SIMULATION TRAINING IN HYSTEROSCOPIC SURGERY

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Simulation Training in Hysteroscopic Surgery

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SIMULATION TRAINING IN HYSTEROSCOPIC SURGERY

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(met een samenvatting in het Nederlands)

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Skill is the unified force of experience, intellect and passion in their operation.
John Ruskin

Voor mijn zusje

CONTENT

CHAPTER 1

GENERAL INTRODUCTION AND OUTLINE OF THE THESIS

Based on:
"Hysteroscopy training and the progress of simulation models: A narrative review"
J.A. Janse, S. Veersema, F.J. Broekmans, H.W.R. Schreuder

Submitted for publication

The uterus is the reproductive organ in the genital tract that connects the cervix, which opens into the vagina, with the fallopian tubes that lead to the pelvic peritoneal cavity in close vicinity to the ovaries. Hysteroscopy (Greek: ὑστέρα – uterus, σκοπειν – to look at) detects uterine cavity pathology by direct visualisation, making use of a vaginally inserted endoscope. The additional insertion of an instrument through the endoscope and the incorporation of irrigation channels provide the opportunity for obtainment of histology and treatment of these pathologies, and for sterilisation of women. Due to the development of thinner endoscopes and working channels and the introduction of the vaginoscopic insertion technique, it has become possible to perform hysteroscopy in an outpatient setting without anaesthesia.

The principles of this minimally invasive technique were first described by Bozzini in 1805, but it was not before the 1970s that gynaecologists started to apply hysteroscopy in their daily practice(1). Technology afforded more practical and usable instruments and refinement continues to this day. Hysteroscopy has become an essential diagnostic and therapeutic tool in the current practice of general gynaecology and reproductive medicine.

ENDOSCOPIC SKILLS

Even though hysteroscopic skills are often perceived to be less complicated in comparison to laparoscopy (endoscopic surgery of the abdominal cavity), they are far from innate abilities. Psychomotor skills need to be learned to overcome the barriers that are known for hysteroscopy, namely the fulcrum effect, loss of binocular vision, and decreased range of motion(2,3). In addition, skills unique to camera navigation include maintaining a correct horizontal axis while centring the operative field, focusing and sizing, and maintaining a steady image(2,4). Especially angled scopes, by the addition of off-axis viewing, require more complex visuospatial skills(5).

Training of endoscopic skills outside the operating room is increasingly implemented in residency programs around the world. The exponential growth of minimally invasive surgery(6), the limited resident availability for educational endeavours by work hour restrictions(7), and the legal and ethical concerns about learning on the patient(8) are changes in modern medicine. These changes have led to the growing realisation that parts of the endoscopic learning curves can be accomplished without the interference of a patient, to improve patient safety and to save operating time and costs(9). In addition, the Dutch Healthcare Inspectorate stated in reports the need for the implementation of structured training programs to train minimally invasive surgery, and to aim at as little as possible risk exposure for patient safety hazards(10-12).

In gynaecology, several laparoscopic training models have been validated and are used in residency programs, providing skills transfer from the simulator to the operating room(13-15). However, the application of hysteroscopic training models seem to lag far behind in daily practice. Only a small number of models have been developed and validation studies are lacking.

VALIDATION OF TRAINING MODELS

Before discussing the available training models in hysteroscopy, the concept of validity should be emphasised. The effectiveness of training on simulators largely depends on the validity of the models and simulators used[16,17]. Validity defines whether a simulator is actually teaching or evaluating what is intended to be taught or measured. Prior to implementation of a new training tool in a curriculum, validation of the simulator and its parameters is mandatory[18,19]. In ***table 1*** different types of validity are defined. Construct and predictive validity are the most important types of objective evaluation.

Table 1. Definition of simulator validity

TYPE OF VALIDITY	DIMENSION	DEFINITION
Face validity	Subjective	Opinion of experts whether the model resembles the task or procedure it is aiming to train for, by grading the realism of the simulator
Content validity	Subjective	Judgement by experts of appropriateness of the simulator to train a task or procedure, based on the content/components of the device
Construct validity	Objective	Ability of the simulator to measure the quality or ability it is supposed to measure, by differentiating between experienced and inexperienced participants; or in addition, to measure improvement in novices' performance by training
Concurrent validity	Objective	Correlation of simulator scores with performance on the 'gold standard' simulator, an established instrument of skills assessment
Predictive validity	Objective	The extent to which the simulator predicts future performance, by assessing whether the skills acquired on a simulator actually result in improved skills in the clinical setting

Types of validity defined by authors based on definitions of Gallagher et al[18]

SIMULATION MODELS IN HYSTEROSCOPY

Since the 1970s, training aids for hysteroscopic surgery emerged very slowly and started as organic simulators (derived from living organisms), whereas the most recent developments comprise inorganic simulators. ***Table 2*** summarises the most important advantages and disadvantages of training models available for hysteroscopic surgery. In 'wet' models distension medium is used, to be able to apply monopolar and bipolar energy for training of electrosurgical techniques. A 'dry' model indicates that no distension medium is needed; however, only diagnostic and biopsy skills can be practiced.

Table 2. Types of simulation models for hysteroscopy training

SIMULATION	WET/DRY	ADVANTAGES	DISADVANTAGES	BEST USE
Fresh human cadaver	Wet	High fidelity Procedural simulation "True" anatomy	Preparation Availability Single use	Procedural skills
Animal model	Wet	High fidelity Procedural simulation	Preparation Ethical issues Single use Anatomical differences Cost	Procedural skills
Vegetable model	Dry & Wet	Cost Availability Minimal risks	Low fidelity Limited realism Preparation Mostly basic skills	Basic skills for novice trainees Certain discrete skills
Box trainer	Dry & Wet	Cost Portable/reusable Minimal risks	Low fidelity Limited realism Mostly basic skills	Basic skills for novice trainees Certain discrete skills
Virtual reality trainer	NA	Realism Reusable Data capture Objective assessment	Cost Maintenance	Basic skills Procedural skills

NA = not applicable
Adapted from Reznick et al[46]

ORGANIC SIMULATORS

HUMAN MODEL

Fresh cadaver models provide the human anatomy. Kleppinger proposed an educational device for fixating an extirpated uterus for hysteroscopy training in 1977[(20)]. This is the first and last comment in literature on a hysteroscopic model of human material. The situation is not feasible for day-to-day training, the material requires preparation and it is normally not available due to pathology investigations postoperatively.

ANIMAL MODEL

Animals and their organs are used as 'wet' training models since a few decades. Animal uteri do not necessarily have the same consistency as the human uterus. Additionally, from a procedural perspective the pig, cow or other mammalian uterus has no great practical resemblance to the anatomy of the human female. The preparation of a pig bladder was described for the operative hysteroscopy technique in 1988[(21)]. Placing a large suture through the anterior and posterior walls produces the appearance of a septum or synechiae, which can be resected. Endometrial ablation can be practised as well[(21)]. A more recent report confirms the on-going use of pig bladders for this purpose in a minimally invasive surgery course for residents in the Netherlands[(22)]. In Denmark, hysteroscopy courses are currently implemented for training of the endometrial ablation technique on pigs' hearts[(23)]. No research has been performed to determine the validity of these training models and organs.

VEGETABLE MODEL

Hysteroscopy training on vegetable models made its introduction in the 1990s. The vegetables offer a simple training method; they are inexpensive and easily available. Nevertheless, these vegetables are appropriate only for single use and their similarity to the uterine environment is questionable. A red pepper for practicing biopsies is utilised in the national training course in the Netherlands as well[(22)]. In the cavity of a butternut pumpkin, which contains seeds and pulp, both diagnostic and therapeutic hysteroscopies can be practised[(24)]. Validity of these vegetable models has not been investigated in literature.

INORGANIC SIMULATORS

BOX TRAINER

Plastic models (box trainers) are developed since the 1990s to provide simple, safe en reusable training facilities for endoscopy courses as well as individual daily training. In these type of courses the assembly of the hysteroscope is practiced in addition, because real-time instruments need to be used. This advantage also holds for human and animal models. Low fidelity and limited realism are drawbacks of a box trainer.

In Germany, gynaecologists designed the HysteroTrainer™ for both diagnostic and operative hysteroscopic skills development[(25,26)]. This box trainer consists of a basis and a synthetic uterus with an anterior wall of neoprene, to ensure distension simulation of the uterine cavity. Organ modules were designed to allow training of both diagnosing intracavitary pathologies and resection skills. No data regarding validation research is available for this simulation model.

Two research groups investigated the effect of simulation training on a pelvic model (Hysteroscopic Resection Trainer (Limbs and Things, Bristol, UK)) ***(figure 1)*** [27,28].

Figure 1. *Set-up of the Hysteroscopic Resection Trainer (Limbs and Things, Bristol, UK)*

This 'wet' model consists of several hard plastic uteri with varying physiologic and pathologic conditions, fixated on a basis. Construct validity was established and confirmed[27,28]. ***Table 3*** summarises the validation results per model and study.

A recently developed box trainer is the Hysteroscopic Skills Testing and Training (HYSTT) model, designed under auspices of the European Academy for Gynaecological Surgery (Leuven, Belgium). This 'dry' simulator aims at developing basic hysteroscopic skills. Camera navigation with a 30° scope is trained by performing exercises to correctly visualise signs at various positions in a plastic uterus. Instrument handling and hand-eye coordination are practiced by picking and extracting pin objects out of the uterine wall. The hard plastic uterus is situated inside a silicone vulva model, inside a plastic model of a female pelvis. The first validation study for this simulator is part of this thesis.

VIRTUAL REALITY SIMULATOR

The latest development in simulation, and widely used for laparoscopy training, is the virtual reality simulator[15,29]. This type of model creates a safe, controlled and standardised environment. The main advantages of a virtual reality simulator are the ability to train both basic and procedural skills in a realistic environment, the ability to objectively measure the performance of each subject and the automatic presentation of these parameters during and after each exercise. This provides the opportunity to train independently and repetitively to a predefined proficiency level. Disadvantages can be the relatively high costs and the lack of haptic feedback is interpreted as a disadvantage by some users as well.

The earliest references to a virtual reality simulator for training hysteroscopic surgery were published in 1996, shortly summarising the set-up and potential benefits of a prototype model[30,31]. Since then, collaborations of technicians and gynaecologists from the USA, Europe and Australia thoroughly described the development of several other simulator prototypes[32-35]. All prototypes were designed for simulation of both diagnostic and operative hysteroscopies. However, no further signs of development, validation or use of one of these simulators are currently found. Munro et al. reported in 2011 in a pilot study on a prototype of the Virtual Reality Hysteroscopic Simulator (VRHS) for training of instrument handling and myoma resection[36]. Construct

Table 3. Validation studies published per hysteroscopic training model

TRAINING MODEL	TYPE OF VALIDATION	STUDY	HYSTEROSCOPIC SKILL(S)	GROUP(S)	TRAINING	TEST(S)	PARAMETER(S)	OUTCOME*
Box - Hysteroscopic Resection Trainer - Limbs and Things, Bristol, UK	Construct Learning curve	VanBlaricom 2005[27]	Polyp resection	Intervention group: 24 residents (PGY 1-4) Control group: 24 residents (PGY 1-4)	Yearly training session (didactics and hands-on)	Polyp resection on model, 4 to 6 months after curriculum with blinded and unblinded examiners	OSATS	Yes, significantly better performance for intervention group in comparison to control group. Senior residents outperformed junior. Yearly training improved performance.
	Construct	Burchard 2007[28]	Submucosal myoma resection	10 residents (PGY 1-4)	Single training session (instructions and hands-on)	Myoma resection on model: - Pre-training - 1 month post-training - 6 months post-training	Total session time Resection time Knowledge test	Yes, significant improvement for time and knowledge at 1 month post-training. Effect declined at 6 months post-training.
VR - VRHS - Immersion Medical, Montreal, Canada	Construct	Munro 2011[36]	Instrument navigation Myoma resection	11 novices (medical students and PGY-1 without hysteroscopic experience) 3 experts in hysteroscopy	Two training sessions (hands-on)	Measurements at beginning and end of training sessions on model	Procedure time Errors Percentage resected myoma	Yes, experts outperformed novices on all parameters. Novices improved significantly during training sessions.
VR - HystSim™ - VirtaMed AG, Zurich, Switzerland	Face	Bajka 2009[44]	Diagnostic skills Operative skills (rollerball ablation and myomectomy)	36 novice gynaecologists (≤50 hysteroscopies) 26 expert gynaecologists (> 50 hysteroscopies)	20-min hands-on session	Survey directly after hands-on session	Opinion on 7-point Likert scale	Yes, 27% awarded realism 5 points, 66% 6 points, 7% 7 points. 90.3% agreed on applicability for residents training.
	Construct Learning curve	Bajka 2010[45]	Diagnostic skills	24 novices (medical students) 12 experts in hysteroscopy	Two training sessions (hands-on) with 2 weeks interval	Measurements during training sessions on model	4 simulator-derived assessment modules	Yes, experts outperformed novices on 2/4 modules. Significant improvement for novices during both training sessions.

* Validity proven?
Box: box trainer
PGY: postgraduate year
OSATS: objective structured assessment of technical skills, consisting of a task-specific checklist and a global rating scale
VR: virtual reality simulator
VRHS: Virtual Reality Hysteroscopic Simulator

validity was established in a small study ***(table 3)***[36]. Still, no further evidence of development or current use of this simulator is currently available.

A virtual reality simulator that did go through a comprehensive developmental phase is the HystSim™ (Hysteroscopic Surgery Simulator System, VirtaMed AG, Zurich, Switzerland) **(figure 2)**[37-43]. Basic validation studies were performed for the diagnostic hysteroscopy module and this simulator is currently being used for training ***(table 3)***[44,45]. Besides training of diagnostic skills, several modules were designed for specific operative procedures, e.g. loop resection, rollerball ablation, and septum removal. Customized modules were developed for the Essure® sterilisation method and morcellator technique.

HYSTEROSCOPIC SIMULATION IN THE NETHERLANDS

In the Dutch national curriculum for training in Obstetrics and Gynaecology, there is one course for basic surgical skills training incorporated (Cobra-alpha course[22]). This is a two-day basic course, and single attendance is mandatory during postgraduate year 1 or 2. One day focuses on minimally invasive surgery, subdivided into laparoscopy and hysteroscopy. Part of this day is spent on hands-on training. The hysteroscopic models that are being used consist of a pig bladder and paprika model, which have never been subject of validity research at all. Next to this national course, several training regions in the Netherlands also offer a local course which contains basic and/or advanced skills training for minimally invasive surgery.

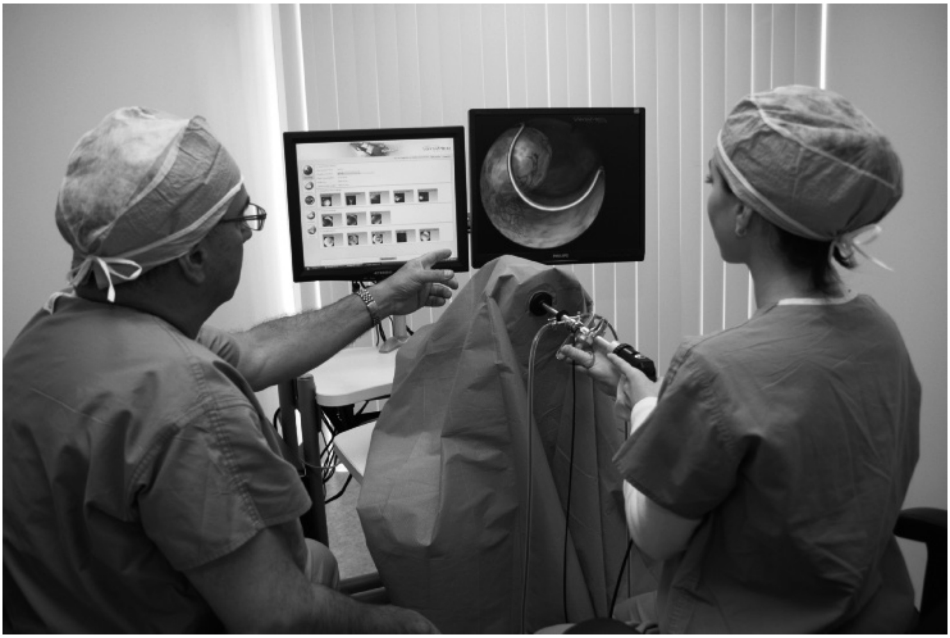

Figure 2. *Set-up of HystSim™ Virtual Reality simulator (VirtaMed AG, Zurich, Switzerland)*

PROBLEM STATEMENT AND THESIS OBJECTIVE

Endoscopy training in an environment without involvement of patients offers a safe, effective and unlimited source of training for the individual. Beneficial results are mainly derived from studies in laparoscopy, but attention is growing for training of the hysteroscopic technique as well. However, only a small number of hysteroscopic training models are currently available. And more importantly, an even more limited number is validated. Advancements are made in the development of hysteroscopic training models and further research needs to be carried out to assess the progress in hysteroscopy training and to determine the effectiveness and quality of modern simulators in hysteroscopy.

AIMS OF THE THESIS

- Inventory the current opinion on the quality of hysteroscopic skills training during gynaecological residency in the Netherlands
- Assess the value and validity of a new box trainer for training of basic hysteroscopic skills
- Assess the value and validity of a new virtual reality model for training of a specific hysteroscopic procedure
- Investigate the effect of simulated and clinical procedures on the learning curve in acquiring hysteroscopic skills.

OUTLINE OF THE THESIS

Chapter 1 provides an overview of the literature on simulation training in hysteroscopic surgery.

Chapter 2 evaluates the current opinion on hysteroscopy training among residents and young gynaecologists in the Netherlands, by a national survey.

Chapter 3 assesses the learning curve of 30° camera navigation skills on a new box trainer for hysteroscopy. The learning curve gives an indication of validity and possible future use in training curricula.

Chapter 4 investigates the correlation between training of camera navigation skills with a 30° optic in hysteroscopy and laparoscopy. If a correlation exists, training in gynaecologic endoscopy could be simplified.

Chapter 5 presents the establishment of face and construct validity of the hysteroscopic sterilisation module on the HystSim™ virtual reality simulator.

Chapter 6 assesses the learning curve of the hysteroscopic sterilisation method on the HystSim™ virtual reality simulator.

Chapter 7 describes the clinical learning curve of the hysteroscopic sterilisation method by 15 gynaecologists in the Netherlands. The learning curve of experts performing a new type of operative hysteroscopy provides information on the future need for training of experts.

Chapter 8 presents the discussion, contains recommendations for future research and gives suggestions for the hysteroscopic training curriculum in the Netherlands.

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CHAPTER 2

TRAINING OF HYSTEROSCOPIC SKILLS IN RESIDENCY PROGRAM; THE DUTCH EXPERIENCE

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ABSTRACT

STUDY OBJECTIVE

To evaluate whether hysteroscopy training in the Dutch gynaecological residency program is judged as sufficient in daily practice, by assessment of the opinion on hysteroscopy training and current performance of hysteroscopic procedures. In addition, the extent of progress in comparison to the residency program of a decade ago is reviewed.

DESIGN

Survey (Canadian Task Force Classification III).

PARTICIPANTS

Postgraduate year 5 and 6 residents in Obstetrics and Gynaecology and gynaecologists who finished residency within 2008-2013 in the Netherlands.

INTERVENTION

Subjects received an online survey regarding performance and training of hysteroscopic, self-perceived competence and hysteroscopic skills acquirement.

RESULTS

Response rate was 66% of the residents and 73% of the gynaecologists. The majority of residents felt adequately prepared for basic hysteroscopic procedures (86.7%), but significantly less share this opinion for advanced procedures (64.5%) (p-value $< .01$). In comparison to their peers in 2003, the current residents demonstrated a 10% higher appreciation of the training curriculum. However, their self-perceived competence did not increase, except for diagnostic hysteroscopy. Regarding daily practice, not only do more gynaecologists perform advanced procedures nowadays, but also their competence level received higher scores in comparison to gynaecologists in 2003. Lack of simulation training was indicated to be the most important factor during residency that could be enhanced for optimal acquirement of hysteroscopic skills.

CONCLUSION

Implementation of hysteroscopic procedures taught during residency training in the Netherlands has improved since 2003 and is judged as sufficient for basic procedures. The skills of surgical educators have progressed towards a level in which gynaecologists feel competent to teach and supervise advanced hysteroscopic procedures. Even though the residency preparation for hysteroscopy is more highly appreciated than a decade ago, this study indicated that simulation training might serve as an additional method to improve hysteroscopic skills acquisition. Future research is needed to determine the value of simulation training in hysteroscopy.

INTRODUCTION

Hysteroscopy is an essential diagnostic and therapeutic tool in the current surgical gynaecological armamentarium. Pathology of the uterine cavity is detected by direct visualisation of the endometrial lining, making use of a vaginally inserted endoscope. The addition of a working channel and irrigation channels provide the opportunity for obtainment of histology and treatment of these pathologies, and for sterilisation of women. Due to the development of thinner endoscopes and working channels and the introduction of the vaginoscopic insertion technique, it has become possible to perform hysteroscopy in an outpatient setting without anaesthesia(1).

Hysteroscopic skills are often perceived to be less difficult to obtain in comparison to laparoscopy because only one scope and instrument are used at the same time. However, hysteroscopic skills are far from innate abilities. Training of hysteroscopic procedures during residency is necessary for the implementation of these techniques in the daily practice of a gynaecologist. During the past decades several surveys among gynaecologists and residents have been performed in North America and Europe, all highlighting an area that merits more attention of medical education programs(2-7).
Specifically, a Dutch survey in 2003 concluded that the implementation of basic, but not of advanced, hysteroscopic procedures had been successful up to then(6). In order to perform the full spectrum of hysteroscopic procedures as a gynaecologist, residents need the opportunity to perform both basic and some advanced procedures up till a certain level of skills. The authors concluded that it was of great importance for surgical educators to improve their skills, in order to improve the exposure to residents. Gynaecologists were still dealing with their own learning curve issues, which diminished the residents' educational experience.

Worldwide, the last decade was characterised by further development and implementation of hysteroscopic procedures in the office setting, the innovation of tools and operative techniques for hysteroscopy and by the implementation of a fellowship for minimally invasive gynaecologic surgery(1,5,8). In the Netherlands especially, attention was drawn towards the importance of patient safety and the need for improved training of minimally invasive surgery by a report of the Dutch Healthcare Incorporate(9).

The aim of this study is to evaluate whether hysteroscopy training in the Dutch gynaecological residency program is judged as sufficient in daily practice. This is performed by assessment of the current opinion of residents and gynaecologists who finished their residency (< 5 years) on their hysteroscopic performance, training and implementation. The second aim is to compare the current results with those of an inquiry of a decade ago, to display possible changes and to find solutions for further optimising hysteroscopic skills acquirement in residency trainings program.

MATERIALS AND METHODS

To assess the opinion of residents and gynaecologists (who finished residency < 5 years) on hysteroscopy performance and training, an invitation email for the online survey (MonkeySurvey® system) was sent in July 2013. All postgraduate year 5 and 6 residents in Obstetrics and Gynaecology, registered at the Dutch Society of Obstetricians and Gynaecologists (NVOG), received this invitation. A similar survey was sent to all gynaecologists working in teaching and non-teaching hospitals, who finished residency within the previous 5 years (2008-2013) and were registered at the NVOG. Names and email addresses were collected from the NVOG. All collected data were registered anonymously. To maximise the response rate, a second and third mailing was sent.

The survey comprised questions regarding personal and practical demographics, interest in and performance of hysteroscopy, self-perceived competence and training, and possible factors influencing hysteroscopic skills acquirement. Guidelines of the European Society of Gynaecological Endoscopy (ESGE) were used to classify hysteroscopic procedures according to three levels of difficulty (***Table 1***)[10].

The Dutch curriculum guidelines contain specific requirements for graduation, such as a number of mandatory hysteroscopic procedures that need to be performed as primary surgeon at a certain level of competence. This competence level (CL) is defined on a 5-point Likert-scale (LS): level 1 – has theoretical knowledge of, level 2 – is able to perform under strict supervision, level 3 – is able to perform under limited supervision, level 4 – is able to perform without supervision, level 5 – is able to supervise and educate others. Basic hysteroscopic procedures that are mandatory according to the current Dutch curriculum guidelines, are diagnostic hysteroscopy (CL 4) and polypectomy (CL 4). Performance of hysteroscopic myomectomy (type 0-II) is mandatory as well, but the competence level is not specified. We consider the myomectomy type I and II as advanced hysteroscopic procedures, together with the other procedures that are not required for graduation (endometrial resection, sterilisation, major synechiolysis).

In this study, a 5-point LS was used to let the respondent express their opinion: 1 (not interested) - 5 (very interested), or 1 (totally disagree) - 5 (totally agree).

Not all respondents completed all items of the survey; therefore subcalculations with different denominators were made. The surveyed residents and gynaecologists were analysed separately.

The statistical analysis was performed with SPSS 20.0 for Windows (SPSS Inc, Chicago, IL) by using the t-test and Mann-Whitney U test. P-values $< .05$ were considered significant.

RESULTS

The response rate of all surveyed residents was 66% (N respondents = 61), and of young gynaecologists in practice 73% (N respondents = 170). The mean age of residents and gynaecologists was 34 (range 30-43) and 38 (range 33-49), respectively. Gynaecologists who are subspecialised in maternal fetal medicine and work in an academic hospital do not perform hysteroscopic surgery anymore. Therefore, these gynaecologists were excluded from further analysis in our study (N = 24, 14%). From here on we continue to analyse the survey of the remaining 146 responding gynaecologists. ***Table 2*** shows general demographics of the participants.

Table 1. Guidelines of the European Society of Gynaecological Endoscopy (ESGE) for classification of hysteroscopic procedures according their level of difficulty[10].

