

Study Title:

Using ‘Guided-Discovery-Learning’ to optimize and maximize transfer of surgical simulation

Internal Short title: GDL-Efficacy

Ethics Ref: H-18041917

NCT: 03684720

Acronym: GDLEFFICACY

Date and Version No: 19.09.2018, vs.0.2

Chief Investigator: Andreas Höier Aagesen, Bach. Med¹

Investigators: Ebbe Thinggaard, MD PhD,²
Jeffrey Cheung, PhD,³
Lars Konge, PhD, MD, Professor¹
Ryan Brydges MSc. PhD³
Kulamakan M. Kulasegaram PhD,³

Sponsors: Copenhagen Academy for Medical Education and Simulation, Capital Region, Denmark

Funder: Application for funding is ongoing.

1, Copenhagen Academy of Medical Education and Simulation, Rigshospitalet; Copenhagen, Denmark.

2. Department of Gynecology and Obstetrics, Hvidovre Hospital, Region H, Zealand, Denmark

3. The Wilson Centre, University Health Network and University of Toronto; Toronto, Ontario

Investigators Aagesen, Thinggaard, Cheung, Konge, Brydges and Kulasegaram have no conflict of interest or financial ties to disclose.

The reporting this study will conform to the CONSORT statement.

Confidentiality Statement

This document contains confidential information that, prior to trial registration at www.clinicaltrials.gov, must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organization, and members of the Research Ethics Committee, unless authorized to do so.

Table of Contents

1.	Synopsis	3
2.	Abbreviations	3
3.	Background and Rationale	3
4.	Objective and Outcome Measure.....	6
5.	Study Design	6
6.	Participant identification	8
7.	Study Procedures.....	8
8.	Statistics and Analysis	10
9.	Data management.....	11
10.	Ethical and Regulatory Consideration.....	11
11.	Finance	12
12.	Publication Policy	12
13.	Appendix A.....	13
14.	Appendix B.....	14
15.	Appendix C.....	15
16.	Appendix D.....	16
17.	Appendix E.....	17
18.	Appendix F	18
19.	Appendix G.....	19
20.	References.....	20

1. Synopsis

Study Title	Using 'Guided-Discovery-Learning' to optimize and maximize transfer of surgical simulation
Research Objective	To explore the effect of guided-discovery-learning in transfer of surgical skills
Study Design	A prospective randomized study and explorative study
Study Participants	Students form the Medical Faculty who have not received suture-training
Planned Sample Size	Sixty-four participants
Planned Study Period	Twenty-four months
Objectives	To explore the effect of guided-discovery-learning vs traditional instructor lead teaching in the transfer of basic surgical skills.

2. Abbreviations

CI	Chief Investigator
ICF	Informed Consent Form
RREC	Regional Research Ethics Committee
ST	Surgical Teacher
OSATS	Objective Structured Assessment of Technical Skill
CAMES	Copenhagen Academy for Medical Education and Simulation

3. Background and Rationale

Technical skills are a core competency in surgical specialties. The level of technical skills is directly linked to patient outcomes and it is an absolute requirement that surgical trainees learn to master basic surgical skills. It is therefore a necessity that medical students also become well equipped with these skills, such as suturing. During the last decade, minimally invasive techniques have made their way to the operating room and improved patient outcomes. Despite these advances it is still necessary for surgeons to master the open surgical skills. Unexpected complication can arise in minimally invasive procedures that require conversion to open access surgery. Furthermore, there are procedures where you cannot use minimally invasive techniques. Because of the extensive use of minimally invasive surgery, it is becoming more difficult for doctors as well as medical students in surgical departments to gain the level of experience needed, to become proficient in open surgical techniques. Pre-clinical teaching and simulation training is a possible solution to this problem.¹ For novice learners, simulation training is an opportunity to acquire fundamental skills such as suturing in a safe and high-feedback environment and without the difficulties of acquiring these skills in the workplace². For more advanced trainees, simulation affords the practice of difficult and complex procedures which may be otherwise too unsafe to acquire during patient care. But, merely implementing simulation training is no guarantee of

educational utility, and instead thoughtful curricular integration of simulation requires considering the role and purpose of the simulator, the student experience, debriefing, and the intended outcomes to evaluate success.^{3,4}

