

Simulation based training for hernia mesh repair for novice learners in Sweden – a randomized trial

Version 5, November 1, 2023

Title page

Title of study: Simulation based training for hernia mesh repair for novice learners in Sweden – a randomized trial

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Abstract

Background

Groin hernia is a common surgical condition. Groin hernia repair is the most commonly performed general surgical procedure in Sweden and globally.

Methods

In this randomized trial, 40 medical students will be randomized into a control group or an intervention group. First, they will all receive a theoretical module on hernia anatomy and surgical technique. They will have access to video material on anterior groin hernia mesh repair. Thereafter, the intervention group will receive practical simulation-based training under supervision and the control group will receive practical simulation-based training without supervision. Both groups will be assessed for hernia repair skill on the model using a standardised operative performance rating system (OPRS). Randomization and allocation to the trial group will be carried out using a central computerised program. The primary endpoint is the mean result of the practical assessment in each group. Secondary outcome measures are trainee satisfaction.

Objective of the study

The objective of the study is to develop and assess a standardised simulation-based training program for novice surgical trainees.

Background

Over 200 million people live with a groin hernia worldwide and if left untreated, this condition causes considerable pain and also leads to 40,000 deaths per year (1). With 20 million operations annually, groin hernia repair is the commonest general surgical procedure performed. In Sweden around 16,000 groin hernia operations are performed each year (2). Currently, residents in general surgery in Sweden participate in a hernia surgery course. They learn how to perform the procedure through supervised surgeries together with senior colleagues.

Optimizing the learning experience and the learning outcome of each surgical procedure that trainee surgeons perform is a goal in surgical training. In the past decades there has been an increase in interest in simulation-based training. With evidence that simulation training compared to no intervention increases knowledge, skills and behaviors (3). Simulation training is an integral part of the education of surgeons in the United States and other high-income countries. The ability to teach surgical skills in a safe environment and as part of a structured program has shown positive transfer of skills to the operating room and mastery of procedural skills in a simulated setting brings several advantages in both educational efficiency and patient safety (4)(5). In the present study, we will investigate the effectiveness of a newly developed simulation-based training program for open hernia repair. Medical students and intern doctors, representing novice learners in surgery, will participate in the study.

Transfer of skills from simulation to the operating room or direct patient care is the impetus for simulation-based learning. Indeed, the transfer of surgical skills from simulation to assessments performed in the same environments has been proven for laparoscopic (6–8) and open skills (9,10). Studies that have looked closely at simulation training's effect on operative performance, have demonstrated that simulation improves operative time and performance among residents (11–13). A smaller number of studies (13) have connected simulation training to clinically-relevant patient outcomes, the ultimate goal of such training. Model-based training is an important adjunct to surgical simulation as it permits practice of skills prior to use in real life settings. Studies have demonstrated that models used in simulation can create a “warm up” (13) effect of simulation, which has the potential to accelerate learning and transference. To extend training opportunities, a model-based approach would allow for additional practice prior to and outside the operating room.

Research question

1. Is there a difference in the ability to perform an open groin hernia repair, step-by-step, for students who have received simulation based training under supervision compared to students who have not received supervision?

Objectives and aims of the study

The general objective of this study is to evaluate the feasibility of model based simulation for open groin hernia repair for novice learners in surgery.

The specific aims are to

- a) Compare the learning outcomes regarding the ability to carry out an anterior groin hernia mesh repair on a 3D model for learners who participate in simulation-based training under supervision versus those who practice in simulation-based training without supervision.
- b) Assess the student's perception of the respective training methods.