FIRST LEVEL
Diagnostic hysteroscopy Simple procedures excluding the use of electrosurgery: Target biopsies Removal of intra-uterine device Minor intra-uterine adhesions
SECOND LEVEL
Polyp resection Resection of type 0 myoma Endometrial ablation Treatment of uterine septum Tubal canulation (sterilisation)
THIRD LEVEL
Resection of type 1 and 2 myoma Major Asherman's syndrome

Table 2. Baseline characteristics of participants.

VARIABLE	RESIDENTS (N = 61)	GYNAECOLOGISTS (N = 146)
Sex		
Male	9 (14.8)	43 (29.5)
Female	52 (85.2)	103 (70.5)
Age, mean (range)	34 (30-43)	38 (33-49)
Type of hospital		
Academic	12 (19.7)	26 (17.8)
Non-academic teaching	49 (80.3)	84 (57.5)
Non-academic non-teaching		36 (24.7)
Fellowship MIGS		
Wishes to undertake	19 (31.1)	
Has undertaken		7 (4.8)

No. (%), unless specified otherwise.
MIGS: minimally invasive gynaecologic surgery

RESIDENTS

Almost every resident was interested in hysteroscopic surgery (98%). Following their residency, 31.1% of all surveyed residents would like to perform a fellowship in minimally invasive gynaecologic surgery. Preparation for basic procedures (diagnostic hysteroscopy and polypectomy) was felt adequate or very adequate by 86.7% of the residents. Significantly fewer residents (64.5%, p-value < .01) expected to be adequately prepared for advanced procedures. ***Table 3*** shows the median self-perceived level of competence per procedure for residents and gynaecologists.

More residents felt (very) adequately prepared for basic and advanced procedures in comparison to 2003 (80.0 and 53.0% respectively). In the current curriculum, the residents felt competent for all basic procedures and scored their competence on diagnostic skills higher in comparison to 2003 (median self-perceived CL 5 vs. CL 4 respectively), indicating that the majority judged themselves to be able to supervise and educate others on this procedure.

Table 3. Median self-perceived level of competence for residents and gynaecologists. Gynaecologists felt significantly more competent in performing every basic and advanced procedure in comparison to the residents (p-value < .05). Ranges in CL are wide because all participants indicated their competence, which could for example consist of solely theoretical knowledge (CL 1).

HYSTEROSCOPIC PROCEDURE	CL (RANGE)	
	RESIDENTS (N = 61)	GYNAECOLOGISTS (N = 146)
Level 1		
Diagnostic hysteroscopy*	5 (3-5)	5 (4-5)
Level 2		
Polypectomy*	4 (2-5)	5 (3-5)
Myomectomy type 0*	4 (2-5)	5 (3-5)
Endometrial resection	3 (1-5)	5 (1-5)
Hysteroscopic sterilisation	1 (1-5)	3 (1-5)
Level 3		
Myomectomy type 1	4 (2-5)	5 (1-5)
Myomectomy type 2	3 (1-5)	5 (1-5)
Major synechiolysis	2 (1-4)	3 (1-5)

Competence level (CL): level 1 – has theoretical knowledge of, level 2 – is able to perform under strict supervision, level 3 – is able to perform under limited supervision, level 4 – is able to perform without supervision, level 5 – is able to supervise and educate others.

*Mandatory procedures for graduation, levels of difficulty according to ESGE[10].

GYNAECOLOGISTS

In daily practice, 97.4% of the responding gynaecologists is interested in performing hysteroscopic surgery and 80.7% is satisfied with their current hysteroscopic skills in general. Only five percent of all respondents did a fellowship in minimally invasive gynaecologic surgery. In addition, a relatively high percentage performs advanced procedures (varying between 25-81% per procedure) nowadays, especially in contrast to a decade ago (varying between 5-52% per procedure) ***(Table 4)***. Not only do more gynaecologists perform advanced procedures, but also does their competence receive higher scores. Nearly all advanced procedures obtained a median self-perceived CL of 5, as is shown in ***Table 3***. In comparison, in 2003 gynaecologists scored 4 points for all advanced procedures.

During their former residency, preparation for basic hysteroscopies was felt adequate or very adequate by 81.6% of the responding gynaecologists. Significantly fewer gynaecologists (52.7%, p-value $<.01$) were satisfied with their former residency preparation for advanced hysteroscopic procedures. In comparison to 2003, these numbers are however 12.6 and 17.7% higher for basic and advanced procedures respectively.

TRAINING

Of postgraduate year 5 and 6 residents, 78.3% never trains hysteroscopic skills outside the

Table 4. Performance of hysteroscopic procedures per level of difficulty, by gynaecologists who finished their residency within the previous 5 years of both surveys[6]. More gynaecologists performed advanced procedures in 2013, in comparison to the survey of 2003.

HYSTEROSCOPIC PROCEDURE	PERFORMS NOW (%)	
	2003 (N = 113)	2013 (N = 146)
Level 1		
Diagnostic*	98	95
Level 2		
Polypectomy*	93	92
Myomectomy type 0*	82	81
Endometrial resection	51	54
Hysteroscopic sterilisation	12	25
Level 3		
Myomectomy type 1	52	81
Myomectomy type 2	22	50
Major synechiolysis	5	25

*Mandatory procedures for graduation, levels of difficulty according to ESGE[10].

patient setting. Only for 3.3% of the residents, a training facility is available in their current clinic to train hysteroscopic skills. Nevertheless, 90% of the residents and 79.9% of the gynaecologists believe that training in a patient-free environment on a hysteroscopic box trainer is important (varying from slightly to very important). A virtual reality simulator is also considered as an important training possibility, by both residents (86.7%) and gynaecologists (90.4%).

Gynaecologists indicate that the lack of simulation training is the most important factor during residency that could be enhanced for optimal acquirement of hysteroscopic skills (LS 4) ***(Table 5)***. In 2003, the factor that was pointed out as the most limiting was lack of opportunity to be primary surgeon (LS 4). In the current survey this item scored a median of 2.5. The lack of appropriate patients was also indicated to be irrelevant (LS 2) in comparison to 2003 (LS 3).

DISCUSSION

The main findings in the present study show that the implementation of hysteroscopic procedures taught during residency in the Netherlands has improved since 2003 and is judged as sufficient for basic procedures by both senior residents and gynaecologists (who finished residency <5 years). Furthermore, the expertise of young gynaecologists increased in comparison to a decade ago. Not only did they consider themselves more competent for basic procedures in comparison to residents, but they also felt more competent for advanced procedures, which is in contrast to 2003[(6)].

Besides evaluation of the current opinion in hysteroscopy training, this study also provides insight in the changes over the previous decade by comparison with an earlier Dutch survey[(6)]. The years between 2003 and 2013 were charac-

Table 5. Estimation of possible limiting factors in the acquisition of hysteroscopic skills during residency; a comparison between both surveys[(6)].

LIMITING FACTOR	LS MEDIAN (RANGE)	
	2003* (N = 113)	2013 (N = 146)
Lack of simulation training	NA	4 (1-5)
Lack of opportunity to be primary surgeon	4	2.5 (1-4.5)
Lack of interest of surgical educator	2	2 (1-4)
Lack of hysteroscopic skills of surgical educator	NA	2 (1-5)
Lack of appropriate patients	3	2 (1-5)
Lack of interest resident	1	2 (1-4)

LS: Likert scale, 1 = absolutely not agree, 5 = absolutely agree
NA: not asked in survey of 2003
* Range not available for results of 2003

terised by further development and implementation of hysteroscopy in the office setting, the innovation of tools and operative techniques for hysteroscopy and by the implementation of the fellowship for minimally invasive gynaecologic surgery[1,5,8]. These changes occur worldwide in all developed countries. The effects of these changes influence further developments in residency curriculum design and implementation of hysteroscopy. Therefore, this study is important for all residents and surgical educators in gynaecology.

In addition to the higher level of competence, advanced procedures were also performed by more gynaecologists in comparison to 2003. This increases the expertise in teaching hospitals and it can enhance the educational experience for residents, by improving exposure and functioning more frequently as the primary operator during both basic and advanced procedures[11]. Moreover, gynaecologists (who finished residency <5 years) are generally not dealing with their own learning curve any more, but the majority feels competent as surgical educators in teaching and supervising these advanced procedures (median CL 5).

Even though the residency preparation for hysteroscopy is higher appreciated than before, the self-perceived competence levels of the residents did not follow this trend. Only for the diagnostic hysteroscopy they did feel more competent (median CL 5) in comparison to 2003 (CL 4). In contrast, a similar comparative survey in the USA was able to show small but significant improvements for both basic and advanced hysteroscopic procedures between 2001 and 2008[5]. The authors believed that part of this finding was the effect of an increased number of fellowship sites and implementation of formal curriculum methods, including simulation training.

As a strong point, the high response rate of this survey implicates a proper representation of the current situation in the Netherlands. Additionally, this study represents both daily practice in academic hospitals and in non-academic teaching and non-teaching hospitals. Furthermore, the use of the (updated) survey of 2003 and the approach of the same target groups as a decade ago enables the current study to compare results. The use of self-perceived competencies may not always reflect the actual competence of a particular respondent, which poses a limitation of this study.

Despite the satisfaction with the Dutch residency preparation, there is scope for improvement. Gynaecologists indicated lack of simulation training as the most important factor during residency that could be enhanced for optimal acquirement of hysteroscopic skills. In laparoscopy, simulation models can fulfil the individual training demands as a source of unlimited and safe training in a patient-free environment. Learning on the patient raises legal and ethical concerns in modern medicine[12]; to accomplish parts of the laparoscopic learning curve without involvement of a patient improves safety and saves operating time and costs[13]. Simulation training is not only being implemented for laparoscopy throughout the world, but other endoscopic procedures are known to benefit from this patient-free training as well, such as cystoscopy[14] and colonoscopy[15]. In hysteroscopy, a small number of box trainers and a virtual reality simulator are currently available[16-18]. However, validation is a crucial step between the development and implementation of models[19,20]. Face and construct validity have been established for several box trainers and virtual reality modules, but predictive validity needs to be investigated to confirm the added value of hysteroscopic simulation training in daily practice. Especially for the advanced procedures in hysteroscopy, models and validity research are deficient.

In the survey of 2003, the factor that was pointed out as the most limiting in training was lack of opportunity to be primary surgeon. In 2013, this was thought to be less important and attention is shifting from training on the patient towards training without involvement of the patient. The answer regarding simulation models was not offered for this particular question in 2003, possibly reflecting the status of early development of simulation facilities at that time.

Even though this study indicated that hysteroscopy training in the Dutch gynaecological residency program is judged as sufficient in daily practice, we could ask ourselves whether it is desirable that all residents must acquire hysteroscopic skills. And which procedures does a resident need to be taught, up to what level? A considerable part of the residents will stop performing hysteroscopies when they finish their curriculum, most commonly because they subspecialise in maternal fetal medicine. One might argue that these residents do not need to acquire hysteroscopic skills at all, but that knowledge of hysteroscopy in general could be sufficient. Furthermore, since the level of competence on advanced procedures among surgical educators has improved according to this survey, it could be debated to incorporate advanced procedures in the residency program. By the implementation of a differentiation program in minimally invasive gynaecologic surgery, residents are selected for advanced training. Because of this selection, a smaller number of residents will have to share in the limited number of advanced procedures, thereby increasing their exposure. These residents are more likely to incorporate the advanced techniques into daily practice as a gynaecologist[20]. The observation in the current study that 31.1% of the responding residents wishes to do a fellowship in minimally invasive gynaecologic surgery indicates a high level of interest for differentiation of skills in gynaecology.

Future research is needed to determine the role of hysteroscopic simulation facilities in residency programs and to develop and validate simulation models in hysteroscopy. Attention should be drawn to the debate on which residents have to learn hysteroscopy, and especially on the level of performance that is required.

CONCLUSION

Implementation of hysteroscopic procedures taught during residency training in the Netherlands has improved since 2003 and is judged as sufficient for basic procedures by both senior residents and young gynaecologists. The skills of surgical educators have progressed towards a level by which gynaecologists feel competent to teach and supervise advanced hysteroscopic procedures. To incorporate these advanced procedures into residency training, a differentiation program could be implemented to select residents specifically interested in minimally invasive gynaecologic surgery. Simulation models might offer an additional training method without involvement of the patient. However, further research is needed to validate these simulators and to determine the role of these training facilities in residency programs before hysteroscopic simulation could be implemented.

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CHAPTER 3

HYSTEROSCOPY TRAINING AND LEARNING CURVE OF 30° CAMERA NAVIGATION ON A NEW BOX TRAINER: THE HYSTT

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ABSTRACT

INTRODUCTION

Despite the upcoming use of hysteroscopy and increased applicability during the last decades, little work has been done regarding the development of hysteroscopic training models in comparison to laparoscopy. Camera navigation is often perceived to be an easy task, but it is far from an innate ability, especially when an angled optic is used. This study investigated the learning curve of hysteroscopic 30° camera navigation on a new box trainer: Hysteroscopic Skills Training and Testing (HYSTT).

METHODS

This prospective study (Canadian Task Force II-2) enrolled thirty novices (medical students) and ten experts (gynaecologists who had performed >100 diagnostic 30° hysteroscopies). All participants performed nine repetitions of a 30° camera exercise on the HYSTT. Novices returned after two weeks and performed a second series of five repetitions to assess retention of skills. The parameter procedure time and structured observations on performance using the Global Rating Scale provided measurements for analysis. The learning curve is represented by improvement per procedure. Two-way repeated measures analysis of variance was used to analyse learning curves. Effect size (ES) was calculated to express the practical significance of the results (ES ≥0.50 indicates a large learning effect).

RESULTS

For both parameters, significant improvements were found in novice performance within nine repetitions. Moderate to large learning effects were established ($p < .05$; ES 0.44–0.71). Retention of skills and prolonged learning curves were observed.

CONCLUSIONS

The learning curve, established in this study, of hysteroscopic 30° camera navigation skills on the HYSTT box trainer indicates a good training capacity and provides the first step towards recommended implementation into a training curriculum.

INTRODUCTION

The exponential growth of minimally invasive surgery and the limited resident availability for educational endeavours by work hour restrictions are recent changes in modern medicine that have led to the increasing demand of valid simulation training models(1). For developing endoscopic skills, simulators offer a safe, effective and attractive way of repeatedly training these skills without causing discomfort or harming patients(2,3). Thus far, the beneficial results of simulator training are mainly derived from studies on laparoscopy(4,5).

Hysteroscopy is generally considered as a safe procedure with a low complication rate(6,7). Its practice ranges from diagnostics in an outpatient setting to a surgical alternative in the operation room for many gynaecological problems. Despite the upcoming use of hysteroscopy and increased applicability during the last decades, little work has been done regarding the development of hysteroscopic training models in comparison to laparoscopy.

Recently, the Hysteroscopic Skills Training and Testing (HYSTT) method has been developed under auspices of the European Academy of Gynaecological Surgery (Leuven, Belgium). This box trainer aims at practicing camera navigation skills with a 30° angled hysteroscope. Camera navigation is often perceived to be an easy task, but it is far from an innate ability. Psychomotor skills need to be learned to overcome the barriers that are known for endoscopic skills in general, namely the fulcrum effect, a two dimensional environment, a fixed access point, and decreased range of motion(8). In addition, skills unique to camera navigation include maintaining a correct horizontal axis while centring the operative field and holding a steady image. Further dexterity and knowledge is required for correct use of the additional degrees of freedom afforded by an angled scope(8-10), which is used routinely in many hysteroscopic procedures(9,11). In a national UK survey among gynaecologists, a disappointing percentage of 25.8% of all responders that use a 30° hysteroscope showed understanding of the principles of 30° angled view(9).

Camera navigation is a basic and essential skill for performing hysteroscopic procedures, especially when an angled scope is used. The HYSTT box trainer might provide a simple, effective and feasible answer to the need for training this skill.

The objective of the present study was to investigate the effectiveness of repetitive training on the HYSTT. This was sought to be achieved by determining the learning curve of novice participants and by investigating whether novices can improve and retain their skills, and whether they can approximate the expert level.

METHODS

PARTICIPANTS

From April to June 2012, 30 novices and 10 experts voluntarily conducted a series of repetitions on the HYSTT. Medical students of the University of Utrecht participated as novices, during or after their gynaecology internship. The novices had a basic understanding of hysteroscopy but had never previously performed nor assisted in a hysteroscopic procedure. All novices were invited to participate via oral and written means, and all agreed. Ten gynaecologists served as experts to set a reference for novice perfor-

3

mance. For the present study, a gynaecologist was considered a hysteroscopic expert after performing > 100 diagnostic hysteroscopies with a 30° scope and still practicing diagnostic hysteroscopy on a weekly base. All gynaecologists were personally invited and all agreed to participate. None had any experience of performing hysteroscopy on this box trainer.

The study was exempt from Institutional Review Board approval, since no potential harm could be done to humans or nonhumans. All participants gave oral consent prior to the start of the study.

BOX TRAINER

The HYSTT has been developed under auspices of the European Academy of Gynaecological Surgery (Leuven, Belgium) and consists of a plastic uterus model in which 14 numbers and characters are placed at 14 anatomical locations, known as: isthmus anterior/posterior/left/right, mid anterior/posterior/left/right, fundus anterior/posterior, cornua left/right and tubal ostium left/right. Six models are available in which each location contains a different number or character (model A-F). This plastic uterus is placed in a silicone model of a vulva, which in turn is situated in a plastic model of a female pelvis ***(Figure 1)***. A 30° hysteroscope (Karl Storz diagnostic continuous-flow) connected to a video-camera, light source and monitor (Telepack, Karl Storz) were used.

EXERCISES

Beforehand, a survey was administered to obtain baseline characteristics. The novices received a short standardised oral introduc-

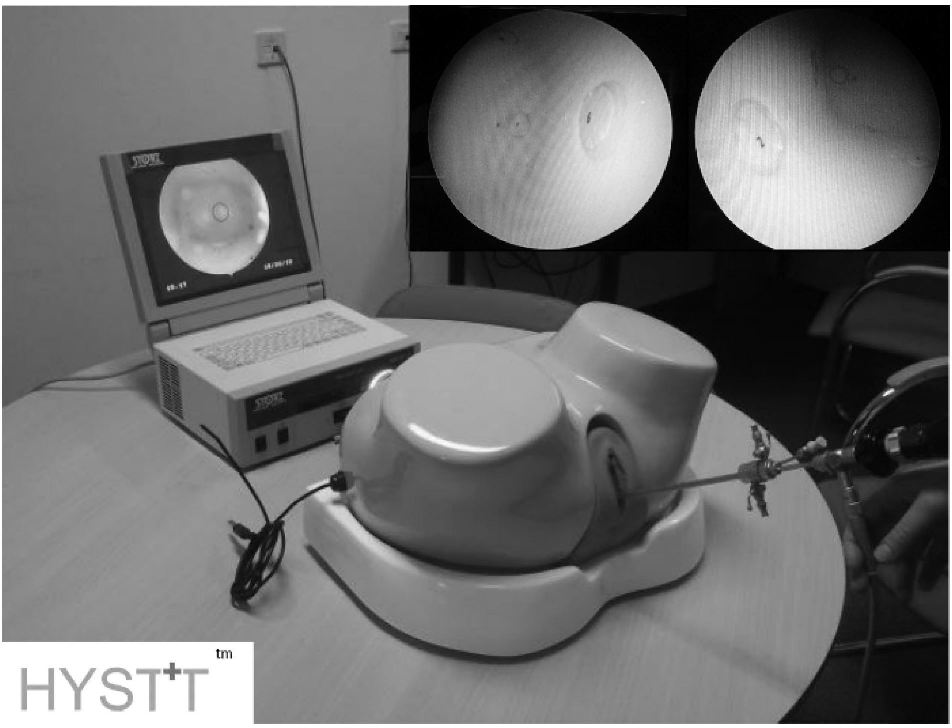

Figure 1. *Set-up Hysteroscopic Skills Training and Testing (HYSTT) box trainer*

tion on hysteroscopy, the box trainer and study protocol. The experts received a standardised oral introduction on the box trainer and study protocol. ***Figure 2*** displays the scheme of exercises per group. One minute practice time was given to each participant to obtain familiarisation with the HYSTT model. One investigator (C.J.T.) supervised all tests to limit inter-supervisor bias. Both groups conducted a series of nine exercises. minutes per session, to optimise the concentration of the subjects. If a participant identified all 14 objects within three minutes, the time to finish the exercise was marked. Each repetition contained a completely different sequence of commands and uterus model A was switched to model B after five repetitions for every participant. This switch was performed since five different command sequences were available per model.

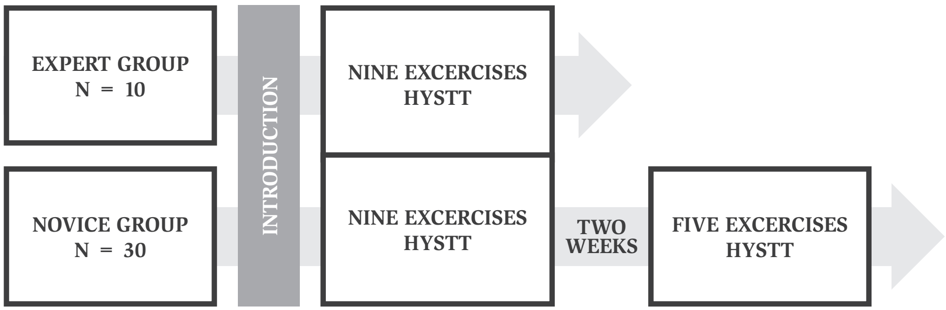

Figure 2. *Scheme of exercises*
Of all repetitions, the even-numbered repetitions were meant for training by the supervisor; during the odd-numbered repetitions no training was provided because these performances were used solely for data-analysis

In detail, the exercise was as follows: the supervisor read out an anatomical location (e.g. fundus posterior), after which the participant had to navigate to that specific location and visualise the associated number or character within a black circle with a diameter of 2.5 cm. Once this was correctly and readably visualised and named, the next command was read out. During each repetition, the participants had to identify as many targets in a correct manner with a maximum of 14. Each repetition ended after three minutes, after which the total number of correctly visualised objects was noted. We chose to end each repetition after three minutes, as specified by the European Academy and because we wanted to limit the training duration per participant to 30

Of all nine repetitions the first, third, fifth, seventh and ninth repetition were used for data-analysis. The other repetitions were meant for training by the supervisor and consisted of answering questions of the participants and giving tips and tricks on the procedure. For this reason, the even-numbered repetitions had a different duration and goal and were consequently excluded from further analysis. During the odd-numbered repetitions, no questions could be asked nor were any tips given because these performances were used solely for data-analysis. To assess retention of skills novices returned for a second series of five repetitions (model C) after 2 weeks. The first, third and fifth repetition were used for data-analysis. The other repetitions were meant for training by the supervisor and were excluded from further analysis.

OUTCOME MEASURES

The main outcome parameter was procedure time, measured as time needed to finish a repetition, by identifying all 14 signs with a limit of three minutes. If less than 14 signs were identified in three minutes, the total number of correctly visualised signs (n) in three minutes was recorded by the investigator. This score was then converted to the parameter time using the following formula: 180 seconds x (14/n) = score (in seconds). Participants were not only assessed by procedure time because performing a procedure very fast does not necessarily mean it is performed properly and/or with good results. For that reason, a 5-point Global Rating Scale (GRS) was used to assess competence from another (clinical) perspective. The GRS was adjusted for hysteroscopic 30° camera navigation training ***(Figure 3)*** and has not yet been validated[12]. Aspects that were rated included respect for tissue, handling of the hysteroscope, time and motion, flow and forward planning and procedure knowledge. Blinding was not possible due to the clear differences between age and status of the groups and the necessity to score both the simulator screen and the participant behaviour.

EXPERT OPINION

To investigate the expert opinion on this new box trainer, the experts completed a questionnaire at the end of the training session. The experts rated six statements on a 5-point Likert-scale, concerning the applica-

GRS 1 RESPECT FOR TISSSUE	Scope frequently pushed into wall of uterus.		Scope occasionally pushed into wall of uterus.		No trauma to uterus with scope.		
	1	2	3		4	5	
GRS 2 TIME AND MOTION	Many unnecessary moves.		Made some unnecessary moves, but time more efficient.		No unnecessary moves and time is maximised.		
	1	2	3		4	5	
GRS 3 HANDLING OF HYSTEROSCOPE	Scope poorly aligned during procedure.		Moderate use of scope angle during procedure.		Scope always set in good angle throughout the procedure.		
	1	2	3		4	5	
GRS 4 FLOW OF PROCEDURE AND FORWARD PLANNING	Frequently stopped or needed advice or assistance from examiner.		Demonstrated ability to think forward with relatively steady progression of procedure.		Obviously planned procedure from beginning to end with fluid motion.		
	1	2	3		4	5	
GRS 5 KNOWLEDGE OF PROCEDURE	Deficient knowledge. Needed specific instruction at most procedural steps.		Knew all important aspects of procedure.		Demonstrated familiarity with all aspects of procedure.		
	1	2	3		4	5	

Figure 3. *Global Rating Scale, adjusted for hysteroscopic 30° camera navigation training*

bility of the HYSTT for testing and training camera navigation, for training residents and/or medical students and for learning anatomy. The experts also valued the realism of the HYSTT in simulating a diagnostic hysteroscopy.

STATISTICAL ANALYSIS

Data were analysed using commercially available software (SPSS version 20.0; SPSS, Inc., Chicago, IL). No power analysis was performed prior to the study. To analyse the improvement within the novice group, a sample size of 30 was considered sufficient.