One potential area for optimizing simulation-based training is to clarify instructors' roles when providing guidance and direct supervision. One of the challenges with simulation training is the amount of resources this sort of education requires. Especially the amount of time a student spends interacting with an instructor. Supervision and instruction are key to an effective simulation-based training, and there is mounting evidence, which suggest, that we need to reconsider the balance between instruction and discovery, allowing for a good interaction between student and teacher, encouraging learning^{5,6} Therefore the question is; on what level should simulation-based teaching be instructor-orientated? When teaching technical medical skills, the answer to the question, whether the training should be discovery-orientated or instructor-orientated has been thoroughly researched.⁷ Medical Education literature has long moved away from the question of either or, and is now more focused on, in which order discovery- and instruction-teaching should be, to provide the best learning outcome.^{8,9} Recent studies has shown some positive results of guided-discovery-learning, which in its simple form, combines both elements from discovery and instruction-based teaching.¹⁰ Especially the ability to '*transfer*' learning seems vastly improved, with this teaching method. Transfer tasks faced by learners exist on spectrum with a common challenge being new problems which are more complex or in new contexts but essentially require replication of previously learned skills, i.e. near transfer. While near transfer can be difficult for learners, even more challenging is transfer that requires they apply their previous skills and understanding to learn new skills or concepts, i.e. far transfer. Guided-discovery learning has been shown to especially positively impact this latter type of transfer task^{11,12}. Thus guided-discovery may promote student-autonomy and self-learning which subsequently enables students to take responsibility for their own future learning.^{11,12}

In a pilot-study completed by our research-partners at the Wilson-Centre in Toronto, Canada, they compared groups of *discovery followed by direct discovery* (DD) with *instruction followed by discovery* (IP). In the case of DD, the participants, where given the materials needed to complete a simple suture, and a finished suture to look at. After the discovery-phase, they were parred with an instructor who demonstrated how it was to be performed. In the IP-case they were first instructed on how to perform the suture, and were afterwards allowed to practice it. At the end of the course both groups were given a post-test of ability, and a week-later both groups were given a retention test as well as a transfer test. The pilot-study included 26 participants in total, divided in two groups of 13. The participants were randomized, and everything was filmed and scored by blinded raters after an international standard. There were no significant results for the immediate post-test as well as the retention test. But in the case of the transfer test, the DD-group was far superior.

Our study will expand on the pilot-study to provide a comparison of guided discovery to traditional instruction for the learning of suturing tasks in surgery, seeing *if* Guided-discovery-learning works in a much larger research group. Using a double randomized, mixed-methods experimental design, we will investigate the effect of discovery followed by direct instruction (DD) vs. instruction followed by practice (IP) for the acquisition and two types of transfer of surgical skills. To understand *how* and *why* guided-discovery learning changes the learning processes of trainees, we will also film and analyze the interactions of a small-subset of participants in each condition as well as conducting focus-group interviews. Using an exploratory approach, we will explore how discovery learning prior to direct instruction might

change participants' interactions with instructors and task compared to their interactions during initial direct instruction. We will seek to uncover which exploratory approach or approaches provide the best qualitative data. This part is elaborated and investigated in a separate additional protocol.

We hypothesize that:

- 1) Participants in the DD condition will be better able to transfer their knowledge to learning a new skill (i.e., preparation for future learning).
- 2) Participants in the DD condition will have equivalent performance to IP on post-test, but a similar or slightly improved performance on transfer of suturing skill to a more complex task (near-transfer).
- 3) Participants in the DD condition will interact differently with instructors and will use their learnings from the discovery phase to scaffold their learning during the direct instruction phase as well as interacting differently with the task at hand.

PERSPECTIVES

Faculty instructors are a limited resource in formal simulation-based training during post-graduate training. The rise of structured learning activities such as surgical boot camps and the emphasis on greater feedback and support for trainees means that instructor time is at a greater premium than ever before. Instructors must take time away from their busy clinical and workplace-based education activities in order to teach. Not only does this cost the healthcare system, the time commitment can reduce willingness to participate in education. Additional costs may be incurred by programs that must offer financial incentives for instructors. This trade-off between education and clinical work occurs in all academic postgraduate programs. Given the cost and investment required to recruit faculty for training, research is needed to maximize the efficiency of faculty involvement¹³. Our work directly contributes to this goal by identifying how instructor guidance is most helpful to trainees. Guided-discovery may be one approach to reducing the cost of training and instructor time in both post-graduate as well as pre-graduate learning courses¹⁸.

Post-graduate training also requires that trainees develop autonomy and are able to learn new skills or concepts effectively (Scholar role; Competency 1, Enabling 1.1, 1.2)^{19,20}. Further, Medical Expert^{19,20} (Competency 3, Enabling 3.1, 3.4) stresses trainees' abilities to transfer their training when faced with uncertainty and or complexity in future scenarios. Guided-discovery may be an effective organizing principle for educational design that can achieve these competencies across a wide range of disciplines and training environments. Our proposal would thus establish evidence of efficacy for guided-discovery for these competency roles.

