



A Pilot Study on Oocyte Retrieval Simulator: A New Tool for Training?

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Abstract

This prospective study was aimed at assessing the usefulness of a box simulator in oocyte pick-up and at establishing whether it could be an appropriate training tool for egg retrieval. Forty-four clinicians, divided in two groups on the grounds of the previous experience (Novices and Experts), participated to two training sessions with a pick-up simulator. Data concerning the mean number of follicles correctly aspirated (%OK med), the average time needed to correctly aspirate one follicle (t foll med) and the ratio between the two afore-mentioned parameters (%OK med/t foll med) were collected. At the end of the two sessions all participants completed a questionnaire aimed at assessing the performance of the simulator in terms of realism and acceptability for use. A significant improvement in efficiency (mean number of follicles correctly aspirated, 82% versus 75%), speed (mean time needed to aspirate one follicle, 21 versus 28 s) and accuracy (mean percentage of follicles correctly aspirated in one minute, 2.53% versus 1.86%) was noted in the total sample. The performance accuracy was significantly increased in both groups (2.34% versus 1.83% for Novices and 2.50% versus 2.06%, for Experts). Speed was significantly improved in the Novices' group. Simulator-based training has been shown to be effective and useful and it should be considered in training programs.

Keywords Oocyte retrieval · Oocyte pick-up · Medical simulation training · Education · Simulator

Introduction

A surgical expert has been defined as one who displays consistency and automaticity of performance as well as the ability to anticipate adverse events. The surgical expertise is generally built on the so-called repeated “deliberated practice”, which effectiveness depends on the conditions in which it occurs. Temporal spacing plays a key role in the process: a spaced schedule (over 3 days or weeks) has been proven superior than massed training in building and consolidating neural pathways and in the long-term retention of surgical skills [1]. According to the adult learning theory proposed by Fitts and Posner [2] the acquisition of motor skills includes three

consequential phases: cognitive, associative and autonomous. During the initial stages the learner, supervised by a teacher, understands the task and identifies the sequence of actions required to achieve the end goal. In the autonomous phase the actions become ultimately unconscious and minimal cognitive processing is required.

Historically, graduating obstetrics and gynecology residents have been expected to learn following the adage ‘see one, do one, teach one’, which required a high volume experience. Nowadays, as the complexity of procedures increases and surgical volume decreases, in order to acquire surgical skills rapidly there is the need to integrate surgical simulation into modern residency training alongside traditional teaching methods. In addition, recent changes in the field (e.g. work-hours restrictions, decreased bedside teaching) have high lightened these necessities [3]. Surgical simulation has been introduced in surgical training since 1920 [4] following the example of airline and military industry [5]. Recently, the Association of American Medical Colleges commented on the increased use of simulation in different medical specialties, recognizing its potential ability to improve patients safety and to enhance healthcare in general [6]. Several studies have shown positive effects of virtual reality simulators on gastrointestinal [7], urologic [8] and orthopedic surgical training [9] and on laparoscopic education [10–14].

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In the field of Reproductive Endocrinology and Infertility (REI) some surgical skills are required for independent practice and one of them is transvaginal oocyte pick-up. Oocyte retrieval is a common surgical procedure in Assisted Reproductive Technologies (ART) and it is held to be easily mastered. Commonly, the trainee performs a recommended number of procedures under supervision, but this approach is not well tailored to the individual and could be influenced by subtle differences between patients [15]. A further problem linked with supervised hands-on training is the risk of reducing overall patient safety. Aim of this study is to investigate participants' acceptability of a simulation device for this specific procedure and to establish whether it could be an appropriate training tool.

Materials and methods

This is a prospective, single-centre study held at Ferrara University Hospital. Obstetrics and Gynaecology (Ob/Gyn) residents and attending physicians were asked to use the oocyte retrieval box simulator in two separate training sessions, held one week apart from each other. The participants performed oocyte pick-up in eight different scenarios each time. An expert in the field held the course. At the beginning of the first session, a short explanation of the goals of the training program alongside a theoretical lecture on basic skills and principles of oocyte pick-up were given. Active coaching and feedback were provided during both sessions. At the end of the second training sessions, all participants were asked to fill in a feedback questionnaire.

