Mesh Matters: Evaluating the Efficacy of Suture Mesh vs. Planar Mesh in Ventral Hernia Treatment – a randomized, blinded multicenter study

Version 1.3 (07.07-25)

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Sponsor: _____ Kathrine Holte, associate professor, MD, DMSc

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PROTOCOL SUMMARY

Title:	Mesh Matters: Evaluating the Efficacy of Suture Mesh vs. Regular Mesh in Ventral Hernia Treatment – a randomized, blinded, multicenter study
Acronym:	**MeMa**
Study Sponsor:	Kathrine Holte
Protocol version:	1.3 (07.07.2025)
Coordinating investigator:	Vitaly Gameza
Study sites:	a) Regionshospital Nordjylland, Hjørring b) Regionshospital Randers c) Regionshospitalet Viborg d) Regionshospital Horsens
Investigators and clinical study coordinators:	Coordinating investigator: Vitaly Gameza Site investigators (according to above mentioned sites): a) Kathrine Holte, MD, DMSc/Vitaly Gameza , MD b) Marlene Sørensen, MD c) Marie Kirk, MD d) Michael Festersen, MD, PhD
Other collaborators:	Center for Klinisk Forskning, Regionshospital Nordjylland Dansk Center for Sundhedstjenesteforskning, Aalborg Universitet.
Funding organizations	Investigator initiated. Funding will be sought from various non-profit foundations. As of now (July 7th 2025) only internal funding from Regionshospital Nordjylland has been secured.
Indication:	Patients with small (< 3*3 cm) ventral hernia, with indication for onlay mesh repair.
Aim:	Superiority of mesh suture repair.

Hypothesis:	By using mesh suture, most of the subcutaneous dissection may be avoided and thus our hypothesis is that by reducing the surgical trauma, we may reduce wound complications from 14% to 4%, as well as reduce the operation time.
Study design:	Multicenter, blinded, randomized, controlled trial.
Planned sample size:	280 (140 in each arm)
Total number of centers:	4
Screening:	All patients presenting with small (< 3*3 cm) ventral hernia in the outpatient clinic.
Selection criteria:	Capable adults (age > 18 years) where indication for open surgery with onlay planar mesh is found.
Study interventions:	Mesh suture vs. planar mesh repair.
Primary outcome	Surgical site occurrences (SSOs)
Analysis plan:	No interim analysis is planned. Full analysis will thus be performed after inclusion of the planned sample size of 280 participants.
Duration of study:	Patient inclusion 1,5-2 years, 5 years follow up.

INTRODUCTION

In this multi-center, blinded, randomized study, we compare two medical devices to treat small ventral hernias: Mesh suture (intervention) vs. planar mesh (standard treatment).

Implantation of mesh suture does not require the subcutaneous preparation of abdominal wall needed to implant planar mesh. Thus, we hypothesize that the reduced surgical trauma following mesh-suture implantation promotes better postoperative outcomes, primarily reduced wound complications such as seroma, hematoma and wound infections. Additionally, the shorter operation time associated with mesh-suture implantation may substantially reduce hernia waiting lists, which approximate 41 weeks in some public hospitals in Denmark. Finally, we will assess patient-reported outcomes (PROMs) such as Quality of Life (QoL) before and after surgery and analyze socio-economic parameters potentially affected by mesh-suture implantation, such as return to work and contact with family physician/primary sector.

BACKGROUND

Surgery for small ventral hernias (< 2 cm) is one of the most frequently performed operations in Denmark, with 2469 procedures performed in 2023. Despite it being a relatively small operation, up to 7.1% of patients are readmitted to emergency departments <90 days after surgery, primarily due to wound problems, and up to 2.2% of patients are reoperated <30 days after surgery[1]. Historically, the two most important outcome measures following small ventral hernia repair are postoperative wound events and long-term hernia recurrence[2]. Current standard treatment of these hernias in Denmark is open surgery with onlay planar mesh placement. With onlay planar mesh, the hernia sack is dissected and reduced, the abdominal wall defect closed with a non-dissolvable suture, subcutaneous tissue dissected from the underlying fascia and non-resorbable mesh implanted on top of the fascia. This method is proven superior to closure of the hernia defect with only a suture in terms of recurrence rates[3,4]. There is, however, a higher risk of seroma/hematoma formation and wound infection when planar mesh is used compared to suture closure[5,6]. Rates of postoperative seroma formation are reported to be as high as 46% and in our clinical practice, readmission to hospital is predominantly caused by seroma formation related to the operative site[7].

