aim of phase I was to define the learning curve of flexible ureteroscopic stone extraction on the UroMentor™ simulator (*Simbionix, Cleveland, Ohio, USA*) and the aim of phase II was to assess transfer of this skill to the operating theatre, thus establishing the predictive validity of performance on this simulator. During phase I, participants were trained on the UroMentor™ simulator task 10 for three consecutive weekly sessions lasting one hour each. Three hours of practice was arbitrarily chosen since there are no previous publications on the learning curve of ureteroscopic stone extraction on this simulator.

Prior to the first training session, participants were oriented to the simulator. The participants received objective feedback from simulator and a feedback based on URS-GRS after each flexible ureteroscopy on the simulator and based on URS-GRS in the operating theatre. Therefore, PGTs were able to consider provided feedback for future practice on the simulator or performing surgery in the OR.

Task 10 or ureteroscopic stone extraction procedure, was chosen since it is the most complex task on the UroMentor^{TM} simulator. This task required the use of a rigid cystoscope to enter the bladder and place a guidewire in the left ureteral orifice. Then a flexible ureteroscope and a stone basket were used to extract two stones from the left proximal ureter and renal pelvis under fluoroscopic guidance. At the end, a systematic examination of the left renal calyces was performed. Following completion of the task, the simulator generated performance reports with several objective parameters, such as operative time, fluoroscopy time, number of ureteral wall traumas, and number of ureteral perforations. In addition, a single assessor (Mehdi Aloosh) used the validated Ureteroscopy-Global Rating Scale (URS-GRS) tool to subjectively assess the performance of participants performing successive trials of task 10 during the three weekly sessions (61). The assessor was not blinded to PGY levels. This assessment tool contained seven parameters, each scored on a Likert scale from 1 to 5 bringing the maximum score to 35. These parameters included respect for tissue, instrument handling, endoscope handling, time and motion, forward planning, use of assistants, and knowledge of the procedure (61). Competency on the learning curve of flexible ureteroscopic stone extraction using task 10 on the UroMentor^{TM} simulator was determined when the URS-GRS scores reached a plateau. Technically, the first performance of the PGTs on the simulator was considered as their baseline performance on the UroMentor.

In phase II, participants, who received training on the simulator, were observed performing consecutive flexible ureteroscopic stone extraction in the operating theatre during their endourology rotation. Participants were subjectively assessed by one assessor (Mehdi Aloosh) using the same URS-GRS tool. Furthermore, operative time, fluoroscopy time and intra-operative complications were collected. The procedure and fluoroscopy times included all of the required components for ureteroscopic stone extraction including retrograde pyelography, possible balloon dilatation, possible usage of ureteral access sheaths and insertion of indwelling ureteral stents. Correlation between the URS-GRS scores on the simulator and inside the operating theatre was performed to assess the transfer of flexible ureteroscopic stone extraction skill from the simulator to the operating theatre, thus establishing predictive validity. In the second phase of the study, we were not able to assess a baseline for the performance of PGTs. Because some of them were novice residents without any experience in the OR on performing flexible ureteroscopy. Therefore, it was not ethical to allow novice residents practice on patients.

Data gathered from the questionnaires, the UroMentor™ simulator, and intra-operative variables were tabulated and analyzed. The Statistical Package of Social Sciences for Windows (SPSS, Chicago, IL) software version 20 was used. Descriptive data were presented in terms of numbers and percentages, or means and standard deviations. Spearman's correlation coefficient was used to determine associations between continuous variables and significance was considered whenever the two tailed p-value was <0.05.

The required sample size to assess correlation of scores obtained on the simulator and in the operating theatre was computed, using GPower software version 3.1. To compute the sample size these elements were considered: an effect size of 0.65 form previous studies, α error of 0.05, and power ($1-\beta$) of 0.7. Total required sample size was computed 9 with power of 0.74.

Chapter 4: Results

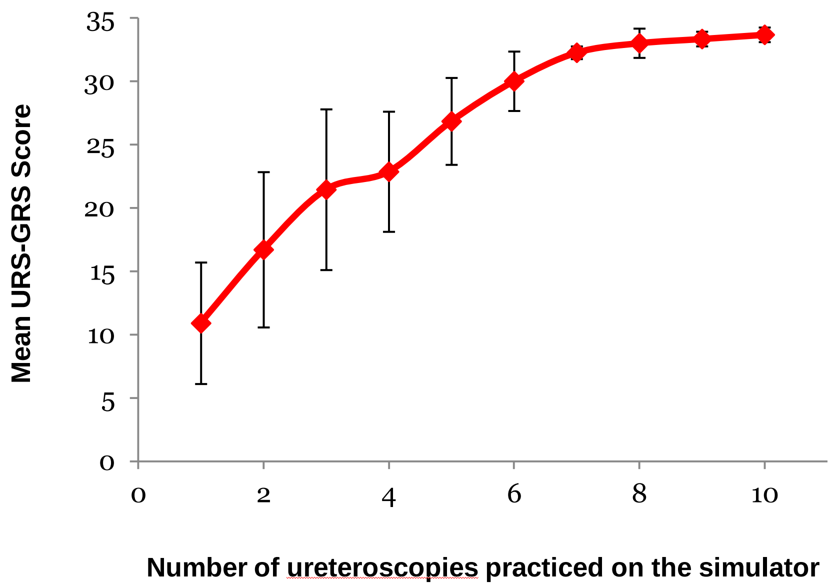
In this section, complementary results and analyses are presented compared with the results in the published manuscript in the appendix, since I continued to gather data while publishing the preliminary results, following the suggestion of my advisory committee. The result will present in two phase: phase one on the simulator and phase two in the operating theatre.

4.1. Phase 1: Training and assessment on the UroMentor™ simulator

During phase one of the study, ten urology PGTs (1 PGY-1, 4 PGY-2, 3 PGY-3, 2 PGY-4) with a mean age of 27.6±1.98 (25-31) years participated in the study. All PGTs were right handed and two were female. Only one participant had practiced on a virtual reality simulator and none of them had previous practice on the UroMentor™ simulator prior to this study. On average, participants had performed 89±150 cystoscopies, 39±65 semirigid and flexible ureteroscopies and 12±20 transurethral resections.

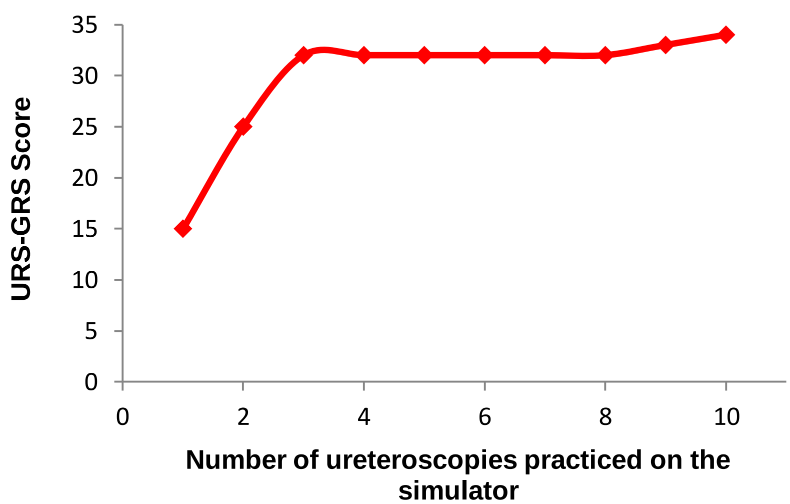
During the three weekly practice sessions, PGTs performed task 10 on the UroMentor™ simulator 62 times (mean: 6.1±2.9; range: 3-10) with a mean operative time of 13.8±7.3 minutes and mean fluoroscopy time of 9.7±16.4 seconds. The learning curve for the group of participants on the UroMentor™ simulator reached a plateau after seven trials of task 10. Please see figure 3. Accordingly, the mean practice time required to reach the plateau was around 95 minutes.

Figure 3: Learning curve of flexible ureteroscopic stone extraction on the UroMentor™ simulator for the PGT group.



It should be noted that the group learning curve is different from individual learning curves. As an example an individual learning curve has been shown in figure 4. In this instance the PGT has a shorter learning curve than the group learning curve.

Figure 4: Learning curve of flexible ureteroscopic stone extraction on the UroMentor™ simulator for one of the PGTs



Furthermore, fluoroscopy time decreased reaching a plateau at the fifth trial (Figure 5). Operative time and number of traumas from the scope, guidewire and basket decreased reaching a plateau after the sixth trial (Figure 6, 7). Moreover, there was no ureteral perforation.