The independent t-test and chi-square test were used to compare general demographic data of the experts and novices. Two-way repeated measures analysis of variance was used to analyse learning curves. The between-subject factor 'group' was added to investigate novice and expert performance separately. Retention of skills was investigated by within-subject contrasts and was assessed by comparing the last repetition of both series; a significant improvement by repetitive training was defined as a prolonged learning curve[13]. A p-value of $< .05$ was considered as statistically significant for all tests. Means and 95% confidence intervals (CI) were used to compare data for the learning curves because these are applicable to the analysis of variance.

While statistical significance provides information on evidence of any effect at all, the practical significance of the results was quantified by the effect size (ES), which indicates whether a learning effect is meaningful or important[14]. The ES is independent of sample size and a scale-free index. The effect size was extracted from the analysis of variance output in SPSS. ES of 0.10, 0.30 and 0.50 were considered to indicate small (negligible), medium (moderate) and large (crucial) effects, respectively. ES was considered relevant only if a significant ($p < .05$) result was found.

RESULTS

DEMOGRAPHIC DATA

General demographic data of novices and experts are given in ***Table 1***. As expected, there is a significant difference between gender ($p < .001$), age ($p < .001$) and prior hysteroscopic experience ($p < .001$). To assess retention of skills, novices returned after a median of 14 days (range, 11-19 days) for a second series of repetitions. None of the experts had previous experience of performing exercises on HYSTT.

LEARNING CURVE

The main outcome measure was procedure time. The secondary outcome parameter was clinical performance, which was assessed by the mean GRS score. Results of novice performance in both series of repetitions are given in ***Table 2*** (original measurements). A graphic presentation of the novice learning curve with the expert performance as a reference curve is shown in ***Figure 4***.

Novices showed a significant and moderate learning effect for the time needed to complete a repetition ($p < .05$, ES 0.44). A large difference was observed between experts and novices in procedure time, in favour of the experts (experts, mean 215.8 sec, 95% CI 154.9 – 276.7 sec; novices, 869.4 sec, 95% CI 570.1 – 1168.6 sec). As recognised in the graph, novices progressed towards expert level in time and reached a plateau phase at the seventh repetition,

Table 1. Baseline characteristics of all participants

CHARACTERISTICS	NOVICES (N = 30)	EXPERTS (N = 10)		
Demographic data				
Sex, male/female, No (%)	6:24 (20:80)	8:2 (80:20)		
Age, median in years (range)	24.0 (21 – 27)	51.5 (42 – 56)		
Handedness, right/left, No (%)	27:3 (90:10)	10:0 (100:0)		
Days between series, median (range)	14 (11–19)	NA		
Training experience in hysteroscopy, No (%)		**Animal**	**Box**	**VR**
0 hours	30 (100)	5 (50)	7 (70)	7 (70)
1–10 hours	0	5 (50)	3 (30)	3 (30)
> 10 hours	0	0	0	0
Novice experience				
Hysteroscopies seen, No (%)				
0	17 (56.7)			
1 > 10	12 (40.0)			
> 10	1 (3.3)			
Hysteroscopies performed, No (%)	0 (100)			
Expert experience				
Hysteroscopies performed[a], No (%)		**Level 1**	**Level 2**	**Level 3**
0		0	0	0
1-30		0	0	2 (20)
31–50		0	0	3 (30)
> 50		10 (100)	10 (100)	5 (50)

NA = not applicable
Animal = animal cadaver model
Box = box trainer
VR = virtual reality simulator
[a.] According to European Society for Gynaecological Endoscopy (ESGE) classification of hysteroscopic complexity[(15)].

while experts performed stable after their first exercise. Both plateau phases did not coincide (experts, mean 108.3 sec, 95% CI 87.8 – 128.8 sec; novices, mean 154.3 sec, 95% CI 130.3 – 178.3 sec).

For mean GRS score, the novice group demonstrated a significant and large learning effect ($p < .05$, ES 0.71). The expert group received higher GRS scores from the start (experts, mean 3.4, 95% CI 3.0 – 3.8; novices, mean 1.8, 95% CI 1.6 – 2.1) and the difference between both groups only moderately decreased. No plateau phase was recognised in the novice learning curve.

RETENTION OF SKILLS

For both procedure time and GRS, analysis of novice performance after two weeks showed retention of skills. Comparing the last repetitions of both series, no significant decrease in performance was found. Instead, a significant improvement of performance parameters was observed by repetitive training ($p < .05$, ES 0.35-0.65), indicating a prolonged learning curve (***Table 2***).

EXPERT OPINION

All experts completed the questionnaire concerning the realism and training capacity of the HYSTT. ***Table 3*** summarises the scores awarded by the experts. The ability to test and train camera navigation skills was scored with a median of 5.00 points on a 5-point Likert-scale. The experts indicated the HYSTT to be very applicable in training residents (median 5.00). The box trainer was considered less applicable for training medical students (median 3.50) and for learning anatomy (median 3.00). The realism of the HYSTT in simulating a diagnostic hysteroscopy was awarded a median of 3.00 points.

3

Table 2. Results of novice performance in both series

	FIRST SERIES: LEARNING CURVE			SECOND SERIES: RETENTION OF SKILLS	
Parameter	**First repetition**	**Last repetition**	**Significance[a]**	**Last repetition**	**Significance[b]**
Time (sec)	869.4 (95% CI, 570.1–1168.6)	154.3 (95% CI, 130.3–178.3)	$p < .05$, ES: 0.44	121.0 (95% CI, 103.3–138.8)	$p < .05$[c], ES: 0.35
Mean GRS (5-point scale)	1.83 (95% CI, 1.59–2.08)	3.78 (95% CI, 3.50–4.06)	$p < .05$, ES: 0.71	4.13 (95% CI, 3.95–4.32)	$p < .05$[c], ES: 0.65

CI = confidence interval

ES = effect size (only applicable if result is significant)

GRS = Global Rating Scale

[a] Implicates significance of comparison between first and last repetition of first series (analysis of variance).

[b] Implicates significance of comparison between last repetition of first and second series (analysis of variance).

[c] Indicates prolonged learning curve.

DISCUSSION

The present study assessed the learning curve for performance of hysteroscopic 30° camera navigation skills using the HYSTT, a new box trainer for diagnostic hysteroscopy. For all parameters significant improvements were found in novice performance within 9 repetitions. Retention of skills was demonstrated and a prolonged learning curve was established. These results indicate an adequate training capacity of the HYSTT and the effectiveness of repetitive training. One or more training sessions substantially improve the speed of acquiring 30° camera navigation skills on the HYSTT.

Strong points of this study are its realistic study design, additional assessment of retention of skills, and that one investigator supervised all tests in both groups. Furthermore, the use of ES adds information as to whether significant learning curves can be translated into meaningful and important learning effects. Besides procedure time, a clinical parameter (GRS) was used to assess competence from another perspective. Performing a procedure very fast does not necessarily mean it is performed properly and/ or with good results.

Differences between the performance levels of both groups give an indication of construct validity, which is an important investigation before implementation of a model into a training curriculum(16). The results imply that the HYSTT is indeed able to teach and evaluate those skills that are intended to be taught and measured, by differentiating between levels of expertise. However, the present study was not designed to investigate construct validity or powered to differentiate. Therefore, the indication of construct validity should be interpreted with caution.

The GRS was adjusted for hysteroscopic 30° camera navigation training and has not yet been validated, though similar rating scales have been implemented and validated for use in a general hysteroscopic training program and diagnostic cystoscopy in urology(17,18).

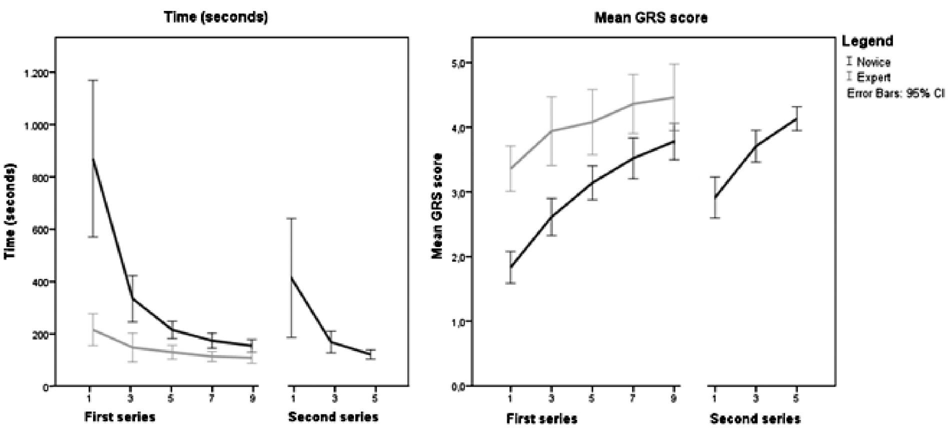

Figure 3. *Learning curve for novices (black) and experts (grey) in the first series of exercises and for novices in the second series*

It can be argued whether the first repetition(s) should be used for data analysis in a study assessing the learning curve, considering the improvement in performance parameters for both groups. The time needed to become familiar with a simulation model could influence results. The chosen study design reflects reality and integrates the possibility of feedback and training in the process(19). The expert curve functions as a reference, and possible improvement during the first cases is likely to represent reality. Experts also must become accustomed to the new environment because this is by definition a deduction of reality.

The learning curve for GRS shows that the experts continue to improve their score until the seventh repetition, which might be a later plateau phase than one expects. A possible explanation could be that the white plastic HYSTT model does not resemble the uterus in a very close matter, as indicated by the expert opinion. The anatomical terms were considered confusing for several uterine locations. For example, "cornua" implies the region were a fallopian tube enters the uterine cavity. The HYSTT model contains specific spots for both "cornua" and "tubal ostium", which are located very close to each other and without any further clues concerning the differentiation between these anatomical terms. These locations were frequently mixed up by several experts throughout the repetitions, which led to lower GRS scores. Also, in the HYSTT model the cervical canal is absent and therefore the hysteroscope can slip out of the uterus without visual warning.

To improve the use and applicability of the HYSTT, the realism of the model might be enhanced by improving the visual aspects of the uterine cavity, e.g. silicone material with realistic colour effects, augmented uterine shape with real tubal ostia and a cervical canal. A different possibility might be to remove the cornual locations and change the anatomical terms into more general terms, e.g. front / mid / rear, combined with anterior / posterior / left / right.

Table 3. Results of expert opinion

THE HYSTT…	EXPERTS (N = 10)
1. … is able to train 30° hysteroscopic camera navigation skills	5.00 (4.75-5.00)
2. … is able to test 30° hysteroscopic camera navigation skills	5.00 (4.00-5.00)
3. … is applicable for training OBGYN residents	5.00 (5.00-5.00)
4. … is applicable for training medical students	3.50 (2.75-5.00)
5. … is applicable for learning uterine anatomy	3.00 (1.75-4.00)
6. … simulates a diagnostic hysteroscopy realistically	3.00 (2.00-4.00)

Median scores (with interquartile ranges) are given on a 5-point Likert scale.

A recent study by the current authors investigated the learning curve of hysteroscopic sterilisation on a virtual reality (VR) simulator[20]. The curves of both training models show similar shapes, indicating an adequate training capacity of repetitive training for both exercises and models. Concerning procedure time, the novices learned somewhat faster and reached a plateau phase within 9 repetitions on the camera navigation box trainer in comparison to the VR sterilisation simulator. Regarding GRS score, the novice group showed a slightly greater improvement of clinical skills on the VR sterilisation simulator; a prolonged learning curve was observed for both training models.

Enabling a good training model to be successful in daily practice, it should be implemented into a well-thought-out training curriculum[21,22]. This curriculum preferably contains training sessions taking place on an interval basis rather than massed into a short period of extensive practice. In addition, expert performance should be used to provide a proficiency criterion[21]. This gives trainees an objectively established goal they would have to reach before progressing to a next level or the operating room. Furthermore, feasibility is important to consider, for easy employment of the training model in a curriculum. The present box trainer showed promising results for interval training and the expert level was determined to provide an indication of the proficiency criterion. Also, the HYSTT is portable and reusable and the instruments are available at any institution providing hysteroscopic procedures.

Assessment of predictive validity is a further important step in determining the applicability of a simulator in a training curriculum. The predictive validity indicates the extent to which the training model predicts future performance and there remains a paucity of predictive validity testing of gynaecologic simulators at this time, especially for hysteroscopy.

CONCLUSIONS

In conclusion, the learning curve of the present box trainer for hysteroscopic 30° camera navigation skills indicates a good training capacity because large improvements were made for novice training on this box trainer. Furthermore, retention of skills and prolonged learning curves were observed for both parameters procedure time and GRS. In addition, experts awarded the HYSTT the highest scores for training camera skills and applicability in residency training. Improvements can be made on the realism and anatomy of the uterus model.

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CHAPTER 4

CORRELATION OF LAPAROSCOPIC AND HYSTEROSCOPIC 30° SCOPE CAMERA NAVIGATION SKILLS ON BOX TRAINERS

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ABSTRACT

INTRODUCTION

This study investigated a possible correlation between training of camera navigation skills with a 30° optic in hysteroscopy and laparoscopy, by exploring whether 30° camera navigation training in hysteroscopy provides a certain level of expertise in laparoscopic camera navigation. If a correlation exists, training models and programs in gynaecology could be simplified.

METHODS

In this prospective, randomised, non-blinded study 34 medical students were divided into 2 groups. Group A (N = 17) performed 5 exercises on a box trainer for hysteroscopy (HYSTT) and 5 exercises on a box trainer for laparoscopy (LASTT). Group B (N = 17) performed 2 x 5 exercises on the LASTT model. Both groups performed a LASTT post-test directly afterwards. The outcome parameter recorded was time to correctly perform the exercise.

RESULTS

Comparing the results of the LASTT post-test between group A and B, a similar performance of both groups was shown ($p = .131$). A slightly faster performance in group A is displayed, when comparing the first LASTT exercise between group A (with previous HYSTT training) and group B (without previous HYSTT training); however this was a non-significant finding ($p = .114$). Both groups display quite similar learning curves and after 5 LASTT repetitions both groups have reached comparable levels for procedure time, despite the earlier HYSTT training of group A.

CONCLUSION

Previous training on the HYSTT model offers some advantage for training on the LASTT model. However, training of 30° camera navigation skills in a hysteroscopic environment does not seem supportive for obtaining the same level of camera expertise in laparoscopy. Therefore, 30° camera navigation in hysteroscopy and laparoscopy should be trained separately to reach adequate levels of expertise for each procedure.

INTRODUCTION

Laparoscopy and hysteroscopy have become standard procedures in gynaecology. During endoscopic procedures good visualisation of the surgical field is essential and this is achieved by adequate camera navigation[1-3]. Camera navigation is often perceived to be an easy task, but it is far from an innate ability. Psychomotor skills need to be learned to overcome the barriers that are known for endoscopic skills in general, namely the fulcrum effect, loss of binocular vision, a fixed access point, and decreased range of motion[3,4]. In addition, skills unique to camera navigation include maintaining a correct horizontal axis while centring the operative field, focusing and sizing, maintaining a steady image and tracking instruments in motion[2,3]. Especially angled scopes, by the addition of off-axis viewing, require complex visuospatial skills[5].

In laparoscopy, handling of the camera is often performed by the least experienced person present. Incorrect camera handling results in poor visualisation and may cause frustration of the operator, increased operating time and errors[1,3,5]. In hysteroscopy, camera navigation is essential due to the decreased range of motion when navigating through the narrow cervical canal and uterine cavity. A 30° angled scope affords an increased view with fewer movements and is increasingly used for vaginoscopic hysteroscopy in the office setting. But when knowledge and skills are lacking, the 30° angled scope can lead to unnecessary damage of the cervical canal and endometrium. In a national UK survey among gynaecologists, a disappointing percentage of 25.8% of all responders who perform 30º hysteroscopy showed understanding of the principles of 30º angled view[6].

Despite the importance of camera navigation skills, they are not often explicitly addressed in training programs[7,8]. However, camera navigation skills can be trained easily and effectively outside the operating room[5, 9-11]. During the past years several models have been developed and validated for camera navigation training in laparoscopy[3,12,13] and to a lesser extent in hysteroscopy[14]. The same principles can be observed in urology as well, for laparoscopy and cystoscopy[15].

Even though endoscopy comprises different types of procedures (e.g. laparoscopy and hysteroscopy), they all require mastering of adequate camera navigation skills with a 30° optic. One could question whether a possible correlation exists between the training of camera navigation skills with a 30° optic in hysteroscopy and laparoscopy, even though the environments of the abdominal and uterine cavity are fairly different. If this correlation exists, it implies that obtaining 30° camera navigation skills in hysteroscopy also indicates the built up of a certain level of expertise in laparoscopic camera handling. This would mean that training models and programs in gynaecology could be simplified. Furthermore, it might also apply for other specialties, for example cystoscopy and laparoscopy in urology. That could lead to a situation in which several endoscopic specialties could train 30° camera navigation on a uniform training model, without a direct relation between the model, a specific organ, cavity or specialty, and the type of endoscopy.

The aim of the present study is to investigate whether 30° camera navigation practice in hysteroscopy also creates a built up of expertise in laparoscopic 30° camera navigation.

Two box trainers have been used in this study: the Laparoscopic Skills Testing and Training (LASTT) model and the Hysteroscopic Skills Testing and Training (HYSTT) model. Both were designed under auspices of the European Academy for Gynaecological Surgery (Leuven, Belgium). These models train various psychomotor skills including specific exercises for 30° camera navigation training[12,14].

METHODS

PARTICIPANTS AND SETTING

From April to June 2013, 34 novices voluntarily participated in this study. Medical students served as novices and they were invited during or after their gynaecology internship via oral and written means, and all agreed to participate. The study was carried out at the University Medical Centre Utrecht and at the teaching hospital St. Antonius Ziekenhuis Nieuwegein, the Netherlands. All participating students filled out a questionnaire which recorded their baseline characteristics. The study was exempt from Institutional Review Board approval, since no potential harm could be done to humans or nonhumans. All participants gave written consent prior to the start of the study.

DESIGN

This study is a prospective, randomised, non-blinded trial. The participants were divided into two groups by randomisation by sealed envelopes. Short series of exercises were designed for the present study, because Molinas et al. observed a plateau phase for the LASTT 30° camera navigation exercise after 5-15 repetitions[12]. ***Figure 1*** displays the scheme of exercises per group. In addition, the scheme shows the two comparative analyses. Analysis 1 addresses the

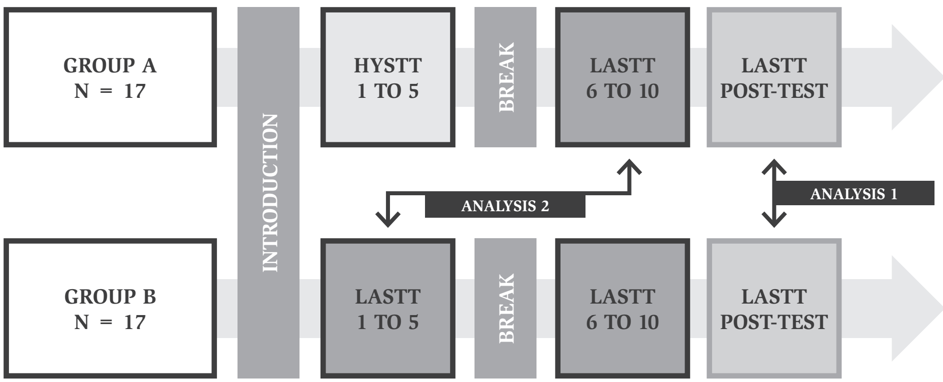

Figure 1. *Study design: scheme of exercises per group*
Analysis 1 addresses the question whether mixed training will lead to the same laparoscopy level as only-laparoscopy training under the condition of equal time investment, by comparing the LASTT post-test between both groups. Analysis 2 addresses the question whether prior hysteroscopy training will lead to a higher achievement in laparoscopy in comparison to a short laparoscopy training only, by comparing the first LASTT exercise of group A (with previous HYSTT training) with the first LASTT exercise of group B (without previous HYSTT training)

question whether mixed training will lead to the same laparoscopy level as only-laparoscopy training, by comparing the LASTT post-test between both groups. Analysis 2 addresses the question whether prior hysteroscopy training will lead to a higher achievement in laparoscopy in comparison to a short laparoscopy training only. This analysis will compare the first LASTT exercise of group A (with previous HYSTT training) with the first LASTT exercise of group B (without previous HYSTT training).

Both groups received a short standardised introduction on 30° optics and the study protocol. Group A (N = 17) was given a specific introduction on hysteroscopy and the HYSTT model, while group B (N = 17) received a similar standardised introduction on laparoscopy and the LASTT model. One minute practice time was given to each participant to obtain familiarisation with the model; during this practice time feedback and instructions were provided. Then, group A performed the HYSTT exercise 5 times, followed by a 5 minute break. During the break, group A received the standardised introduction on laparoscopy and the LASTT model, and one minute practice time was provided. After the break group A performed the LASTT exercise 5 times, followed by a final LASTT repetition which was recorded as a post-test. Group B performed the LASTT exercise 5 times, also followed by a 5 minute break. After the break, this group repeated the LASTT exercise another 5 times and performed the post-test on the LASTT model. The post-test, performed by both groups, consists of a single repetition of the camera navigation exercise on the LASTT model and is performed directly after the training sessions, in the same environment. One investigator (E.H.) supervised all exercises and tests to limit inter-supervisor bias. During all exercises and tests, no feedback or instructions were provided, nor could any questions be asked. After each repetition, the participant could ask questions and feedback was offered.

MATERIALS

The LASTT model consists of a wooden platform (16.5x30cm) with two modules in the back, two modules in the middle and two modules in the front. These modules contain in total 14 targets. Each target consists of a large symbol, only identifiable from a panoramic view, and a small symbol, only identifiable from a close-up view[12]. The LASTT model was inserted into a Szabo trainer box (Karl Storz, Tutlingen, Germany). ***(Figure 2a)***

The HYSTT model consists of a white plastic uterus model in which twelve symbols are placed at twelve locations, known as front / mid / back (referring to the depth of the space) combined with anterior / posterior / left / right (referring to the walls of the space). Six models are available in which each location contains a different symbol (model A-F). This plastic uterus is placed in a silicone model of a vulva, which in turn is situated in a plastic pelvis model ***(Figure 2b)***. Originally, the HYSTT model contained 14 target locations with anatomical names as “fundal anterior”, “cornual left”, “tubal ostium right” and “isthmic posterior”. Due to the observation in a previous study that these anatomical names seem confusing when applied in this simple uterus, the model was adjusted by covering the “cornual” symbols and by renaming the other twelve locations by general terms as front / mid / back.

Both models were designed under auspices

Figure 2a. *Set-up LASTT model*

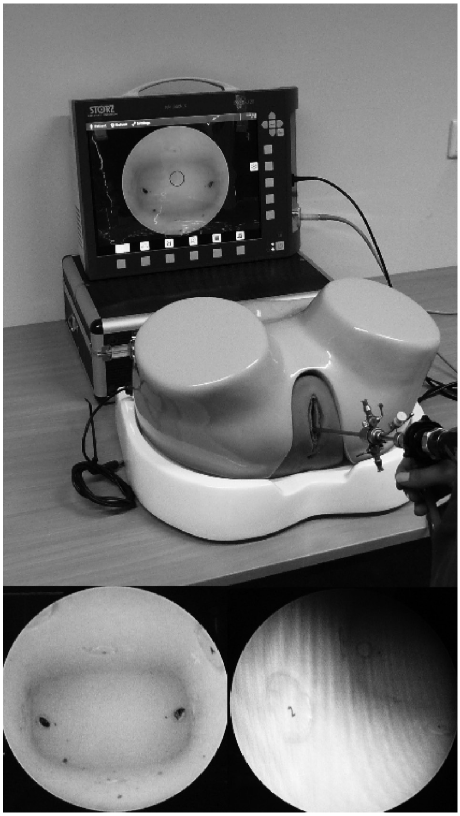

Figure 2b. *Set-up HYSTT model*

of the European Academy for Gynaecological Surgery (Leuven, Belgium). The exercises on the LASTT model were performed with a 10 mm 30° scope and the exercises on the HYSTT model with a 5 mm 30° scope (Karl Storz), both connected to the same straight video-camera, light source and monitor (Telepack, Karl Storz). With regards to the exercises, a black circle (2.5 cm diameter) was applied in the centre of the monitor. The box trainers and the monitor were set up on a large table in line with each other.

EXERCISES

The participants stood behind the box trainer in the midline, holding the camera with their dominant hand and the fibre optic cable with their non-dominant hand for lateral, rotatory and zoom-in/out navigation. For the LASTT exercise, the scope was inserted through the middle port of the trainer box. At the start of the exercise the participant had to visualise the first large symbol (i.e. 1) and then identify the small one situated next to it. The small symbol had to be sharply visualised inside the black circle on the screen. This small symbol indicated the next large symbol that had to be visualised. The exercise was finished when the small symbol on the last target (end) was identified correctly. After every run the targets were ordered differently according to a standardised schedule to prevent memorisation.

For the HYSTT exercise, the scope was inserted into the uterus model (model B) through the silicone vulva. The participant had to navigate to a specific location (e.g. mid posterior) as commanded by the investigator and visualise the corresponding symbol inside the black circle on the monitor, after which a new command was given until all 12 symbols were correctly visualised. After every completed session the sequence of the commands was changed according to a standardised schedule and after three sessions another uterus model (model C) was inserted for the last two sessions to prevent memorisation.

OUTCOME MEASURE

The outcome measure for both the HYSTT and LASTT exercises was the total time (recorded in seconds) needed to correctly visualise all the signs.