The participants

The study was approved by the Ethics Committee of Ferrara University Hospital and informed consent was obtained for participation to the study. A total of 44 participants from a single institution were included in the study and categorized according to their training level into Novices ($n = 32$) and Experts ($n = 12$). The "Novices" were Ob/Gyn residents with no previous experience in oocyte pick-up, while the "Experts" were attending physicians who had performed more than 50 oocyte pick-ups each.

The device

The *PickUpSim*TM device (*Accurate Srl*) is a box simulator, which can display different scenarios based on real clinical images on a wide-view monitor (Fig. 1). The device is equipped with a transvaginal probe and with an Ovum Aspiration Needle (Fig. 2). The transvaginal probe permits both sagittal view (allowing the user to investigate the volume of the follicles and to choose the proper entry plane for the needle) and transverse view (allowing the user to investigate blood vessels and to differentiate them from follicles). Needle movements are allowed both in the forward and in the backward direction. The haptic feedback simulates the resistance to penetration of the soft tissues traversed by the needle, in particular the ovarian surface and the ovarian follicles. Simulated aspiration of follicles is driven by a foot pedal pump and the level of the follicular fluid aspirated is shown on the monitor (the image of a test tube that should be changed by a second operator when it is filled with 10 mL of liquid) (Fig. 3). As the

Fig. 1 The box simulator (PickUpSimTM device)



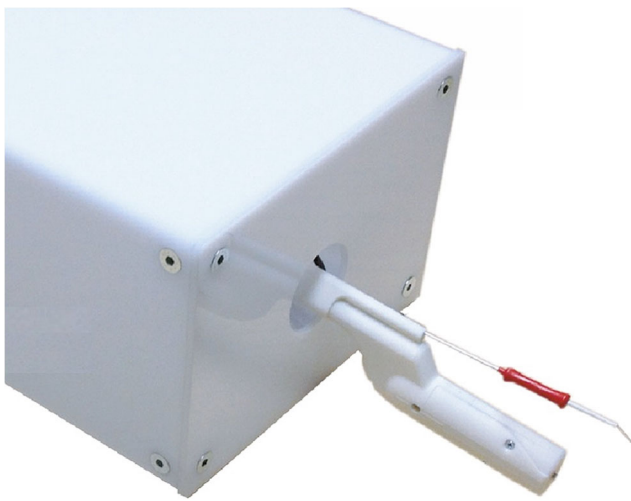


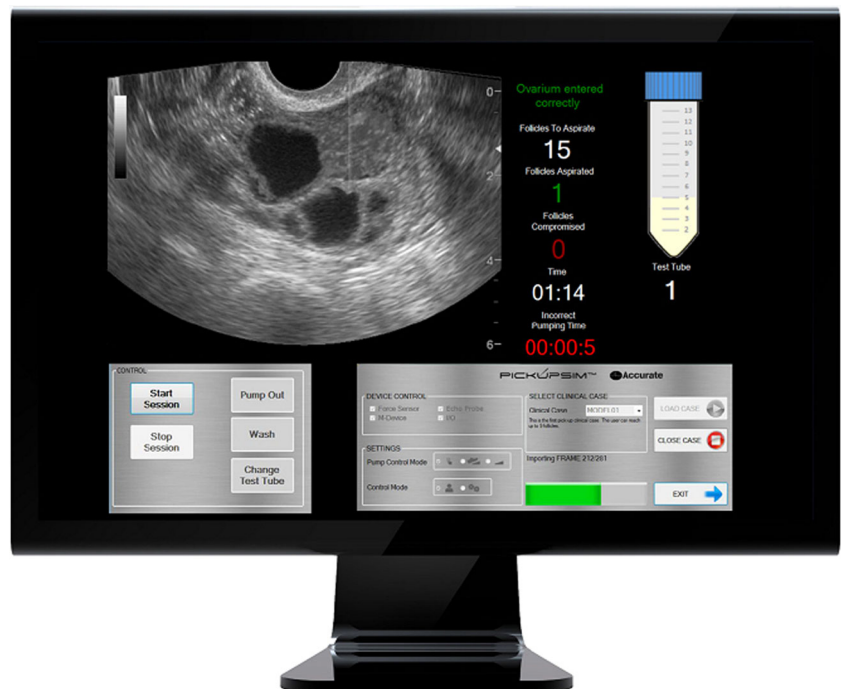
Fig. 2 The transvaginal probe and the Ovum Aspiration Needle