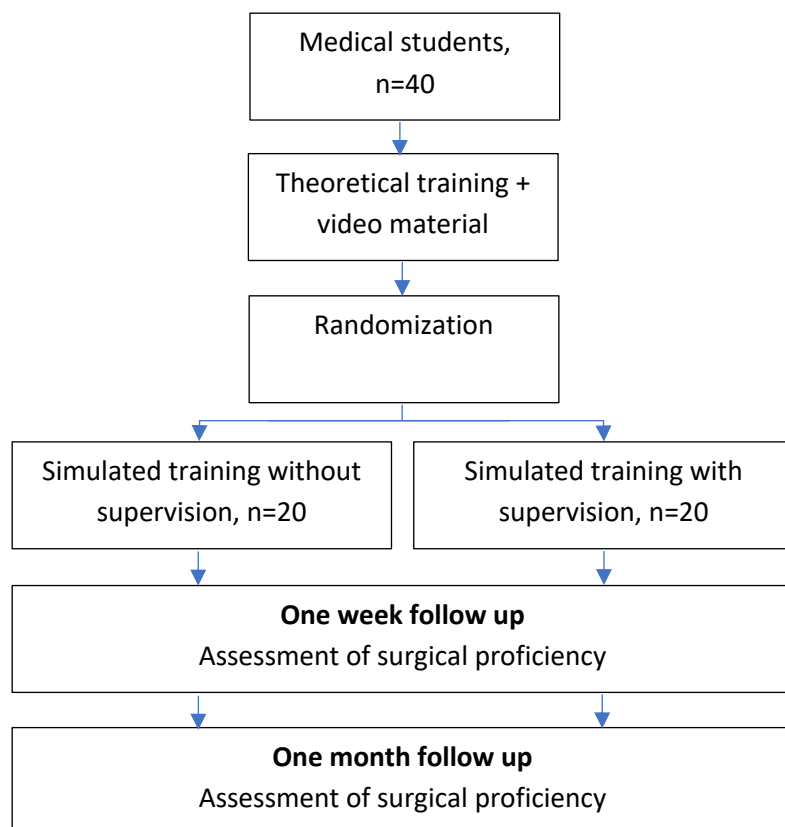
Hypothesis

Simulation based training under supervision will improve the ability to perform an open groin hernia mesh repair on the 3D model.

Method and materials

Study design: This is an un-blinded, randomized trial. The allocation ratio is 1:1.

Figure 1. CONSORT flow chart



a. **Control group**

The trainees in the control group will receive theoretical and audio-visual material. They will have access to the OPRS. They will be introduced to the 3-D model and be given time to practice on the model without supervision.

b. **Intervention group**

The trainees will receive theoretical and video material. Thereafter, they will participate in simulation-based training. They will be assessed for proficiency using the 3-D model and the OPRS, by an MD in the research team.

Training intervention

All trainees will receive theoretical lectures in person delivered as a half-day workshop. The trainees will have access to E-based material for tablet/smartphone including anatomy and video material on mesh IH repair from the week before the training. After the theoretical lectures, the trainees will be randomized to the control group or the intervention group.

The model-based training will be used to teach both anatomy and the anterior mesh repair under local anaesthesia. This curriculum will be competency-based/mastery learning (14). The trainees will perform surgeries on the models following an e-based instruction video, with support from a trainer on site. They will have access to the OPRS. When the trainees think they are ready, they will be examined on performing an open anterior groin hernia repair on the model. Proficiency will be set using a panel of experts in mesh inguinal hernia repair, the experts will be blinded to the allocation arms (15). Blinding will be assured by video recordings of the examination procedures and the experts filling in the OPRS will not have partaken in the training sessions. The trainees will also be evaluated on their ability to perform anatomical structures, this will be achieved by using a checklist at the examination (appendix 4), the examiner filling in the checklist will not be blinded to the allocation arms.

The training material:

Hernia model

The model for use in the study is a multi-use high-fidelity 3-D printed scaffold with low-fidelity reloadable materials. The model has been designed to reflect the necessary anatomical structures for performing open IH repair with mesh.

Video/E-learning materials:

Video materials will be provided that include patient and model examples of open mesh IH repair.

Surgical technique

The surgical technique is the open anterior mesh inguinal hernia repair according to Lichtenstein under local anaesthesia (16)(17).

Follow up

One month after the training intervention, the retention of the anatomical knowledge and ability to perform a mesh repair on a model will be assessed.

Study setting

The study will be carried out at Karolinska University Hospital, Solna.

Inclusion criteria:

- Medical student or intern doctor at Karolinska Institutet
- Interest in surgery
- Willingness to participate in the study

Exclusion criteria:

- Having been the main operator on one or more groin hernia repairs.
- Having been the primary assistant on three or more groin hernia repairs.

Sample size calculation

The hypothesis is that the students who participate in the simulation-based training under supervision will be able to perform a mesh hernia repair, correctly and step-by-step, on the model, one month after the training intervention. The sample size has been calculated based on the following assumption:

Alpha = 5%

Power = 80%

Expected mean score on the OPRS in the intervention group = 4

Expected mean score on the OPRS in the control group = 3

A score of 4 or more on the OPRS is considered a passing grade.

This assumptions, in a binary superiority trial, requires a total sample size of 32 participants in total. An additional 8 participants are added to account for potential drop outs.

8.10 Study outcomes

Primary outcome: ability to score 4 or higher on the OPRS, one month after the training intervention.

Secondary outcomes: Ability to name anatomical structures important for inguinal hernia repair. (appendix 4). Students rating of the hernia training modules (Appendix 5).

Randomization method

The trainees will be randomized at inclusion into the study. A computer-based program will be used to generate the sequence of randomization in blocks of four, six and eight. The allocation ratio between the study arms will be 1:1.