STATISTICAL ANALYSIS

The statistical analysis was performed with SPSS 20.0 for Windows. A power analysis was performed prior to the study to determine the minimal sample size. It showed that a power level of 0.8 with a desired significance level of 0.05 and a difference of 1 SD between groups should be reached at a minimal total sample size of 34 participants. To compare the participants' characteristics the chi-square test was used. Differences in the time measurements between the two groups were analysed using the non-parametrical Mann-Whitney U test for independent samples. The results are presented as medians with interquartile ranges (IQR) and were considered significant in case of a p value $< .05$.

Table 1. Demographic characteristics of the participants
Participants were randomised by sealed envelopes. No statistically significant differences were found between both groups (statistical analysis performed with chi-square test).

CHARACTERISTICS	GROUP A (N = 17)	GROUP B (N = 17)
Age, mean (range)	22.71 (21-26)	23.47 (22-25)
Sex		
Male	5	5
Female	12	12
Dominant hand		
Right	13	15
Left	4	2
Desired future specialty		
Surgical	8	10
Non surgical/don't know	9	7
No. of attended hysteroscopy / laparoscopy		
1-10	11	8
> 10	6	9

RESULTS

The baseline characteristics of the participants are reported in ***table 1***. The participants were randomised into two groups (N = 17 per group) and there were no significant differences regarding personal characteristics between these groups. Both groups existed of 5 men (29.4%) and 12 women (70.6%). The median age in group A was 23 years (range 21-26) and in group B 23 years (range 22-25). All participants had attended at least one hysteroscopy and/or laparoscopy.

When comparing the results of the LASTT post-test between group A and B (analysis 1), a similar performance of both groups is shown. The median time needed to complete the post-test was 100.3 (IQR 88.1 – 121.8) s for group A and 91.1 (IQR 77.2 – 104.4) s for group B (p = .131) (***figure 3***). ***Figure 4*** displays the median time of both groups per LASTT exercise graphically. It shows that both groups have reached approximately the same level of procedure time during their post-test and this endorses the results of a similar performance described above. However, despite of their earlier training on the HYSTT model, group A follows more or less the same (steep) learning curve as group B in the first LASTT series instead of following the (flatter) curve in the second LASTT series of group B.
Analysis 2 compares the first LASTT exercise between group A (with previous HYSTT training) and group B (without previous HYSTT training). Group A performed the exercise slightly faster than group B, but this was a non-significant finding (p = .114). The median performance time of group A was 214.3 (IQR 152.2 – 261.6) s, whilst group B recorded a median time of 249.6 (IQR 178.9 – 307.0) s ***(figure 3)***.
Both groups display quite similar learning curves and after 5 LASTT repetitions both groups have reached comparable levels for procedure time, despite the earlier HYSTT training of group A.

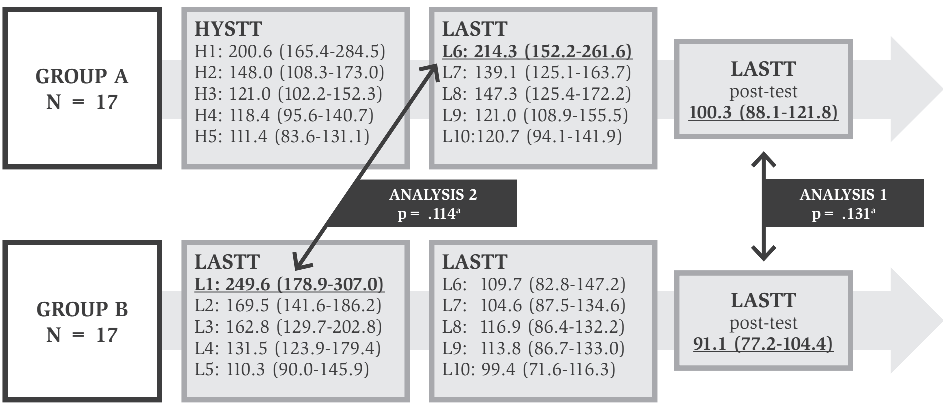

Figure 3 *Median results with interquartile ranges (IQR) in seconds per exercise per group, for both HYSTT and LASTT exercises. Analysis 1 compares the outcome of the LASTT post-test of both groups. Analysis 2 compares the first LASTT exercise of group A (with previous HYSTT training) with the first LASTT exercise of group B (without previous HYSTT training).*
[a] *Statistical analysis performed with Mann-Whitney U test*

DISCUSSION

Training programs for endoscopic skills vary throughout institutions worldwide. Furthermore, every specialty has its own training models for specific procedures. As described in the introduction, the basic skills required for different endoscopic procedures are fairly similar and endoscopy training outside the operating room could be standardised[7,12]. This led to the idea that certain general endoscopic skills, such as 30° camera navigation, might be trained on a uniform training model. This study investigated whether a correlation exists between training of camera navigation skills with a 30° optic in hysteroscopy and laparoscopy, by exploring whether 30° camera navigation training in hysteroscopy provides a certain expertise in laparoscopic camera navigation.

Firstly, the results show that regardless of training on the HYSTT or the LASTT model, 30° optic skills are easily learned when a standardised explanation and specific exercises for camera navigation are provided. Medical students were able to strongly improve their performance within 5 repetitions on the LASTT model, reaching a time score of 110 seconds. This was faster than expected by the results of Molinas et al, where novices (students and inexperienced gynaecologists) needed approximately 10 repetitions to reach a procedure time of 110 seconds[12]. However, in both studies certain variability between subjects is observed. In the current study it is not investigated whether this fast performance is lasting.

Secondly, concerning a possible correlation for camera navigation, a similar performance of both groups during the LASTT post-test was found (analysis 1). This might

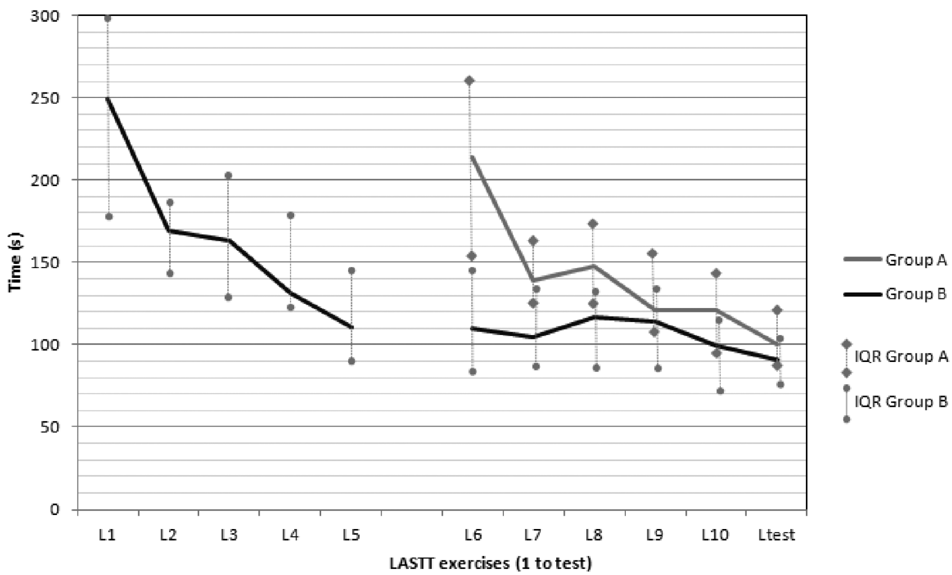

Figure 4 *Median time in seconds of the LASTT repetitions of group A (grey line) and group B (black line). Interquartile ranges (IQR) are presented by the vertical, grey lines. Both groups have reached approximately the same level of procedure time at the end of their LASTT exercises. Group A more or less followed the same learning curve as group B in the first LASTT series.*

indicate that previous hysteroscopy training does provide built up of expertise in laparoscopic camera navigation. However, after apprehending the fast learning curve in this study, a similar performance after 5 repetitions can be expected regardless of previous training. And even though group A (with previous HYSTT training) did perform slightly better than group B (without previous HYSTT training) during their first LASTT exercise, this finding was not significant (analysis 2). In addition, the learning curve of both groups was fairly similar when they started performing exercises on the LASTT. Therefore, according to these results, the existence of a pronounced correlation between training of 30° camera navigation skills in hysteroscopy and laparoscopy seems implausible.

A possible explanation for not finding a correlation could be that, even though the principles of angled optics are easy to learn when time, attention and exercises are provided, the abdominal and uterine cavity are too different regarding space and shape. In the uterus and in the corresponding HYSTT model, camera navigation takes place within a small and narrow cavity (a specific organ) which requires subtle movements of the scope combined with extensive angled optic use. In the abdomen and in the corresponding LASTT model, a distinctly higher degree of freedom of scope movement is observed. This is due to the wide space after CO^2 inflation during laparoscopy and the environment within the spacious box trainer, respectively. One has to train how to navigate and to apply the principles of angled optics in each different cavity. Camera navigation in hysteroscopy and laparoscopy should be trained separately to reach adequate levels of expertise for each procedure.

Strong points of the present study are the power analysis performed prior to the study and the randomisation process, which was executed effectively. The study was non-blinded, because blinding was not possible due to the distinctly different appearances of the two box trainers. Medical students were included in this study as novices, because of their blank training background which gave all participants the same starting point.

The current study design was not established as a proficiency-based training curriculum, since the aim was to investigate a correlation between skills acquisition in two training environments and not to evaluate the efficacy of a curriculum. The number of repetitions was kept small to ensure that participants were not yet fully proficient at the HYSTT model before training at the LASTT box. We wanted to see if the change of environment would alter the ongoing learning curve in comparison to the group that continuously trained at the LASTT model. One could argue that a proficiency-based study design with a ‘retention test’ performed several weeks to months after the training might also provide a good way to investigate our hypothesis and this presents an area for future research. For clinical use, it should be emphasised that the design of an efficient training curriculum needs to be proficiency-focused to accommodate the ability and development of each individual[16].

One of the factors that might have influenced the current results is the fact that the exercises per model differ in the way they have to be executed. During the HYSTT exercise the participants had to follow the investigator’s commands, whereas in the

LASTT exercise the visualised sign itself included the next command. Furthermore, time to correctly perform the exercise is the only outcome parameter recorded and it is recorded by a person. One can imagine that a computerised system as in a virtual reality simulator can offer a more objective scoring and that other factors might affect performance; after all, a faster performance does not automatically mean a better performance. Outcome parameters as the number of errors, path length, camera stability and number of collisions were not recorded, which is inherent to the design of box trainers. In addition, box trainers in general often lack a realistic display of human anatomy. Nevertheless, box trainers have proven to be simple and relatively cheap models that can effectively train specific psychomotor skills needed for endoscopy[4,12,17]. On the other hand, the possibly influencing factors of a box trainer might be overcome by using virtual reality simulators, which objectively record various parameters. The software could provide similar commands for both exercises and record parameters that could display the varying nuances in camera navigation that one has to train when performing both hysteroscopy and laparoscopy. This might provide an area for future research. In addition, it could be an interesting idea for future research to include a test on visuospatial abilities for all participants, in order to retrieve extra information on the training capacity for endoscopic skills.

CONCLUSIONS

Correct camera navigation skills with a 30° optic are essential in endoscopy and need to be trained outside of the operating room. This study shows that, regardless of training on the HYSTT or the LASTT model, 30° optic skills are easily learned when specific exercises for camera navigation are provided. Previous training on the HYSTT model offers some advantage for training on the LASTT model, compared to no previous training. However, training of camera navigation skills in a hysteroscopic environment does not seem supportive for obtaining the same level of camera expertise in laparoscopy. The two environments appear too distinct to train both procedures on one unified model. Therefore, 30° camera navigation in hysteroscopy and laparoscopy should be trained separately to reach adequate levels of expertise for each procedure.

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CHAPTER 5

A VIRTUAL REALITY SIMULATOR FOR HYSTEROSCOPIC PLACEMENT OF TUBAL STERILISATION MICRO-INSERTS; THE FACE AND CONSTRUCT VALIDITY

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ABSTRACT

INTRODUCTION

This study investigated the validity of a virtual reality simulator for hysteroscopic tubal sterilisation. Initially performed laparoscopically, the hysteroscopic sterilisation method is becoming increasingly popular. An adequate training model could enhance one's skills prior to the start of performing the procedure on the real patient.

METHODS

This prospective study (Canadian Task force II-2) enrolled 69 residents and gynaecologists who were divided into three groups, based on vaginoscopic hysteroscopy and Essure® experience level: novices (N = 17), intermediates (N = 35) and experts (N = 17). Participants completed two cases on a virtual reality simulator (EssureSim™) in which four Essure® placements were performed. A questionnaire was completed to assess face validity and reality was scored on a 5-point Likert scale. Construct validity was represented by the ability of six simulator derived parameters to differentiate significantly between different hysteroscopic experience levels.

RESULTS

Reality of the sterilisation procedure was scored with a median of 5.00 points on a 5-point Likert scale by all participants with prior sterilisation experience. Of these participants, 95.5% indicated the simulator as a useful preparation for real-time Essure® placement. The expert and intermediate group performed both cases significantly faster than novices ($p = .001$). Novices had a significantly longer path length in comparison to the other groups ($p = .006$). Analysis of the remaining parameters did not show a persistent ability to differentiate between experience levels.

CONCLUSIONS

Satisfactory validity was demonstrated for the EssureSim™ by high reality scores and moderate ability to distinguish between different performance levels.

INTRODUCTION

Female sterilisation is the most common method of contraception worldwide[1]. More than 600.000 tubal sterilisations are performed annually in the United States[2]. Initially performed laparoscopically, the hysteroscopic sterilisation method is becoming increasingly popular[3, 4].
Hysteroscopy is generally considered as a safe procedure with a low complication rate[5, 6]. Its practice ranges from diagnostics in an outpatient setting to a surgical alternative for many gynaecological problems. Teaching hysteroscopic skills has traditionally been based on a mentored model, where trainees are exposed to procedures with the guidance of an experienced teacher. However, in recent years, the surgical volume has been limited by restrictions on resident working hours and less highly skilled teachers are available[7, 8]. This results in difficulties in acquiring sufficient skills in advanced endoscopic surgery[9, 10]. Effective usage of simulation and training models is a possible solution to this problem[9-11].

Development and validation research on training models and simulators has been mainly focused on laparoscopy. Training models allow a surgeon to safely overcome the learning curve of a new technique before practicing on a patient[9, 12, 13]. Virtual reality simulators especially, allow more independent instruction and objective immediate feedback for more reliable, unbiased assessment of psychomotor skills[9, 12, 14]. In addition, it allows for repeated practice without any risk to patients. Training on a virtual reality system bypasses the ethical concerns associated with practice on animals or cadavers. Besides, many virtual reality systems allow for practice at varying levels of difficulty and across a wide range of scenarios, thus accommodating trainees at many levels[14, 15].

Prior to implementation of a new training tool in a curriculum, evaluation and validation of the simulator and its parameters is mandatory[16-19]. Validity measures whether a simulator is actually teaching or measuring what it is intended to teach or measure[17]. Different aspects of validity exist. Face validity refers to whether the model resembles the task or procedure it is aiming to train for, by determining the opinion of users on realism of the simulation. Objective approaches consist of construct and predictive validity. Construct validity refers to whether the model measures the quality or ability it is supposed to measure[17]. In this regard, the simulator must be able to differentiate between the experienced and the inexperienced surgeon; or in addition, measure improvement in novices' performance by training. Predictive validity is the extent to which the simulator predicts future performance, by assessing whether the skills acquired on a simulator actually result in improved skills in patients in the real-time clinical setting[17, 20].
Excellent data are available to support the validity and effectiveness of virtual reality training of surgical skills in general surgery[21-23], urology[20] as well as in gynaecology[24, 25]. Virtual reality training leads to more efficient movements and less errors, which translates into less operating time and improved patient safety.

In comparison to laparoscopy, little work has been done regarding hysteroscopy training despite its upcoming use and applicability during the last decades. Several training methods have been designed, focusing mainly on the development of physical models and box trainers[26-28]. A collaboration between gynaecologists and technicians in Switzerland led to the development of the HystSim™ (Hysteroscopic Surgery Simulator System); a virtual reality simulator for hysteroscopic interventions. Face and construct validity have been established for a diagnostic training module[29, 30]. Recently, a new procedural training module became available by which the Essure® sterilisation method can be practiced (EssureSim™).

The hysteroscopic sterilisation method by Essure® Permanent Birth Control system (Conceptus; Mountain View, CA, USA) was approved in 2001 by the European Health Office and in 2002 by the U.S. Food and Drug Administration (FDA). Micro-inserts placed in both tubal ostia cause a sterile inflammatory response of the intramural and isthmic parts of the Fallopian tube, thereby occluding the tubes within three months. Since the introduction of this method, it is performed by gynaecologists around the world and has become an accepted alternative to laparoscopic sterilisation. Initially taught with significant hands-on supervision, the EssureSim™ is developed to train gynaecologists who want to start performing this procedure in a more efficient manner and without risks for the patient.

The aim of this study is to determine the face and construct validity of this virtual reality training module for the hysteroscopic placement of tubal sterilisation micro-inserts.

METHODS

PARTICIPANTS

Between June 2010 and April 2011, 25 OBGYN residents and 44 consultant gynaecologists (N = 69) were randomly recruited at the Annual Meeting of the Dutch Society of Obstetrics and Gynaecology and from a university hospital and a major teaching hospital in the Netherlands.
Given that hysteroscopic sterilisation is performed as a type of therapeutic vaginoscopic hysteroscopy, without use of a speculum and tenaculum, three groups were made. This division was based on a combination of Essure® experience level and experience level in therapeutic vaginoscopic hysteroscopy. 'Novices' (N = 17): never performed an Essure® placement nor a therapeutic vaginascopic hysteroscopy, 'experts' (N = 17): performed > 25 Essure® placements and > 25 therapeutic vaginascopic hysteroscopies, 'intermediates' (N = 35): any experience varying between a novice and expert. The assessment of the participants' experience was made by self estimated numbers of both procedures.

EQUIPMENT

The EssureSim™ consists of an adapted hysteroscope (10-mm resectoscope), an Essure® simulation device, simulation hardware and software ***(Figure 1)***. The simulation software runs on standard laptop hardware (2.40 GHz Intel® Core™ 2 DUO CPU P8600, 2 GB RAM, NVIDIA Quadro FX 2700M graphic card). The system does not possess haptic feedback. Software contains eight different cases with varying degree of difficulty.

FACE VALIDITY

Participants completed a questionnaire immediately after completing the cases on

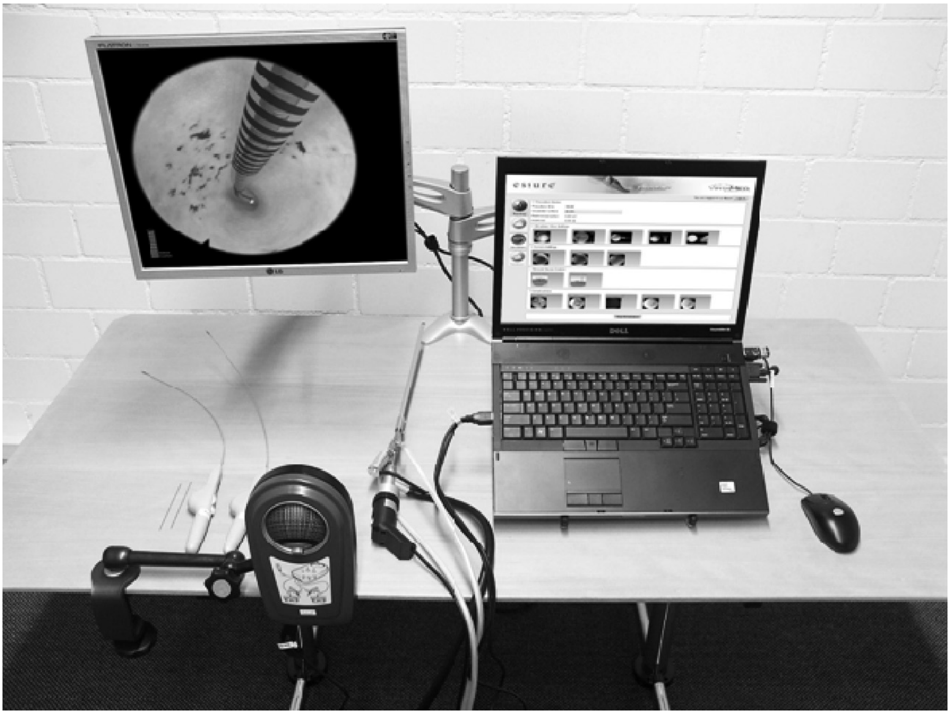

Figure 1 *Set-up EssureSim™ (VirtaMed AG, Zurich, Switzerland)*

the simulator. It included questions about participants' demographics and experience level in hysteroscopy training, several hysteroscopic procedures and hysteroscopic sterilisation. The opinion of each participant was assessed with 14 questions about the simulator and sterilisation module. These questions concerned the realism of the simulation and training capacities, and were presented on a 5-point Likert scale[31]. Additionally, two statements were proposed for further opinion inquiry. These were answered with "agree", "disagree" or "no opinion". Face validity was determined by analysing the opinion of the participants with prior Essure® experience. In this manner, realism and training capacity of the simulator were evaluated only by the participants who had knowledge of the real-time procedure and who could make a comparison between both environments.

CONSTRUCT VALIDITY

To investigate construct validity, the participants performed tasks on the simulator. To all participants, a standard introduction of the simulator and sterilisation procedure was given. A familiarisation with the simulator was executed, consisting of one tubal micro-insert placement in a uterus with normal tubes. In the first case (case 1), the participant performed a bilateral sterilisation in a uterus with normal tubes, as shown in the animation. The second case (case 2) comprised a bilateral placement in a uterus of a more difficult level, because of the thickened endometrium of this uterus, decreased visibility and slightly more lateral insertion of the tubes. All participants were supervised by one supervisor (J.A.J.), who gave answers to questions and gave instructions if one was not able to proceed. Case 1 and 2 were used for analysis. Parameters being measured by the simulator and used for data analysis were task time, path length, trauma, patient comfort, amount of distension fluid used and successful placement. A description of all parameters used is given in ***Table 1***. These parameters were compared between the different groups for both cases separately, since they were of a different level.

USE OF STATISTICS

Data were analysed using the statistical software package SPSS 17.0 (SPSS Inc, Chicago, IL). Differences between the general demographics and performances between the three groups were analysed using the Kruskal-Wallis test for non-parametric data. If the Kruskal-Wallis test resulted in a significant difference, then a comparison between two separate groups was done using the Mann-Whitney U test with post hoc Dunn's (Bonferroni) correction. To verify the minimum sample size, a power analysis was performed. A total sample of 69 subjects achieves a power of $>.80$ with the Kruskal-Wallis test with a target significance of .05. The average within group standard deviation assuming the alternative distribution is 1.0 (PASS 2008 NCSS; LCC, Kayville, UT). A p-value of $<.05$ was considered to be statistically significant. Values are presented as medians with interquartile ranges unless stated otherwise.

RESULTS

Table 2 shows the general demographics of the participants. A significant difference for age was seen between groups ($p<.05$), while gender and handedness did not differ significantly. Of all participants, 1 expert and 3 participants of the intermediate group had been introduced to the HystSim™ at other conference venues.

FACE VALIDITY

Of the 69 participants, all completed the

Table 1. Description of all parameters used

PARAMETER	DESCRIPTION
Task time	Time of the total procedure, from insertion of scope into cervix to removal of scope, in seconds
Path length	Path length of the tip of the hysteroscope in millimetres
Trauma	Cumulative number of contacts of scope with cervix and uterine wall
Patient comfort	Combination of number of trauma and the distension pressure of the fluids exerted on the uterine wall, given on a 10-point scale, 1 = extreme uncomfortable, 10 = no discomfort at all
Correct placement	1 to 8 coils of the micro-insert need to be visible after placement
Distension fluid used	The amount of distension fluid used in millilitres

entire questionnaire. ***Table 3*** summarises the median values of the scores considering the realism and training capacity of the simulator, awarded by the participants with prior Essure® experience (N = 22). In the questionnaire, realism of the sterilisation procedure was scored with a median of 5.00 points on a 5-point Likert scale. Training capacity of the sterilisation procedure was awarded a median of 5.00 points. Of all

Table 2. Baseline characteristics of all participants

CHARACTERISTICS	ALL PARTICIPANTS (N = 69)	NOVICES (N = 17)	INTERMEDIATES (N = 35)	EXPERTS (N = 17)
Age, median in years (IQR)	39.0 (31.5-48.0)	26.0 (25.5-32.5)	41.0 (33.0-52.0)	43.0 (37.5-48.0)
Gender, % male : female	28.6 : 71.4	17.6 : 82.4	31.4 : 68.6	23.5 : 76.5
Handedness, % right : left	91.3 : 8.7	82.4 : 17.6	94.3 : 5.7	94.1 : 5.9
Status, % resident : consultant	36.2 : 63.8	82.4 : 17.6	31.4 : 68.6	0.0 : 100.0
Hysteroscopy training courses, in hours (%)				
0	20 (29.0)	12 (70.6)	7 (20.0)	1 (5.9)
1-10	29 (42.0)	5 (29.4)	19 (54.3)	5 (29.4)
11-20	15 (21.7)	0	5 (14.3)	10 (58.8)
> 20	5 (7.2)	0	4 (11.4)	1 (5.9)
Experience with virtual reality in general, in hours (%)				
0	38 (55.1)	13 (76.5)	15 (42.9)	10 (58.8)
1-10	21 (30.4)	4 (23.5)	12 (34.3)	5 (29.4)
11-20	7 (10.1)	0	5 (14.3)	2 (11.8)
> 20	3 (4.3)	0	3 (8.6)	0
Experience with HystSim (%)	4 (5.8)	0	3 (8.6)	1 (5.9)
Number of therapeutic vaginoscopic hysteroscopies performed (%)				
0	17 (24.6)	17 (100.0)	0 (0.0)	0
1-25	17 (24.6)	0	17 (48.6)	0
26-50	10 (14.5)	0	9 (25.7)	1 (5.9)
> 50	25 (36.2)	0	9 (25.7)	16 (94.1)
Number of Essure® placements performed (%)				
0	47 (68.1)	10 (100.0)	30 (85.7)	0
1-25	5 (7.2)	0	5 (14.3)	0
26-50	6 (8.7)	0	0	6 (35.3)
> 50	11 (15.9)	0	0	11 (64.7)

IQR = interquartile ranges

participants with prior Essure® experience, 100.0% agreed with the statement that the hysteroscopic simulator offers procedural training of hysteroscopic skills. Furthermore, 95.5% indicated the training module for the Essure® sterilisation method as a useful preparation for real-time placement.