Reported rates of surgical site occurrences (SSO) after operations for small ventral hernias vary greatly in the literature, additionally there is a lack of standardized definitions and reporting[2]. In settings comparable to ours, one study from Sweden showed complication rates of 23.7% after onlay planar mesh repairs[8]. The higher rate of hernia recurrence with suture only repair is attributed to the suture cutting through tissue ("cheese wire cutter effect/ or suture pull-through effect"), which occur when the sharp leading edge of the suture applies focused pressure at the suture/tissue interface and the pressure causes either abrupt cutting of tissue or a more gradual process of tissue ischemia and scarring, remodeling over time. In experimental studies, low suture tension has been found to promote more favorable collagen composition of the incisional region[9]. Planar mesh implantation redistributes tension forces over a large surface area so the edges of fascia have optimal conditions for healing, but at the cost of higher wound complications rates and longer operation time.

Several methods have been developed to reduce fascial tension during healing without extensive dissection of suprafascial or subfascial tissue. Among those are mesh sutured repairs where 2 cm wide mesh strips are used to close fascial defects just as with single tread interrupted suture. Mesh sutured repairs showed promising results even in contaminated fields and larger defects[10]. Mesh sutured technique is however subject to many variables that may alter its efficacy, such as accurate strip cutting, strip passing technique and mesh availability at the hospital.

Recently, a mesh suture has been developed (our proposed study intervention), with an attached needle and a tubular design with pores in the wall, combining functions of both suture and mesh, allowing ingrowth of tissue without capsule formation, while having the tensile strength nearly identical to those of a 0-

polypropylene suture[11]. Available data support the safety and efficacy of this mesh suture for abdominal wall closure[12].

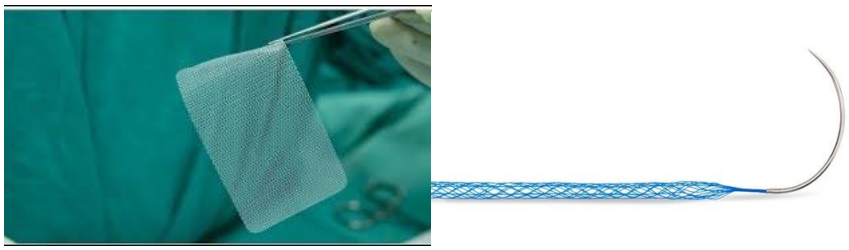
AIM/PURPOSE

The aim of this randomized, blinded multicenter trial is to investigate differences in wound complication rates (SSO), PROM (Quality of Life) and operation time among patients operated for small ventral hernias either with mesh-suture or planar mesh as well as evaluate potential influence of mesh-suture on wider socio-economic parameters such return to work and contact with family physician/primary sector.

HYPOTHESIS

By using mesh suture, extensive subcutaneous dissection is avoided and surgical trauma is minimized, leading to reduced wound complication rates.

MEDICAL DEVICE



In this head-to-head study we intend to compare two medical devices. Both devices are used under the respective CE approved indications.

In **the control group** we use Optilene® Mesh. Manufacturer: B. Braun Surgical, S.A. Ctra. d e Terrassa, 121 08191 Rubí (Barcelona), Spain. CE Certificate G1 025701 0090 Rev.01.

Optilene® Mesh is a mesh implant for reinforcement of connective tissue structures. It is constructed from monofilament polypropylene, knitted to a thin and elastic shape-stable mesh. After implantation, the Optilene® Mesh adapts to the longitudinal and latitudinal expansions taking place in the connective tissue. Optilene® Mesh is coloured blue with copper phthalocyanine (Phthalocyaninato (2-) copper) for a better visibility. Optilene® Mesh does not possess any independent pharmacological properties. The polypropylene mesh is biostable and is not degraded in the body.