fluid is aspirated, the device faithfully reproduces the collapse of the follicle and the subsequent formation of corpus luteum. When a follicle is accidentally damaged, the corresponding image disappears. The simulator can also mimic vascular complications. Iliac vessels are shown on the screen and they can be accidentally punctured. The device records the number of follicles correctly aspirated, the number of ruptured follicles and the time needed to complete a single procedure.

The user can practice and develop competency using simulation scenarios based on real clinical images. The scenarios available take into account:

- the proper movements to reach the target follicles,
- the proper suction and washing time,

Fig. 3 The virtual echographic monitor



- the avoidance of critical anatomical structures.

The feedback questionnaire

The feedback questionnaire was aimed at assessing the performance of the simulator in terms of realism and acceptability for use and it was divided into two sections. The first part included 6 questions concerning participants' first impression of the simulator, while the second one was made up of 9 more specific questions on the usefulness of the simulator and the training course in general. Two questions of the second section were focused on participant's willingness to train with the box simulator. The questions were adapted and modified from a questionnaire previously used on the validation of an endoscopic simulator [16] and of a laparoscopic surgery simulator [17]. The first section questions were answered on a scale from 1 (poor) to 5 (excellent). The second section statements were to be answered with "agree", "disagree", or "no opinion". The questionnaire was anonymous, but participants were asked to indicate their age, gender and previous experience.

Statistical analysis

We collected the data for each participant and calculated the mean between the 8 different clinical scenarios proposed, thereby obtaining three different parameters:

- the mean number of follicles correctly aspirated (%OK med), as a parameter of efficiency;

Table 1 Baseline characteristics of the participants

	Novices' group	Experts' group	Total sample
Number (percentage of the total sample)	32 (72.7%)	12 (27.2%)	44
Age (yrs \pm standard deviation)	29.25 \pm 1.49	47.67 \pm 11.6	34.27 \pm 10.12
Gender (female; male)	30; 2	10; 2	40; 4

- the average time needed to correctly aspirate one follicle (*t foll med*), as a parameter of speed;
- the ratio between the two afore-mentioned parameters (%OK med/*t foll med*) indicating the mean percentage of follicles correctly aspirated in one minute and representing globally the accuracy of the performance.

Data were analyzed using Microsoft Office Excel 2016. Student's T test was applied to calculate the change in the participants' performance between the first and the second attempt for the whole study population (total group performance) and for the single groups separately (Novices; Experts) (intra-group performance). A *P* value of <0.05 was considered statistically significant.