CONSTRUCT VALIDITY

All of the 69 participants completed all cases. Median values of the assessed parameters for case 1 and 2 are shown in ***Table 4***. The simulator was able to differentiate between subjects with varying hysteroscopic experience for two out of six parameters.

The parameter task time was able to differen-

Table 3. Results face validity

Median scores (with interquartile ranges) are given for the realism and training capacity of the simulator on a 5-point Likert scale. Results are presented for those participants who have prior Essure® experience.

PARTICIPANTS WITH PRIOR ESSURE® EXPERIENCE (N = 22)		
What is your opinion about the realism of the following items?		**(1. not realistic… 5. very realistic)**
Instrumentation		4.00 (3.75-5.00)
Setting		4.00 (3.00-5.00)
Navigation		4.00 (4.00-5.00)
In- and outflow valves		4.00 (4.00-5.00)
Quality of images		5.00 (4.00-5.00)
Depth perception		4.00 (3.00-4.25)
Essure® procedure		4.00 (4.00-5.00)
General impression		5.00 (4.00-5.00)
What is your opinion about the training capacity of the following items?		**(1. very bad… 5. very good)**
Camera navigation		4.50 (4.00-5.00)
Hand-eye coordination		5.00 (4.00-5.00)
Depth perception		4.00 (3.00-4.25)
Operative hysteroscopy		4.00 (4.00-5.00)
Essure® procedure		5.00 (4.00-5.00)
Training capacity in general		4.00 (4.00-5.00)
Statement 1: The HystSim™ offers procedural training of hysteroscopic skills		
Agree: 100.0%	Disagree: 0.0%	No opinion: 0.0%
Statement 2: The EssureSim™ offers a useful preparation for the real-time Essure® sterilisation procedure		
Agree: 95.5%	Disagree: 4.5%	No opinion: 0.0%

tiate significantly between all groups in both cases. The novice group performed both cases significantly slower in comparison to the other groups (p = .001 for both cases). In addition, all groups required more time to finish the second case, a uterus of a more difficult level, in comparison to the first case.

Similarly, the parameter path length showed significant differences between groups in both cases. The novices had a significantly longer path length in comparison to the intermediate and expert group (case 1, p = .001 in both groups; case 2, p = .006 in comparison with the intermediate group).

The results for parameters task time and path length are visualised in ***Figure 2***. Both

Table 4. Results of construct validity for each group
Median values (interquartile ranges) for all analysed parameters are given. For every parameter a p-value is stated per exercise to indicate whether a significant effect between any of the groups is observed (non-parametric, Kruskal-Wallis test).

	NOVICES (N = 17)	INTERMEDIATES (N = 35)	EXPERTS (N = 17)	P VALUE
Case 1				
Time (seconds)	203.40 IQR 172.65-302.65	161.90 IQR 123.00-180.40	118.70 IQR 103.80-146.60	.001
Path length (millimetres)	647.30 IQR 583.55-946.05	498.60 IQR 412.60-553.80	462.20 IQR 383.05-545.60	.001
Trauma (number)	11.00 IQR 5.50-17.00	7.00 IQR 2.00-9.00	6.00 IQR 3.00-8.50	.033
Patient comfort (10-point scale)	6.90 IQR 6.80-7.80	7.10 IQR 6.70-7.70	7.30 IQR 6.75-7.70	.831
Distension medium (millilitres)	558.90 IQR 267.15-791.40	600.20 IQR 449.95-905.55	489.60 IQR 193.08-571.15	.102
Correct placement left/right (percentage)	94.1 / 82.4	91.4 / 91.4	82.4 / 94.1	.481 / .481
Case 2				
Time (seconds)	224.90 IQR 180.30-279.25	177.60 IQR 150.30-197.40	136.70 IQR 120.35-174.30	.001
Path length (millimetres)	665.40 IQR 586.40-837.85	538.70 IQR 504.90-626.20	561.40 IQR 495.95-677.75	.009
Trauma (number)	8.00 IQR 4.50-28.00	10.00 IQR 5.00-28.00	13.00 IQR 6.50-25.50	.791
Patient comfort (10-point scale)	7.90 IQR 6.60-8.10	7.20 IQR 6.20-8.00	7.30 IQR 7.00-8.10	.377
Distension medium (millilitres)	671.45 IQR 180.55-831.40	836.50 IQR 503.45-1141.63	635.55 IQR 438.48-873.38	.173
Correct placement left/right (percentage)	100.0 / 100.0	97.1 / 100.0	100.0 / 100.0	.615 / 1.00

IQR = interquartile ranges

parameters reflect a more efficient performance of hysteroscopy by experienced gynaecologists; however the clinical relevance of a shorter duration of 1 to 1.5 min per patient is uncertain.

In the first case, the parameter trauma displayed a significant difference between the novices and the intermediate group and a similar trend in comparison to the expert group. However, in the second case a reversed (non-significant) effect is observed. The novice group achieved a median score of 8 contacts in comparison to 13 in the expert group. A similar contradictory trend in both cases is seen for the parameter patient comfort.

Analysis of the parameter distension medium did not show significant results, while the intermediate group used the largest amount of fluid in both cases. The last parameter, the number of correctly placed devices, did not differ significantly between the three groups and no specific trend could be observed. Both inexperienced and experienced participants were able to position the sterilisation micro-inserts in a correct manner.

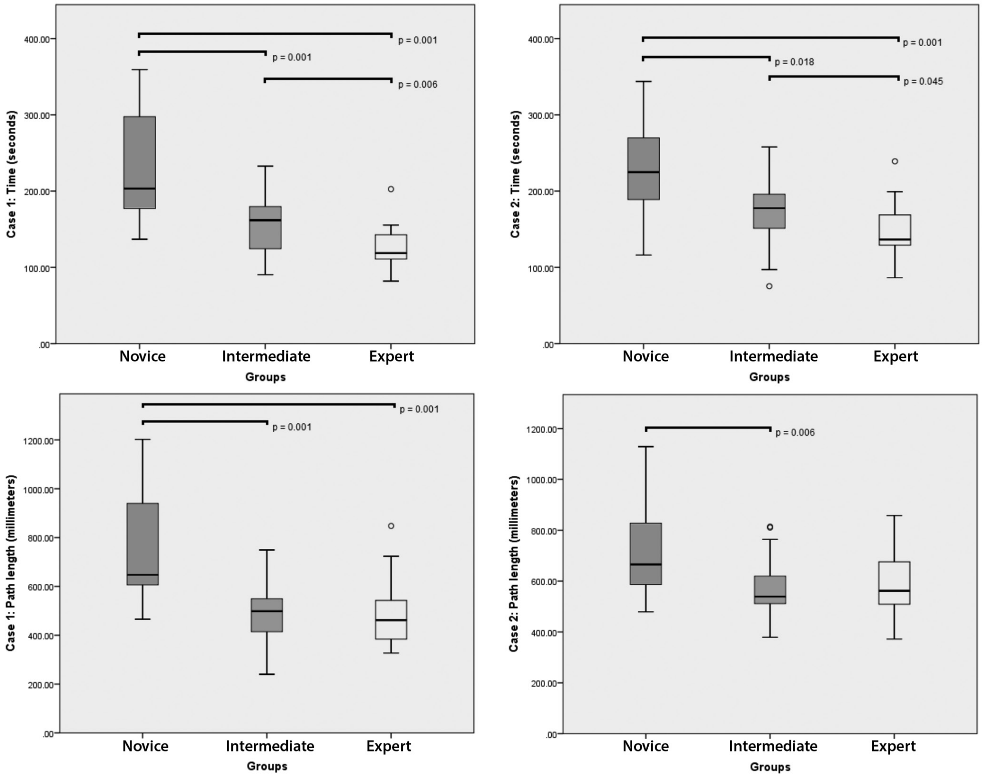

Figure 2 *Results of construct validity in box plots*
Box plots for parameters task time and path length, for all groups performing case 1 and 2. Bars are medians, boxes show interquartile range, whiskers show range, dots are outliers and large horizontal bars indicate statistically significant differences, specified with p-values.

DISCUSSION

The aim of this study was to determine the validity of a new training module by which the Essure® sterilisation method can be practiced on a commercially available virtual reality simulator. We assessed the realism of the simulator by questionnaires (face validity) and determined the capacity of the simulator to distinguish between experienced and inexperienced hysteroscopists (construct validity). Face validity was established with high scores, while construct validity showed moderate results.

The study was preceded by a power analysis and contained a sufficient number of participants. One supervisor coached all participants to limit inter-supervisor bias.
According to the fact that hysteroscopic sterilisation is usually performed as a type of therapeutic vaginoscopic hysteroscopy[32, 33], participants were grouped by their experience in both procedures.

In general, gynaecologists with ample experience in performing hysteroscopies are considered experts. In the absence of generally accepted criteria for the classification of experience levels, we applied the arbitrary number of 0 and 25 therapeutic procedures to form three levels. Both the novice and expert group were of similar size (N = 17), whereas the intermediate group consisted of clearly more participants (N = 35), indicating that the majority of our study population had some or more therapeutic vaginoscopic hysteroscopy experience. Face validity was assessed by taking into account only the opinion of those participants who had tubal sterilisation experience (performed ≥1 Essure®). In this manner, realism was evaluated only by those participants who had knowledge of the real-time procedure.

Not all performance parameters measured by the simulator were able to differentiate between participants with varying hysteroscopy experience. Hereby we confirm findings of previous studies by Bajka et al[30] and Panel et al[34], who investigated the face and construct validity of the diagnostic and sterilisation module on this hysteroscopy simulator, respectively. Both studies found that less than half of all used parameters significantly correlated with hysteroscopic experience.

A possible reason for the moderate results of the construct validity as established in this study could be the fact that an active coaching strategy was adopted, by which the supervisor was easily accessible for questions and practical advice. It should be emphasised that this might have reduced possible differences between experienced and inexperienced participants. Another reason may possibly be the lack of haptic feedback, which might impair especially the experienced hysteroscopist. Not only the visual aspect but also haptic feedback gives guidance to the operator for efficient and safe hysteroscopies. Both parameters trauma and patient comfort, which is a combination of number of trauma and the distension pressure of the fluids exerted on the uterine wall, might not be able to differentiate in a consequent manner between novices and experts as a result.

Also, the parameter distension medium should be interpreted with caution due to a number of missing data, as the simulator tended not to register fluid use during all placements. Further refinement of software and scoring systems is therefore necessary. Incorrectly placed devices were mainly caused by placing them too deeply into the tubes, by which the coils were not visible in the uterine cavity after deployment. The fact that novices scored high percentages for correctly placed devices might be explained by the observation that those participants without any hysteroscopic experience tended to adhere more closely to any practical advices given during device placement, in contrast to the more experienced groups. In addition, one needs to realise that the assessment of the participants' experience was self-reported and therefore is subject to recall bias. Also, the division into three levels of experience could be seen as a potential source of bias since the norm of both sufficient hysteroscopic ánd sterilisation experience must be met to be classified as an expert.

One could ask himself in general if a slower performance with more use of distension medium is not preferred when a higher correct placement rate is achieved with better patient comfort. The parameters used by this simulator might not be the only measures of hysteroscopic performance. For procedural exercises, one could design a global rating scale (GRS), which is a scoring system that is built on certain clinically relevant performance parameters[35, 36].

CONCLUSIONS

In conclusion, this simulator received the highest scores regarding both procedural realism and training capacity. It was able to differentiate between subjects with varying hysteroscopic experience for two out of six parameters. We consider this study as an essential basic step in the validation cascade of a virtual reality simulator for training operative hysteroscopies, and for hysteroscopic sterilisation in particular. Also, we believe this simulator could be suitable for future training of hysteroscopic sterilisation skills, after further refinement of the software. The next important step would be the investigation of the learning curve, with concurrent use of a clinically relevant GRS. The learning curve is a vital part of construct validity and in addition addresses implementation of the simulator in hysteroscopic training curricula. The learning curve could possibly indicate the necessary number of training sessions contributing to efficient and safe daily practice. Assessing predictive validity would be a last and ideal step in the validation cascade, providing data to which extent the simulation can predict real-life hysteroscopic performance.

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CHAPTER 6

HYSTEROSCOPIC STERILISATION ON A VIRTUAL REALITY SIMULATOR: ASSESSMENT OF THE LEARNING CURVE

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ABSTRACT

STUDY OBJECTIVE
To assess the learning curve of a virtual reality simulator for the hysteroscopic sterilisation method Essure®.

DESIGN
Prospective multicentre study

DESIGN CLASSIFICATION
Canadian Task Force II-2

SETTING
University and teaching hospital in the Netherlands.

PARTICIPANTS
30 novices (medical students) and 5 experts (gynaecologists who performed >150 Essure® sterilisations) voluntarily participated.

INTERVENTIONS
All participants performed 9 repetitions of a bilateral Essure® placement on the simulator. Novices returned after 2 weeks for a second series of 5 repetitions to assess retention of skills. Structured observations on performance by a Global Rating Scale (GRS) and parameters derived from the simulator provided measures for analysis.

MEASUREMENTS AND MAIN RESULTS
The learning curve is represented by the improvement per procedure. A two-way repeated measures analysis of variance (ANOVA) was used to analyse learning curves. Effect sizes (ES) were calculated to express the practical significance of the results (ES ≥ 0.50 indicates a large learning effect). For all parameters significant improvements were found in novice performance within 9 repetitions. Large learning effects were established for six out of eight parameters ($p < .001$, ES: 0.50 - 0.96). Novices approached expert level within 9 to 14 repetitions.

CONCLUSIONS
The learning curve established in this study endorses future implementation of the simulator in curricula on hysteroscopic skill acquisition for clinicians who are interested in learning this sterilisation technique.

INTRODUCTION

Virtual reality trainers have emerged and successfully been implemented for a wide variety of surgical training purposes like laparoscopy, robot-assisted surgery and cystoscopy[1-3]. Until now, in gynaecology virtual reality simulators have primarily been used for laparoscopic and robotic skills training[4-6]. Hysteroscopic skills training can benefit from virtual reality simulators likewise.

The effectiveness of training on simulators and other models largely depends on the validity of the models and simulators used[7,8]. Validity defines whether a simulator is actually teaching or evaluating what is intended to be taught or measured. In order to implement the model in training curricula, a learning curve provides helpful information and is essential by determining the training capability of the simulator (9). A learning curve depicts the rate of learning and is defined as the relationship between the parameters measured through training repetitions[9].

The HystSim™ (Hysteroscopic Surgery Simulator System, VirtaMed AG, Zurich, Switzerland) is a validated virtual reality simulator for hysteroscopic interventions[10,11]. Recently, a new training module has become available by which the Essure® sterilisation can be practiced on this simulator (EssureSim™). As hysteroscopic sterilisation using the Essure® system is a technique that is becoming widely adopted a valid training system is urgently needed. As with every new (endoscopic) procedure one has to obtain new skills to gain a sufficient proficiency and safety level. Face and construct validity have recently been established for the EssureSim™[12,13]. Investigating the effectiveness of repetitive training on the EssureSim™, the aim of this study was to determine the learning curve of the participants; whether novices can improve their skills, whether they reach a plateau phase, to what extent this plateau phase approximates the plateau phase of the expert participants and whether retention of skills occurs.

METHODS

STUDY DESIGN

Prospective multicentre study (Canadian Task force II-2)

PARTICIPANTS

From May to June 2011, 30 novices and 5 experts voluntarily conducted a series of repetitions on the EssureSim™. Fourth- until sixth-year medical students from the University Medical Centre Utrecht participated as novices. The novices had never performed nor assisted in a hysteroscopic procedure before, but had as a medical student a basic understanding of hysteroscopy. All novices were invited by oral and written invitation and all participated consequently. Five gynaecologists served as experts to set a reference for novices' performance. In this study, a gynaecologist was considered a hysteroscopic sterilisation expert after performing >150 Essure® sterilisations. In the Netherlands only a limited number of gynaecologists was available who had performed >150 hysteroscopic sterilisations (University Medical Centre Utrecht, Utrecht; Sint Antonius Ziekenhuis, Nieuwegein; Lucas Andreas Ziekenhuis, Amsterdam; Ziekenhuis Rivierenland, Tiel). All gy-

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naecologists were personally invited and all joined as a participant. None of them had any experience of performing an Essure® procedure on this simulator.

ETHICAL APPROVAL

The study was exempt from Institutional Review Board approval, since no potential harm could be done to humans or nonhumans. All participants gave oral consent prior to the start of the study.

EQUIPMENT

The EssureSim™ consists of an adapted diagnostic hysteroscope, simulation hardware and software ***(figure 1)***. The software runs on standard laptop hardware (2.40 GHz Intel Core 2 DUO CPU P8600, 2 GB RAM, NVIDIA Quadro FX 2700M graphic card). The system does not possess haptic feedback. The software contains eight different cases with varying degree of difficulty. A case consisting of a uterus with lateral insertion of the Fallopian tubes was selected (case number 6); this case was considered to be more difficult.

MEASUREMENTS

Beforehand, a survey was done to obtain baseline characteristics. The novices received a short standardised introduction on hysteroscopy, hysteroscopic sterilisation with tubal micro-inserts, the simulator and study protocol. The experts received a standardised explanation on the simulator and study protocol. One investigator (R.S.A.G.) supervised all tests to limit inter-supervisor bias. Both groups conducted a series of nine repetitions of the same case. After every repetition an au-

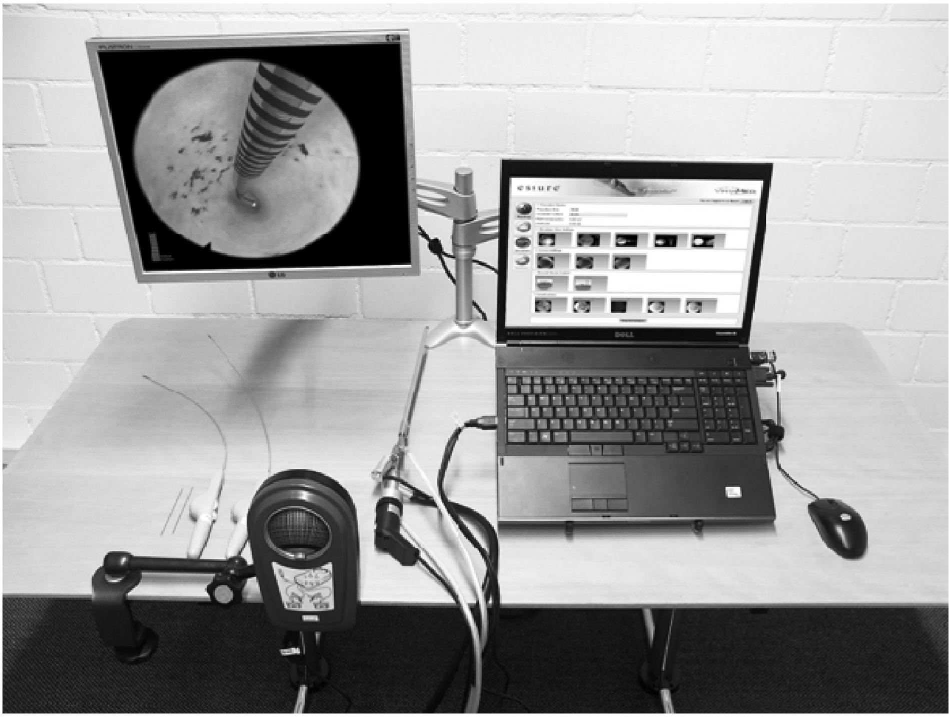

Figure 1 *Set-up EssureSim™ (VirtaMed AG, Zurich, Switzerland)*

tomatic feedback report was provided by the simulator and points for improvement were discussed. The first, third, fifth, seventh and ninth repetition were used for data-analysis. The repetitions in between were meant for training by the supervisor and consisted of answering questions of the participants and giving tips and tricks on the procedure. For this reason the even repetitions had a different duration and goal, and were consequently excluded from further analysis. During the odd repetitions no questions could be asked nor were any tips given, since these performances were solely used for data-analysis. To assess retention of skills, novices returned for a second series of five repetitions after two weeks. The first, third and fifth repetition were used for data-analysis. The repetitions in between were meant for training by the supervisor and excluded from further analysis. Parameters were derived from the simulator software and included time, path length, patient comfort, trauma (the cumulative number of cervical and uterine wall contacts), number of correctly placed devices, amount of distension fluid used, time the view obscured and time the uterus collapsed. Participants were not only assessed on simulator-derived parameters, since performing a procedure very fast or in an efficient manner does not necessarily mean it is performed in a proper manner and/or with good results. For that reason, a 5-point Global Rating Scale (GRS) was applied as well, to be able to assess competence from another (clinical) perspective. The GRS was adjusted for hysteroscopic sterilisation ***(figure 2)*** and has not yet been validated[14].

GRS 1 RESPECT FOR TISSSUE	Scope frequently pushed into wall of cervix or cavum.		Scope occasionally pushed into wall of cervix or cavum.		No trauma to wall of cervix or cavum.
	1	2	3	4	5
GRS 2 TIME AND MOTION	Many unnecessary moves.		Made some unnecessary moves, but time more efficient.		No unnecessary moves and time is maximised.
	1	2	3	4	5
GRS 3 HANDLING OF HYSTEROSCOPE	Frequently had scope pointing away from ostia. Scope poorly aligned during procedure.		Had scope centered for the most part. Better use of scope angle during procedure.		Scope always centered. Scope always set in good angle throughout the procedure.
	1	2	3	4	5
GRS 4 FLOW OF PROCEDURE AND FORWARD PLANNING	Frequently stopped or needed advice or assistance from examiner.		Demonstrated ability to think forward with relatively steady progression of procedure.		Obviously planned procedure from beginning to end with fluid motion.
	1	2	3	4	5
GRS 5 KNOWLEDGE OF PROCEDURE	Deficient knowledge. Needed specific instruction at most procedural steps.		Knew all important aspects of procedure.		Demonstrated familiarity with all aspects of procedure.
	1	2	3	4	5

Figure 2. *Global Rating Scale, adjusted for hysteroscopic sterilisation*

Aspects that were rated included respect for tissue, handling of the hysteroscope, time and motion, flow and forward planning and procedure knowledge. ***Table 1*** gives a description of all parameters used. Blinding was not possible due to the clear differences between age and status of the groups and the necessity to score both the simulator screen and the participants' behaviour.

STATISTICAL ANALYSIS

Data were analysed with SPSS version 15.0 (SPSS Inc, Chicago, IL). No power analysis was performed prior to the study. To analyse the improvement within the novice group, a sample size of 30 was considered sufficient.

Independent t-test and chi-square test were used to compare general demographics of the expert and novice, accompanied by medians and ranges. A two-way repeated measures analysis of variance (ANOVA) was used to analyse learning curves. The between subject factor 'group' was added to investigate novice and expert performance separately. Retention of skills was investigated by within subject contrasts and was assessed by comparing the last repetition of both series; significant improvement was defined as a prolonged learning curve[15]. A p-value of $< .05$ was considered as statistically significant for all tests. Means and 95% confidence intervals (CI) were used to compare data of the learning curves, because these are applicable to the ANOVA analysis.

The practical significance of the results was quantified by the effect size (ES), which is independent of sample size and a scale-free index[16]. In this manner, the results can be further interpreted in terms of learning. Significant curves provide information on the

Table 1. Description of all parameters used

PARAMETER	DESCRIPTION
Time	Time of the total procedure, from insertion of scope into cervix to removal of scope, in seconds
Path length	Path length of the tip of the hysteroscope in millimetres
Patient comfort	10-point scale, 1 = extreme uncomfortable, 10 = no discomfort at all
Trauma	Cumulative number of contacts of scope with cervical wall and endometrial cavity
Mean GRS score	Global Rating Scale by clinical observation, 5-point scale, see figure 2
Correct placement	1 to 8 coils of the micro-insert need to be visible after placement
Time uterus collapsed	Inadequate uterine distension in seconds, indicating a suboptimal surgical condition
Time view obscured	Obscured visibility in seconds, indicating a suboptimal surgical condition
Distension fluid used	The amount of distension fluid used in millilitres

evidence of any effect at all, ES indicates whether a learning effect is meaningful or important. The ES was extracted from the ANOVA-output in SPSS. ES of 0.10, 0.30 and 0.50 were considered to indicate small (negligible), medium (moderate) and large (crucial) learning effects, respectively. ES was considered relevant only if a significant ($p < .05$) result was obtained.