Figure 5. Effect of training on fluoroscopy time

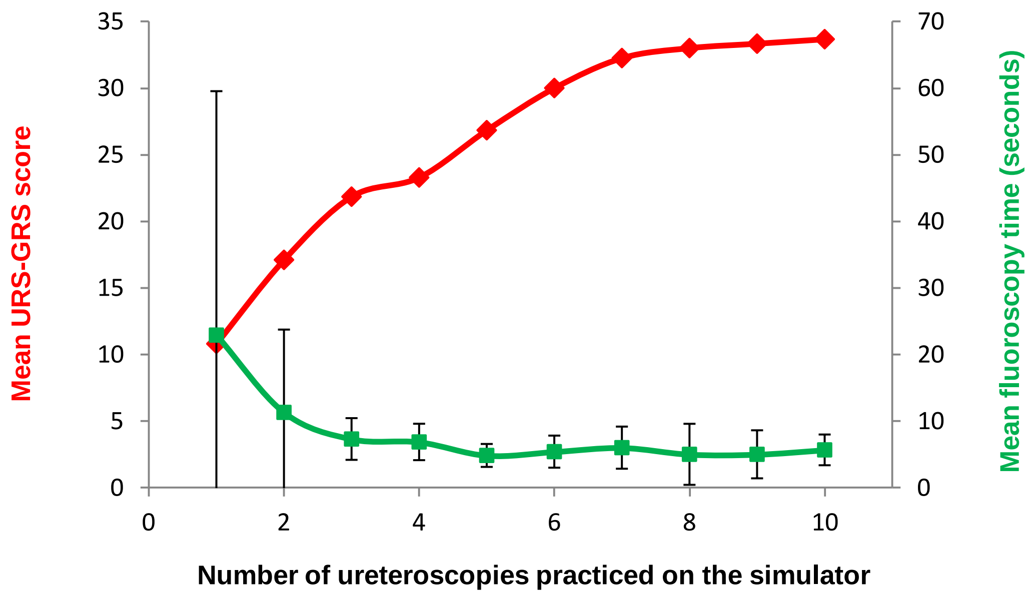


Figure 6. Effect of training on operating time

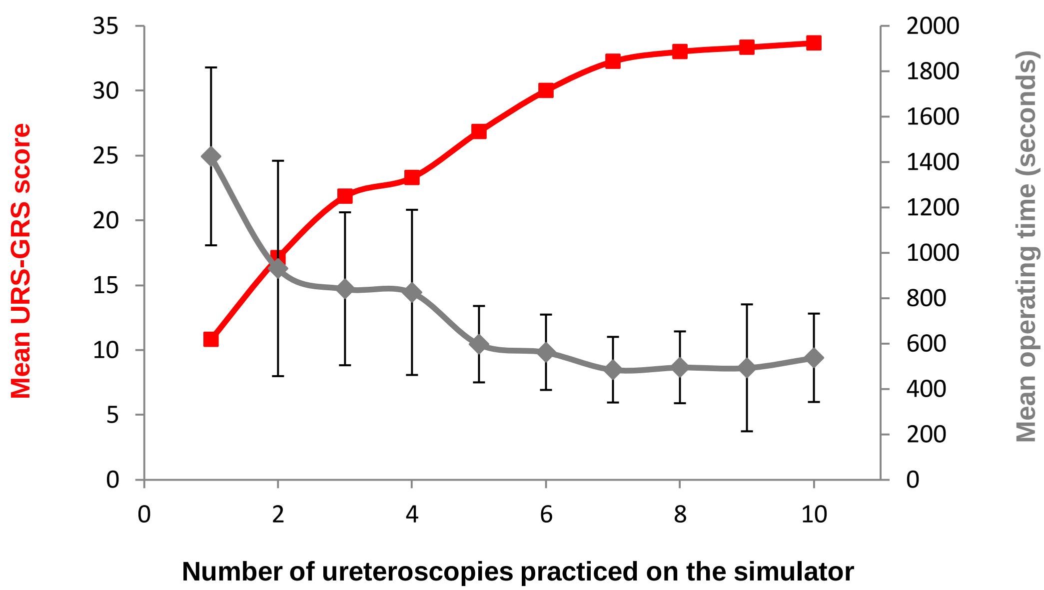
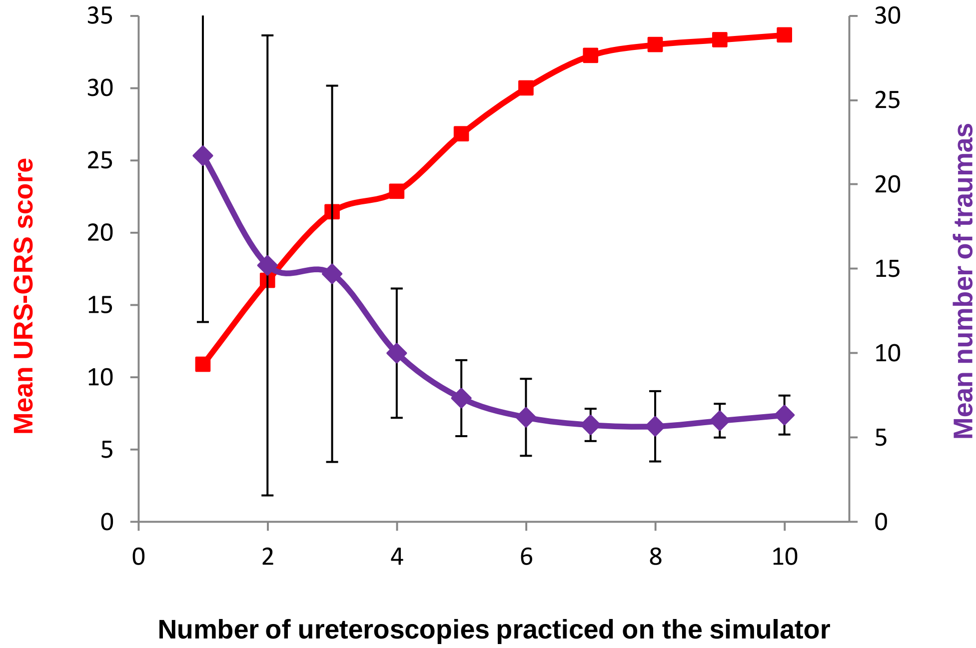
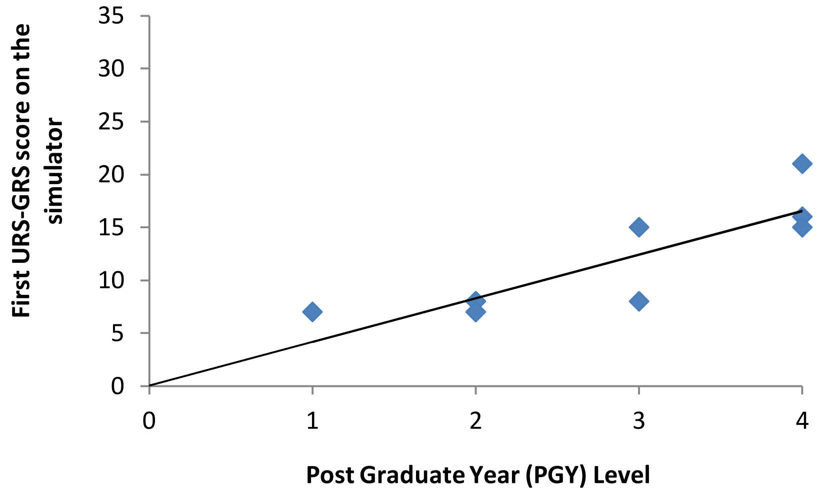


Figure 7. Effect of training on number of traumas from the scope and instruments during practice on the simulator



Moreover, there was a significant and strong correlation between first URS-GRS score obtained on the simulator and PGY level of the participants (r= 0.86, p= 0.001). Please see figure eight.

Figure 8. Correlation of PGY levels and first score obtained on the simulator



Furthermore, there was a positive correlation between the mean URS-GRS scores obtained on the first trial on the simulator and the number of previously performed semi-rigid and flexible ureteroscopies (r= 0.629, p= 0.051) (Figure 9). In the new analysis, previous semi-rigid and flexible ureteroscopic experience still has no correlation with fluoroscopy time and operative time of the first trial on the simulator. Moreover, there was no correlation between previous experience and the number of traumas caused by scope and instruments.

Figure 9. Correlation of previous ureteroscopy experience and first score obtained on the simulator