In **the intervention group** we use suturable mesh, DURAMESH™. Manufacturer: Mesh Suture Inc. 1444 North Astor Street, Chicago, IL, 60610, United States. Authorized representative: Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands. CE Certificate US21/819944390

DURAMESH™ is a non-absorbable polypropylene suturable mesh and combines the desirable principles of a mesh repair with the placement precision of a suture. DURAMESH™ distributes forces at the suture-tissue

interface, while dramatically minimizing the amount of implanted foreign material and surgical complexity required for implantation. DURAMESH™ is constructed from monofilament polypropylene and has an open walled, hollow core design that allows fibrovascular incorporation into the device during healing. DURAMESH™ does not possess any independent pharmacological properties. The polypropylene suturable mesh is biostable and is not degraded in the body.

METHOD

Study design

Multicenter, blinded, randomized controlled trial. The study is powered as a superiority study with intention to treat analysis.

Study population and sample size

In the litterature, wound complication incidences vary greatly (from 0.7 to 63.3%), at least in part due to a lack of standardized definitions and reporting[2]. We know that in our department the readmission rate after small ventral hernia repair is 7% (data from the National Hernia Database, 2023)[1]. The majority of these readmissions is due to wound complications. We estimate that least as many patients are treated for minor SSO in primary sector as in the hospitals (unpublished data), so the true incidence of wound complications is estimated around 14 percent for onlay mesh.

In the literature[12] the reported *surgical site event* rate for umbilical hernias is 2.4%, with infection rates of 4.9%. For ventral hernias, surgical site events range from 1% to 8.2%, while infections range from 3.1% to 5.2%.

It is also important to note the *wound classification* in the referenced study[12]:

- **Umbilical hernias:** 14.6% were classified as *clean-contaminated*
- **Ventral hernias:** 18.6% *clean-contaminated* and 12.4% *contaminated*

In our study, all procedures are performed in an **outpatient setting** and involve only **clean wounds**.

Additionally, **13% of patients** in the referenced cohort were **active smokers**, despite smoking being a well-established risk factor for postoperative wound complications. In our study, the rate of active smoking is **0%**, as all participants are required to be smoke-free for at least **six weeks preoperatively**, with random testing performed to verify compliance.

Based on these distinctions, our *realistic* expectation for wound complications is **1–3%**. However, to remain appropriately conservative, we have chosen to report an estimated complication rate of **4%**.

A reduction in wound complications from 14% to 4% is considered clinically significant.
A sample size of 254 participants was determined to have 80% power to detect a clinically significant between-group reduction in surgical site occurrences (seroma/hematoma formations and postoperative wound infections) from 14 to 4% and a type I error of 5%, without increase in recurrences. This number was increased to 280 participants to account for conversions and cases lost to follow-up.

No interim analyses are planned. The planned sample size is 280 patients with equal assignment to the two groups.

Inclusion criteria

All patients presenting with small ventral hernia, maximum 3x3cm, where indication for open surgery with planar mesh is found.

Exclusion criteria

Age <18 years

Acute operation

Pregnancy

Women with plans of future pregnancies

Withdrawal of informed consent during admission

Recruitment of study subjects

Patients are screened at the participating centers outpatient departments. If the candidate meets the inclusion criteria, the candidate will receive oral and written information about the study from one of the operating surgeons. Patients will be asked to read the information in the entity before signing. All patients are invited to discuss the entry into the study with a relative or other entrusted person if they so choose. Informed consent will take place in a quiet room without interruption on the day of the inclusion. Patients are informed that the consent could be withdrawn at any time prior to randomization (or after) and so the real timeframe to decide if patients wish to participate would be approximately 4 weeks.

Randomization

After provision of consent, randomization is performed by the operating surgeon during the operation, the moment where it is ensured that onlay planar mesh is not superior to mesh-suture e.g. more/larger fascia defects than anticipated are not found. Random sequence generator with random block size (of maximum 10) will be used to create randomized sequences in 1:1 ratio. In all participating centers, a case of

sequentially marked opaque envelopes will be made available. The envelopes contain patient study ID, information on the assigned intervention group and the registration schematics along with information on when to perform registrations.

Blinding

Patients will be blinded until the end of follow-up, which is planned to be 5 years.