RESULTS

DEMOGRAPHICS

General demographics of novices and experts are listed in ***table 2***. There is a significant difference between gender ($p < .05$), age ($p < .001$), and the number of tubal micro-insert placements performed ($p < .001$), as expected. To assess retention of skills,

Table 2. Baseline characteristics

CHARACTERISTICS	NOVICES (N = 30)	EXPERTS (N = 5)		
Demographics (%)				
Gender, male : female	10 : 20 (33 : 67)	5 : 0 (100 : 0)		
Age, median (range)	23 (21 – 26)	54 (44 – 59)		
Handedness, right : left	24 : 6 (80 : 20)	5 : 0 (100 : 0)		
Days between series, median (range)	14 (7 – 21)	NA		
General VR simulator experience (%)				
0 hours	21 (70.0)	0		
1-10 hours	7 (23.3)	4 (80.0)		
11-20 hours	2 (6.7)	1 (20.0)		
Hours on HystSim, median (range)	0	1 (0 – 3)		
Hysteroscopies seen (%)				
0	15 (50.0)	NA		
1 – 5	9 (30.0)	NA		
6 – 10	5 (16.7)	NA		
> 11	1 (3.3)	NA		
Sterilisation experience (%)		**Adiana®**	**Essure®**	**Ovabloc®**
0	30 (100)	2(40)	0	3 (60)
1 – 50	0	2(40)	0	0
51 – 100	0	0	0	0
101 – 150	0	0	0	0
> 150	0	1 (20)	5 (100)	2 (40)

NA = not applicable
VR = virtual reality

novices returned after a median of 14 days (range 7 – 21) for a second series of repetitions. All experts had previous experience on any other type of a virtual reality simulator, whereas 80% of the expert group had shortly practiced on the hysteroscopy simulator before (without the Essure® module).

LEARNING CURVE

Results of novice performance in both series of repetitions are listed in ***table 3*** (original measurements). A graphic presentation of the novice learning curve with the expert performance as a reference curve is given in ***figure 3***.

Novices showed large improvement in the necessary time to complete a repetition ($p < .01$, ES: 0.77). A large difference was observed between time needed by novices and experts to complete a repetition, in favour of the experts. Novices progressed towards expert level in time, but no plateau phase was observed in the graph.

For path length a similar large improvement of novice performance was found ($p < .001$, ES: 0.73). A moderate difference between novices and experts was seen, favouring experts. No plateau phase was observed in the novice-group.

Novices demonstrated large improvement in patient comfort ($p < .001$, ES: 0.50). During all repetitions novices outperformed experts, although performance during the last repetition was approximately equal. In the graphic presentation, a plateau phase could be recognised at the fifth repetition.

For trauma (the cumulative number of contacts with the cervical wall and endometrial cavity) novices also showed a large improvement ($p < .001$, ES: 0.70). A similar learning curve by the experts was found. A plateau phase was reached by the novices at the fifth repetition, as observed in the graph.

Regarding mean GRS score, novices showed a very large improvement ($p < .001$, ES: 0.96). The fact that experts scored quite stable from the beginning contributed to a large between-group difference in favour of the experts. No plateau phase was recognised for the novices.

There was moderate progression in the number of correctly placed micro-inserts by the novices ($p < .001$, ES: 0.44). Experts performed consistently with zero placements failures. A plateau phase for the novices could be recognised in the graph at the seventh repetition.

For mean time that the uterus collapsed, a moderate improvement of novice performance was noticed ($p < .05$, ES: 0.31). For mean time that the view obscured, large improvement of novice performance was noticed ($p < .001$, ES: 0.51). Data for the expert group was inconsistent for these parameters.

RETENTION OF SKILLS

No significant decrease in performance between the last repetitions of both series was found for the parameters time ($p = .064$), patient comfort ($p = .12$), trauma ($p = .06$), correctly placed devices ($p = .33$), time the uterus collapsed ($p = .45$) and time the view obscured ($p = .91$), indicating retention of skills by the novices after two weeks. A significant increase in performance for the parameters path length ($p < .01$, ES: 0.58) and mean GRS score ($p < .01$, ES: 0.52) was seen, indicating a prolonged learning curve for both parameters in the novice group (***table 3***). Novices approached expert levels in 9-14 repetitions.

Table 3. Results of novice performance in both series

	FIRST SERIES - LEARNING CURVE			SECOND SERIES - RETENTION OF SKILLS	
Parameter	**First repetition**	**Last repetition**	**Significance[a]**	**Last repetition**	**Significance[b]**
Time (seconds)	513.9 CI: 440.0 - 587.7	190.2 CI: 171.4 - 208.9	$p < .001$ ES: 0.77	165.9 CI: 145.5 - 186.4	$p = .06$
Path length (millimetres)	1710 CI: 1356 - 2064	577 CI: 511 - 642	$p < .001$ ES: 0.73	469 CI: 422 - 516	$p < .01$[c] ES: 0.58
Patient comfort (10-point scale)	6.79 CI: 6.36 - 7.23	7.82 CI: 7.56 - 8.08	$p < .001$ ES: 0.50	8.08 CI: 7.88 - 8.28	$p = .12$
Trauma (number of contacts)	85.1 CI: 60.9 - 109.2	11.8 CI: 7.2 - 16.3	$p < .001$ ES: 0.70	6.9 CI: 4.2 - 9.6	$p = .06$
Mean GRS (5-point scale)	1.38 CI: 1.18 - 1.58	4.69 CI: 4.58 - 4.81	$p < .001$ ES: 0.50	4.90 CI: 4.84 - 4.96	$p < .01$[c] ES: 0.52
Correctly placed devices (0 to 2)	1.53 CI: 1.32 - 1.75	1.97 CI: 1.90 - 2.00	$p < .001$ ES:0.44	2.00 CI: 2.00 - 2.00	$p = .33$
Uterus collapsed (seconds)	93.5 CI: 37.8 - 149.2	20.5 CI: 1.9 - 39.1	$p < .05$ ES: 0.31	12.5 CI: 3.8 - 21.2	$p = .45$
View obscured (seconds)	6.2 CI: 5.3 - 7.0	3.0 CI: 2.2 - 3.8	$p < .001$ ES: 0.51	3.1 CI: 2.2 - 3.9	$p = .91$

CI = 95% confidence interval. ES = effect size (only applicable if result is significant)

[a] Implicates the significance of the comparison between the first repetition and the last repetition of the first series (ANOVA test)

[b] Implicates the significance of the comparison between the last repetition of the first and second series (ANOVA test)

[c] Indicates a prolonged learning curve

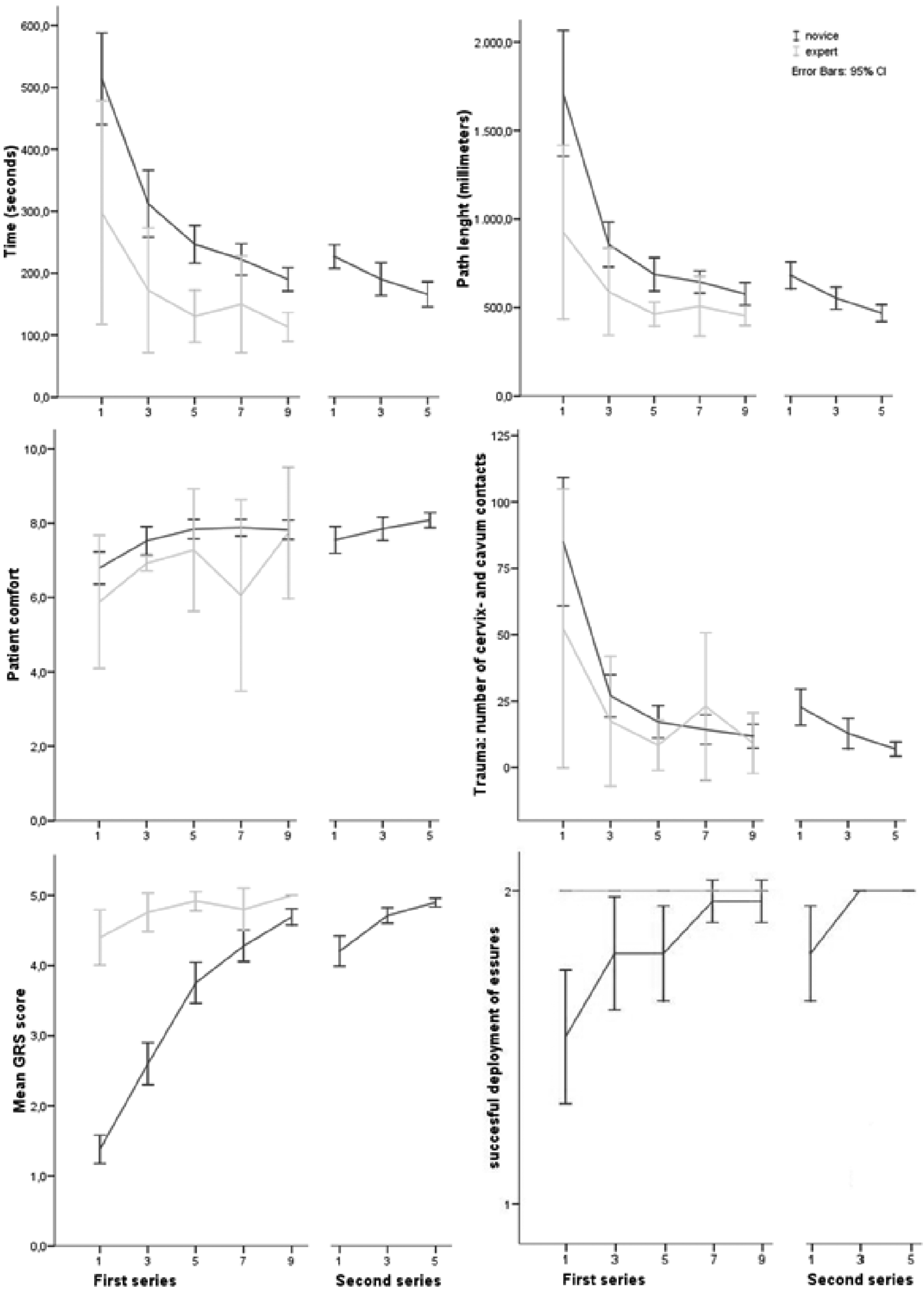

Figure 3. *Learning curve*
Learning curve for novices (black) and experts (grey) in the first series of exercises and for novices in the second series

DISCUSSION

The present study assessed the effectiveness of repetitive training for performance using the EssureSim™, a virtual reality simulator for hysteroscopic sterilisation. For all parameters significant improvements were found in novices' performance within 9 repetitions. Retention of skills was demonstrated for all parameters, and although for some parameters an early plateau was reached, a prolonged learning curve was observed for path length and mean GRS score. Results of this study endorse future implementation of the simulator in curricula on hysteroscopic skill acquisition for clinicians who are interested in learning this sterilisation technique. One or more training sessions improve the speed of acquiring sterilisation skills on the simulator significantly, which could contribute to consistent, efficient and safe daily practice. Training sessions include regular feedback from the simulator and, if needed, from a supervisor.

Strong points of this study are the realistic study design, additional assessment of retention of skills and the fact that one investigator supervised all tests in both groups. Furthermore, the use of effect size adds information on whether significant learning curves can be translated into meaningful and important learning effects. Moreover, use of a clinical parameter (global rating scale) in addition to the parameters derived from the simulator shows the direct improvement of skills. Also, the GRS can be of value in future transfer of skills obtained on the simulator to a setting with real patients. Although the GRS used has not been validated for hysteroscopic sterilisation yet, similar rating scales have been used and validated for a general hysteroscopic training program, a HystSim™ myoma resection module and comparable cystoscopic procedures in urology[3,17,18].

The most difficult part of the procedure is the actual placement of the micro-inserts at the appropriate angle in both tubal ostia. To challenge this aspect and avoid measuring solely basic hysteroscopic skills, a difficult case consisting of a uterus with lateral insertion of the fallopian tubes was chosen out of the 8 available cases. Nonetheless, during the study several experts expressed doubt about the realism of placement angle on the right side. Three experts considered this angle possibly too lateral in comparison to difficult cases in reality. This might have led to a wider variance in results for a number of parameters and to lower scores on patient comfort for experts. The fact that novices outperformed experts on patient comfort could be due to a tendency of novices to operate more carefully under new or difficult circumstances, whereas experts might tend to accept a higher level of patient discomfort to achieve efficient placements. An alternative to the current study design, could be one in which hysteroscopic surgeons with no sterilisation experience are compared with experts in the hysteroscopic sterilisation technique.

Considering the improvement in several parameters for both novices and experts, it can be argued whether the first repetition(s) should be used for data analysis in a study assessing a learning curve; the time needed to familiarise with a simulation model could influence results. On the other hand, the chosen study design reflects reality and integrates the possibility of feedback and training in the process[9]. The expert curve functions as a reference and their possible improvement during the first cases is likely to represent reality, in which experts also must become accustomed to the virtual environment[9,19].

Due to the lack of a definition of an Essure® expert in literature, gynaecologists were included who had an undeniable experience in hysteroscopic sterilisation (performed >150 Essure® procedures), to ensure that the experts were indeed competent. This may have resulted in a small number of experts included in this study. Since face and construct validity have been established, the expert group did not need to serve for a statistical comparison; this simulator already proved to be able to differentiate between experience levels[12,13]. In the current study the experts served as a reference, to see where the experts reach a plateau and to display this plateau in a figure combined with the learning curves of the novices.

Four of the participating gynaecologists already had limited experience on this virtual reality simulator in general, although not with the sterilisation module. It is possible that this might have resulted in a shortened learning curve for the expert group. Nevertheless, a marked improvement of their performance in the first repetitions was seen. A similar learning curve for experts has been described in other studies, indicating that time is needed for anyone to become familiar with a simulation model[23,24].

The distension medium parameter is not reported because of a high number of missing values. This is possibly due to incorrect calibration of in- and outflow valves on the hysteroscope and the chosen statistical analysis in which cases with missing values are excluded. For the parameters "mean time the uterus collapsed" and "mean time the view obscured" missing values were observed for the expert group as well. Therefore, these parameters were not displayed in the graphical presentation of the curves of both groups ***(figure 3)***.

In a recently published article establishing construct validity of the EssureSim™, a correlation in a multivariate analysis was found between the number of cavity contacts and the cumulative path length[12]. This finding might imply that improvement of the parameter trauma could be explained in part by shortening of the cumulative path length in general.

The results of the current study indicate a large training capacity of the virtual reality simulator for the hysteroscopic sterilisation method, because large improvements were made by novices training on the EssureSim™. Furthermore, retention of skills was established for all parameters and a prolonged learning curve was observed for path length and the clinical parameter GRS. Therefore, this virtual reality simulator could be recommended for future training purposes. When one trains by using all eight cases provided by the simulator, a shortened learning curve could possibly be expected because of the variety of circumstances.

Assessment of the learning curve is an important step in determining the applicability of a simulator in a training curriculum. Another vital step is investigation of predictive validity, which indicates whether skills trained on a simulator can be transferred to the procedure in patients. Additionally, the adjusted GRS for hysteroscopic sterilisation could be validated for subsequent use. These are interesting focus areas for future studies.

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CHAPTER 7

LEARNING CURVE OF HYSTEROSCOPIC PLACEMENT OF TUBAL STERILISATION MICRO-INSERTS IN 15 GYNAECOLOGISTS IN THE NETHERLANDS

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ABSTRACT

OBJECTIVE

To evaluate the learning curve of hysteroscopic placement of tubal sterilisation micro-inserts of gynaecologists in the Netherlands.

DESIGN

Prospective multicentre study (Canadian Task Force II-2)

SETTING

Ten community (teaching) hospitals in the Netherlands.

PATIENTS

A total of 631 women, who underwent permanent sterilisation by tubal micro-inserts were included.

INTERVENTION

Hysteroscopic placement of tubal sterilisation micro-inserts performed by 15 gynaecologists who are experienced in performing operative hysteroscopy, starting from their very first placement.

MAIN OUTCOME MEASURES

The effect of increasing experience in time on procedure time, pain score, successful bilateral placement and complications.

RESULTS

Bilateral successful placement with confirmation of adequate positioning at follow-up was achieved in 480 (76.1%) patients at first attempt and in 44 (7.0%) at second attempt. Median procedure time was 8.0 minutes (range 3-40) and 31 (4.9%) patients were lost to follow-up. Gravidity showed to be a confounding factor and was consequently adjusted for.

A learning curve was seen in a statistically significant decrease of procedure time with increasing experience. The decrease in procedure time extended to 11-15 cases and was followed by a plateau phase of the subsequent 60 cases. In contrast, pain scores, successful placement and complication rate appeared not to improve with increasing experience.

CONCLUSION

A learning curve for hysteroscopic tubal sterilisation was seen for procedure time, but successful placement, pain score and complication rate were not clearly influenced by increasing experience.

INTRODUCTION

Tubal sterilisation is the most common form of permanent contraception worldwide[1,2]. The transcervical hysteroscopic sterilisation method with the Essure® device (Conceptus Inc, Mountain View, California) was approved in 2001 by the European Health Office and in 2002 by the U.S. Food and Drug Administration (FDA). Since the introduction of this sterilisation method[3], it is performed by gynaecologists around the world and has become an accepted alternative to laparoscopic sterilisation. Worldwide, more than 600,000 women have been sterilised by this method. Since the introduction of the Essure method in the Netherlands in 2002, around 18,000 women have been sterilised in this country. Every year, more gynaecologists begin to perform this procedure[4,5].
Several articles have been published confirming the safety and efficacy of this sterilisation method[1,2]. This is demonstrated with high successful bilateral placement rates in various studies, varying between 83 and 98% ([3,6-12]. Important benefits of the hysteroscopic approach in comparison with a laparoscopic procedure are the possibility of performing the procedure in an outpatient setting, the use of minimal analgesia and local anaesthesia, a minimally invasive approach and rapid patient recovery.

As with every new (endoscopic) procedure one has to obtain new skills, to gain a certain proficiency and safety level. A learning curve depicts the rate of learning, the progress in the mastery of a skill against the time required for such mastery.
In varying specialties learning curves are investigated for new endoscopic procedures, as they give important information on how many repetitions of a procedure should be performed before sufficient expertise and safety level is reached[13,14].

Despite several studies concerning the efficacy of the Essure® sterilisation method, only limited research has been published concerning the effect of increasing experience and learning curve. The studies that do address this subject consist of small patients groups, often performed by only one gynaecologist and in most cases without a statistical analysis[6-8,10]. Nonetheless, the articles do mention a steep and short learning curve. Another study that specifically assessed the difference between experienced versus newly trained physicians found a high successful placement rate in both groups; however, the experienced physicians performed the procedure significantly faster[12].
Our study assessed the effect of increasing experience on the procedure time, pain scores during the procedure, number of successful placements, and complication rates with the hypothesis that increased experience improves these outcome parameters.

MATERIALS AND METHODS

A prospective multicentre study was undertaken and data of hysteroscopic sterilisation procedures using Essure® were recorded. Procedures were performed by 15 different gynaecologists over the period of January 2005 to December 2009, in 10 different community and teaching hospitals in the Netherlands (Sint Antonius Ziekenhuis, Nieuwegein; Ziekenhuis Rivierenland, Tiel; Máxima Medisch Centrum, Eindhoven; Ziekenhuis Nij Smellinghe, Drachten; Alant Vrouw, Bilthoven; Franciscus Ziekenhuis, Roosendaal; Sint Lucas Andreas Ziekenhuis, Amsterdam; Rijnstate Ziekenhuis, Arnhem; Spaarne Ziekenhuis, Hoofddorp; Gelre Ziekenhuis, Apeldoorn). These hospitals were approached for voluntary participation due to their known expertise with hysteroscopic procedures. All participating gynaecologists performed hysteroscopies on a regular basis and had performed >300 ambulatory hysteroscopies and >100 operative hysteroscopies. They received a standardised introduction to the sterilisation device and a proctor attended the first procedures of each gynaecologist. Starting from the very first tubal sterilisation performed by each gynaecologist, various details concerning the procedure and patient were collected. Questionnaires regarding the procedure and pain sensations (using a visual analogue score) were provided directly after placement and filled out immediately by the patient.

Before the start of the study the institutional review board (IRB) was consulted for approval. Given that the study concerns regular patient care and only regards registration of patient data, the IRB considered approval not necessary. All patients gave written and oral informed consent for anonymous data collection.

ESSURE® PROCEDURE

The procedure was preferably performed in an outpatient setting. Analgesia (diclofenac, 100 mg) was provided for the patients 1 to 2 hours before the procedure. A vaginoscopic hysteroscopy was performed using a 5.5 mm or 5.0 mm continuous-flow hysteroscope with a 5-Fr working channel. The time of the procedure commenced upon introduction of the hysteroscope vaginally and continued until it was removed. After visualising both tubal ostia, the Essure® devices were placed in both tubal ostia. The number of coils protruding from the tubal opening was counted, 3 - 8 coils being a normal range. After placement, the hysteroscope was removed. Patients were discharged within two hours.

In 2007 the ESS205 device was replaced by the ESS305 according to new developments.

CLINICAL FOLLOW-UP

After placements of inserts, patients were instructed to rely on alternative contraception for three months until the adequate positioning of the devices was confirmed. Accurate positioning of the Essure® device was assessed through transvaginal ultrasound or pelvic x-ray, or tubal patency was tested by hysterosalpingography (HSG) at 12 weeks when indicated (e.g. difficult placement).

LEARNING CURVE

To assess the effect of increasing experience of the gynaecologist, the following outcome measures were studied: procedure time, pain score during procedure, successful bilateral placement during the first session with adequate position during follow-up evaluation, and number of complications, defined as nausea, vomiting, vasovagal collapse, perforation or bleeding. Short- and long-term learning curves were defined to analyse different possible learning effects. The short-term learning curve consisted of placement number 1 - 30, coded as a categorical variable in steps of 5 placements. The long-term learning curve comprised placement number 1 - 80, coded as a categorical variable in steps of 20 placements. Furthermore, we investigated the possibility of a plateau phase reached after performing a certain number of procedures.

STATISTICAL ANALYSIS

To analyse the relationship of continuous and categorical outcome measures with the categorically coded placement number and taking into account the hierarchic structure of our data (different gynaecologists) a 'Generalized Estimating Equation' (GEE) model was used[15]. Statistical analysis was performed using the software package SPSS for windows version 17.0 (SPSS Inc, Chicago, IL). To visualise the learning curves data was exported to Excel (Microsoft Office Excel 2007) and curves were created. $P < .05$ was considered statistically significant.

For the parameters procedure time and pain score the linear version of the model was used, with log transformation for procedure time. For the parameters complications and successful bilateral placement the logistic version of the GEE model was used. Possible confounding factors (age, body mass index (BMI), gravidity, use of local anaesthetics, analgesia before procedure and phase of menstrual cycle at procedure) were included in the GEE model and adjusted for when indicated by the model. Learning curves, adjusted for confounders, were obtained from the GEE model by calculating Estimated Marginal Means. Analysis of the learning curve of the parameters procedure time, pain score and complications was performed with the database consisting of only those cases with successful bilateral placements. This was done to overcome differences in outcome due to unilateral placement or failed placement. To assess the learning curve in successful bilateral placement all cases were included.

RESULTS

A total of 631 patients underwent hysteroscopic sterilisation using Essure® in the period from January 2005 to December 2009. Place-

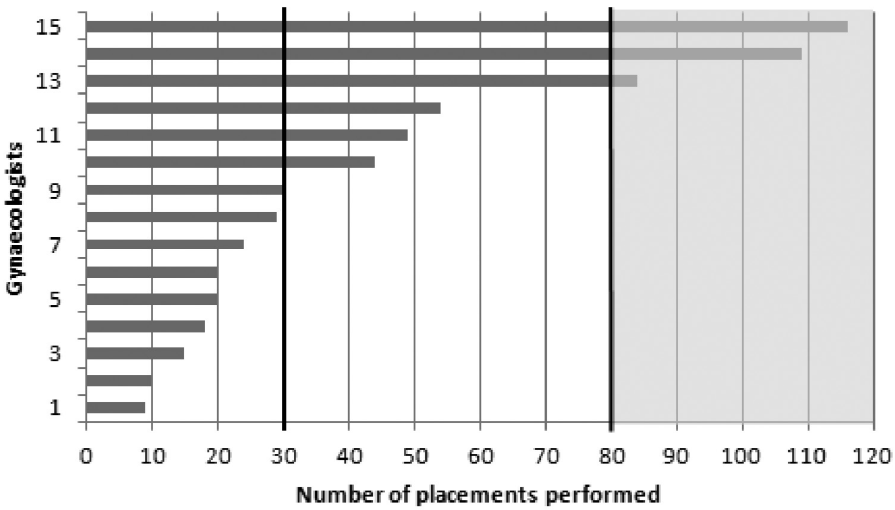

Figure 1 *Distribution of placements per gynaecologist*
The number of placements performed by each gynaecologist is displayed, showing a wide distribution. The black line at placement number 30 indicates the end of the short learning curve (placement 1 – 30), while the black line at number 80 represents the end of the long learning curve (placement 1 – 80). Placement numbers > 80 were not used for learning curve analysis and are therefore indicated by a grey zone.

Table 1. Baseline characteristics of 631 patients

CHARACTERISTICS	VALUE
Age (years)[a]	39.0 (25-50)
Gravidity[a]	2.0 (0-9)
BMI (kg/m^2)[a]	24.4 (16.0-44.1)
History of ... (N, %)	
Caesarean deliveries (≥1)	84 (13.4)
Abortion (≥1)	150 (23.7)
Curettage for abortion (≥1)	73 (11.6)
Curettage for other reasons than abortion (≥1)	16 (2.5)
Pelvic inflammatory disease	8 (1.3)
Hysteroscopic surgery (≥1)	11 (1.7)
Abdominal or pelvic surgery other than Caesarean delivery (≥1)	60 (9.5)

[a] Value is median (range)

ments were performed by 15 gynaecologists with a median number of patients per gynaecologist of 29.0 (range 9 - 116) ***(figure 1)***, affiliated in 10 different community and teaching hospitals. The median age of the patients was 39.0 years (range 25 - 50) and median gravidity 2.0 (range 0 - 9). The median BMI was 24.4 (range 16.0 - 44.1). Patients' characteristics are outlined in ***Table 1***.