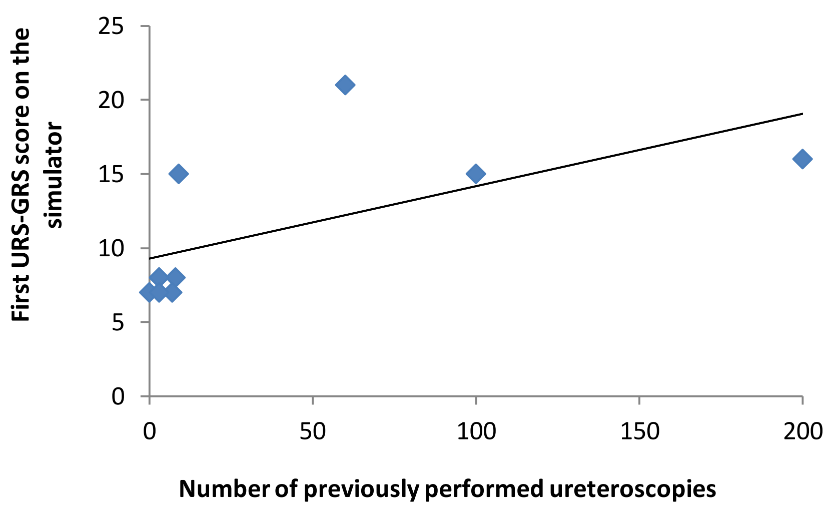
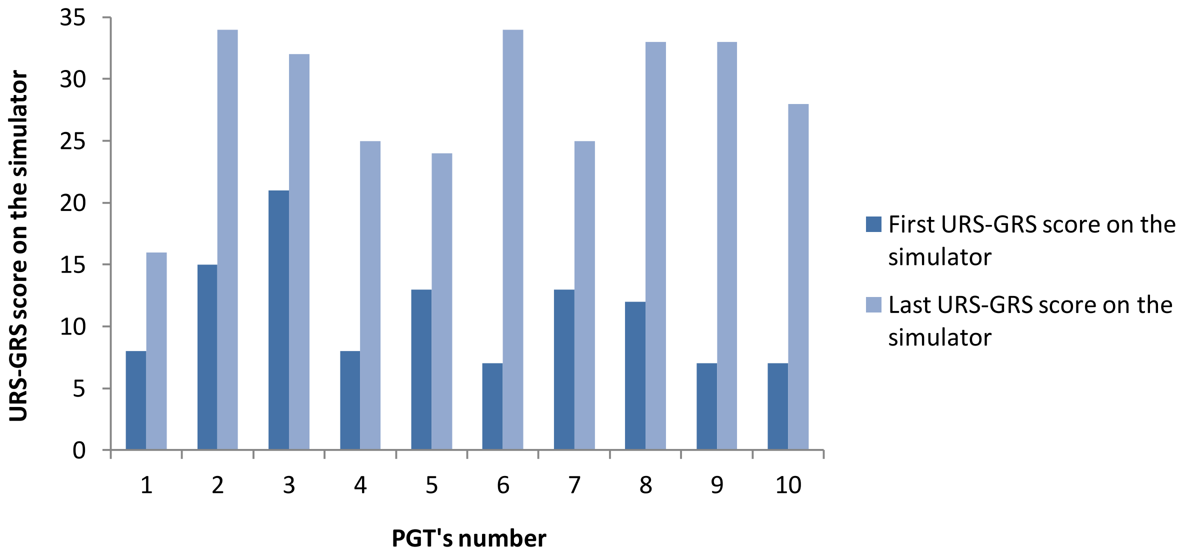


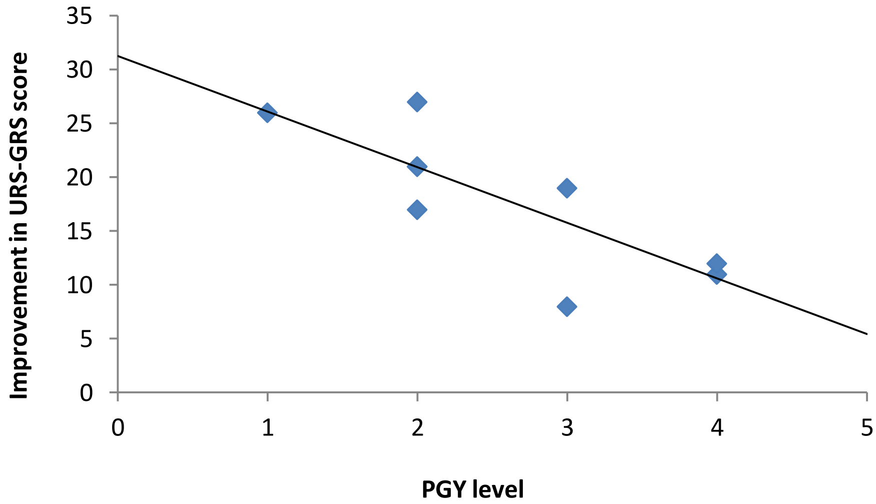
Figure 10 shows improvements in the performance of each resident on the simulator. This graph presents a comparison between URS-GRS score each resident obtained on the first trial and the last trial on the UroMentor^{TM} simulator. The difference between the two scores was significant, using student t-test ($p<0.001$). However, some of PGTs did not complete the three training sessions. Therefore, their scores did not improve to the competency level. For instance, resident number 1 practiced only for one hour on the simulator, thus, his/her final URS-GRS score is very low.

Figure 10. Comparison between baseline and the final URS-GRS score each resident obtained on the UroMentor^{TM} simulator



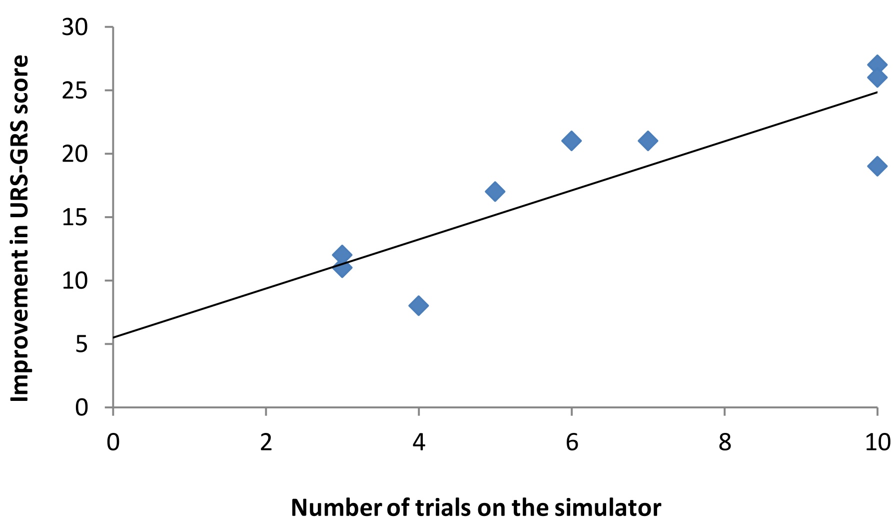
Furthermore, analysis showed that the PGY level has a strong negative correlation with the improvement in performance on the UroMentor^{TM} simulator ($r=0.825$, $p= 0.003$). Please see figure 11. Vertical axis represents the difference between the first score obtained on the simulator and the score on the last trial on the simulator and horizontal axis shows the PGY level.

Figure 11. Correlation of PGY level with improvement in performance on the UroMentor™ simulator



Moreover, analysis showed that there is a significant and strong correlation between improvement in URS-GRS score obtained on the simulator and number of trials on the simulator ($r=0.877$, $p<0.001$). Please see figure 12.

Figure 12. Correlation of number of flexible ureteroscopies performed on the simulator with improvement in performance on the UroMentor™ simulator



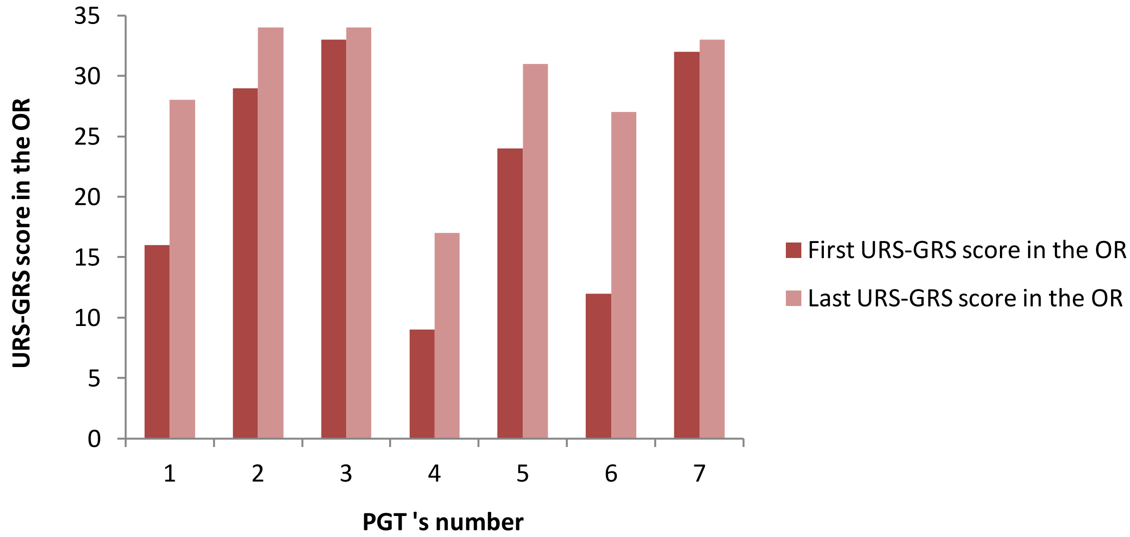
Finally, analysis of the data revealed that there is a moderate but significant correlation between URS-GRS scores obtained on the simulator and fluoroscopy time reported by the simulator. (r=0.47, p=0.02). Similarly, there was a moderate correlation between URS-GRS scores and operating time (r=0.48, p=0.02), as well as, a correlation between URS-GRS score and number of traumas caused by instruments and scope. (r=0.46, p=0.03)

4.2. Phase 2: Assessment of performance in the operating theatre

During phase II, seven PGTs (2 PGY-2, 2 PGY-3, 3 PGY-4) out of the ten, who practiced on the UroMentor™ simulator during phase I, were assessed while performing flexible ureteroscopic stone-extraction in the operating theatre during their endourology block. They performed 62 consecutive flexible ureteroscopic stone extractions with an average of 5.1±3.9 (range: 5-15) procedure per PGT. These procedures were all of the flexible ureteroscopic lithotripsy performed in the same endourology block that each PGT attended. Therefore, we were able to control extra training or exposure to the procedure in the operating room. The average operative time was 55.6±14.6 minutes and average fluoroscopy time was 28.6±6.4 seconds.