4. Objective and Outcome Measure

Objective	Outcome measure
<p>Primary outcome:</p> <p>To examine the effect of Guided-discovery-learning on far transfer of simple surgical skills</p> <p>Secondary outcome:</p> <p>To examine the effect of Guided-discovery-learning on near-transfer of simple surgical skills</p> <p>To examine the primary learning-efficiency of the two types of teaching.</p> <p>To examine the effects on the different types of transfer for the intervention and control groups.</p> <p>Explorative outcomes:</p> <p>To examine the difference in interaction between students receiving Guided-discovery, and those that didn't.</p> <p>To examine the difference in student interaction and approach to the task.</p> <p>To examine different explorative approaches for examining the mechanics behind Guided-discovery</p> <p>To examine how students, experienced the training.</p>	<p>Difference in the two groups OSATS-scores on a far-transfer test evaluated by blinded raters</p> <p>Difference in the two groups OSATS-scores on a near-transfer test evaluated by blinded raters</p> <p>Difference in OSATS-scores between immediate post-test.</p> <p>Difference in OSATS-scores between near-transfer and far-transfer-tests.</p> <p>Using whole-room angle video recordings to observe the student-teacher interactions.</p> <p>Using task-focused video recordings to observe student-task interaction.</p> <p>Using think aloud video-recordings for select students.</p> <p>Using focus group interviews</p>

5. Study Design

The study is a randomized experimental study comparing guided-discovery-learning to traditional instructional learning. The study will be performed at CAMES, including n=64 pre-clinical students from the Medical Faculty of Copenhagen University. Part 1 of this study is an experimental design with two phases that will test the efficacy of guided discovery: Phase 1 will be a learning phase with the experimental manipulations, and Phase 2 will take place one week later and be outcome assessment for near- and far transfer. Part 2 of this study will be an observational analysis of films of a sub-set of participants in the DD and IP conditions in order to establish differences in learning behaviors

between both conditions and possible mechanisms for guided-discovery learning. The analysis will compare how participants interact with the task in each learning condition including documenting activities in each phase and interactions with instructors.

For *Phase 1*, participants will be enrolled and randomly allocated to either the DD or IP groups. Each group consists of 8 participants. Participants will be randomized and the method of teaching allocated on the date of teaching. This will ensure generalization and ease of statistical analysis. In the DD group, participants will be given an example of a completed simple interrupted suture and their own skin pad, and suturing kit. They will then attempt to replicate the suture using the equipment and their own knowledge over 30 minutes. During the same period of time, the IP group will be taught using an instructor. The instructor will provide two demonstrations and explanations of the simple interrupted suture following which the participants will attempt the suture individually on their own skin pads and suturing kit (see Appendix A for Instructor directions; modifications will be made by an experienced surgical instructor on our team ST). The instructor will be told to provide feedback and guidance to the participants as well as answer any questions that participants may have. After the initial time, the DD group will be paired with an instructor who will provide two demonstrations and explanations of the suture and then interact with participants as they attempt the suture. The IP group will practice the suture without any further instructor guidance. At the end of the teaching session, all participants will complete a post-test requiring them to complete two simple interrupted sutures. Afterwards participants willing will be interview in short focus-group interviews. This entire session is expected to last 2 hours including consent and setup time.

After a 1-week delay, participants will return for *Phase 2* for the tests of near- and far transfer. Each group will again be randomly allocated a transfer task. Two transfer tasks will be used in this study: To test Hypothesis 1, (the impact on transfer to future learning), participants will be taught the interrupted vertical mattress suture. To ensure equivalency of design and to prevent biasing in favor of one group, all participants will be taught didactically, which will involve viewing a 15-minute video designed by an expert surgeon on our team (ST) to teach the novel suturing task. Participants will then be given 20-30 minutes to practice the suture following which they will perform two vertical mattress sutures on a typical skin pad. To test Hypothesis 2 (the impact on transfer of learning to a more complex version of the initial task) participants will perform two simple interrupted sutures on a suturing pad representing in an abdominal simulator with the added contextual change of different instruments and suture. In both groups, participants willing, will afterwards be recorded for a 'Think-Aloud' interview, in which they describe their approach to the suturing task out-loud. This phase is expected to last 1.5 hours. (See Appendix B for flow chart). All the interviews, Focus and Think-Aloud, as well as the observational filming will be investigated further and expanded upon in a separate additional protocol, which focuses on the qualitative data.

Outcomes, Measures, and Data Collection

Transfer Tasks

We chose our transfer task based on transfer theory¹⁵ which stresses the spectrum of possible applications of learning. Transfer to a complex variation of the skill, in this case, the simulated organ tissue in an abdominal trainer, is expected to create significant contextual barriers for participants to successfully enact their mental representation of the simple interrupted suture¹⁶. Whilst also including different instruments and suture, the haptic feedback and force required to complete the task are significantly different from the previous learning while the essential schema for the suture is preserved. Similarly, the vertical mattress suturing task involves the fundamental skills of suturing which participants will have developed from prior learning but creates new motor and perceptual patterns which must be scaffolded and developed from the initial learning experience. It will also require participants to engage any learning using their own self-regulation and capacity^{11, 12}.