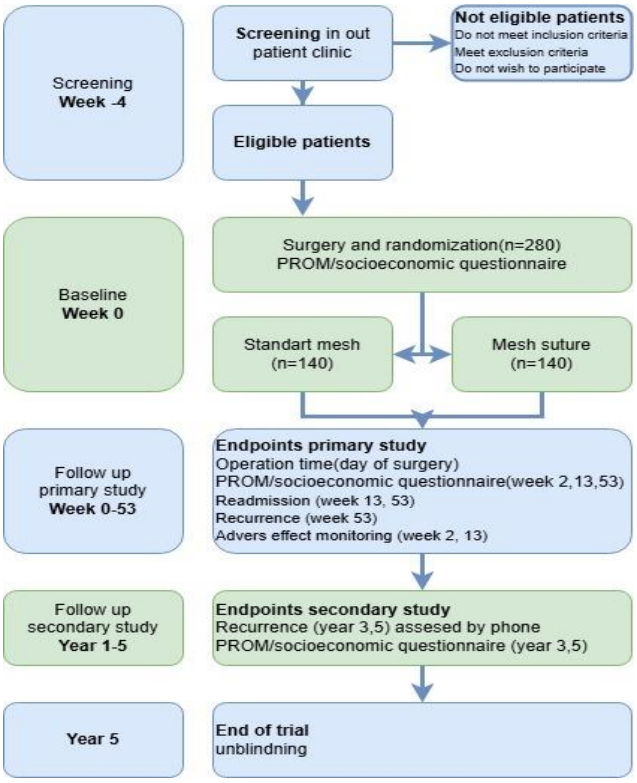
Blinding of trial participants:

Blinding is maintained by ensuring that the operative report only states: *"... a mesh is implanted according to the study protocol and randomisation number ..."*. This prevents patients from being able to see which type of mesh was used.

Blinding of the assessing physician:

The physician who performs the follow-up assessment for wound complications is never the operating surgeon. Furthermore, the local database is configured so that the assessing physician does not have access to the section where the operating surgeon records the specific type of implanted mesh.

Furthermore, all surgeons involved will receive detailed information about entering relevant basic data in a local database (redcap) and all performed operations are registered in the Danish National Herniadatabase as well. All patients will be contacted by a nurse/study group member who is unaware of randomization results and treatment given in order to collect PROM data.



Study interventions

The objective criteria for surgery are described in the guidelines of the Danish Hernia Database (appendix 2), and all participating centres are obliged to follow them. The guidelines are also attached.

Included patients will be randomized to either standard treatment with planar mesh or interventional treatment with mesh-suture. All hernia will be operated by consultant surgeons, fellows or residents after proven competency, possibly with supervision. Details of the operation with either planar mesh or Duramesh, in appendix 3 and 4. Centers involved in the trial will be invited to a session where we go through operation details to secure that the procedure is performed in a standardized manner in all centers. Younger surgeons in all centers will be allowed to perform the operation under supervision of senior colleagues who attend the educational session and later without supervision if they are evaluated as being able to do so. Detailed information with pictures regarding steps for both operations with suture or planar mesh will be available in every center.

Baseline data and preoperative QoL score will be collected during the first visit in the out-patient clinic or immediately preoperatively, if the patient consents to study participation.

All patients will be called in for clinical examination on postoperative day 7-13, where standardized wound inspection (see appendix 1) and ultrasound will be performed just as QoL will be assessed by a standardized, validated questionnaire. QoL will be assessed by telephone on day 90, 1 year, 3 years and 5 years after surgery as well.

Operation time is defined as time from first incision to last cutaneous suture and is registered by the floor-nurse in the operation room.

90 days after surgery patient journals will be assessed concerning data on potential readmissions.

