Effect of virtual reality training on laparoscopic surgery: randomised controlled trial

Christian R Larsen, clinical research fellow,1 Jette L Soerensen, assistant professor and consultant,2 Teodor P Grantcharov, assistant professor and consultant,3 Torur Dalsgaard, consultant,4 Lars Schouenborg, consultant,4 Christian Ottosen, consultant,4 Torben V Schroeder, professor and consultant,5 Bent S Ottesen, managing director and professor at the Juliane Marie Centre6

ABSTRACT
Objective To assess the effect of virtual reality training on an actual laparoscopic operation.
Design Prospective randomised controlled and blinded trial.
Setting Seven gynaecological departments in the Zeeland region of Denmark.
Participants 24 first and second year registrars specialising in gynaecology and obstetrics.
Interventions Proficiency based virtual reality simulator training in laparoscopic salpingectomy and standard clinical education (controls).
Main outcome measure The main outcome measure was technical performance assessed by two independent observers blinded to trainee and training status using a previously validated general and task specific rating scale. The secondary outcome measure was operation time in minutes.
Results The simulator trained group (n=11) reached a median total score of 33 points (interquartile range 32-36 points), equivalent to the experience gained after 20-50 laparoscopic procedures, whereas the control group (n=10) reached a median total score of 23 (22-27) points, equivalent to the experience gained from fewer than five procedures (P<0.001). The median total operation time in the simulator trained group was 12 minutes (interquartile range 10-14 minutes) and in the control group was 24 (20-29) minutes (P<0.001). The observers’ inter-rater agreement was 0.79.
Conclusion Skills in laparoscopic surgery can be increased in a clinically relevant manner using proficiency based virtual reality simulator training. The performance level of novices was increased to that of intermediately experienced laparoscopists and operation time was halved. Simulator training should be considered before trainees carry out laparoscopic procedures.

INTRODUCTION
Laparoscopy has become the standard approach for many conditions in most surgical specialties.1-3 This development has been driven by the desire for less surgical trauma, faster postoperative recovery, shorter hospital stay, and better cosmetic results, and a sales drive by the medical industry.1 It is evident, however, that laparoscopy is associated with a longer operation time and a higher rate of surgical complications during the learning curve of the surgeons. This has been verified in many different specialties, including general1-5 urological,6-8 paediatric,9 and gynaecological surgery.10 The possibility of overcoming these problems during the learning curve by appropriate training and ensuring that surgeons perform a sufficient number of procedures has also been documented.11 The technical skills needed for laparoscopic surgery are fundamentally different from those for traditional open surgery, leading to a prolonged learning curve. The primary obstacles in learning laparoscopy are psychomotor and perceptual. The unique nature of laparoscopic surgery combined with an increasing focus on patients’ safety and rights, the present decrease in working hours, and concern over costs of operating theatre time are factors that challenge the traditional surgical approach and contribute to a growing need for novel methods in the training of laparoscopic surgeons.12 Although virtual reality simulation has the potential to offer important advantages in the area of training for new skills and procedures, evidence on the transfer of skills from the simulated environment to the operating theatre is still limited.13-14

We investigated the impact of training using a virtual reality simulator on the quality of skills acquired for a key gynaecological procedure. The investigation was carried out as a prospective, randomised, observer blinded, controlled trial, according to the guidelines of the consolidated standards of reporting trials (www.consort-statements.org).

METHODS
From September 2006 to June 2007, 32 trainees in gynaecological specialty training years 1 and 2 (postgraduate years 3-8; see box), with no experience of advanced laparoscopy (defined as all laparoscopic procedures involving coordination of more than one instrument), were included in the study. Of a total cohort of 42 (38 women and four men) trainees in the
region, eight were not eligible, as they were too experienced and four came from the two departments that did not participate in the trial. Of the remaining 30 eligible trainees, the first 24 who volunteered were enrolled. They came from seven of nine gynaecology departments in the Zeeland region of Denmark (population 2.3 million): Gentofte hospital (five trainees), Herlev hospital (n=4), Roskilde hospital (n=4), Hillerød hospital (n=1), Holbaek hospital (n=1), Hvidovre hospital (n=2), and Rigshospitalet hospital (n=7).