Blinded raters will evaluate participants' suturing performances using a 5-point global rating scale taken from the OSATS tool which has previously demonstrated high inter-rater reliability across multiple contexts and good evidence of association with changes in trainee skill¹⁷(see Appendix C for scale). We will use a repeated measures analysis to account for the multiple attempts.

6. Participant identification

6.1 Study Participants

Participants will be students primarily at the Medical Faculty of Copenhagen University who haven't received surgical education yet. Eighty participants will be included split into two groups. Both groups will be taught, filmed and tested at CAMES.

6.2 Inclusion and exclusion criteria

Participants are students currently attending a Danish bachelor at a Medical Faculty and who are willing and consent to participation in the study. Participants who have received prior suturing education are excluded from participating in the study.

7. Study Procedures

7.1 Recruitment

Participants will be recruited from the Medical Faculty of Copenhagen University, Zealand, Denmark. Everyone recruited will be given an information leaflet. (Appendix D)

7.2 Informed Consent

Participants must personally sign and date the 'Informed Consent Form' (appendix E) before they can participate in the study. Both written and verbal versions of the consent form and Participants information will be presented to participants, including everything that is to happen to the participants throughout the study. This included the known side effects and risks, associated in participating in the study. It will be clearly stated, that the participants are under no obligations to complete the study, and can withdraw at any time, without giving a specific reason for their withdrawal. Participants will be allowed as much time, as they wish to consider the information. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced and have been authorized to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site in a locked cupboard which only the chief investigator has access to.

7.3 Randomization

Randomization

The study is a double randomized study. Participants will be randomized using en-bloc randomization sequence in groups. After enrollment participants will be assigned a group and a date for teaching. And the groups will then be randomized, and assigned a teaching method, which will be revealed on the date of teaching. Each group will then again be randomized to either to a near-transfer or a far-transfer group for the second phase of the study.

Groups range from A through H, making 8 groups in total. All groups assigned an uneven number will be allocated the intervention, whereas groups assigned an even number will be allocated the control. Furthermore, the 4 groups in the control and the intervention will be randomly assigned to a new number. Groups assigned an uneven number will be allocated the near-transfer group, and groups assigned an even number will be allocated the far transfer group.

For the recording and rating of the test each participant will assigned an identification number (A_1, B_1 etc) which will correspond to an identification key-number in the video (eg. 18920, 32, 564). The conversion key will be stored by the principle investigator and only he will have access to it, thus allowing the raters to score the participants blinded.

All randomization will be done using www.random.org and disclosed by an external party.

7.4 Definition of End of Study

The end of study is after the last of the groups has finished their transfer test in the second week. Any participant, who hasn't shown at any of the teaching days, will be considered as having dropped out of trial.

8. Statistics and Analysis

8.1 Description of Statistical Methods

To examine the effects of guided-discovery-learning contra traditional instructional learning, the following outcomes will be measured:

- Difference in OSATS scores between the control and intervention groups far-transfer-test
- Difference in OSATS scores between the control and intervention groups near-transfer-test
- Difference in OSATS scores between the groups post-test.
- Difference in OSATS scores between the groups development from post-test to transfer-test.

To establish whether there is a significant level of difference in the above-mentioned measurements, students t-test will be used. A statistical software package will be used to calculate these (SPSS vs. 25.0, Chicago, IL).

Analysis

Analysis of the experimental data will be through a mixed-effects linear models with participants as random and instructional condition as fixed factors. We will conduct separate analysis for each hypothesis. For hypothesis 1, we will analyze post-test and near-transfer test scores through a multivariate model (repeated MANOVA or similar depending on model fit and sampling adequacy)¹⁸ with the expectation of a significant interaction indicating differences between groups at near-transfer but not on post-test. To address hypothesis 2, we will analyze performance on the vertical mattress suture using a univariate model (ANOVA). Where appropriate, covariates for performance such as post-test performance will be included to account for individual skill difference and to increase statistical power. A mixed-effects model will also compare participants' near- and far-transfer test scores across both conditions.

The qualitative data analysis is described in more detail in the additional protocol

8.2 The Number of Participants

Learners:

We will recruit n=64 pre-clinical students from the Medical Faculty of Copenhagen University. We are targeting undergraduate students, rather than surgical residents, because we want novice learners, and we believe it is worthwhile to establish efficacy of our intervention group using simpler tasks which can be feasibly studied. We based our sample size on the previous pilot-study which suggests that detecting a large effect on a global rating scale (Hedges g of >0.5) with an alpha of 0.05 and power of 80% requires at least 13 participants per group with additional participants recruited for potential loss to follow-up²⁴ for a total of 16 per group. Participants will receive a certificate showing completed suturing course, as an honorarium to compensate for their time in the study.