Median procedure time as measured from hysteroscope insertion to removal was 8.0 minutes (range 3-40). Median pain score during procedure was 5.0 (range 0 - 10), measured on a visual analogue scale (VAS) 0 - 10. Of the 631 patients, bilateral successful placement with satisfactory positioning and configuration during follow-up was achieved in 480 (76.1%) at first attempt, 44 (7.0%) at second attempt and 13 (2.1%) patients had successful unilateral placement because of prior contralateral tubectomy. Thirty-one (4.9%) patients were lost to follow-up evaluation. Excluding the patients lost to follow-up, a success rate of 80.0% for bilateral placement at first attempt was observed. If successful unilateral placement at first attempt is included, a success rate of 82.2% was achieved. Including the successes at second attempt, an overall success rate of 89.5% was achieved. Placement failures were due to unapproachable or nonvisible tubal orifices, lateral insertion, blockage of the proximal tube, or technical problems. No serious complications were observed. Of all procedures, 92.3% was performed during the follicular phase of the menstrual cycle. ***Table 2*** displays the results for the outcome parameters whereas ***Table 3*** shows additional data regarding the procedure and follow-up.

The possible factors that may have influenced the outcome measures in the GEE model were analysed, which resulted in gravidity as a statistically significant factor for both outcome

Table 2. Results of outcome measures

PARAMETER	VALUE
Procedure time (min)[a]	8.0 (3-40)
Pain score (VAS 0-10)[a]	5.0 (0-10)
Placement outcome, N (%)	
Successful bilateral during 1st procedure	480 (76.1)
Successful bilateral during 2nd procedure	44 (7.0)
Successful unilateral during 1st procedure	13 (2.1)
Placement failure	63 (10.0)
Lost to follow-up	31 (4.9)
Overall success of sterilisation	537 (89.5)[b]
Complications, N (%)	40 (6.3)
Perforation	0 (0.0)
Bleeding	1 (0.2)
Nausea	7 (1.1)
Vomiting	4 (0.6)
Vasovagal collapse	9 (1.4)
Other[c]	19 (47.5)

[a] Value is median (range)
[b] Percentage excluding number lost to follow-up
[c] E.g. non employment of device

measure complications and pain score. No statistically significant factors were identified for successful bilateral placement or procedure time. The influential factor gravidity was included in the model and consequently adjusted for.

The learning curves are displayed in ***Figure 1***. Considering the learning curve of procedure time, both the short- and long-term curves show a statistically significant overall decrease of time with increasing experience ($p < .05$). A statistically significant decrease extended to placements 11 through 15 and was followed by a plateau phase in the subsequent cases.

The curves of the pain score demonstrate no specific learning effect. In the short-term curve, both statistically significant decreases and increases of the pain score were found ($p < .05$); the long-term curve showed a trend for increasing pain scores with increasing experience (not statistically significant).

Observing both learning curves of bilateral successful placement, non-significant effects are seen. In the short curve both an increase to 86% and a decrease to 69% are demonstrated. The long learning curve shows a more steady curve, but with small gain of successful placements (75 - 80%).

The curves addressing the complication rate also show diverse effects, with several increases and decreases. The short-term learning curve demonstrates no complications during placements 11 to 15; afterward, the complication rate increased to 9% during placements 21 to 25. The long-term learning curve shows an improvement of the complication rate after 60 placements, but this value was not statistically significant.

Table 3. Data regarding procedure and follow-up (N = 631)

VARIABLE	VALUE
Analgesia, N (%)[a]	569 (90.2)
Type of anaesthesia, N (%)	
None	616 (97.6)
Local/regional	14 (2.2)
General[b]	1 (0.2)
Dilatation, N (%)	24 (3.9)
Menstrual phase at procedure, N (%)	
Follicular	
Cycle day 1-7	141 (22.3)
Cycle day 8-14	251 (39.8)
Luteal	
Cycle day 15-21	18 (2.9)
Cycle day 22-28	10 (1.6)
Cycle day 29-35	5 (0.8)
Cycle day >35	0
Intracavitary pathology diagnosed during sterilisation, N (%)[c]	38 (6.0)
Number of coils visible after placement, median (range)	
Right tube	4.0 (0-12)
Left tube	3.0 (0-12)
Follow-up, N (%)	
Transvaginal ultrasound 4 weeks	123 (19.5)
Transvaginal ultrasound 12 weeks	450 (71.3)
Pelvis X-ray 12 weeks	32 (5.1)
HSG 12 weeks	147 (23.3)

[a] Oral NSAIDs 1-2 hours prior to procedure
[b] General anaesthesia because of concurrent prolaps surgery
[c] E.g. myoma, polyp, synechiae, unknown prior to the procedure

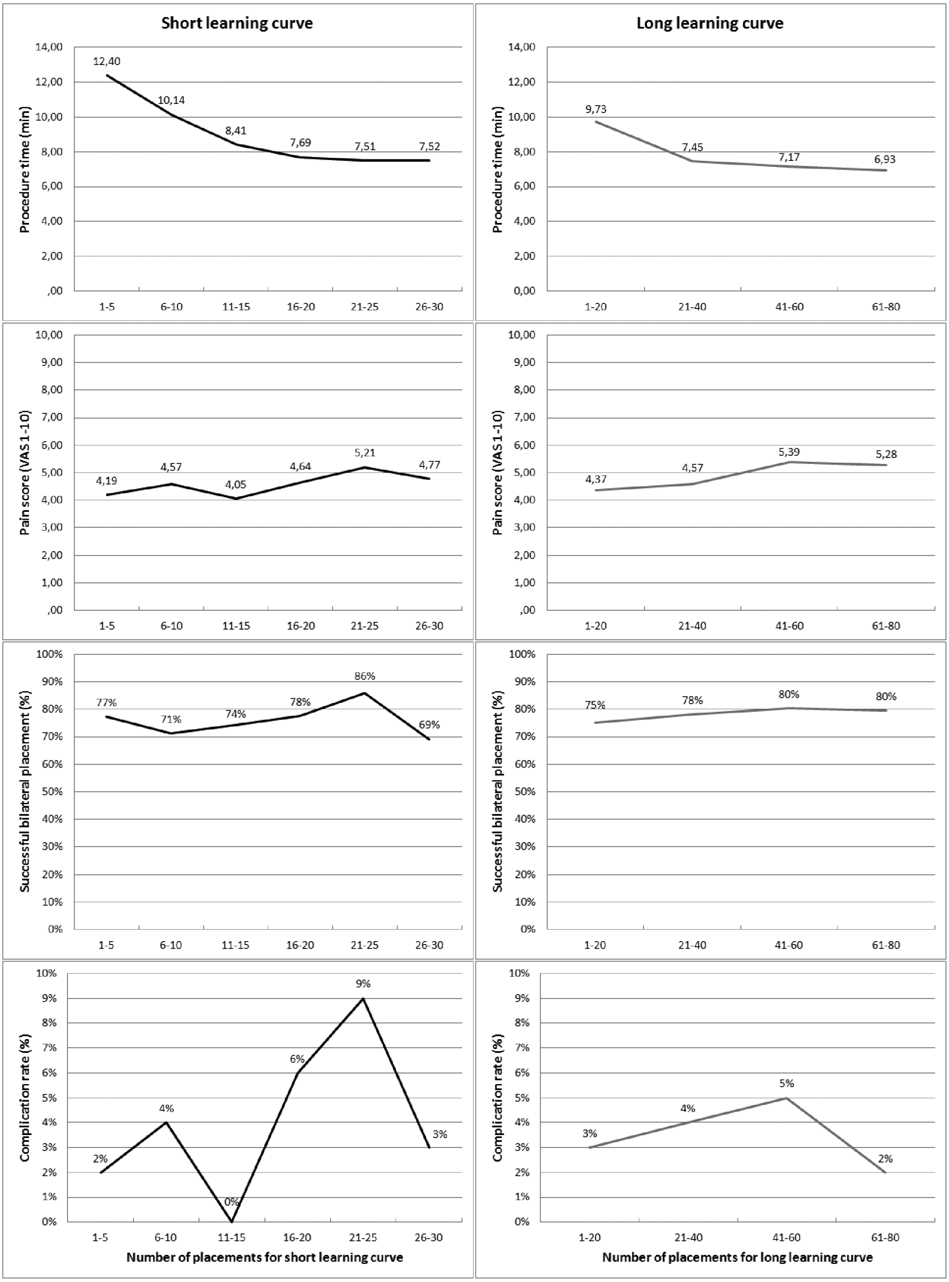

Figure 2 *Short and long learning curve for each parameter*
The short learning curves (placement 1 – 30) are indicated by a black line and grouped by 5 placements.
The long learning curves (placement 1 – 80) are indicated by a grey line and grouped by 20 placements.
The corresponding outcome per group is stated above the line.

DISCUSSION

This prospective multicentre inventory of the learning curve for the hysteroscopic placement of tubal sterilisation micro-inserts demonstrated a significant decrease in procedure time with increasing experience. In contrast, successful placement, pain scores, and complication rates showed no improvement with increasing experience.

A strong point in our study approach is the choice of statistical model. To analyse our data and taking into account the hierarchic structure we used the 'Generalized Estimating Equation' (GEE) model. This hierarchy is represented by gynaecologists who each performed their own series of consecutive sterilisations. The GEE model offers the possibility to analyse the learning curve per gynaecologist whereby we take into account interpersonal differences and determine an average learning curve. Besides adjusting for procedures performed by different gynaecologists, this model can identify significant factors that could influence the outcome measure. Gravidity[6], analgesia before procedure[16] and phase of menstrual cycle at procedure[6,11] are factors previously recognised in literature as potentially influential. Age, BMI and use of local anaesthetics seemed argumentative factors and were also included in the current study. In our analysis, gravidity was identified as a confounding factor, and was consequently adjusted for.
Secondly, we analysed the learning curve for the outcome measures procedure time, pain score and complications for the 480 patients who had a successful bilateral placement during the first attempt with confirmed positioning the follow-up evaluation. The rationale is to overcome plausible differences in outcome due to unilateral placement or failed placement. It is likely that unilateral placement procedures are significantly shorter than bilateral placements. Similarly, it is probable that pain scores are higher in patients who underwent a difficult procedure with placement failure. Thus, to prevent possible bias, only data of the patients with successful bilateral placement were analysed. To assess the learning curve for the parameter successful bilateral placement all patients were included.

What should be taken into consideration is the fact that the database is composed of data from 15 gynaecologists who each performed a different number of sterilisations. Of all gynaecologists, six performed >30 procedures and three gynaecologists performed >80 procedures. Therefore, the long learning curve is based on a smaller group of cases in comparison to the beginning of the curves, which may lead to bias of results. These differences per gynaecologist are due to the varying number of participating gynaecologists per hospital and the local demands for sterilisation for each hospital and region. Furthermore, the number of procedures per gynaecologist depends on the varying start date of each hospital during the study period. We do not consider the introduction of a newer Essure® device as a potential source of bias, because the new device only had a slightly different release mechanism of the coil and each participant had a varying start date during the study period.

Literature addressing the learning curve of the Essure® method confirms a (short) learning curve for procedure time, but does not mention a learning curve analysis of other important outcome measures as number of successful placements or complication rate[6-8,10,12]. Besides, most studies contain small groups of patients or procedures were performed by only one or an unknown number of gynaecologists. Learning curves were mainly analysed without the use of statistical models and no analysis for possible confounding factors was performed. Levie et al. investigated the efficacy of the Essure® method and found a decrease in the procedure time in the first 13 cases, although it is not clear whether one or more gynaecologists participated in these first cases[7]. Rosen et al. studied the first 80 sterilisations of one gynaecologist, after splitting the population in three cohorts of 25 - 30 cases; he found a decrease in procedure time with increasing experience[6]. Vleugels et al. evaluated the efficacy of the first 175 procedures performed by one gynaecologist and mentioned a learning curve in decreasing procedure time with a maximum effect after 140 cases[8]. Vellayan et al. investigated the first 100 sterilisations of one centre with three gynaecologists, with an increasing number of bilateral successful placements with confirmation at follow-up when ones experience increased (average 83%)[10]. Another study by Levie et al. compared the data of 37 novices versus 39 experienced gynaecologists, performing 7.7 procedures on average[12]. This study mentioned a significant decrease in procedure time after 10 procedures for all gynaecologists. Before the start of the study, the novices had each performed 3 - 5 proctored placements during the training program.

Although the parameter of procedure time showed a statistically significant learning curve in our study, the remaining parameters (successful placement, pain scores, and complication rate) did not statistically significantly improve with increasing experience. A possible explanation could be that the Essure® procedure is not difficult for a gynaecologist experienced in performing hysteroscopies, so immediate high success percentages can be achieved[12]. The fact that all participating gynaecologists in this study were highly experienced in hysteroscopy could thus have been a possible limitation on the applicability of the results to the daily practice of less experienced practitioners. A potential explanation for the parameter of pain is that pain may depend on patient characteristics such as pain threshold and may be independent of whether a gynaecologist has experience with the procedure because it is the first time for the patient. Furthermore, scoring of pain may be influenced by the way the patient was coached during the procedure and how the scoring system was presented. In addition, a gynaecologist who is experienced in the sterilisation procedure might perform more difficult cases, or accept more pain, or allow more time to elapse before accepting a placement failure. In terms of the complication rate, no serious complications were observed, which may be in line with the parameter of successful placement.

The percentage successful placements in the literature varies between 83% and 94.7%[6–8, 10, 12]. However, the studies often do not clearly describe how these percentages were calculated, specify whether a follow-up evaluation took place, or explain how this might have influenced the actual success percentage. Frequently, the studies made no distinction between the first or second attempt, nor did they state whether the patients lost to follow-up evaluation were excluded. In our study, we found a success rate of bilateral placement on the first attempt with confirmation of adequate positioning at follow-up evaluation of 76.1%, which is relatively low compared with the percentages found in other studies. If the patients lost to follow-up evaluation are excluded and successful unilateral placement at first attempt and successful bilateral placements at second attempt are combined, we had a success rate of 89.5%, which is a fairly average percentage compared with those in the literature. The initial percentage of 76.1% may be a more realistic representation of daily practice, where second attempts and follow-up evaluations do count for the patient.

Our study investigated in a unique manner the learning curve for the hysteroscopic placement of tubal sterilisation micro-inserts by examining both the short- and long-term learning curves in 15 Dutch gynaecologists. To this end, we used an adequate statistical model and took into account several outcome measures and the results of the follow-up evaluations. A learning curve for hysteroscopic tubal sterilisation was seen for the procedure time, with significant improvements seen for the first placement and a maximum effect after 15 procedures. In contrast, the parameters of successful placement, pain score, and complication rate did not improve with increasing physician experience. This indicates that the Essure® procedure can be rapidly performed by an experienced hysteroscopist in an efficient manner, so safe and successful practice can start immediately.

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CHAPTER 8

GENERAL DISCUSSION AND FUTURE PERSPECTIVES FOR THE HYSTEROSCOPIC TRAINING CURRICULUM IN THE NETHERLANDS

Hysteroscopy detects uterine cavity pathology by direct visualisation of the endometrial lining, making use of a vaginally inserted endoscope. The additional insertion of an instrument through the endoscope and the incorporation of irrigation channels provide the opportunity for obtainment of histology and treatment of these pathologies, and for sterilisation of women. It is therefore an essential diagnostic and therapeutic tool in the current practice of gynaecology and reproductive medicine. Due to the development of thinner endoscopes and working channels and the introduction of the vaginoscopic insertion technique, it has become possible to perform hysteroscopy in an outpatient setting without anaesthesia.

Even though hysteroscopic skills are often perceived to be less complicated in comparison to laparoscopy, they are far from innate abilities. Psychomotor skills and spatial abilities need to be trained to overcome the barriers that are known for endoscopic procedures in general and for hysteroscopy in particular. The fulcrum effect, loss of binocular vision and limited haptic feedback are acknowledged factors[1,2]. Manipulation of an instrument through a working channel in the endoscope gives a considerable decreased range of motion. Skills unique to camera navigation include maintaining a correct horizontal axis while centring the operative field, focusing and sizing, and especially the use of an angled scope requires training[1,3,4].

Training without involvement of a patient is increasingly valued and implemented in residency for various disciplines in endoscopic surgery. Laparoscopy is the main example, but simulators are also being used for robotic surgery, colonoscopy, bronchoscopy and cystoscopy[5-8]. Especially the cystoscopic procedure is comparable to hysteroscopy, due to the resemblance in size and shape of the bladder and uterine cavity. Parts of the technical learning curve can be overcome outside the patient setting, in order to decrease errors and time when the patient is involved[9]. Also, when performing a surgical procedure more than just technical skills are required; communication and leadership are essential items, as well as equipment-related competence. Especially in office hysteroscopy, communication with the patient is vital.

It seems illogical and unethical to let novices train all competencies from the start with involvement of patients, when there are models and manners to simulate the procedure and tasks outside the patient setting. However, the development and use of hysteroscopic training models seem to lag far behind in daily practice. Therefore, in this thesis we investigated simulation training in hysteroscopic surgery focusing on the following topics:

- the current opinion on the value of hysteroscopy training during residency
- the valuation and validation of a new box trainer for training of basic hysteroscopic skills
- the valuation and validation of a virtual reality simulator for training of a specific hysteroscopic procedure
- the learning curves of both simulated and clinical procedures in hysteroscopy

CURRENT OPINION ON HYSTEROSCOPY TRAINING

Worldwide, the last decade was characterised by further development and implementation of hysteroscopy in the office setting, and by the innovation of tools and operative techniques for hysteroscopy[10,11]. Also, the implementation of a fellowship for minimally invasive gynaecological surgery has started in various countries[12]. Our survey demonstrated that in the Netherlands the implementation of hysteroscopic procedures has improved since 2003. In addition, more residents and gynaecologists (who finished residency between 2008 and 2013) judged their residency training for hysteroscopy as adequate in comparison to their peers of a decade ago[13]. Moreover, the skills of surgical educators have progressed towards a level by which the majority of these gynaecologists feel competent to teach and supervise advanced hysteroscopic procedures. A differentiation program for selected residents could improve the exposure and offer a way to incorporate training of advanced procedures into the residency program.

Besides the satisfactory opinion on the current hysteroscopy training, room for improvement is indicated. Gynaecologists pointed at simulation training as the most important factor during residency that could be enhanced for optimal acquirement of hysteroscopic skills. It can be argued whether gynaecologists can already truly value hysteroscopic simulation; even though a small number of hysteroscopic simulators have been developed, these are not yet being used for training and validity research has only just started. However, 99% of these gynaecologists have performed laparoscopic simulator training. If they have experienced and acknowledged the added value of simulation in laparoscopy, they might expect this added value for hysteroscopy too. Nonetheless, research is needed to validate hysteroscopic simulators and to determine the role of these training facilities in residency programs before simulation of hysteroscopy can be implemented.

VALIDATION OF THE BOX TRAINER FOR HYSTEROSCOPY

Plastic models (box trainers) are developed to provide relatively inexpensive, simple, safe and reusable training facilities for endoscopy courses as well as individual daily training. Low fidelity and limited realism are drawbacks of a box trainer. The application of distension medium (‘wet’ model) gives the opportunity to practice electrosurgical techniques during training courses, but increases preparation and cleaning time.

As a box trainer for daily practice, the Hysteroscopic Skills Training and Testing (HYSTT) method has recently been developed under auspices of the European Academy of Gynaecological Surgery (Leuven, Belgium). This ‘dry’ model aims at practicing camera navigation skills with a 30° angled scope. Camera navigation is a basic and essential skill for performing hysteroscopic procedures, especially when an angled scope is used. The only other hysteroscopic box trainer that has previously been described and validated in literature aims at diagnosing intra-uterine pathologies and resection of these polyps and myomas during a yearly training course (Hysteroscopic Re-

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section Trainer, Limbs and Things, Bristol, UK)[14].

Our study on the HYSTT box trainer indicates an adequate training capacity and construct validity. Observations during this study might imply that the white plastic HYSTT model does not resemble the uterus in a very close matter, as was also indicated in the expert questionnaire. Suggestions for improvement were provided. In addition, it could be that the exercise in itself – a commanded search for certain anatomical positions – is far from the expert reality when performing a hysteroscopic procedure in patients. Nonetheless, this new box trainer was designed for training of novices; the experts indicated the HYSTT to be very applicable for residents preparation.

FURTHER RESEARCH CONCERNING THE BOX TRAINER

Additional research is needed to confirm construct validity and to answer the question whether this box trainer translates into improved camera navigation skills in the real-time performance (predictive validity). For example, novice residents are divided into two groups. The control group receives standard information on 30° camera navigation in the endoscopy room and performs their first diagnostic hysteroscopy at the patient. The intervention group receives similar information in the simulation room, performs the camera navigation program at the HYSTT consisting of e.g. 10 repetitions, and subsequently performs their first real-time diagnostic hysteroscopy at the patient. A Global Rating Scale can be used to score the performance at the patient, by a blinded supervisor. Scores are compared between both groups to evaluate whether prior training at the HYSTT translates into an improved performance in the real-time setting.

The HYSTT also contains a module for the practice of taking biopsies, but it has not been validated yet.
This hysteroscopic box trainer offers a promising training facility for basic skills training in daily practice of novices. Together with the Hysteroscopic Resection Trainer, both basic and procedural skills training could be incorporated into a structured training course, to provide a safe and standardised environment without involvement of the patient.

VALIDATION OF THE VIRTUAL REALITY SIMULATOR FOR HYSTEROSCOPY

A virtual reality simulator creates a safe, controlled and standardised environment. However, the main advantage of a virtual reality simulator is the ability to objectively measure the performance of each subject and the automatic presentation of these parameters during and after each exercise. Repetitive training of both diagnostic and therapeutic procedures is possible without having to renew the uterine model or clean the simulator when electrosurgery is practiced. This provides the opportunity to train easily, independently and repetitively to a predefined proficiency level. Realism of the simulated procedure and environment is an important factor for optimal procedural training. Disadvantages of these simulators are the relatively high costs. The lack of haptic feedback is interpreted as a disadvantage by some users as well.
The only virtual reality simulator for hysteroscopy currently available is the Hyst-

Sim™ (Hysteroscopic Surgery Simulator System) (Zurich, Switzerland). Our study validated a new procedural training module for hysteroscopic sterilisation (EssureSim™). Realism and training capacity were awarded with high scores (face validity), while construct validity showed moderate results. In accordance with the literature on the HystSim™ and various laparoscopic virtual reality simulators[15-17], not all parameters of a simulator are capable of differentiating between novices and experts. Besides technical parameters, a clinical parameter like a global rating scale (GRS) could also contain relevant information about the performance. In this thesis the GRS was applied during assessment of the EssureSim™ as well. Of all parameters the GRS differentiated most explicitly between experts and novices. This could endorse construct validity, since the differences in expertise are recognised during the simulated procedure as they are during the real-time procedure. On the other hand, the technical parameters do not (yet) surpass a clinical parameter.

FURTHER RESEARCH CONCERNING THE VIRTUAL REALITY SIMULATOR

One could argue whether this virtual reality simulator for hysteroscopy is worth the relatively high cost. It seems too early at this moment. More research needs to be done to further develop the application of technical parameters. Also, investigation in predictive validity is essential to prove the transfer of procedural simulation training into the real -time procedure. Additionally, to have a useful hysteroscopic virtual reality simulator in daily practice various types of procedures should be available for training. Modules for different types of myomectomy and polypectomy have been developed but they need to be validated as well. Ideally, a cost-effectiveness study would analyse the costs and benefits of this virtual reality simulator when incorporated into a residency curriculum.

When both diagnostic and therapeutic modules are validated and integrated into a structured program, and when this program consists of increasing levels of difficulty of virtual patients, then this virtual reality simulator could play an important role in hysteroscopy training. The relatively high costs could be shared among several training hospitals or regions, and the simulator could rotate among the participating hospitals. This would offer both junior and senior residents a validated and realistic training opportunity to improve their basic and procedural skills.

LEARNING CURVES IN BOTH SIMULATORS

A learning curve can be defined as the relationship between the parameters measured through training repetitions[18]. A graphic presentation shows the changing rate of learning for a given procedure before a preset level of competence is reached, often based on mean performance of experts. Due to the novices' lack of experience with the tasks simulated, their curve height is indicative for the performance difference between novices and experts. Ideally, the novice curve should approach the expert curve in time by training.

The learning curves of hysteroscopic procedures on the box trainer and virtual reality simulator as established in this thesis showed significant improvements for novices, indicating the training capacity of the models. However, there are differences between both

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models when the expert curves are taken into account. Regarding the virtual reality simulator, the simulator derived parameters showed fairly similar learning curves for both novices and experts. The two groups continue to learn alongside each other. This could be due to the virtual environment and lack of haptic feedback which could restrict the experts, or possibly because of limited quality of the parameters. At the box trainer, the only parameter that is recorded (procedure time) demonstrated different learning curves for both groups, with a fairly flat and stable performance of the experts. The novices' approach of the expert curve can be more clearly visualised. This would favour the use of the box trainer in future training programs.

One important technical aspect of hysteroscopy is not or not realistically trained at any model: the introduction of the scope through the cervix. A relatively frequent complication during hysteroscopy is perforation of the uterine or cervical wall (0,76-1%), of which approximately half to two-third is entry-related[19,20]. Both the vaginoscopic approach and dilatation of the cervical canal before introduction of the instruments should ideally be possible to practice on simulators.