Results

Participants' characteristics are shown in Table 1. In total, 44 physicians participated to the study, 32 of them were classified as Novices (72.7%), while 12 were defined Experts (27.3%). Data concerning the performance of the total sample are presented in Table 2. All the considered parameters showed a significant improvement in the second simulation session. The rate of follicles correctly aspirated increased in the second attempt (75% first session vs 82% second session, $p < 0.05$) and the time needed to aspirate the follicles was significantly reduced (21 s in the second attempt, as compared to 28 s in the first, $p < 0.05$). Consequently, the overall accuracy of the performance improved (1.86% first session vs 2.53% second session, $p < 0.05$). Tables 3 and 4 display Novices' and Experts' performances, considered separately. When comparing second

Table 2 Performance of the total sample (% OK med = mean number of follicles correctly aspirated; *t foll med* = average time needed to correctly aspirate one follicle; %OK med/*t foll med* = mean percentage of follicles correctly aspirated in one minute). A *P* value of <0.05 was considered statistically significant

	I simulation session	II simulation session	P value
% OK med	75%	82%	<0.05
<i>t foll med</i> (sec)	28	21	<0.05
%OK med/ <i>t foll med</i>	1.86%	2.53%	<0.05

Table 3 Performance of the Novices' Group (% OK med = mean number of follicles correctly aspirated; *t foll med* = average time needed to correctly aspirate one follicle; %OK med/*t foll med* = mean percentage of follicles correctly aspirated in one minute; NS = non significant). A *P* value of <0.05 was considered statistically significant

	I simulation session	II simulation session	P value
% OK med	82%	81%	NS
<i>t foll med</i> (sec)	30	23	<0.05
%OK med/ <i>t foll med</i>	1.83%	2.34%	<0.05

simulation session data with the first, we can infer that the Novices became significantly quicker (23 s vs 30 s, $p < 0.05$), while keeping constant the mean number of follicles aspirated (81% versus 82%) hence, the accuracy of their performance was globally improved (2.34% versus 1.83%, $p < 0.05$). As to the Experts, the speed of their performance was not significantly increased (22 s vs 23 s), but there was a trend towards a higher number of follicles aspirated, yet not significant (86% versus 76%). As a result, the accuracy of the performance was significantly improved (2.50% versus 2.06%, $p < 0.05$). Tables 5 and 6 display the results of the feedback questionnaire provided by each group and by the total sample. The scores assigned by Novices and Experts were similar. As to the first section (Table 5), the average rating obtained by the box-simulator was very high (4.45). In particular, most of the participants found the *PickUpSim*TM as a useful tool for training in oocyte pick-up and believed that it could be helpful to improve hand-eye coordination. As to the possibility to teach basic skills in oocyte pick-up and to the user-friendliness, the *PickUpSim*TM was attributed an average score of 4.6 and 4.5, respectively. Appearance/design and realism of the box simulator were also appreciated by participants (4.2 and 3.9, respectively). Even though only 63.6% believed that the simulator could be used for training at home, 100% participants considered the *PickUpSim*TM appropriate for training in a hospital (Table 6). As to the evaluation of this training program, 100% participants affirmed it had been useful to acquire basic skills in oocyte pick-up. The majority of the participants (90.9%) would like to attend a training course

Table 4 Performance of the Experts' Group (% OK med = mean number of follicles correctly aspirated; *t foll med* = average time needed to correctly aspirate one follicle; %OK med/*t foll med* = mean percentage of follicles correctly aspirated in one minute; NS = non significant). A *P* value of <0.05 was considered statistically significant

	I simulation session	II simulation session	P value
% OK med	76%	86%	NS
<i>t foll med</i> (sec)	23	22	NS
%OK med/ <i>t foll med</i>	2.06%	2.50%	<0.05

Table 5 Result of the Questionnaire - I Section (E = Experts; N=Novices; T = Total). Rating Scale: 1 = poor; 2 = below average, 3 = average, 4 = above average, 5 = excellent

I SECTION			
QUESTIONS		Average rating (single question)	Average rating (total)
1	What is your opinion of the appearance and design of the simulator?	4.3 (N); 4 (E); 4.2 (T)	4.47(N); 4.6 (E); 4.45(T)
2	What is your opinion of the realism of the simulator?	3.8 (N); 4 (E); 3.9 (T)	
3	What is your opinion of the user-friendliness of the simulator?	4.6 (N); 4.3 (E); 4.5 (T)	
4	What is your opinion of the introduction of the box simulator in training programs?	4.8(N); 4.6 (E); 4.8 (T)	
5	What is your opinion of the value of basic skills in oocyte pick-up with the simulator?	4,6 (N; E; T)	
6	What is your opinion of the simulator’s usefulness in improving hand-eye coordination?	4.75 (N); 4.6 (E); 4.7(T)	

with the *PickUpSim*TM box simulator in future. Furthermore, most of the sample (81.8%) supported the use of the box simulator as a tool to assess the quality of the clinicians’ performances in oocyte pick-up.