Instructor and Raters:

We will recruit one 2nd year post-graduate surgical trainees to serve as an instructor. We will recruit an instructor who has some experience in teaching or coaching undergraduate students. Additionally, participant performance on the post-

and transfer tasks will be assessed by a blinded rater who will receive video-tapes of all relevant participant performances.

9. Data management

9.1 Access to Data

Direct access will be granted to authorized representatives from CAMES monitoring and/or audit of the study to ensure compliance with regulations. All the written consent forms, other paperwork and video files will be locked in a cupboard at PhD office at CAMES and only the chief investigator will have direct access to it. Associates of the study, can be granted access through the chief investigator, as they are needed for the study

9.2 Data Recording and Record Keeping

Data will be collected and entered by the principle investigator. It will be entered in a pre-formatted form and stored in a database under password protection.

10. Ethical and Regulatory Consideration

10.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

10.2 Approvals

The study will be reported to the Danish Data Protection Agency in Region H and all data will meet the criteria set forth by the General Data Protection Regulation. According to Danish law it is not a requirement for the study to be submitted to the Regional Research Ethics Committee (RREC) for approval.

10.3 Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. All documents will be stored securely and only accessible by study staff and authorized personnel. The study will comply with the Data Protection Act, which requires data to be anonymized as soon as it is practical to do so.

11. Finance

11.1 Funding

Application for funding is ongoing. Training facilities will be provided by the Copenhagen Academy for Medical Education and Simulation. Further application for funding is ongoing

12. Publication Policy

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge the source of funding. Authorship is determined as;

1st Andreas Höier Aagesen, 2nd Ebbe Thinggaard, 3rd Jeffrey Choung, 4th Lars Konge, 5th Ryan Brydges, 6th Kulamakan M. Kulasegaram

In accordance with the ICMJE guidelines, other contributors will be acknowledged.

13. Appendix A

Instructor Template and Script for Phase 1 Teaching

Today we will learn a simple interrupted suture.

Begin by selecting a 3-0 nylon suture. Open the packet, and grasp the needle of the suture with the suture driver. Position the needle so that it sits right at the tip of the needle driver and such that the needle driver grasps the needle $\frac{1}{2}$ to $\frac{2}{3}$ of the way from the sharp end to the blunt end of the needle. Sutures have “memory”, meaning they will stay curled up and difficult to work with after removing them from the package. Pull gently on the suture material in a constant manner for a few seconds to reduce the coiling.

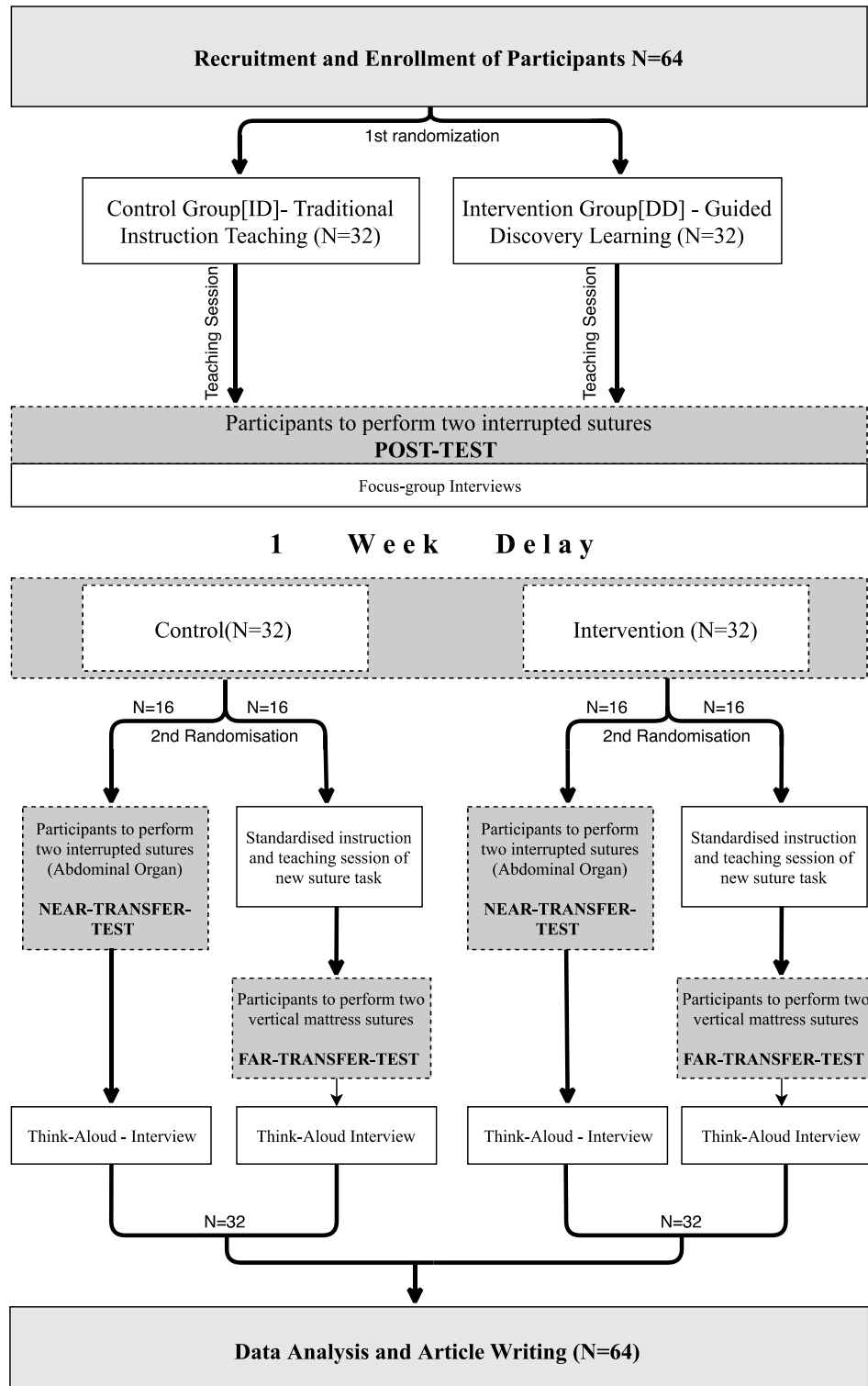
With the suture driver in your dominant hand and the toothed Addson forcep in your non-dominant hand begin the procedure for the interrupted simple suture. Start by elevating the skin gently on one side of the wound. Pronate your hand to position the needle 5-10mm from the wound edge, and 90 degrees to the plane of the skin. Supinate your hand you pierce the epidermal and dermal layers to curve the needle through and into the wound. Continue to supinate to bring the full needle through the skin. Next elevate the other side of the wound. Enter at the same depth (under the dermal layer) as you exited on the opposite side. Supinate aiming to have the needle exit the skin the same distance from the wound edge you entered on the opposite side. Release the needle driver and grasp the needle outside the skin. Continue to supinate to curve the needle completely out of the skin. Pull the suture through leaving a short trail and prepare for an instrumented tie.