Randomisation and blinding
To ensure that the trainees’ baseline characteristics were similar within and between each group, we chose a stratified randomisation based on previous experience of simple laparoscopy (defined as laparoscopic procedures performed using a single instrument, such as diagnostic laparoscopic sterilisation (clips) or diagnostic laparoscopy). The Clinical Trial Unit at Copenhagen University independently randomised the trainees by computer to intervention or control groups. The randomisation procedure was concealed and achieved by using the trainees’ unique personal identification number (central personal register number).

Trainees in the intervention group were given an oral introduction to the simulator and the rating scale used for outcome measure. Any operations done during the study were recorded. Owing to the nature of the trial it was not possible to blind the trainees to their allocated group, but all involved departments, supervisors, and staff in the operating theatres were blinded to the trainee’s group, and the assessors of outcome were blinded to both the trainee and their allocated group. The primary investigator saw the data only after completion of all assessments and once data had been loaded in a database.

The control group was to continue standard clinical education. During the study no trainee in either group was allowed to perform advanced laparoscopic surgery, only simple laparoscopy or to assist senior colleagues. To check that randomisation had been successful, the control group were trained in the simulator after the trial. Their baseline performances were indistinguishable from those of the intervention group.

Equipment
The virtual reality laparoscopy simulator program (LapSim Gyn v 3.0.1; Surgical Science, Gothenburg, Sweden) was run on an IBM T42 computer in a docking station (Pentium M 1.8 GHz/512 MB RAM; IBM, Armonk, NY, USA) using an interface with a diathermy pedal (Virtual Laparoscopic Interface; Immersion, San Jose, CA, USA). The operations took place in the operating theatres of the participating departments and were recorded on DVD using a camera attached to the laparoscope for later blinded evaluation. During the operation one of the authors (CRL or designated TD) observed the procedure to record the handling of the surgical instruments, any involvement of the supervisor, whether the standard procedure for the operation was followed, and whether the recording was done correctly, finalised, and assessed.

Simulator training
The intervention group undertook a specific training programme in the simulator. The programme comprised two parts: firstly, training in the two basic skills of “lifting and grasping” and “cutting” during which the trainees were introduced to the simulator environment and the different instruments; secondly, one procedure specific task in which the trainee had to carry out a complete right sided salpingectomy while preserving the ovary. The training in basic skills was done once in each training cycle of 45-60 minutes and the salpingectomy repeated continually during the remainder of the cycle. The simulator provided the trainees with instant feedback on time, path length and angular path of the instruments’ movements, bleeding, cutting of uncoagulated arteries, and use of diathermy on non-target tissue. The training sessions were repeated until the expert criterion level was reached in two consecutive and independent simulations. The proficiency criteria were established by experts in previous studies of construct validity and learning curves. The requirements and settings of the simulator are available at www.skopisimulator.rh.dk.

Surgical procedure
The trainees performed their first salpingectomy at their local gynaecological department and were supervised by a senior colleague who was told about the purpose of the trial. To make comparison of performance easier, the trainees all carried out procedures on the right side. The patients were admitted for elective salpingectomy before treatment for infertility or for prophylactic removal of fallopian tubes and ovaries owing to a positive test result for breast cancer gene 1 (BRCA1). The trainees were not allowed to operate on patients who had undergone previous open or laparoscopic surgery below umbilicus, had possible abdominal malignant disease, had an American Surgical Association score ≥3 (patients with severe systemic disease), had a body mass index less than 18 or more than 27, had haemophilia, or had other factors of potential influence on the surgical procedure. The operations followed a modified standard procedure on the basis of expert consensus. The supervisors were allowed to give oral instructions only, and one researcher was present to observe the procedure and to record who handled the instruments.