Discussion

According to our results, simulator-based training significantly improved the performance of both residents and attending physicians in oocyte pick-up. In particular, Novices became significantly quicker, while keeping constant the efficiency of their performance. On the contrary, Experts increased the average number of follicles aspirated, without reducing the time needed to complete the procedure. The device was held useful in training hand-eye coordination and in teaching basic skills in oocyte pick-up. The simulator was considered particularly suitable for training residents and fellows, especially in a hospital setting and its introduction in training programs was

strongly supported. Furthermore, even the Experts expressed the wish to have more training sessions with the simulator in future, perhaps in order to assess or to maintain the quality of their performance (audit of practice). Recently, simulation was also tested for warm-up before surgery. “Warm-up” is generally defined as something that helps the operator to achieve high level of efficiency before a certain activity and it is performed to improve the overall performance [18, 19]. Regardless of the level of training, warm-up exercises on box-simulator have been proven to be very useful [20–22]. In the study published by Lendvay et al. residents and expert surgeons of different surgical specialties (general surgery, urology and gynecology) tried virtual reality warm-up with a significant reduction in errors and a general improvement in efficiency when asked to complete basic robotic surgery tasks [22]. On the other hand, some other studies failed to demonstrate an improved performance [23, 24]. In a recent randomized controlled trial, residents were evaluated during laparoscopic hysterectomy after warm-up by two master surgeons

Table 6 Result of the Questionnaire - II Section (E = Experts; N=Novices; T = Total). Possible answers were “agree”, “disagree”, or “no opinion”

II SECTION		
QUESTIONS		% of Agreement
1	The simulator is a useful instrument to train novice gynaecologists in oocyte pick-up	100% (N; E; T)
2	The simulator is a useful instrument to teach basic skills in oocyte pick-up	100% (N; E; T)
3	The simulator is a useful instrument to teach hand-eye coordination.	100% (N; E; T)
4	The simulator is appropriate for training at home.	62.5%(N); 66.7% (E); 63.6% (T)
5	The simulator is appropriate for training in a hospital.	100% (N; E; T)
6	The simulator can become a useful instrument to measure the clinicians’ performance in oocyte pick-up procedures.	87.5%(N); 66.7% (E); 81.8% (T)
7	I would you like to train with the simulator in the future	100% (N; E; T)
8	I would like to attend a training course with this box simulator in the future	87.5%(N); 100% (E); 90.9%(T)
9	The current training course was helpful in the training of basic skills in oocyte pick-up.	100% (N; E; T)

and no difference was reported when compared to the group with no warm-up activity [24].

As for the field of REI, a recent study was published on how the use of an embryo-transfer (ET) simulator may improve pregnancy rates in REI fellows [25]. After device development, in this retrospective cohort study pregnancy rates of 12 REI fellows were evaluated: 6 before ET trainer and 6 after ET trainer. Post trainer fellows during their first 10 ETs showed increased pregnancy and clinical rates when compared to the group with no training, suggesting that simulation may lead to a more rapid ET proficiency.