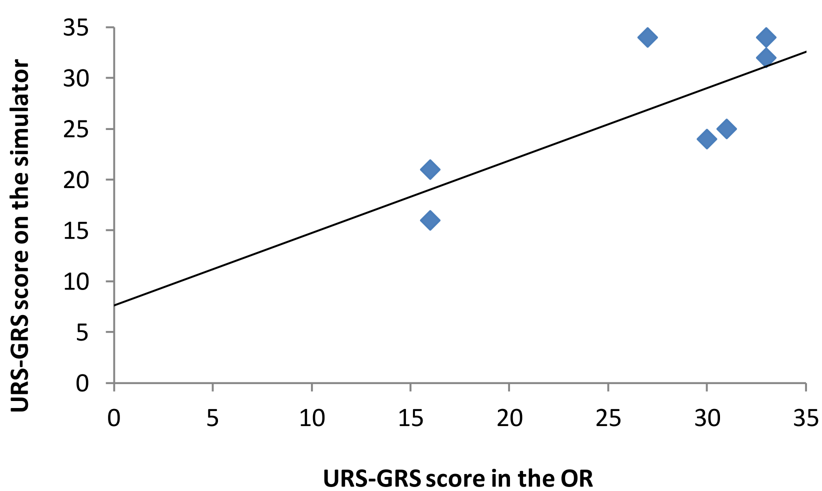
All of participants performed better in the operating theatre after training on the simulator. Please see Figure 13. The first URS-GRS score represents the baseline performance of each PGT in the operating theatre and the last URS-GRS score is the score PGTs obtained in the operating theatre after completion of their training on the simulator. The difference between the two scores was significant, using student t-test (p=0.006).

Figure 13. Comparison between baseline and final assessment of performance in the operating theatre.



Regression analysis showed that there was a strong correlation of mean URS-GRS scores obtained on the simulator and in the operating theatre (r= 0.766, p= 0.044) (Figure 14), thus, establishing the predictive validity of performance on the UroMentor™ simulator.

Figure 14. Correlation of URS-GRS scores obtained on the simulator and in the operating theatre



In addition, there was a significant and negative correlation between improvement in URS-GRS score obtained in the operating theatre and first URS-GRS score obtained on the simulator (r= 0.826 , p= 0.021), as well as, first score obtained in the operating theatre (r=0.848, p=0.015). (Figure 15 and 16)

Figure 15. Correlation between improvement in performance in the operating theatre and first URS-GRS score obtained on the simulator

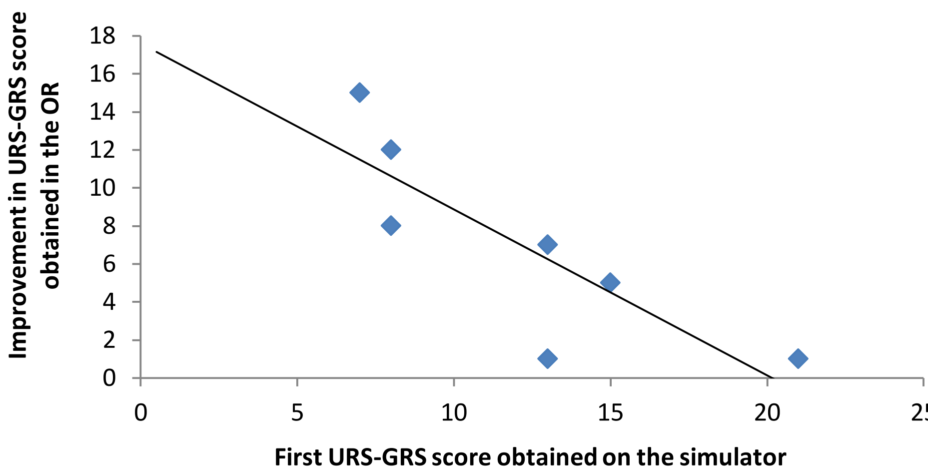
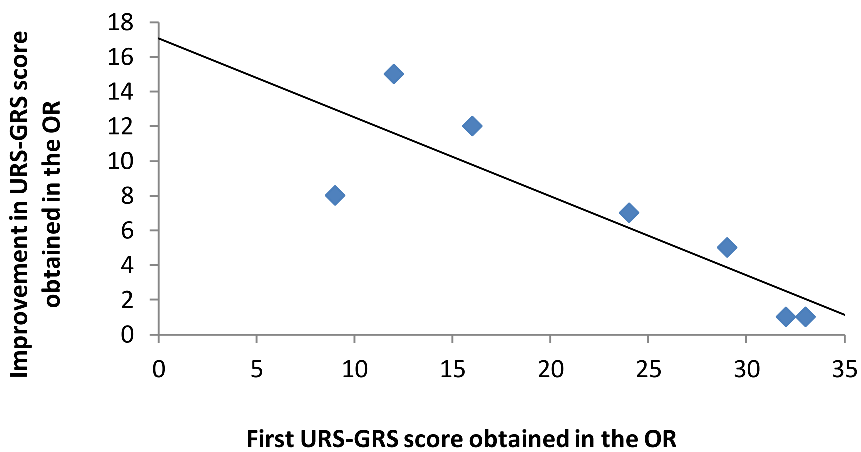


Figure 16. Correlation of improvement of performance in the operating theatre and first URS-GRS score obtained in the operating theatre.



In addition, analysis showed that there was no a linear correlation between URS-GRS score obtained in the operating theatre and fluoroscopy time (r=0.6, p=0.61). Similarly, there was no a linear correlation between URS-GRS scores and operating time in the operating theatre (r=0.6, p=0.64).

Finally, when the participants asked about their experience on the simulator and usefulness of the simulator, novice PGTs believed that the UroMentor™ simulator was very useful for their familiarity with basic technical skills and instruments. However, senior residents believed that this simulator has low face validity and did not represent a real experience in the operating theatre.

Chapter 5: Discussion

To achieve competency in performing a surgical procedure, Halsteadian model of training recommends introduction of the procedure in the operating theatre from early phases of training (35). This training can provide theoretical and practical knowledge of the procedure. Moreover, it provides the experience of being in the operating theatre environment. It also improves development of other vital elements of surgical competence, which affect outcome of surgery, such as, cognitive aspects of surgery (e.g. decision-making, communication and collaboration skills).

However, training in clinical environment is opportunistic and on the go, because of the unexpected nature of this setting. Moreover, there are various distracters in the clinical situation. As a result, restrictions in PGTs work hours, besides patient safety concerns, especially in the early phases of the learning curve have caused dramatic reductions to operating theatre time and case exposure. Consequently, learning opportunities seems insufficient and patients would be at more risk in the current clinical situation. Using new technologies to overcome these shortcomings in the surgical field is one of the best available options. Accordingly, simulation and incorporation of validated virtual-reality simulators into the curricula of post graduate medical training programs, specifically in the early phases of the learning curve, is one of the most important alternatives to operating theatre. It should be mentioned that medicine is not the only field that uses simulators to train novices. Simulation and simulators have extensively been used to train procedural skills in a wide range of fields, such as aviation (106) and military (107), for more than half a century.

Studies have shown that many components of surgical procedures, such as, psychomotor (e.g. manual dexterity) and cognitive skills (e.g. risk assessment) could be acquired by training on simulators (108). Watterson and colleagues showed that the manual dexterity of novice PGTs in performing semi-rigid ureteroscopy was enhanced following training on a low-fidelity simulator (39). Similarly, it has been shown that training on simulators improve dexterity during performing ureteroscopy. This training is a structured training that has effectively been used for deliberate practice, which is the cornerstone of learning surgical procedures. Ericson et al. has defined elements of deliberate practice, including a clear learning goal, repetitive and concentrated exercise, a precise assessment tool and formative feedback (39, 109).

To perform the current research, all of specifications of deliberate practice have been considered in training of PGTs on the UroMentor simulator. Learning objectives was clearly defined and presented to PGTs. It was achieving competency in performing flexible ureteroscopy stone extraction task on the simulator. The focused task that was used on the simulator was task 10, which was repeatedly practiced. Moreover, the same procedure was performed in the operating theatre. Assessment was conducted by using the validated URS-GRS assessment tool. After competency in performing the procedure was achieved on the simulator, PGTs demonstrated their competency in the operating theatre, being assessed by the same assessment tool and same evaluator (myself). Moreover, the simulator provided real time feedback while a PGT was performing the procedure and at the end of each session it produced a report. These formative feedbacks improve learning by improving insight to one's own performance and facilitate correction of possible errors. The importance of these feedbacks has been supported by closed loop theory (110).

The UroMentor™ simulator is a validated computer-based virtual-reality simulator (35, 37, 111) offering semi-rigid and flexible ureteroscopy modules. Two prospective randomized controlled trials on the UroMentor™ simulator showed educational impact of this model in training semi-rigid and flexible ureteroscopy for medical students, using a global rating scale (39, 40). These studies reported improved acquisition of ureteroscopic skills in novice trainees following training on the UroMentor™ simulator. However, there is no data regarding the learning curve of flexible ureteroscopic stone extraction on the UroMentor™ simulator. The learning curve could be used as a means of assessing surgical expertise and the number of procedures needed to gain surgical competence (35). However, the learning curve may differ according to the selected outcome criteria. For instance, when operative time was used as an outcome for percutaneous nephrolithotomy, the estimated case load of sixty patients was necessary to reach a plateau (112). However, when the stone-free rates were considered as an endpoint, the plateau was achieved at the very initial cases (113).