**Duration of specialist training in Denmark**

<table>
<thead>
<tr>
<th>Trainee Type</th>
<th>Duration</th>
</tr>
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<tbody>
<tr>
<td>Preregistration house year</td>
<td>one year</td>
</tr>
<tr>
<td>Introduction before specialist training</td>
<td>one year</td>
</tr>
<tr>
<td>Optional additional training to qualify for further specialisation (possibility for writing PhD thesis)</td>
<td>1-3 years</td>
</tr>
<tr>
<td>Specialist training</td>
<td>four years</td>
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Outcome measures
The primary outcome measure was technical performance, measured as total score (10-50 points) using the objective structured assessment of laparoscopic salpingectomy, which comprises a five item general rating scale and five item task specific rating scale.19 Two independent observers blinded to trainee and allocated group assessed the recorded operations. The secondary outcome measure was operating time in minutes. The reliability of the assessment was determined by calculating the inter-rater agreement (number of agreements for each of the assessed items divided by total number of assessed items) and the γ coefficient. We present outcomes as medians and inter-quartile ranges.

Power calculation
The power calculation was based on a previous validation study on the procedure specific scale of the objective structured assessment of laparoscopic salpingectomy.19 This study showed a difference of six points between novice laparoscopists (0-5 procedures) and immediately experienced laparoscopists (30-50 procedures). An improvement of skills to the level of 30 or more points was considered acceptable. On the basis of these findings we chose the minimal relevant difference to be six points. We determined that with an α of 0.05 (two sided) and a power of 80% (β=0.2 giving Zα=1.96 and Zβ=0.84, largest SD=4.40) we required 18 or more trainees. To compensate for possible drop outs, we added an additional third to the 18, totalling 24 trainees.

Statistical analysis
We present cumulated scores as medians (average score of two observers), compared using non-parametrical analysis (Mann-Whitney U test). We considered a two tailed P value of 0.05 or less to be statistically significant and an inter-rater agreement and γ coefficient of 0.8 or more for each to be acceptable. Analysis was done using SPSS 13.0 for Windows. Graphics were made using Graph pad Prism (Graph Pad, San Diego, CA, USA).

RESULTS
Eight of the total cohort of 42 trainees (38 women, four men) were ineligible for the study as they were too experienced and four came from the two departments not participating in the trial. The remaining 30 trainees agreed to participate. The first 24 were enrolled; 22 (90%) were women, representing the current sex distribution among trainees in obstetrics and gynaecology in Denmark (figure). The average age of the trainees was 32.8 years (range 26-42 years), and 23 were right handed. Eleven trainees were randomised to virtual reality training in laparoscopic salpingectomy and 10 were randomised to traditional clinical education.

Table 1 Baseline characteristics of gynaecology trainees randomised to virtual reality simulator training in laparoscopic salpingectomy or to standard clinical education (controls). Values are numbers of trainees unless stated otherwise

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Simulator trained group (n=13)</th>
<th>Control group (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Women</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Mean (range) age (years)</td>
<td>33.3 (30-42)</td>
<td>32.4 (26-38)</td>
</tr>
<tr>
<td>Experience of simple laparoscopy</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>No experience of simple laparoscopy</td>
<td>7</td>
<td>6</td>
</tr>
</tbody>
</table>
The median total score on the general and task specific rating scale reached 33 points (interquartile range 32-36 points) in the simulator trained group and 23 (22-27 points) in the control group (P<0.001, table 2).

The median total time to complete the procedure was 12 minutes (interquartile range 10-14 minutes) in the simulator trained group compared with 24 (20-29 minutes) in the control group (P<0.001, table 2). Twenty one operations were assessed.