Recruitment

The students will primarily be recruited from course participants in the elective course on global surgery, for medical students at Karolinska Institutet. If needed, additional students will be recruited.

Data collection tools

The tools consist of participant information, consent forms, contact information, and the OPRS (see appendix 1-3). Answers will be coded.

Data management and analysis

The data will be managed by observing strict collection protocols, entry, cleaning and analysis. The data will be stored securely in both hard and soft copies.

Data entry and cleaning

The Principal Investigator together with the co-investigators are responsible for the data entry and cleaning of the data. They may delegate some tasks to research assistants. Data will be entered into excel spread sheets.

Analysis plan and dissemination plan

Data analysis will be performed using primarily Excel and SPSS. Counts will be presented as numbers and per cent and comparison of binary values will be done using chi square test, Fischer exact test or an exact binomial test as appropriate. Continuous data will be presented as mean and standard deviation and analysis will be done using students t-test. Absolute difference between the study groups for the primary and secondary endpoints will be calculated and presented with 95% confidence intervals. A p-value of 0.05 is considered statistically significant.

The PI is responsible for the quality control. The findings of the study will be disseminated through presentations in local and international conferences as well as publications in peer reviewed journals.

Ethical considerations

Ethical clearance was applied for from the Swedish Ethical Review Authority and it was concluded that no ethical approval was required for this study.

Confidentiality is assured for the study participants. Questionnaires will be stored at Karolinska Institutet. De-identification of data will be done at data entry. No one part from the research team will be involved in the management of the data.

No patients are involved in this study and the risk of physical and psychological harm to the study participants is minimal.

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APPENDICES

In the following pages, the consent forms, the data collection tools as well as the information and training materials are outlined.

Consent forms

Appendix 1. Written informed consent for trainees

Appendix 2. Basic trainee information

Data collection forms for trainees

Appendix 3 – Operative performance rating system

Appendix 4 – Examination checklist for structures

Appendix 5 – Training experience forms

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Appendix 1. Written informed consent for trainees

Information till forskningspersonerna

Vi vill fråga dig om du vill delta i ett forskningsprojekt. I det här dokumentet får du information om projektet och om vad det innebär att delta.

Vad är det för projekt och varför vill ni att jag ska delta?

Ljumsckbråck är ett vanligt tillstånd över hela världen. Bland män var prevalensen nästan 10% i en tidigare studie utförd i Iganga, Uganda. Operationsmetoden som vanligtvis används för att behandla ljumsckbråck hos män använder sig av ett nät för att förstärka bukväggen och minska risken för återfall. ST-läkare inom kirurgi i Sverige lär sig detta förfarande under sina första utbildningsår. I denna studie kommer vi att utbilda 40 läkarstudenter hur man utför ljumsckbråcksoperation med nät under lokalbedövning med hjälp av en 3D-modell. Vi har utvecklat två olika utbildningsprogram, båda med hjälp av en 3D-modell, ett program utförs under handledning och ett genomförs utan handledning. Vi kommer att jämföra vilken metod som ger bättre resultat vad gäller kirurgisk teknik. De forskningspersoner som erbjuds vara med i studien har begränsad kirurgisk erfarenhet vilket är en förutsättning för studien, därför önskar vi erbjuda dig att delta i projektet. Vi har fått tillgång till dina kontaktuppgifter genom deltagarlistan för kursen global kirurgi.

Forskningshuvudman för projektet är Karolinska institutet. Med forskningshuvudman menas den organisation som är ansvarig för studien.

Hur går studien till?

I denna studie kommer ca 40 läkarstudenter och AT-läkare vid Karolinska Institutet att rekryteras. De kommer att delta i ett av de två olika utbildningsprogrammen. Program 1 innehåller teori och en introduktion till 3D-modellen följt av ej handledd träning på 3D-modellen. Program 2 innehåller teori och en introduktion till 3D-modellen följt av handledd utbildning om 3D-modellen. Modulerna i utbildningen är:

- 1) **Teori:** Teoretiska föreläsningar och tillgång till videomaterial.
- 2) **Simuleringsbaserad träning:** Deltagande i simuleringsträning på en ljumsckbråcksmodell som studieteamet har utvecklat. Under denna träning kommer du att träna anatomi och lära dig stegen i öppen nätplastik för ljumsckbråck på modellen. Efter denna introduktion fortsätter du antingen att träna på 3D-modellen på egen hand eller under handledning av en av läkarna i studieteamet.