In the current study, URS-GRS scores were used as the main outcome to establish the learning curves of the procedure, since the simulator does not provide an overall objective score. However, this study also defined learning curves based on objective outcomes provided by simulator, such as, fluoroscopy time, operating time and number of traumas caused during surgery. Using the URS-GRS tool, the learning curve of ureteroscopic stone extraction while performing task 10, reached a plateau after performing seven trials on the UroMentor™ simulator. The estimated time to complete 7 trials of task 10 was 95 minutes. Therefore, on average PGTs need to spend 95 minutes on the UroMentor™ simulator to achieve competency in performing ureteroscopic stone extraction on the simulator prior to performing ureteroscopic stone extraction in the operating theatre. Moreover, learning curves defined by other objective outcomes are similar to the learning curve defined by URS-GRS score. These findings would be valuable for incorporation of the simulator in the training program of urology PGTs as in the case for training urology PGTs at McGill University.

This study showed that the mean operative time on the simulator was 14.6 minutes and the operative time reached a plateau after the sixth trial. Knoll et al. reported that untrained PGTs performed flexible ureteroscopy as rapid as trained residents on the UroMentor™ simulator by the fifth trial (28). In addition, in the current study, the increase in URS-GRS score was associated with a decrease in fluoroscopy time and the number of mucosal traumas (Figure 5 and 7). Interestingly, URS-GRS scores correlated with objective variables provided by the simulator, such as, operating time and fluoroscopy time. Although this correlation was significant, it was moderate. This may indicate that objective variables may have limited value in the assessment of performance in the operating theatre. Perhaps a combination of objective variables and URS-GRS scores are better for evaluation of competency.

Furthermore, the first trial URS-GRS scores on the simulator correlated with the number of previously performed semi-rigid and flexible ureteroscopies in the operating theatre (Figure 9). In addition, the baseline performance on the simulator correlated strongly with PGY level (Figure 8). These results show that previous exposure with clinical cases improved performance on the simulator. Moreover, those without any experience in the procedure received lower baseline scores. All of these results support construct validity of the flexible ureteroscopy task 10 of the simulator, which is ability of simulator in differentiating individual performances from novice to competent and expert. Most of previous studies on construct validity of the simulator in this task recruited medical students (90, 98, 103). Only Jacomides and colleagues recruited medical students and PGTs for their study (100). They trained both groups on the UroMentor and assessed their performance before and after training on the UroMentor simulator. They observed a significant shorter operating time for PGTs compared with students.

Ogan et al. and Matsumoto et al. have demonstrated the predictive validity of UroMentor^{TM} simulator in performing flexible ureteroscopy task in two studies (37, 38). They recruited medical students for this purpose and reported the transfer of diagnostic flexible ureteroscopy skills from the UroMentor^{TM} simulator to the cadaveric model. However, there is a lack of high quality studies on the predictive validity of the UroMentor^{TM} simulator among urology PGTs regarding the transfer of ureteroscopic stone extraction skill to the operative theatre. In the present study, transfer of flexible ureteroscopic stone extraction skill from the UroMentor^{TM} simulator to the operating theatre was shown by finding a correlation between the URS-GRS scores on the simulator and in the operating theatre. URS-GRS assessment tool was used on the simulator and in the operating theatre for consistency in the assessment. It has been recommended that the same assessment tool should be used in both "prove" and "do" steps of training a procedural procedure (42). The first step was performed on the simulator and the second one, "do", was performed in the operating theatre.

The results of the current study show that all of the participants benefited from training on the simulator ($p<0.05$), despite various levels of training at baseline (PGY level). (Figures 10 and 13). Moreover, the results revealed that junior PGTs benefited more from training on the simulator, compared with senior PGTs. First, there is a strong correlation between PGY level of the participants and improvements in their performance on the simulator (Figure 11). In other words, PGTs whose performance improved more on the simulator were more junior. Second, improvement in the performance in the operating theatre significantly correlated not only with baseline performance in the operating theatre (Figure 16), but also with the baseline performance on the simulator (Figure 15). In fact, performance of those with lower baseline scores on the simulator and in the operating theatre (less surgical experience), which were junior PGTs, improved more in performing flexible ureteroscopy. This means that less experienced junior PGTs improved their performance to the level of more experienced senior PGTs by training on the simulator.

The data showed that those who practiced more on the simulator benefited from training on the simulator. In fact, improvement in the performance on the simulator correlated with the number of trials on the simulator (Figure 12). This has been supported by deliberate practice concept which has been described by Ericsson et al. (48, 49). Therefore, for optimal benefit from training on the simulator, novice urology PGTs should practice on the simulator until reaching the plateau in their performance (seven trials in general). This finding is also supported by the general opinion of participants about training on the UroMentor. The novice PGTs believed that the simulator is a useful instrument to enhance their learning.

Considering the strong correlation of URS-GRS scores on the simulator and in the operating theatre, it can be concluded that flexible ureteroscopy skill obtained on the simulator can be transferred into the operating theatre. In the validation process, the transfer from simulator to the operating theatre has been addressed in two studies. These studies agreed that individual experiences correlated with individual performances on the simulator and simulator training was helpful in improving clinical skills (28). Thus, it can be concluded that the simulator can be effectively incorporated into the curriculum of urology residency programs. Brunckhorst et al. suggested that a curriculum in urology would best begin with E-learning and observership, followed by simulation-based curriculum, which would begin with virtual reality models followed by cadaveric models (114). Despite the fact that the simulator provides feedback on the performance of PGTs after each ureteroscopy procedure, designing a curriculum where an expert provides constructive feedback is recommended. In fact, an educator has various key roles in the training process of PGTs, such as, instructor and coach in developing clinical judgment (36). PGTs would have the chance to receive an individualized training and feedback from an expert supervisor. This real time formative feedback, which is a component of deliberate practice, facilitates learning. However, these may require resources and investment, such as, faculty development. Nevertheless, it would be beneficial in several ways.

On the other hand, UroMentor simulator may not be a perfect tool for training senior PGTs, who have a good experience in performing flexible ureteroscopy in the operating theatre. Although this group performed better on the simulator (figure 8) and in the operating theatre after training on the simulator, the magnitude of improvement in their performance was less than novice PGTs' (Figure 11). Moreover, senior PGTs believed that simulator did not simulate what they really experience in the operating theatre. They believed that simulator is a computer game far from reality and if they learn the tricks, they would perform on the simulator perfectly. Further studies are required to examine cost and benefits of training of senior urology PGTs on virtual reality simulators in performing flexible ureteroscopy. These findings may be considered in the curriculum design for urology training programs, where UroMentor simulator is available. Based on Miller's pyramid, training on a simulator passes through these levels:"knows", "knows how", "shows how", and "does" (42). Accordingly, training on a simulator could place at "knows how" level. Assessment on a simulator could be placed on "shows how" and assessment of competence in performing the skill in real practice would be aligning with the "does" level. Therefore, novice residents, who need to "know how" to perform the procedure would benefit most from training on the simulator, while expert residents, who may "know how" to perform the procedure may benefit from simulator for assessment of "shows how".

It is necessary to note that the simulation training is not enough for real clinical practice. In this research, lower URS-GRS scores in the operating theatre compared with URS-GRS scores obtained on the simulator, even after training on the simulator, demonstrated the fact that there is a natural difference between simulation and real clinical practice. Therefore, competency achieved on a simulator cannot be considered as competency in performing the procedure on patients. In fact, competency obtained on the UroMentor simulator could be considered as competency in performing the basic flexible ureteroscopy tasks and using the instruments on the simulator. Moreover, it is notable that competency based assessment of trainees takes place in the testing environment to make sure that the trainee has achieved competencies required to perform the task and if he/she is ready to perform the task, independently. And this is different from assessing performance of PGTs in the real clinical setting, which is called performance based assessment. Therefore, we may consider this competency based assessment as a screening tool in transition from training on the simulator to training in clinical setting (115).

Defining competency of a PGT in performing a specific procedure is a challenging task. Several methods have been reported to be used in the determination of competency including case logs, which defines the number of procedures a PGT has performed, or tracking failure rate of PGTs in performing the procedure (42). Previous studies have shown that assessment of performance on a virtual reality simulator correlates with real life performance in various minimally-invasive urological procedures in the operating theatre (8, 77, 116-119). This research also confirmed the correlation between performing flexible ureteroscopy task on the simulator and in real practice. Therefore, the UroMentor simulator may be used in a combination with other assessment methods to reliably assess competency of PGTs in performing ureteroscopic stone extraction procedure.

Despite the various advantages of incorporating simulators in training of PGTs, there are some limitations for using these simulators. For instance, the high price of these simulators (around $100,000) makes them impossible for all training programs to use. Moreover, some studies did not find significant differences between performance on an expensive high-fidelity model and an inexpensive low-fidelity model (60). In a study performed by Chou and co-workers, the ability to perform ureteroscopic stone extraction was independent of whether the training method was based on a virtual reality simulator or a low-fidelity ureteroscopy training model (120). This indicates that cost benefit and appropriateness of a training method for educational purposes should be evaluated based on the task itself and trainees' educational needs. Another challenge of a simulator based curriculum is faculty development and the time required for this training.