The median number of simulated salpingectomies needed to reach the proficiency level in the simulator trained group was 28 (24-32 salpingectomies). The control group was offered simulator training after the study operation; nine of the 11 trainees in this group volunteered and a median of 26 (23-32) simulated operations were needed to reach the proficiency level (P=0.70). The mean time spent on training using the simulator was 7 hours and 15 minutes (5 hours 30 minutes-8 hours 0 minutes) in the intervention group and 7 hours and 0 minutes (5 hours 15 minutes-7 hours 45 minutes) in the control group (P=0.65; table 3). The baseline score (first attempt) was 8 (5-15) in the simulator trained group and 9 (7-19) in the control group after training (P=0.70; table 3). All trends of differences in baseline characteristics were not statistically significant.

The time used by the assessors to fill in the rating chart was the mean total operation time plus five minutes for each DVD recording. The inter-rater agreement was 0.79 (166/210). The γ coefficient used to investigate strength of correlations among the observers at single subject level reached 0.83 (95% confidence interval 0.69 to 0.99).

DISCUSSION
Proficiency based virtual reality training in laparoscopic salpingectomy compared with standard clinical education was associated with a clinically important improvement of operative skills during the actual procedure. The learning curve in the operating theatre was also shorter. On the rating scale used in this study, which had previously been validated in a separate investigation, novices (fewer than five procedures) scored a median 24 points, and intermediate experienced trainees (20-50 procedures) a median 33 points compared with a median 39 points for experts.19 The clinical implications of the present findings are thus extensive. After training in a specific procedure to a predefined (proficiency based) level inexperienced trainees progressed from the performance level of a novice to that of an intermediatively experienced gynaecologist, assessed in their first complex laparoscopic procedure. By using simulator training it might be possible to bypass the early learning curve, which is known to be associated with an increased rate of complications.20 This study was not designed to investigate complication rates, and conclusions in this area must be drawn cautiously. In general it is difficult to use patient outcomes to evaluate a medical training course. Firstly, in contrast with trials of a single intervention (for example, a new drug) medical education is a complex intervention involving many interconnecting parts and different layers.21 Secondly, assessment of surgical technical skills of individual trainees will need to be based on surrogate end points rather than outcomes such as morbidity or mortality because it is an ethical imperative that an operation performed by a supervised novice ought to have the same outcome as that of the supervisor. Training may cost time and some inconvenience for the patient but should never jeopardise safety or outcome. Thirdly, to show differences in outcome, based on a training course, the numbers of trainees should by far outnumber the total number of trainees available, thus making such a trial unfeasible.

Operating time
Although operating time might be greater with novice surgeons, the outcomes of a supervised operation ought to be the same. The time to complete the laparoscopic salpingectomy was reduced by half. As the operating theatre serves both productivity and educational purposes, shorter operation times are of benefit.

The present results emphasise that by using virtual reality simulator training the surgical community can meet the need for proficiency based basic training in laparoscopy. These results also show that criterion based procedural training using a virtual reality simulator can help compensate for reduced working hours by bringing trainees to a higher level of performance more quickly. Traditional training depends on the supply of suitable procedures for training purposes, whereas simulator training can be used according to demand. To achieve an average of 28 salpingectomies can take a year or more in clinical practice, compared with eight hours of intensive training using the simulator.

Finally, reducing the operating time by half, from 24 minutes in the control group to 12 minutes in the

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Table 3 | Number of sessions and duration of training in virtual reality simulator training programme in intervention group before training and in control group after surgery