Om du accepterar att delta kommer du att slumpmässigt tilldelas grupp 1 eller grupp 2. Träningen tar cirka fem dagar för båda grupperna. Examination följer ett protokoll för utvärdering av kirurgisk teknik. Detta kommer att testa hur väl du har behållit den förvärvade färdigheten.

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Möjliga följder och risker med att delta i studien

Potentiella fördelar med denna studie: Du kommer att lära dig en färdighet som få läkarstuderenter i Sverige får möjlighet att lära sig. Du kommer att instrueras och övervakas av kirurger för att du ska kunna maximera inlärningsresultatet. Du kommer att delta i utbildningsprogrammet utan kostnad.

Om utbildningsprogrammen är effektiva kommer vi att arbeta med att implementera dem i större skala i Sverige och internationellt. Således kan läkarstuderenter och läkare också dra nytta av resultaten av denna studie.

Potentiell skada från denna studie: Dina färdigheter och kompetensutveckling kommer att bedömas kontinuerligt. Detta kan göra att du känner dig pressad eller orolig. Vi kommer att behandla dig med respekt och kommer att ge konstruktiv feedback för att förbättra ditt lärande. Denna återkoppling ges individuellt.

Vad händer med mina uppgifter?

Projektet kommer att samla in och registrera information om dig.

Informationen du ger oss kommer att bevaras på ett säkert sätt så att ingen förutom utredarna har tillgång till den. All data kommer att avidentifieras så att ditt namn inte kommer att visas i analysen eller några resulterande publikationer. Om du har några frågor om studien, fråga Olof Bladin (olof.bladin@ki.se) eller Jenny Löfgren (jenny.lofgren@ki.se). Det är ditt beslut att delta i studien och du är fri att när som helst sluta delta i studien utan några konsekvenser eller straff.

Du kommer att tilldelas ett studienummer som är knutet till ditt namn och förvaras i en låst fil på en av Karolinska institutets servrar. Vi kommer inte be dig att dela med dig av ditt personnummer.

Ansvarig för dina personuppgifter är Karolinska institutet. Enligt EU:s dataskyddsförordning har du rätt att kostnadsfritt få ta del av de uppgifter om dig som hanteras i studien, och vid behov få eventuella fel rättade. Du kan också begära att uppgifter om dig raderas samt att behandlingen av dina personuppgifter begränsas. Om du vill ta del av uppgifterna ska du kontakta Olof Bladin eller Jenny Löfgren.

Hur får jag information om resultatet av studien?

Du kan begära att ta del av dina individuella data genom att kontakta Olof Bladin eller Jenny Löfgren. Studien kommer publiceras i en vetenskaplig tidskrift där du kommer kunna ta del av resultatet av hela studien.

Försäkring och ersättning

Inget försäkringsskydd utöver det som redan finns för läkarstuderenter under studier på KI finns. Ingen ekonomisk ersättning för förlorad arbetsinkomst finns.

Deltagandet är frivilligt

Ditt deltagande är frivilligt och du kan när som helst välja att avbryta deltagandet. Om du väljer att inte delta eller vill avbryta ditt deltagande behöver du inte uppge varför, och det kommer inte heller att påverka

din framtida vård eller behandling. Om du vill avbryta ditt deltagande ska du kontakta den ansvariga för studien (se nedan).

Trainee number

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Ansvariga för studien

Ansvarig för studien är Jenny Löfgren.

Samtycke till att delta i studien

Jag har fått muntlig och skriftlig informationen om studien och har haft möjlighet att ställa frågor. Jag får behålla den skriftliga informationen.

- ☐ Jag samtycker till att delta i studien Kirurgisk simulering av öppen ljumskbråckskirurgi- en utvärdering av användbarhet och användarupplevelse inom öppen kirurgisk simulering med en 3D modell
- ☐ Jag samtycker till att uppgifter om mig behandlas på det sätt som beskrivs i forskningspersonsinformation.

Namn för studiedeltagande

Signatur för studiedeltagande _____

Plats och datum _____

Namn för person som tar emot samtycke

Signatur för person som tar emot samtycke _____

Plats och datum _____

Trainee number

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Appendix 2. Basic trainee information

Filled in by _____

Date and place _____

A. Identification of trainee

1. Name: _____

2. Trainee study number _____

3. Age _____

4. Gender (Male/female/other/prefer not to specify) _____

5. Telephone number _____

6. Email adress _____

B. Previous surgical experience

1. Apart from being a student at the medical program, do you have any surgical experience? If yes, please specify

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Appendix 3. Operative performance rating system**Operative Performance Rating System (OPRS)****OPEN INGUINAL HERNIA MESH REPAIR****Evaluator:****Resident****Resident Level:****Program:****Date of Procedure:****Time Procedure Was Completed:****Date Assessment Was Completed:****Time Assessment Was Initiated:**