At this point the long tail of the suture should be closest and the short farthest from you on opposite sides of the wound. Place your needle driver between the two tails. Loop the long tail around the needle driver and towards the short tail twice, this produces a surgeon's knot. Grasp the short tail with the needle driver and pull through the loop, cross your hands as you pull the knot tight to lay it down flat. Place the needle driver back between the two tails. Again loop the long tail towards the short tail, which should now be on opposite sides than previous. Continue this process until at least 3 throws are completed.

Grasp the short tail in the suture driver when completed tying the knot. Pass the needle driver and long end of the suture into your non-dominant hand. Grab the straight Mayo scissors in your dominant hand and cut both suture tails at least 1 cm in length.

14. Appendix B


Study Design – Flow Chart



15. Appendix C

Objective Structured Assessment of Technical Skills (OSATS)

OSATS is a validated assessment tool for grading overall technical proficiency for open surgical skills. Below are the performance anchors and rating scale for the OSATS tool. Each scale is scored 1 - 5, which means the total score could range from 8- 40.

	University of Toronto Department of Surgery OSATS Global Rating Scale	UofT Department of Surgery Wound Closure GLOBAL RATING SCALE OF PERFORMANCE
Please circle the number corresponding to the candidate's performance regardless of the candidate's level of training.		
Respect for tissue		
1	2	3
Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments		Careful handling of tissue but occasionally caused inadvertent damage
		4
		5
		Consistently handled tissue with toothed forceps and caused minimal damage to tissue
Time and motion		
1	2	3
Many unnecessary movements		Efficient time/motion but some unnecessary moves
		4
		5
		Clear economy of movement and maximum efficiency
Instrument handling		
1	2	3
Repeatedly made tentative or awkward moves with instruments didn't load needle correctly or follow curve of needle; did not handle needle safely		Competent use of instruments but occasionally appeared stiff or awkward
		4
		5
		Fluid movements with instruments and followed curve of needle; needle protected at all times
Knowledge of Instruments		
1	2	3
Frequently used inappropriate instrument; used incorrect suture for the tissue layers		Familiar with instruments and used appropriate instrument
		4
		5
		Obviously familiar with Instruments; used correct suture
Flow of Procedure		
1	2	3
Frequently stopped operating and seemed unsure of next move		Demonstrated some forward planning with reasonable progression of procedure
		4
		5
		Obviously planned course of operation with effortless flow from one move to the next
Knowledge of Specific Procedure		
1	2	3
Deficient knowledge; required specific instruction at most steps of operation		Knew all important steps of operation
		4
		5
		Demonstrated familiarity with all steps of the operation; correct knot tying technique with appropriate tension and square throws
OVERALL PERFORMANCE		
1	2	3
Very poor		Competent
		4
		5
		Clearly superior
QUALITY OF FINAL PRODUCT		
1	2	3
Very poor; dog ears present; sutures engage more than one tissue layer; strangulation of tissue/failure to approximate wound edges		Competent; edges everted or opposed; sutures close wound effectively
		4
		5
		Clearly superior; all knots to one side of wound, edges everted; sutures evenly spaced; equidistant bites
<div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; padding: 10px; text-align: center; width: 45%;"> Examiner Sticker </div> <div style="border: 1px solid black; padding: 10px; text-align: center; width: 45%;"> Candidate Sticker </div> </div>		