<table>
<thead>
<tr>
<th>Variable</th>
<th>Simulator trained group (n=11)</th>
<th>Control group (n=9)*</th>
<th>P value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>No (range) of training sessions</td>
<td>28 (16-39)</td>
<td>6 (19-43)</td>
<td>0.76</td>
</tr>
<tr>
<td>Duration (range) of training</td>
<td>7h 15m (4h 15m-9h 30m)</td>
<td>7h 0m (4h 0m-9h 15m)</td>
<td>0.70</td>
</tr>
<tr>
<td>Median (range) score on first attempt (%)</td>
<td>8 (5-15)</td>
<td>9 (7-19)</td>
<td>—</td>
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*Voluntary simulator training after surgery.
†Mann-Whitney U test.
sparse.13 To date no published studies on the transfer of
trainers on performance in the operating theatre is still
more than a decade ago, evidence on the effect of simu-
lar to other laparoscopic procedures, although the effect
would be more visible on the technical side than in
the knowledge of procedural skills. These suppositions
are supported by a contemporary Swedish study on
procedural virtual reality simulator training of cholecys-
tectomy, which reached conclusions similar to
those of the present study.26

Observer reliability
In the present study the $\gamma$ coefficient showed that there
was no systematic discrepancy among the raters. The
inter-rater agreement also reached a sufficient level,
which is evidence of a valid and reliable assessment.

The investigation was carried out in the same way
that a curriculum integrated training course most likely
would be implemented. The internal consistency of the
trial could have been higher if all the trainees had oper-
ated in the same theatre, using the same technical
equipment, and with the same supervisor and staff.
However, by showing the effects of simulator training in
settings closely resembling a regional simulator
training course the external validity was improved.
The primary investigator helped the trainee to use the
simulator and introduced the different training mod-
ules but did not teach laparoscopic techniques. The
feedback on performance was based on assessment in
the simulator. A designated supporter at the training
session could, however, be a source of bias. A setting
where trainees practise by themselves could eliminate
this potential source of bias. Finally, performing
laparoscopic surgery also consists of identifying dis-
cased anatomy, communication, teamwork, decision
making, and leadership, alternative plans, and con-
version to open surgery if needed.29,30 These non-tech-
nical skills are taught in the currently existing virtual
reality systems to a limited degree only. In this study
we did not provide training in these non-technical skills
or assess them. Simulator training should probably be
considered only as a supplement or preoperative train-
ing; further education and practice in the operating
theatre as well as further development of more com-
plex virtual surgical environments (hybrid simulation)30
is still required.

Conclusion
It is possible to transfer skills acquired during profi-
ciency based training using a virtual reality simulator
to a real operation. Training in proficiency based skills
should be incorporated in a comprehensive surgical
training and assessment curriculum for all residents
before they operate on real patients. This can poten-
tially improve patients’ safety and improve efficiency
in the operating theatre.
WHAT IS ALREADY KNOWN ON THIS TOPIC

The European Working Time Directive has put extra pressure on surgical training programmes. Virtual reality simulators could contribute to the training of core skills for laparoscopy. High grade evidence of the effect of virtual reality simulator training on real operations is sparse.

WHAT THIS STUDY ADDS

Training using a virtual reality simulator improved performance in a laparoscopic procedure.

We thank Jorn Wetterslev at the Copenhagen Trials Unit for critical revision of the research protocol, assistance with the power calculation, and the conceived computer-based randomisation of the participants.

Contributors: CRL (principal investigator) acquired the data, drafted the paper, did the statistical analysis, and obtained funding. TPG and JLS provided administrative support and critically revised the manuscript. JLS had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. TD acquired the data, provided technical support, and critically revised the manuscript. LS and CO acquired the data, provided administrative support, and critically revised the manuscript. TVS and BSO provided administrative support and supervised the study, critically revised the manuscript, and obtained funding. All authors conceived and designed the study and analysed and interpreted the data.

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Competing interests: None declared.

Ethical approval: The investigation fully complied with the Helsinki II declaration on biomedical research. The study was approved by the Danish National Committee on Biomedical Research Ethics (approval code: KF 08 37 56). All study participants and patients were provided with written study documentation and were included in the trial after informed consent. The Danish Data Protection Agency approved the collection, analysis, and storage of the DVD recordings (approval code: 2005-41-5817).


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