5.1. Limitations of the study

This study has some limitations. First, despite recruiting all PGTs rotating at the endourology service for duration of one year, the sample size was small. Therefore, future studies with larger sample size are recommended to confirm these results. Second, we did not perform randomization in the study, which could be a source of bias. However, ethically we were not able to deny access to the simulator, considering patient safety. Third, uncontrolled variables among participants may have affected the learning curve. These variables include PGY level, previous ureteroscopic experience, number of sessions on the UroMentor™ simulator, and ureteroscopic stone extraction cases. Fourth, all evaluations were performed by one assessor

(Mehdi Aloosh). However, the URS-GRS is a validated assessment tool and the researcher (Mehdi Aloosh) received one month of training to perform a reliable assessment. Having one rater may have introduced bias. MA watched several ureteroscopies performed by experts and compared his scoring of PGTs' performance while performing the procedure with the expert's, during a one month of time before starting the study. Once the researcher's evaluation using URS-GRS was considered valid and reliable, he began to gather data and assess PGTs on the simulator and in the operating theatre. Moreover, there was a significant correlation between URS-GRS scores and objective feedbacks provided by the simulator, implying that the URS-GRS scoring system was valid. Finally, as the assessments based on URS-GRS were not blinded, the halo effect may have introduced bias. However, correlation of objective assessments provided by the simulator with URS-GRS scores collected by the researcher suggested that most probably the scoring was not biased. Nonetheless, this is the first prospective study on the UroMentor™ simulator to define the learning curve of ureteroscopic stone extraction task and to assess the predictive validity of this simulator in transferring this skill to the operating theatre.

Summary

Competency in flexible ureteroscopic stone extraction task on the UroMentor^{TM} simulator was achieved after seven trials. Since there was a strong positive correlation between URS-GRS scores on the simulator and in the operating theatre, the flexible ureteroscopic stone-extraction skill obtained on the simulator could be transferred to the operating theatre. Therefore, predictive validity of performance on this simulator was demonstrated.

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Appendix:

Manuscript

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Transfer of Flexible Ureteroscopic Stone-Extraction Skill from a Virtual Reality Simulator to the Operating Theatre: A Pilot Study

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Abstract

Aim: To assess the learning curve of flexible ureteroscopic stone extraction using the UroMentor^{TM} simulator and transfer of the flexible ureteroscopy skill to the operating theatre.

Methods: After obtaining ethics approval, urology Post-Graduate Trainees (PGTs) from Post-Graduate Years (PGY) 1-4 were recruited. During phase I, participants completed three weekly one-hour training sessions on the UroMentor^{TM} simulator practicing task 10, where two stones from the left proximal ureter and renal pelvis were extracted using a basket. Objective assessments by the simulator and subjective assessments using the validated Ureteroscopy-Global Rating Scale (URS-GRS) were used to establish the learning curve. During phase II, the URS-GRS tool was used to assess performance of participants in the operating theatre. URS-GRS scores obtained on the simulator and in the operating theatre were correlated.

Results: In phase I, eight urology PGTs (PGY1-4) with mean age of 27.8±2 (25-31) years participated in the study. PGTs practiced a total of 52 times, with a mean operative time of 14.6±4.3 minutes and a mean fluoroscopy time of 10.4±12 seconds. Competency in task 10 was achieved after seven trials on the UroMentor^{TM} simulator. In phase II, five PGTs were assessed during 55 consecutive flexible ureteroscopic stone extraction in the operating theatre. The mean operative time was 51.4±15.2 minutes and the mean fluoroscopy time was 29±6 seconds. There was a significant positive correlation between URS-GRS scores obtained on the simulator and in the operating theatre ($r=0.9$, $p=0.03$), thus establishing predictive validity of performance on the UroMentor^{TM} simulator.

Conclusions: Competency in task 10 on the UroMentor^{TM} simulator (flexible ureteroscopic stone-extraction) was achieved after seven trials. Since there was a strong positive correlation

between URS-GRS scores on the simulator and in the operating theatre, the skill obtained on the simulator could be transferred to the operating theatre.

Introduction

Nephrolithiasis is a prevalent medical problem, affecting 1 in 11 individuals in the population (1). While percutaneous nephrolithotomy, ureteroscopy (URS), and extracorporeal shockwave lithotripsy are different minimally-invasive options for management of nephrolithiasis, the latest American Urological Association guidelines recommend ureteroscopic lithotripsy as the gold standard for management of most ureteral and some renal stones (2). In addition to being used in the management of nephrolithiasis, flexible ureteroscopes are also used in the management of uretero-pelvic junction obstruction and upper tract urothelial carcinomas (3, 4).

Although flexible ureteroscopic lithotripsy is a minimally invasive surgery, it carries potential risks of major complications, such as ureteric perforations and avulsions (5). In addition, fluoroscopy is used intra-operatively; thus the risk of excessive radiation exposure to patients and operating theatre personnel. Finally, flexible ureteroscopy is associated with a steep learning curve requiring up to 50 cases to achieve competency (6). Therefore, the Accreditation Council for Graduate Medical Education requires that Post-Graduate Trainees (PGTs) perform at least 60 ureteroscopies prior to finishing urology training program (7). However, given the latest reduction in work hours of PGTs, there are concerns regarding whether this number of ureteroscopic cases could be reached (8). It is difficult for surgical educators to rely exclusively on the operating theatre for teaching technical skills. Therefore, virtual reality simulators were introduced and validated for training and assessment of technical skills (9-14). These simulators give the opportunity for PGTs to obtain the early phase of the learning curve of certain procedures prior to performing them in the operating theatre. Thus, these simulators compensate for the deficiency in training hours for PGTs and improve patient safety.

The UroMentor^{TM} simulator has been validated for training cystoscopy and ureteroscopy (8,11). However, there is no data on how many times ureteroscopic stone extraction should be performed on the UroMentor^{TM} simulator prior to performing this procedure in the operating theatre. In addition, it is still unknown whether skills acquired from practicing flexible ureteroscopic stone extraction on the UroMentor^{TM} simulator are transferable to the operating theatre. There is paucity of high quality studies demonstrating the predictive validity of performance on the UroMentor^{TM} simulator to performance in the operating theatre. Therefore, the aim of the present study was to assess the learning curve of flexible ureteroscopic stone extraction using the UroMentor^{TM} simulator. The second aim was to assess the transfer of this skill to the operating theatre, thus establishing predictive validity of performance on the UroMentor^{TM} simulator.

Materials and methods

This study was conducted at McGill University Health Center after obtaining McGill University ethics approval (No. A05-E38-15A) and informed consents from all participants. Urology residency training in Canada is five years. At McGill University Health Center, there are 3 urology PGTs (one PGY1-2, one PGY3-4, and one PGY-5) at a given time rotating on the endourology service. Prior to implementation of this training program on the UroMentor^{TM} simulator, flexible ureteroscopic stone extraction was performed by PGTs in the PGY4 level. Regardless of their PGY lever, PGTs who wanted to participate in this study were recruited to be trained on the simulator immediately prior to starting their clinical endourology rotation and thus prior to performing ureteroscopic stone-extraction in the operating theatre. Since each endourology rotation is 12 weeks, consecutive PGTs from PGY 1 to 4 rotating on the endourology service were recruited for the study between September 2015 and May 2016. Each participant filled out a questionnaire regarding age, gender, handedness, PGY level, previous practice on virtual reality simulators, and previous experience in performing endourologic procedures, such as cystoscopy, semirigid and flexible ureteroscopy.

This study was conducted in two phases. The aim of phase I was to define the learning curve of flexible ureteroscopic stone extraction on the UroMentor^{TM} simulator (*Simbionix, Cleveland, Ohio, USA*) and the aim of phase II was to assess transfer of this skill to the operating theatre, thus establishing the predictive validity of performance on this simulator. During phase I, participants were trained on the UroMentor^{TM} simulator task 10 for three consecutive weekly sessions lasting one hour each. Three hours of practice was arbitrarily chosen since there are no previous publications on the learning curve of ureteroscopic stone extraction on this simulator. Prior to the first training session, participants were oriented to the simulator. Task 10, or ureteroscopic stone extraction procedure, was chosen since it is the most complex task on the UroMentor^{TM} simulator. This task required the use of a rigid cystoscope to enter the bladder and place a guidewire in the left ureteral orifice. Then a flexible ureteroscope and a stone basket were used to extract two stones from the left proximal ureter and renal pelvis under fluoroscopic guidance. At the end, a systematic examination of the left renal calyces was performed (Figure 1). Following completion of the task, the simulator generated performance reports with several objective parameters, such as operative time, fluoroscopy time, number of ureteral wall traumas, and number of ureteral perforations. In addition, a single assessor (MA) used the validated Ureteroscopy-Global Rating Scale (URS-GRS) tool to subjectively assess the performance of participants performing successive trials of task 10 during the three weekly sessions (15). This assessment tool contained seven parameters, each scored on a Likert scale from 1 to 5 bringing the maximum score to 35. These parameters included respect for tissue, instrument handling, endoscope handling, time and motion, forward planning, use of assistants, and knowledge of the procedure (15). Competency on the learning curve of flexible ureteroscopic stone extraction using task 10 on the UroMentor^{TM} simulator was determined when the URS-GRS scores reached a plateau.