February 25, 2015

16. Appendix D

Study Title: “Using ‘Guided-Discovery-Learning’ to optimize and maximize transfer of surgical simulation”

We want to ask, if you wish to participate in a scientific study.

It is voluntary to participate, and you can at any time and without giving a specific reason, take back your informed consent.

The Study will be carried out at:

Copenhagen Academy for Medical Education and Simulation (CAMES)

Rigshospitalet / Copenhagen University.

Blegdamsvej 9

2100 København Ø

The study objective is to explore the effect of guided-discovery-learning vs traditional instructor lead teaching in the transfer and retention of basic surgical skills.

As participant in the study, you will either be allocated to a control group or an intervention group. The study will take place over 2 weeks, where you will participate on a single every week for about 1 ½ to 2 hours. In both groups you'll in the first week be taught simple suturing technique. On the same day, you'll perform a post-teaching test. A week later you'll be undertaking a retention-test much like the one you'll meet on the 8th semesters OSCE-examine. Afterwards you'll be asked to perform a new suture technique without prior teaching to test your abilities to transfer learning.

The control-group will be taught using traditional principles whereas the intervention group will be taught after the guided-discovery-principle. It is an exclusion criteria if you have received prior suture training in the form of a SAKS-course or through the university (7th semester and henceforth).

Information about the test:

To be able to compare the two groups suturing ability you will be filmed carrying out the suture. This will be a camera recording you will perform the suture in a test situation. These recordings will be anonymized, so that blinded raters can score the procedure in an international context.

Information about the teaching:

Your teaching session will take place at CAMES in the Teilm building. Throughout the first week, there will be recordings of the teaching session in chosen groups, so we can compare the teacher/student interaction in each group. The recordings will be transcribed for their verbal communication and anonymized, afterwards they will be analyzed.

Besides contributing to the study, you will also receive a diploma stating completed course and achieved ability of simple suturing. Throughout the participation, there will be refreshments and food. Before participating you'll be asked to sign an informed consent form, but you are always welcome to withdraw from the study.

If you have any questions, you are always welcome to contact us:

Andreas Höier Aagesen

Asminderødgade 7, 2tv

2200 København N

andreas.hoier.aagesen@gmail.com

tlf: 30274904

Best regards,

Andreas Höier Aagesen

17. Appendix E

Informed consent for participation in a health-science scientific study.

Study Title: "Using 'Guided-Discovery-Learning' to optimize and maximize transfer of surgical simulation."

Declaration from participant:

I have received sufficient written and verbal information, and I know enough about the objective, method, pros and cons to give my consent to participating in the study. I know it is voluntary to participate, and that I can always withdraw my consent without losing my present and future rights to treatment. I give my consent to participate in the study, and I have received a copy of this consent form, as well as a copy of the written information about the study for personal use.

Participant's name: _____

Date: _____

Signature: _____

Declaration from study responsible investigator:

I declare, that the participant has received written and verbal information about the study.

It is my belief that sufficient information has been given to the participant, so that he/she can make an informed decision about whether or not to participate for the study.

Name of the study responsible investigator: _____

Date: _____

Signature: _____

Project identification: ()

18. Appendix F

Informed consent for dissemination of study data for use in academic purposes.

Study Title: "Using 'Guided-Discovery-Learning' to optimize and maximize transfer of surgical simulation."

Declaration from participant:

I have received sufficient written and verbal information, and I know enough about the objective, method, pros and cons to give my consent to dissemination of the study data. I know it is anonymized, and that I can always withdraw my consent without losing my present and future rights to treatment. I give my consent to dissemination of the study data, and I have received a copy of this consent form, as well as a copy of the written information about the study for personal use.

Participant's name: _____

Date: _____

Signature: _____

Declaration from study responsible investigator:

I declare, that the participant has received written and verbal information about the dissemination of the study data. It is my belief that sufficient information has been given to the participant, so that he/she can make an informed decision about whether or not to consent to the dissemination of the study data.

Name of the study responsible investigator: _____

Date: _____

Signature: _____

Project identification: ()

19. Appendix G

Open-ended questionnaire concerning benefits and drawbacks of teaching.