However, there are some limitations to consider in a simulator-based training. In our case, the box-simulator could only mimic vascular injury as a possible oocyte retrieval complication and it obviously does not teach non-technical skills, such as patient communication. In addition, the device cannot completely replicate every patient's anatomy. On the other hand, the traditional approach based on training on real patients also presents some drawbacks. First, it is not devoid of risk for the patients. According to a 4-year prospective study analyzing a series of 2670 consecutive oocyte retrievals, the complication rate of the procedure, although very low, accounts for vaginal hemorrhage (8.6%), infection (0.6%) and pelvic abscess formation (0.3%), while vascular, gastrointestinal, and genitourinary injuries are extremely rare [26]. In a recent report, a series of 7098 oocytes retrieval was analyzed: authors report 6 cases of severe complications (4 peritoneal bleeding requiring surgery (0.06%) and 2 case of pelvic abscesses (0.03%)) [27]. However, these data are based on oocyte pick-up performed by experts, while no study has assessed the rate of complications in case of novices that could be reasonably higher. Furthermore, training on real patients is not tailored to the individual, i.e. it does not take into account possible individual differences in skill acquisition between the single trainees. Egg retrieval has measurable clinical outcomes, such as the number of oocyte retrieved, but it is not clear whether this is a reliable criterion to assess the clinician's competency in this procedure. Even though practice standards require the physicians to perform 'an adequate number of aspirations and transfer procedures under direct supervision that demonstrates proficiency within a practice that meets these standards' and to 'continue performing a minimum number of aspirations per year to maintain their proficiency' [28], no data exist to set the minimum number of egg retrievals required to reach proficiency. In fact, it has been proven that the learning curve can markedly differ across clinicians. Goldman et al. [29] have performed a retrospective analysis of fellows in training from 2005 to 2007 and from 2008 to 2010: even though the majority of fellows in training achieved proficiency in follicular aspirations within 20 procedures, a minority required 50 procedures to reach the level of an attending physician and one fellow did never reach the proficiency score. Accordingly, Dessolle et al. [15] prospectively

analyzed oocyte retrievals performed by three first-year residents over a 6-months period: the first two trainees reached adequate performance after 43 and 17 procedures, respectively, while trainee 3 did not reach the required level of performance by the end of the study. Simulator-based training can virtually provide unlimited training, allowing every clinician to reach proficiency according to his initial skills and learning curve. An additional limit of training on real patients is the fact that it is not a standardized technique, as it can be influenced by subtle differences between patients, therefore experience on real patients cannot be considered a reliable method to assess the clinician's competency in oocyte pick up. In the aforementioned study performed by Goldman et al. [29], proficiency scores were defined by dividing the number of oocyte retrieved by the number of oocytes predicted on the basis of the total number of follicles >12 mm measured by ultrasound scan on the day of human chorionic gonadotropin (hCG) trigger. The procedures performed by attending physicians were averaged to calculate the target proficiency score that was used to deem the fellow "proficient".

New tools for quantitative and individual assessment of the learning curve have been provided by Biau and colleagues [30]. They refined the evaluation of clinicians' competency with the learning curve-cumulative summation test (LC-CUSUM) and the CUSUM test. The LC-CUSUM was used to decide when the learning curve of the fellow was complete by indicating when he had reached a predefined level of performance. Once the fellow had reached the proficiency level, his performance was monitored via the CUSUM test [31] (Biau & Porcher, 2010). These tools represent an exportable methodology to simulator-based training for prospective evaluation of the learning process and for the continuous monitoring of individual performance.

Conclusions

Considering advantages and disadvantages of both apprenticeship models (traditional training and simulator-based training), a blended approach which combines simulator-based training with didactic and more traditional training on real patients could be introduced. The simulator could be useful especially in the initial part of a structured training for novices, enabling them to acquire basic skills in oocyte retrieval and to reach a predefined level of performance in a safe and controlled environment, before applying the procedure to real patients. To our knowledge, this is the first trial aimed to assess prospectively the usefulness of a box simulator for oocyte pick-up. Even though our results are encouraging, the design of the study (single centre study) and the small sample size limits the power of our findings. In addition, further data are needed to validate these results in clinical practice to see if there is the same improvement on *in vivo* oocytes pick up.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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