In phase II, participants, who received training on the simulator, were observed performing consecutive flexible ureteroscopic stone extraction in the operating theatre during their endourology rotation. Participants were subjectively assessed by one assessor (MA) using the same URS-GRS tool. Furthermore, operative time, fluoroscopy time and intra-operative complications were collected. The procedure and fluoroscopy times included all of the required components for ureteroscopic stone extraction including retrograde pyelography, possible balloon dilatation, possible usage of ureteral access sheaths and insertion of indwelling ureteral stents. Correlation between the URS-GRS scores on the simulator and inside the operating theatre was performed to assess the transfer of flexible ureteroscopic stone extraction skill from the simulator to the operating theatre, thus establishing predictive validity.

Statistical analysis:

Data gathered from the questionnaires, the UroMentor^{TM} simulator, and intra-operative variables were tabulated and analyzed. The Statistical Package of Social Sciences for Windows (SPSS, Chicago, IL) software version 20 was used. Descriptive data were presented in terms of numbers and percentages, or means and standard deviations. Spearman's correlation coefficient was used to determine associations between continuous variables and significance was considered whenever the two tailed p-value was <0.05.

Results

During phase I, eight urology PGTs (1 PGY-1, 3 PGY-2, 3 PGY-3, 1 PGY-4) with a mean age of 27.8±2 (25-31) years participated in the study. All PGTs were right handed and two were female. Only one participant had practiced on a virtual reality simulator and none of them had previous practice on the UroMentor^{TM} simulator prior to this study. On average, participants had performed 45 cystoscopies, 36 semirigid and flexible ureteroscopies and 23 transurethral resections.

During the three weekly practice sessions, PGTs performed task 10 on the UroMentor^{TM} simulator 52 times (mean: 6.4±3.1; range: 3-10) with a mean operative time of 14.6±4.3 minutes and mean fluoroscopy time of 10.4±12 seconds. The learning curve on the UroMentor^{TM} simulator reached a plateau after 7 trials of task 10 (Figure 2A). The mean practice time required to reach the plateau was 100 minutes. Furthermore, fluoroscopy time decreased reaching a plateau at the third trial (Figure 3A). Operative time and number of traumas from the scope, guidewire and basket decreased reaching a plateau after the fifth trial (Figure 2B, 3B). There were no ureteral perforations. Furthermore, there was a positive significant correlation between the mean URS-GRS scores obtained on the first trial on the simulator and the number of previously performed semirigid and flexible ureteroscopies (r=0.809, p=0.015) (Figure 4A). Previous semirigid and flexible ureteroscopic experience also had a negative correlation with fluoroscopy time (r=-0.299, p=0.471) and operative time (r=-0.228, p=0.588) of the first trial on the simulator. However, there was no correlation between previous experience and the number of traumas (r=-0.055, p=0.898).

During phase II, five PGTs (2 PGY-2, 2 PGY-3, 1 PGY-4) out of the eight who practiced on the UroMentor^{TM} simulator during phase I were assessed perform flexible ureteroscopic stone extraction in the operating theatre. They performed 55 consecutive flexible ureteroscopic stone extractions with an average of 9.1±3.9 (range: 5-15) procedure per PGT. The average operative time was 51.4±15.2 minutes and average fluoroscopy time was 29±6 seconds. Regression analysis showed that there was a strong correlation of URS-GRS scores obtained on the simulator and in the operating theatre (r=0.9, p=0.03) (Figure 4B), thus establishing the predictive validity of performance on the UroMentor^{TM} simulator.

Discussion

The Halsteadian model of training relies on the introduction of trainees in the operating theatre from early phases of their learning curve to achieve competency in performing a particular surgical procedure (8). This training provides theoretical and practical knowledge of the procedure. It also satisfies several crucial surgical elements such as the experience of operating room environment and development of cognitive aspects of surgery, including decision-making, communication and collaboration skills. However, concerns about patient safety in addition to restrictions in trainee work hours have resulted in dramatic reductions to operating theatre exposure necessitating the incorporation of validated virtual-reality simulators into the curricula of training programs to teach PGTs the early phases of the learning curve (16, 17). Interestingly, both psychomotor and cognitive skills, such as risk assessment could be acquired by appropriate training on the simulators (18). For instance, it has been shown that training on simulators improve dexterity during ureteroscopy. In a study by Watterson and co-workers, the manual dexterity was enhanced following training of 26 urology PGTs on a low-fidelity model while performing semi-rigid ureteroscopy (17).

The UroMentor™ simulator is a validated computer-based virtual-reality simulator (8, 19, 20) offering semi-rigid and flexible ureteroscopy modules. Two prospective randomized controlled trials on the UroMentor™ simulator showed educational impact of this model in training semi-rigid and flexible ureteroscopy for medical students using a global rating scale (17, 21). They reported improved acquisition of ureteroscopic skills in novice trainees following training on the UroMentor™ simulator. However, there is no data regarding the learning curve of flexible ureteroscopic stone extraction on the UroMentor™ simulator. In addition, there is a lack of high quality studies regarding the predictive validity of this simulator indicating whether performance on this simulator predicts performance in the operative theatre. Learning curve is used as a mean of assessing surgical expertise and the number of procedures needed to gain surgical competence (8). However, the learning curve may differ according to the selected outcome criteria. For instance, when operative time was used as an outcome for percutaneous nephrolithotomy, the estimated case load of 60 patients was necessary to reach a plateau (22). However, when the stone-free rates were considered as an endpoint the plateau was achieved at the very initial cases (23). In the current study, URS-GRS scores were used as the outcome to establish the learning curves since the simulator does not provide an overall objective score. Using the URS-GRS tool, the learning curve of ureteroscopic stone extraction while performing task 10, reached a plateau after performing seven trials on the UroMentor^{TM} simulator. The estimated time to complete 7 trials of task 10 was 100 minutes. Therefore, on average PGTs need to spend 100 minutes on the UroMentor^{TM} simulator to achieve competency in performing ureteroscopic stone extraction on the simulator prior to performing ureteroscopic stone extraction in the operating theatre.

This study showed that the mean operative time on the simulator was 14.6 minutes and the operative time reached a plateau after the fifth trial. Similarly, Knoll et al. reported that untrained PGTs performed flexible ureteroscopy as rapid as trained residents on the UroMentor^{TM} simulator by the fifth trial (5). In addition, in the current study, the increase in URS-GRS score was associated with a decrease in fluoroscopy time and the number of mucosal traumas (Figure 3). Furthermore, the first trial URS-GRS scores on the simulator correlated with the number of previously performed semirigid and flexible ureteroscopies in the operating theatre. This is similar to other studies on the GreenLight^{TM} and PercMentor^{TM} simulators where performance on these simulators correlated with previous intra-operative experience (11, 12).

Previous studies have demonstrated the validity of the UroMentor™ simulator (5, 20, 21, 24-26). While Ogan et al. reported the transfer of diagnostic flexible ureteroscopy skills from the UroMentor™ simulator to cadavers, Schout et al demonstrated transfer of cystoscopy skills from the UroMentor™ simulator to the operating theatre (24, 25). However there is a lack of high quality studies on the predictive validity of the UroMentor™ simulator regarding the transfer of ureteroscopic stone extraction skill to the operative theatre. In the present study, transfer of flexible ureteroscopic stone extraction skill from the UroMentor™ simulator to the operating theatre, or predictive validity, was confirmed by finding a correlation between the URS-GRS scores on the simulator and in the operating theatre.

Despite the various advantages of incorporating simulators in the training of PGTs, there are some limitations for using these simulators. For instance, the high cost of these simulators. Moreover, in a study by Chou and co-workers, the ability to perform ureteroscopic stone extraction was independent of whether the training method was on a virtual reality simulator or a ureteroscopy training model (27).

This study has some limitations. First, the absence of randomization in the study could have introduced bias. However, ethically we were not able to deny access to the simulator as an educational tool to PGTs. Moreover, there was some consideration regarding patient safety and ethical issue of placing patients at higher risk with PGTs performing flexible ureteroscopy without having them first practice on the simulator. Second, despite recruiting all PGTs rotating at the endourology service, the sample size was small. Third, there were variations in PGY level, previous ureteroscopic experience, number of practice sessions on the UroMentor™ simulator and ureteroscopic stone extraction cases among participants. Although this could have introduced bias, this is the reality where PGTs with various technical aptitudes and learning skills are trained on the same simulator. Fourth, all evaluations were performed by one assessor. However, the URS-GRS is a validated assessment tool. Finally, the evaluations were not blinded, therefore the halo effect could have introduced bias. Nonetheless, this is the first prospective study to assess the learning curve of flexible ureteroscopic stone extraction on the UroMentor™ simulator and to assess the predictive validity of this simulator in assessing flexible ureteroscopic stone extraction skill in the operating theatre. Future studies with larger sample size are needed to confirm these results.

Conclusions

Competency in task 10 on the UroMentor™ simulator (flexible ureteroscopic stone extraction) was achieved after seven trials. Since there was a strong positive correlation between URS-GRS scores on the simulator and in the operating theatre, the skill obtained on the simulator could be transferred to the operating theatre. Therefore, predictive validity of performance on this simulator was demonstrated. Future studies with larger sample size are needed to confirm these results.