EXPERT LEARNING CURVE IN THE CLINICAL SETTING

While a simulator is designed for gradual improvement of novice skills, one can expect from experts a steady performance during real-time procedures. But when a hysteroscopic expert is taught a new type of operative hysteroscopy, does he or she start with a safe and steady performance immediately? The transcervical sterilisation method by Essure® was introduced in the Netherlands in 2002 and enticed a new skill of hysteroscopic canulation of the tubes. Despite several studies concerning the efficacy of this sterilisation method, only very limited research had been published regarding the learning curve of experts. Our prospective multicentre study assessed in a unique and adequate manner the learning curve of 15 Dutch gynaecologists, who started performing the Essure® technique from the very first placement. A standardised introduction was provided and a proctor attended the first procedures of each gynaecologist. Our study demonstrated a significant decrease in procedure time with increasing experience, with a maximum effect within 15 procedures. In contrast, successful placement, pain scores and complication rates showed no significant change with increasing experience. This indicates that the hysteroscopic sterilisation method can be performed safely and efficiently by an experienced hysteroscopist, and successful practice can start immediately. According to this study, it seems unlikely that simulation training for experts would have any clinically relevant effect on important outcome parameters. It is therefore not recommended for experienced hysteroscopists.

SUGGESTIONS FOR THE HYSTEROSCOPIC TRAINING CURRICULUM IN THE NETHERLANDS

Considering the results of the studies presented in this thesis, it is too early to implement a hysteroscopic box trainer or virtual reality simulator in the current residency training program in the Netherlands. When further validation research as described above would show beneficial results, the HYSTT box trainer could be used in both local training hospitals and in a national course for basic skills training. The HystSim™, if further validated and indicated cost-effective, could play an important role in procedural training of both basic and advanced hysteroscopies. It could be rotated among sharing training hospitals and regions, and be incorporated in basic and advanced courses.

In the Netherlands, the only mandatory skills training course for hysteroscopy is the Cobra-alpha course[21]. Single attendance at this basic course is obligatory during postgraduate year 1 or 2. The models that are currently being used consist of a pig bladder and paprika model, which have never been subject of any validity research at all. It is important to incorporate validated training models into a training course or facility, to ensure the efficacy of training[22]. The HYSTT box trainer could offer a simple and validated alternative to these organic simulators. Also, since distributed (repetitive) training in comparison to massed training leads to improved skills acquisition[23], we could ask ourselves whether this Cobra-alpha course is efficient for enhancing practical hysteroscopic skills. No data are available to address this question. Advancements in the field of laparoscopy and urology may help us with the design of a structured and efficient training program.

For simulation training in laparoscopic surgery, an immense number of studies has been published since its introduction more than a decade ago. Additionally, simulators are increasingly implemented in laparoscopic training curricula in developed countries. Unfortunately, the two environments of the abdominal and uterine cavity appear too distinct to train both laparoscopic and hysteroscopic skills on the same model, as is shown in our study. Even though there is no strong correlation between the training of both endoscopic procedures, we can learn from the results and insights gained in laparoscopic simulation.
Based on evidence for laparoscopy training, proficiency based curricula have proven to be maximally effective and efficient[1,24,25]. The amount of training time and number of practice trials will vary between trainees, but this brings them to the same level of skills mastery. Training courses are often provided as intensive 1- or 2-day programs on national or international level, such as the Cobra-alpha course, but distributed and continuous training leads to improved skills acquisition[23,26]. If clinical skills application is not possible shortly after a massed course, training simulators offer an alternative. Additionally, deliberate practice is essential and translates into better performance in laparoscopic education[27]. Deliberate practice involves repeated and focused training with immediate feedback on performance.

For the design and implementation of such a structured and proficiency based simulation program, we can also look at the Dutch Training in Urology curriculum[28]. Monthly training for one hour at the local training hospital is mandatory for every resident. Eight modules need to be practiced, including cystoscopic skills training at a box trainer. Other modules incorporate laparoscopic, ultrasound and electrosurgical equipment training. The box trainers that are used have been validated[29,30]. It provides all educators and residents a scheme for local and uniform training of endoscopic procedures. The first phase of implementation is successful; research is ongoing. This curriculum might provide an excellent example for the gynaecological residency program to incorporate both laparoscopic, hysteroscopic and electrosurgical equipment training into a national curriculum for local, uniform and repetitive training alongside the only mandatory, but massed Cobra-alpha course.

Even though training models are emerging to practice hysteroscopic skills in a patient-free environment, the traditional (or additional) method of mentored training during real-time procedures will continue to be a very important manner of skills acquisition. Also, simulation cannot stand by itself as a training tool for gynaecologists[31]. Critically important components include cognitive development, anatomy and physiology knowledge, device and system training and team collaboration. Therefore, future hysteroscopic training curricula should not only include a structured and proficiency based simulation program to overcome the first parts of a trainee's learning curve, but such a curriculum should always consist of a well-thought and structured clinical program as well, to ensure regular exposure supervised by trainers who consistently evaluate knowledge and procedures.

CONCLUSIONS

In this thesis we have shown that the opinion on hysteroscopy training in the Dutch residency curriculum is satisfactory, but that room for improvement is indicated for simulation training. We investigated the first steps of validation of a new box trainer and virtual reality simulator for hysteroscopy successfully. Furthermore, we have shown that it is unlikely that simulation training for experts would have any clinically relevant effect. We have provided recommendations for a future hysteroscopic training curriculum in the Netherlands. More research is needed to determine the role of hysteroscopic simulators in practice and whether simulation training has a positive and clinically important effect on the real-time performance.

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CHAPTER 9

SUMMARY
NEDERLANDSE SAMENVATTING

SUMMARY

CHAPTER 1

The introduction of this thesis describes the endoscopic skills that are needed for the performance of hysteroscopic surgery and the reasoning to train these hysteroscopic skills and procedures in an environment not involving the patient. This chapter is based on a narrative review and a description of the limited number of available training models for hysteroscopy is given. Validity defines whether a simulator is actually teaching or evaluating what is intended to be taught or measured. Validity research is an important step between the development and the use of a training model. However, the majority of the available models lack validation. Advancements are made in the development of hysteroscopic training models and further research needs to be carried out to assess the progress in training and to determine the effectiveness and quality of modern simulators in hysteroscopy.
The aim of this thesis is to investigate the current opinion in the Netherlands on hysteroscopy training in the residency curriculum, to assess the validity of a new box trainer and virtual reality simulator, and to investigate the learning curves of simulated and clinical hysteroscopic procedures.

CHAPTER 2

In this chapter, we describe the current opinion in the Netherlands on the value of hysteroscopy training during gynaecological residency. A survey was sent to postgraduate year 5 and 6 residents and to gynaecologists who finished their residency within the previous 5 years. Response rate was 66% of the residents and 73% of the gynaecologists. This survey could be compared to a previous study in 2003. The main findings showed that the implementation of hysteroscopic procedures taught during residency in the Netherlands has improved since 2003. Training is judged as sufficient for basic procedures by both senior residents and young gynaecologists. Moreover, the skills of surgical educators have progressed towards a level by which the majority of these gynaecologists feel competent to teach and supervise advanced hysteroscopic procedures. On the other hand, room for improvement was also indicated. Gynaecologists pointed at simulation training as the most important factor during residency that could be enhanced for optimal acquirement of hysteroscopic skills.

CHAPTER 3

Camera navigation is often perceived to be an easy task, but it is far from an innate ability, especially when an angled optic is used. This chapter presents the results from a prospective study in which a new box trainer for hysteroscopic 30° camera navigation training is investigated: the Hysteroscopic Skills Training and Testing (HYSTT) model, developed under auspices of the European Academy of Gynaecological Surgery (Leuven, Belgium). Thirty novices (medical students) and 10 experts (gynaecologists who perform diagnostic hysteroscopies on a weekly base) conducted a series of exercises. The learning curve for novices could be clearly visualised in comparison to the stable performance of the experts on the parameter procedure time ($p < .05$, effect size (ES) 0.44-0.71). A second training session provided further improvement of the assessed parameters ($p < .05$). Also, differences between the performance levels of both groups gave an indication of construct validity. Concerning face validity, experts awarded the HYSTT high scores for training camera skills and for the applicability in residency training.

CHAPTER 4

Even though endoscopy comprises different types of procedures (e.g. laparoscopy and hysteroscopy), they all require mastering of adequate camera navigation skills with a 30° optic. One could question whether a correlation exists between the training of camera navigation skills with a 30° optic in hysteroscopy and laparoscopy, even though the environments of the abdominal and uterine cavity are different. If this correlation exists, it implies that obtaining 30° camera navigation skills in hysteroscopy also indicates the built up of a certain level of expertise in laparoscopic camera handling, and possibly that training models could be unified.

Chapter 4 showed that, regardless of training on a hysteroscopic (HYSTT) or laparoscopic (LASTT) box trainer model, 30° optic skills are easily learned when a standardised explanation and specific exercises for camera navigation are provided. Previous training on the HYSTT model offered some advantage for medical students when practising on the LASTT model, compared to no previous training. However, training of camera navigation skills in a hysteroscopic environment did not seem supportive for obtaining the same level of camera expertise in laparoscopy. The two environments appeared too distinct to train both procedures on one model. Therefore, according to this study 30° camera navigation in hysteroscopy and laparoscopy should be trained separately to reach adequate levels of expertise for each procedure.

CHAPTER 5

In this chapter, a new procedural training module for hysteroscopic sterilisation on a virtual reality simulator (EssureSim™) was evaluated for face and construct validity. Participants consisted of 69 residents and gynaecologists, who were divided into 3 groups according to their prior hysteroscopic and Essure® experience. Every participant completed two cases on the simulator. Analysis of the questionnaire showed excellent realism of the procedure and the simulator was indicated as a useful preparation for the real-time procedure (face validity). The simulator derived parameters showed moderate results regarding construct validity. Procedure time and path length were able to differentiate significantly between experience levels, but the other four parameters did not show this capacity persistently.

CHAPTER 6

Besides simulator derived parameters, a clinical parameter like a global rating scale

(GRS) can also contain relevant information about the performance of a simulator. In this chapter, the GRS was applied during assessment of the EssureSim™ as well. The learning curve of 30 novices (medical students) and 5 experts (gynaecologists who performed > 150 Essure® sterilisations) was established during a series of exercises on the simulator. Significant improvements were found in novice performance for all parameters; the GRS showed the largest advancements ($p < .001$, ES 0.96). The ability of the simulator derived parameters to differentiate between both groups varied widely. The GRS differentiated most explicitly between experts and novices. This could endorse construct validity, since the differences in expertise are recognised during the simulated procedure as they are during the real-time procedure.

CHAPTER 7

While a simulator is designed for gradual improvement of novices skills, one could expect from experts a steady performance during real-time procedures. But when a hysteroscopic expert is taught a new type of operative hysteroscopy, does he or she start with a safe and steady performance immediately? Despite several studies concerning the efficacy of the hysteroscopic sterilisation method by Essure®, only very limited research had been published regarding the learning curve of experts. Our prospective multicentre study assessed in a unique manner the learning curve of 15 Dutch gynaecologists, who started performing the Essure® technique from the very first placement. A standardised introduction was provided and a proctor attended the first procedures of each gynaecologist. Our study demonstrated a significant decrease in procedure time with increasing experience, with a maximum effect within 15 procedures. In contrast, successful placement, pain scores and complication rates showed no significant change with increasing experience. This indicates that the hysteroscopic sterilisation method can be performed safely and efficiently by an experienced hysteroscopist, and successful practice can start immediately.

CHAPTER 8

In the final chapter of this thesis, the general discussion and recommendations for further research are reported. It seems illogical and unethical to let novices train hysteroscopic skills from the start with involvement of patients, when there are models and manners to simulate the procedure and tasks outside the patient setting. Research should focus on the role of hysteroscopic simulators in practice and whether simulation training has a positive and clinically important effect on the real-time performance.
Additionally, suggestions for the hysteroscopic training curriculum in the Netherlands are given. In this country, the only mandatory skills training course for hysteroscopy uses a pig bladder and paprika model. These organic models have never been subject of any validity research at all. Considering the results of the studies presented in this thesis, it is too early to implement a hysteroscopic box trainer or virtual reality simulator in the current residency training program in the Netherlands. When further validation research confirms favour-

able results, the HYSTT box trainer could be used in both local training hospitals and in a national course for basic skills training of novices. The HystSim™ could play a role in procedural training of both basic and advanced hysteroscopies, if further validated and ideally indicated to be cost-effective.
Simulators should be implemented into a structured and proficiency based curriculum. We can learn from the results and insights gained in laparoscopic simulation research. Moreover, the Dutch Training in Urology curriculum might provide an excellent example for the gynaecological residency program to incorporate both laparoscopic, hysteroscopic and electrosurgical equipment training into a national curriculum for local, uniform and repetitive training.

NEDERLANDSE SAMENVATTING

HOOFDSTUK 1

In de inleiding van dit proefschrift worden de endoscopische vaardigheden beschreven die nodig zijn voor de uitvoering van hysteroscopische chirurgie en de motivatie om deze hysteroscopische vaardigheden en procedures te trainen in een setting waarbij de patiënt niet aanwezig is en geen schade op kan lopen. Dit hoofdstuk is gebaseerd op een overzichtsartikel en gaat in op de beschikbare trainingsmodellen voor hysteroscopie. Het aantal beschikbare modellen is echter zeer beperkt. De validiteit van een model bepaalt in hoeverre een trainee daadwerkelijk datgene aanleert of evalueert waarvoor de simulator bedoeld is. Onderzoek naar validiteit is een belangrijke stap tussen de ontwikkeling en de eventuele ingebruikname van een trainingsmodel. Toch zijn niet veel van de hysteroscopische trainingsmodellen onderzocht op validiteit. Momenteel wordt vooruitgang geboekt in de ontwikkeling van hysteroscopische trainingsmodellen en er is onderzoek nodig om de validiteit en effectiviteit van moderne simulatoren binnen de hysteroscopische chirurgie te bepalen.

Het doel van dit proefschrift is drieledig. Ten eerste is getracht inzicht te geven in de huidige opinie in Nederland over hysteroscopie training tijdens de opleiding tot gynaecoloog. Daarnaast richt het onderzoek zich op de validiteitbepaling van een nieuwe box trainer en virtual reality simulator voor hysteroscopie training. Tot slot zijn de leercurves van gesimuleerde en klinische hysteroscopische procedures onderzocht.

HOOFDSTUK 2

In dit hoofdstuk beschrijven we de huidige mening in Nederland betreffende de waarde van hysteroscopie training tijdens de opleiding tot gynaecoloog. Er werd een enquête gestuurd aan vijfde- en zesdejaars artsen in opleiding tot gynaecoloog (AIOS) en aan gynaecologen die in de afgelopen vijf jaar hun opleiding hadden afgerond (jonge klaren). Van de AIOS vulde 66% de vragenlijst in, voor de jonge klaren lag dit percentage op 73%. Deze enquête kon worden vergeleken met een studie uit 2003. De belangrijkste resultaten toonden aan dat de implementatie van hysteroscopische ingrepen die werden onderwezen tijdens de opleiding verbeterd is in Nederland sinds 2003. De training van basis ingrepen werd beoordeeld als adequaat, zowel door de AIOS als door de jonge klaren. Daarnaast zijn de vaardigheden van de gynaecologen verbeterd tot het niveau waarop de meerderheid van deze jonge klaren zich competent voelt om gevorderde hysteroscopische procedures te onderwijzen en te superviseren. Tegelijkertijd werd in de enquête ook op ruimte voor verbetering gewezen. Gynaecologen gaven aan dat simulatietraining de meest belangrijke factor tijdens de opleiding is die verbeterd kan worden ten behoeve van optimale vorming van hysteroscopische vaardigheden.

HOOFDSTUK 3

Cameranavigatie wordt vaak gezien als een makkelijke taak, maar het is verre van een aangeboren bekwaamheid, vooral wanneer een optiek met een hoek wordt gebruikt. Dit hoofdstuk toont de resultaten van een prospectief onderzoek waarin een nieuwe box trainer voor hysteroscopische cameranavigatie-training met een 30° optiek werd onderzocht: te weten het Hysteroscopic Skills Training and Testing (HYSTT) model, ontwikkeld onder auspiciën van de European Academy of Gynaecological Surgery (Leuven, België). De beginnergroep bestond uit dertig medisch studenten, de expert groep betrof tien gynaecologen die diagnostische hysteroscopieën wekelijks uitvoeren. Beide groepen voerden een serie oefeningen uit op het model. De leercurve van de beginners kon duidelijk worden gevisualiseerd ($p < .05$, effect size (ES) 0.44), in vergelijking met de constante prestatie van de experts voor de uitkomstparameter tijd. Een tweede trainingssessie gaf een verdere verbetering van de gemeten parameters ($p < .05$). Daarnaast gaven de verschillen tussen de prestatieniveaus van beide groepen een indicatie van de construct-validiteit. Met betrekking tot de face-validiteit kenden de experts de hoogste scores toe aan het HYSTT model wat betreft het trainen van cameravaardigheden en de toepasbaarheid in de opleiding tot gynaecoloog.

HOOFDSTUK 4

Hoewel de endoscopische chirurgie verschillende typen procedures beslaat (bijvoorbeeld laparoscopie en hysteroscopie), vereisen zij allemaal de beheersing van goede cameranavigatie-vaardigheden met een 30° optiek. Men kan zich dan ook afvragen of er een correlatie bestaat tussen de training van cameranavigatie-vaardigheden bij laparoscopie en hysteroscopie, ondanks dat de omgeving van de buikholte en de baarmoederholte van elkaar verschillen. Indien een dergelijke correlatie bestaat, impliceert dit dat het verwerven van cameranavigatie-vaardigheden met een 30° optiek voor de hysteroscopie ook een toename van expertise in de laparoscopische 30° cameranavigatie betekent. In dat geval zouden trainingsmodellen mogelijkerwijs kunnen worden samengevoegd.

Hoofdstuk 4 laat zien dat 30° cameranavigatie-vaardigheden makkelijk kunnen worden aangeleerd wanneer een gestandaardiseerde uitleg en specifieke oefeningen voor cameranavigatie worden gegeven, onafhankelijk van het type model (hysteroscopie – HYSTT, laparoscopie – LASTT) waarop getraind wordt. Eerdere training op het HYSTT model biedt enige voorsprong aan medisch studenten voor training op het LASTT model, wanneer vergeleken wordt met geen eerdere training. Echter, training van cameranavigatie-vaardigheden in een hysteroscopische omgeving bleek niet garant te staan voor het hetzelfde expertiseniveau op een laparoscopisch model. De twee omgevingen schenen te verschillend om beide procedures en vaardigheden op één model te trainen.

HOOFDSTUK 5

Dit hoofdstuk gaat in op de face- en construct-validiteit van een nieuwe procedurele trainingsmodule (EssureSim™) voor de hysteroscopische sterilisatie techniek op een virtual reality simulator. De groep deelnemers bestond uit 69 gynaecologen en gynaecologen in opleiding. Zij werden in drie kleinere groepen verdeeld, aan de hand van hun eerdere hysteroscopie- en Essure®-ervaring. Elke deelnemer voerde twee oefeningen op de simulator uit. Analyse van de enquête gaf aan dat het realisme van de procedure als uitstekend werd beoordeeld (face-validiteit). Tevens waren de deelnemers van mening dat de simulator een bruikbare voorbereiding gaf voor de uitvoering van de procedure op de patiënt. De parameters afkomstig van de simulator toonden een matig resultaat aan wat betreft de construct-validiteit. Proceduretijd en padlengte bleken in staat om in significante mate te differentiëren tussen de expertiseniveaus, maar de overige vier parameters hadden in deze studie niet dit onderscheidend vermogen.

HOOFDSTUK 6

Naast parameters afkomstig van de simulator kan ook een klinische parameter, zoals de Global Rating Scale (GRS), relevante informatie bevatten over de prestatie van een simulator. In hoofdstuk 6 pasten we de GRS toe tijdens een onderzoek naar de EssureSim™. De leercurves van dertig beginners (medisch studenten) en vijf experts (gynaecologen die >150 Essure®-sterilisaties hebben uitgevoerd) werden bepaald tijdens een serie oefeningen op de simulator. Voor alle parameters werden significante verbeteringen gevonden in de beginnergroep, waarbij de GRS de grootste vooruitgang toonde ($p < .001$, ES 0.96). Het vermogen van de parameters afkomstig van de simulator om te differentiëren tussen beide groepen varieerde echter sterk. De GRS kon het meest expliciet onderscheid maken tussen de beginners en de experts. Deze bevinding kan de eerder gevonden construct-validiteit bevestigen, aangezien de expertiseverschillen tijdens de gesimuleerde ingreep worden herkend zoals tijdens de daadwerkelijke ingreep.

HOOFDSTUK 7

Terwijl een simulator is ontwikkeld voor geleidelijke verbetering van de vaardigheden van beginners, mag men van een expert een constante prestatie verwachten tijdens ingrepen uitgevoerd op de patiënt. Dit roept de vraag op of een hysteroscopie-expert die een nieuw type hysteroscopische chirurgie krijgt aangeleerd, direct start met een veilige en constante uitvoering.

Ondanks het feit dat er verscheidene studies zijn uitgevoerd naar de werkzaamheid van de hysteroscopische sterilisatiemethode volgens Essure®, is er slechts een klein aantal onderzoeken gepubliceerd over de leercurve van experts. De prospectieve multicentrische studie, beschreven in hoofdstuk 7, onderzocht op een unieke en adequate manier de leercurve van vijftien Nederlandse gynaecologen, die voor het eerst begonnen met de uitvoering van de Essure®-techniek. De deelnemende gynaecologen kregen een gestandaardiseerde introductie en een supervisor was aanwezig tijdens de eerste ingrepen van elke gynaecoloog. Onze studie toont een significante vermindering in proceduretijd aan tijdens het opdoen van ervaring, met een maximaal effect binnen vijftien ingrepen. Daarentegen werd er geen significante verandering gezien voor de uitkomstmaten ‘succesvolle plaatsing’, ‘pijnscore’ en ‘aantal complicaties’. Dit geeft aan dat de hysteroscopische sterilisatiemethode volgens Essure® vanaf het begin veilig en succesvol kan worden uitgevoerd door een ervaren hysteroscopist.

HOOFDSTUK 8

In het laatste hoofdstuk van dit proefschrift komen de algemene discussie en aanbevelingen voor toekomstig onderzoek aan bod. Het lijkt onlogisch en onethisch om artsen zonder ervaring in de hysteroscopie hun hysteroscopische vaardigheden vanaf het begin te laten trainen op patiënten indien er modellen en manieren voor handen zijn om dergelijke ingrepen te simuleren/trainen in een situatie waarbij géén patiënt betrokken is. Onderzoek zou zich nog meer moeten richten op de rol van hysteroscopische simulatoren in de praktijk en op de vraag of simulatietraining een positief en klinisch belangrijk effect heeft op de uitvoering op de patiënt.

Daarnaast worden in dit hoofdstuk suggesties gedaan voor het huidige hysteroscopische trainingscurriculum in Nederland. De enige verplichte cursus voor hysteroscopische vaardigheidstraining in dit land gebruikt varkensblazen en paprika's als trainingsmodel. De validiteit van deze organische modellen is nooit onderzocht. Gezien de resultaten die beschreven zijn in dit proefschrift, is het op dit moment te vroeg om een hysteroscopische box trainer of virtual reality simulator te implementeren in het huidige opleidingsprogramma voor de gynaecologie. Wanneer toekomstig validatieonderzoek positieve resultaten bevestigt, kan de HYSTT box trainer zowel gebruikt worden voor training in lokale opleidingsziekenhuizen als voor een landelijke trainingscursus van basisvaardigheden voor beginners. The HystSim™ zou een rol kunnen spelen in de procedurele training van zowel basale als gevorderde hysteroscopische procedures, wanneer deze virtual reality simulator verder gevalideerd zou worden en –idealiter– ook kosteneffectief blijkt. Simulatoren moeten worden geïmplementeerd in een curriculum dat gestructureerd is opgezet en specifieke bekwaamheden als eindpunt heeft. Hiervoor kunnen we leren van de resultaten en inzichten die zijn verkregen uit onderzoek naar simulatietraining voor de laparoscopische chirurgie. Daarnaast kan het Nederlandse curriculum "Training in Urology" ons als voorbeeld dienen voor het opzetten van een breed, landelijk programma. Hierbij zou op lokaal niveau op een uniforme en frequente wijze kunnen worden getraind op het gebied van laparoscopische en hysteroscopische vaardigheden en op de omgang met elektrochirurgische apparatuur.

ADDENDUM

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CURRICULUM VITAE

Joline Ariënne (Juliënne) Janse, born on August 31, 1985 in Katwijk (Zuid-Holland) and grown up in Leiden and Oegstgeest, attended the "Stedelijk Gymnasium" in Leiden, from which she graduated cum laude in 2003. Subsequently, she entered medical school at Utrecht University. Obstetrics and Gynaecology caught her special interest during the corresponding internship in Queen Elizabeth Central Hospital in Blantyre, Malawi. Her scientific career started at the Department of Obstetrics and Gynaecology of University Medical Centre Utrecht, under supervision of Dr. H.W.R. Schreuder, with research on cervical carcinoma during pregnancy. After a six-month stay in South-America in 2009, including an internship in Social Medicine in mountain village Quiquijana in Peru, Juliënne returned to Utrecht to finish her last year of medical school.

Her enthusiasm for Obstetrics and Gynaecology was endorsed during her final internship in Tergooi hospital, Blaricum (supervisor H. Visser). After having participated in research on a laparoscopic training model (guided by Dr. H.W.R. Schreuder) and having obtained her medical degree in April 2010, she started her PhD project on hysteroscopy training under supervision of Prof. F.J.M. Broekmans, Dr. H.W.R. Schreuder, and Dr. S. Veersema. Simultaneously, Juliënne worked as a resident (not in training) in St. Antonius hospital in Nieuwegein for three years under supervision of Dr. J.H. Schagen van Leeuwen. She started her official residency in Nieuwegein in November 2013.

Juliënne is engaged to Coen Hendrix. They live happily together in Utrecht.