Questionnaire regarding teaching of basic suture techniques

1. What did you see as the biggest challenges of today's teaching session?	
2. How did you overcome these challenges?	
3. What worked well with your interactions with your instructor?	
4. What didn't work well with your interactions with your instructor?	
5. How did you experience the teaching session as a whole?	
6. Other comments?	

20. References

1. Reznick R, MacCrae H. Teaching Surgical Skills — Changes in the Wind. *NEJM*. 2006; 6;355:2664-9
2. [Dawe SR](#), [Pena GN](#), [Windsor JA](#), [Broeders JA](#), [Cregan PC](#), [Hewett PJ](#), [Maddern GJ](#). Systematic review of skills transfer after surgical simulation-based training. *Br J Surg*. 2014 Aug;101(9):1063-76
3. Zendejas B, Brydges R, Hamstra SJ, et al. State of the evidence on simulation-based training for laparoscopic surgery: a systematic review. *Ann Surg*. 2013;257:586–593
4. [Zendejas B](#)¹, [Cook DA](#). Reply to Letter: "Surgical Simulation: Seeing the Bigger Picture and Asking the Right Questions". *Ann Surg*. 2015 Aug;262(2):e51-2
5. Brydges R, Nair P, Ma I, Shanks D, Hatala R. Directed self-regulated learning versus instructor-regulated learning in simulation training. *Med Educ*. 2012 Jul;46(7):648-56.
6. Brydges R, Dubrowski A, Regehr G. A new concept of unsupervised learning: directed self-guided learning in the health professions. *Acad Med*. 2010 Oct;85(10 Suppl):S49-55.
7. [Lee HS](#), [Anderson JR](#). Student learning: what has instruction got to do with it? *Annu Rev Psychol*. 2013;64:445-69
8. Schwartz DL, Bransford JD. A Time for Telling. *Cognition and instruction*. 1998;16 (4), 475-5223.
9. Hmelo-Silver C, Duncan RG, Chinn CA. Scaffolding and Achievement in Problem-Based and Inquiry Learning: A Response to Kirschner, Sweller, and Clark *Educational Psychologist*. 2006; 42(2) 99-107
10. Kapur M Productive failure in learning the concept of variance. *Instructional Science*. 2012; 40(4), 651-672
11. Schwartz DL, Martin T. Inventing to prepare for future learning: the hidden efficiency of encouraging original student production in statistics instruction. *Cogn. Instr.* 2004;22:129–84
12. Mylopoulos M, Brydges R, Woods NN, Manzone J, Schwartz DL. Preparation for future learning: a missing competency in health professions education? *Med Educ*. 2016 Jan;50(1):115-23
13. [DeCaro MS](#), [Rittle-Johnson B](#). Exploring mathematics problems prepares children to learn from instruction. *J Exp Child Psychol*. 2012 Dec;113(4):552-68.
14. The Wilson Centre, University Health Network and University of Toronto; Toronto, Ontario
15. Kulasegaram K, McConnell M. When I say ... transfer-appropriate processing. *Med Educ*. 2016 May;50(5):509-10.
16. Grierson LE. *Adv Health Sci Educ Theory Pract*. 2014 May;19(2):281-9. Information processing, specificity of practice, and the transfer of learning: considerations for reconsidering fidelity.
17. Hatala R, Cook DA, Brydges R, Hawkins R. Constructing a validity argument for the Objective Structured Assessment of Technical Skills (OSATS): a systematic review of validity evidence. *Adv Health Sci Educ Theory Pract*. 2015 Dec;20(5):1149-75.
18. [Devine LA](#), [Donkers J](#), [Brydges R](#), [Perelman V](#), [Cavalcanti RB](#), [Issenberg SB](#). An Equivalence Trial Comparing Instructor-Regulated With Directed Self-Regulated Mastery Learning of Advanced Cardiac Life Support Skills. *Simul Healthc*. 2015 Aug;10(4):202-9.
19. Frank JR, Snell L, Sherbino J, editors. *CanMEDS 2015 Physician Competency Framework*. Ottawa: Royal College of Physicians and Surgeons of Canada; 2015.
20. De syv lægeroller, Sundhedsstyrelsen, 2013
21. Brydges R, Manzone J, Shanks D, Hatala R, Hamstra SJ, Zendejas B, Cook DA. Self-regulated learning in simulation-based training: a systematic review and meta-analysis. *Medical education*. 2015 Apr 1;49(4):368-78
22. Glaser B. Emergence vs. Forcing: Basics of Grounded Theory Analysis: Strategies for Qualitative Research. Mill Valley, CA: Sociology Press; 1992
23. Denzin NK, Lincoln YS. *Handbook of qualitative research*. 2nd ed. Thousand Oaks, Calif.: Sage Publications; 2000.
24. Norman G, Streiner R. *Biostatistics: the bare essentials*. Oxford; BC Decker Press; 2000