Abbreviations

OR: Operating Room

PGTs: Post-Graduate Trainees

PGY: Post-Graduate Year

SD: Standard Deviation

URS: Ureteroscopy

URS-GRS: Ureteroscopy-Global Rating Scale

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Figures

Figure 1: Description of task 10 on the UroMentor^{TM} simulator. **A.** A rigid cystoscope is used to enter the bladder. **B.** A guidewire is inserted on the left side under fluoroscopic guidance. **C.** A flexible ureteroscope is used to find the left proximal and renal pelvic stones. **D.** The stones are extracted using a basket.

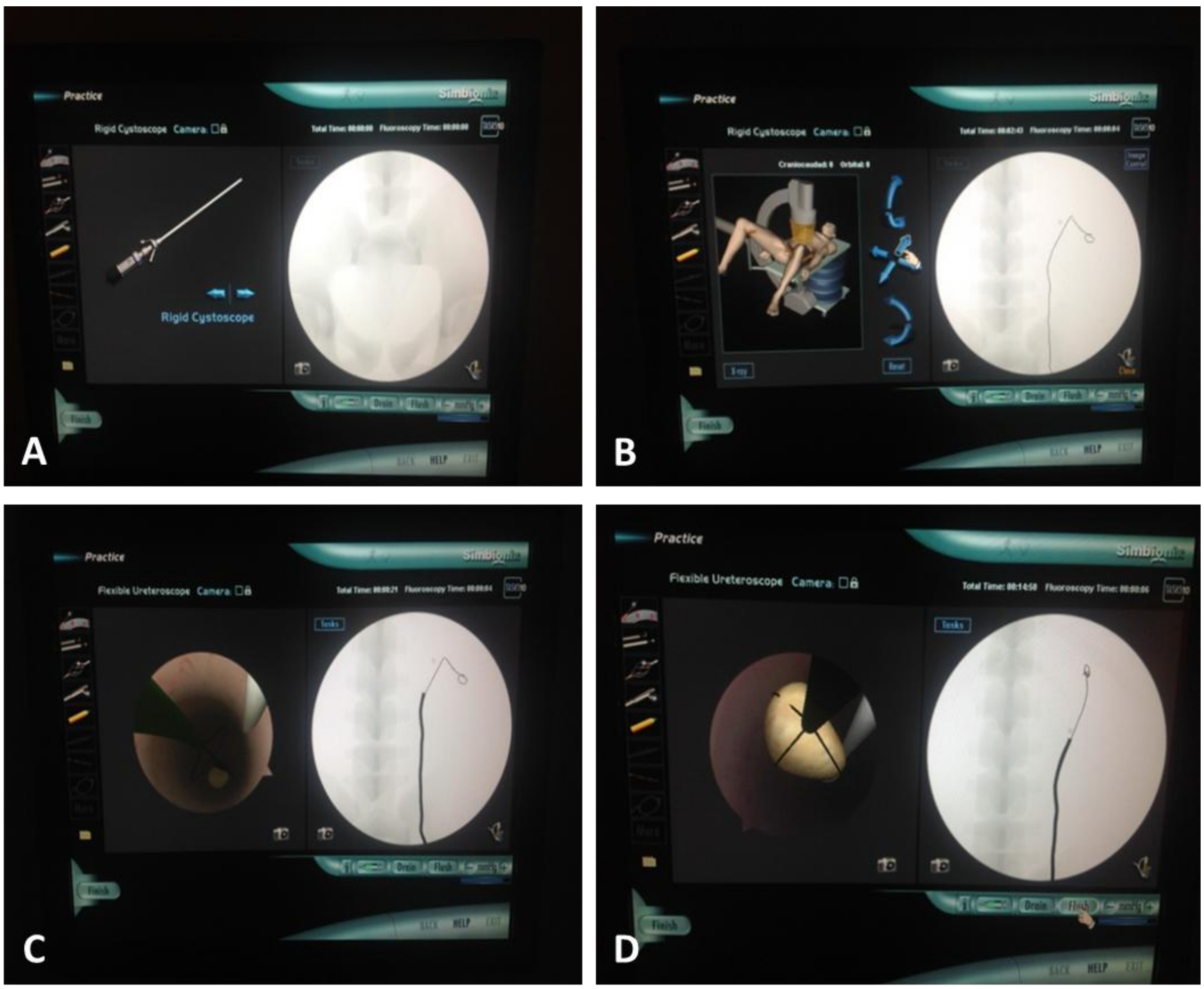

Figure 2: A. Learning curve of flexible ureteroscopic stone extraction on the UroMentor™ simulator. **B**. Mean URS-GRS score and mean operative time on the simulator.

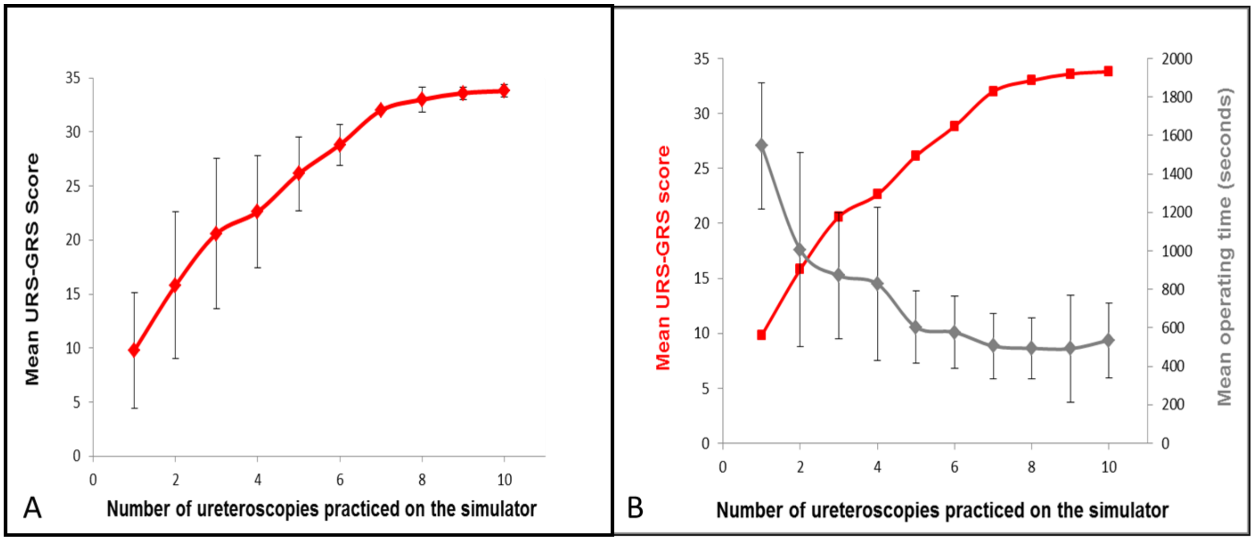

Figure 3: A. Mean URS-GRS scores and fluoroscopy time on the simulator. **B.** Mean URS-GRS scores and the mean number of traumas from the scope and instruments

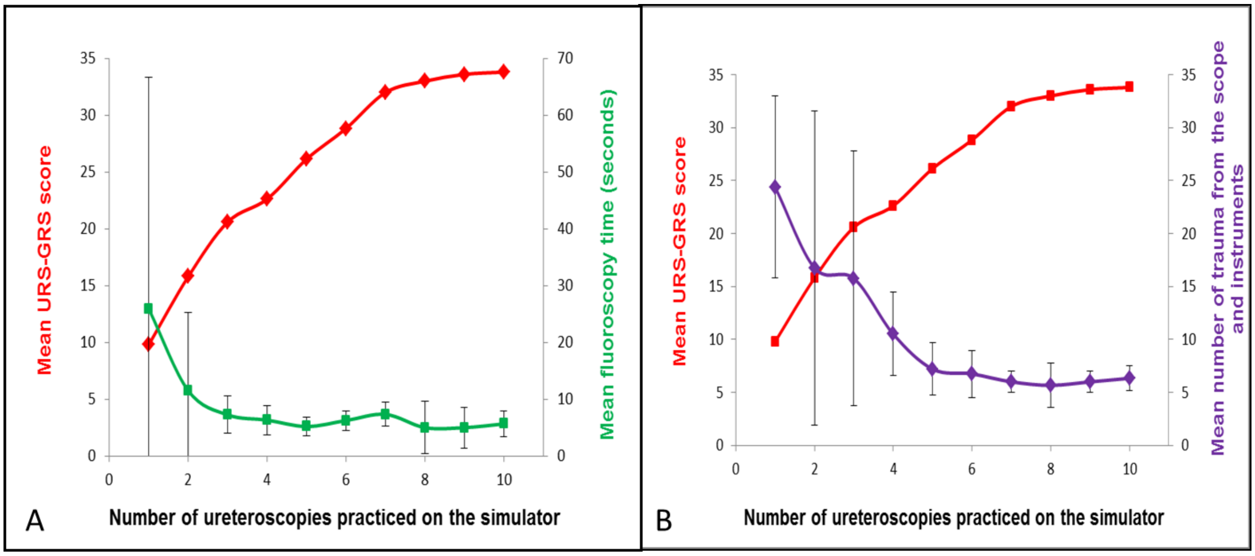

Figure 4: A. Correlation between the first URS-GRS score obtained on the simulator and mean number of previously performed semirigid and flexible ureteroscopies in the operating theatre. **B.** Correlation of mean URS-GRS scores obtained on the simulator and in the operating theatre.