Please rate this resident's performance during this operative procedure. For most criteria, the caption above each checkbox provides descriptive anchors for 3 of the 5 points on the rating scale. **"NA" (not applicable) should only be selected when the resident did not perform that part of the procedure.**

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Case Difficulty

1	2	3	4	5
Straightforward anatomy, no related prior surgeries or treatment		Intermediate difficulty		Abnormal anatomy, extensive pathology, related prior surgeries or treatment (for example radiation), or obesity
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Degree of Prompting or Direction

Substantial Direction 1	2	Some Direction 3	4	Minimal Direction 5
Unable to direct team, use/choose instruments, or anticipate next steps as surgeon or as first assistant without constant attending prompting		Actively assists and anticipates own and attending's needs, performs basic steps with occasional attending direction to resident and/or surgical team. Somewhat hesitant and slow to anticipate or recognize aberrant anatomy, unexpected findings, and/or "slowing down" moments		Performs all steps and directs team with minimal direction from attending to either resident or team, i.e., anticipates needs, sets up exposure for self and assistant, transitions fluently between steps, gives clear direction to first assistant, maintains situation awareness, calmly recovers from error and recognizes when to seek help/advice
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please assess performance and indicate the degree of prompting for **each item**. The assessment score for each item **may differ** from the prompting score for that item.

[illegible][illegible][illegible][illegible]

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[illegible][illegible][illegible]

Poor 1	Fair 2	Good 3	Very Good 4	Excellent 5	NA
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[illegible][illegible][illegible]

Trainee number

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Overall Performance (not included in calculation of mean score)

Rating of very good or higher indicates technically proficient performance (i.e., resident is ready to perform operation independently, assuming resident consistently performs at this level)

Poor	Fair	Good	Very Good	Excellent
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please indicate the weaknesses in this resident's performance:

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Please indicate the strengths in this resident's performance:

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Appendix 4. Examination checklist for structures

Trainee number

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Number	Structure	Named correctly (check if identified)
1	Superficial inferior epigastric artery and vein	
2	External oblique aponeurosis	
3	Superficial inguinal ring	
4	Ilioinguinal nerve	
5	Iliohypogastric nerve	
6	Genital branch of Genitofemoral nerve	
7	Inguinal ligament	
8	Spermatic cord	
9	Vas deferens	
10	Hernia sac	
11	Conjoint tendon	
12	Transversalis fascia	

Name of examiner

Signature of examiner _____

Place and date _____

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Appendix 5. Training experience forms

Fidelity rating scale

Model

This simulation model provides a realistic representation of the abdominal layers

1	2	3	4	5
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This simulation model provides a realistic representation of inguinal canal

1	2	3	4	5
---	---	---	---	---

This simulation model provides a realistic representation of spermatic cord

1	2	3	4	5
---	---	---	---	---

This simulation model provides a realistic representation of the nerves

1	2	3	4	5
---	---	---	---	---

This simulation model provides a realistic representation of the hazards during the surgery

1	2	3	4	5
---	---	---	---	---

The general performance using this simulator was close in comparison to my general performance in the clinical settings

1	2	3	4	5
---	---	---	---	---

Equipment

On this simulation model, I could demonstrate the precise movements of the open inguinal hernia repair

1	2	3	4	5
---	---	---	---	---

I could use all tools/equipment required to perform this procedure in a manner which is close in comparison to the real procedure (in OT)

1	2	3	4	5
---	---	---	---	---

Reinforcing the abdominal wall with sutured technique was accurate on this simulation model

1	2	3	4	5
---	---	---	---	---

Psychological

While performing the procedure on the simulation model, it felt like I was doing the procedure on a patient

1	2	3	4	5
---	---	---	---	---

I felt comfortable performing the procedure

1	2	3	4	5
---	---	---	---	---

The feel of the equipment made me feel as if I were actually doing the real procedure (in OT)

1	2	3	4	5
---	---	---	---	---

My experience with the simulation model seemed (overall) consistent with my real-world experiences

1	2	3	4	5
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Usefulness rating scale**The open inguinal hernia simulation model ...**

... teaches the importance of performing the open inguinal hernia repair

1	2	3	4	5
---	---	---	---	---

... is a useful tool to learn open inguinal hernia repair surgery

1	2	3	4	5
---	---	---	---	---

... is useful for training of experts

1	2	3	4	5
---	---	---	---	---

... is useful for training of surgical residents

1	2	3	4	5
---	---	---	---	---

... is useful for training of medical students

1	2	3	4	5
---	---	---	---	---