Table 1. Overview, patient management

Consultation	V1	V2	V3	TC1	JC1	TC2	JC2	TC3	JC3	TC4	JC4
Visit/phone call/journal check	Clinic	Operation	Sut remov + US	Phone call 1	J check 1	Phone call 2	J check 2	Phone call 3	J check 3	Phone call 4	J check 4
Week	-4	0	1,5 (day 10)	12	12	53	53	159	159	275	275
Month	-1	0	0,5	3	3	12	12	12	36	12	72
Visit window days	n/a	0	3 (+/-)	3 (+/-)	3 (+/-)	7	7	7	7	7	7
Medical history	x										
Physical examination	x										
Inclusion/exclusion criteria	x										
Informed consent	x	x									
Randomise patient		x									
Unblinding											x
Investigational device	V1	V2	V3	TC1	JC3	TC2	JC4	TC3	JC5	TC4	JC6
Implant Duramesh vs standard mesh		x									
Safety assessment			x	x	x						
Patient-reported outcome	V1	V2	V3	TC1	JC3	TC2	JC4	TC3	JC5	TC4	JC6
European hernia questionnaire		x	x	x		x		x		x	
Socio-economic questionnaire (analgesic use, GP visit, return to work)		x	x	x		x		x		x	
Study team reported outcome	V1	V2	V3	TC1	JC3	TC2	JC4	TC3	JC5	TC4	JC6
Operation time		x		x							
Readmission				x	x	x	x	x	x	x	x
Recurrence				x	x	x	x	x	x	x	x

Outcomes

Primary outcome

1. Surgical site occurrences (SSO) on postoperative day 7-13. Definition: We will apply the standardized CDC (Centers for Disease Control and Prevention)[13] and VHWG (Ventral Hernia Working Group)[2] definitions for SSO (appendix 1). Evaluation: Clinical examination. Additionally, an ultrasound examination will be performed.

Secondary outcomes

2. QoL on postoperative day 7-13 and day 90. Definition and evaluation: The EHS (European Hernia Society) validated EuraHS-quality-of-life (QoL) score (attached).

3. Duration of surgery (min).

Sub-study 1: Long-term recurrence

In this sub-study we will assess hernia recurrence events in both study subgroups after 1, 3 and 5 years.

Sub-study 2: Long-term outcomes

In this sub-study we will assess QoL as defined above in both subgroups after 1 year.

Sub-study 3: Socio-economic aspects

In this sub-study we will assess socio-economic parameters (specifically time to return to work, analgesic use and contact with the primary sector) in both groups on postoperative day 7-13, 90 and after 1, 3 and 5 years.

Study duration

Patient inclusion: 2 years from September 2025 - September 2027, plus 5 years follow-up.

Safety assessment and study termination

Conversion of intervention to standard treatment: If, after randomization, interventional treatment is impossible to apply, then standard treatment will be performed.

The study will be terminated if the complication rate for patients operated with mesh suture exceeds known complication rates for planar mesh. Adverse events will be assessed and registered 7-13 days after surgery by clinical examination and 90 days after surgery by phone as well as by going through patient medical records.

Statistical methods

A sample size of 254 participants was determined to have 80% power to detect a clinically significant between-group reduction in surgical site occurrences from 14 to 4% and a type I error of 5%. This number was increased to 280 participants to account for conversions and cases lost to follow-up. No interim analyses are planned.

Data will be analyzed by a blinded analyst on an intention-to-treat basis, according to the prespecified statistical plan. A two-sided P-value < 0.05 is considered significant.

Analysis of the primary outcomes: Depending on the distribution of data, continuous variables will be described with mean (SD, standard deviation) or median [interquartile range (IQR)] and analyzed with students t-test or Mann-Whitney U test, respectively. Categorical variables will be described as frequencies (%) and analyzed using Fisher´s exact test.

Analyses will be conducted using Stata software.

STUDY MONITORING

The coordinating investigator , a medical specialist and a dedicated hernia surgeon with more than 12 years of surgical experience, has the general responsibility for study monitoring and will secure that all legal and practical aspects of the study protocol are followed in all participating centers.

The coordinating investigator will receive weekly reports of performed operations from all participating centers and secure that all relevant data are submitted to a central database. If there is any baseline data missing, participants will be contacted. The database will be monitored on a weekly basis. Medical journals of all participants will be accessed on day 90 after the operation to secure all relevant data are collected. Access to data after submission will be restricted only to relevant study investigators to comply with the blinded study design. A dedicated nurse with over 15 years of experience in nursing hernia patients will contact all study participants on day 90 after operation and if there is any suspicion of deviation from the expected post operative course, participants will be called in for physical/radiological examinations. All study participants are informed to contact medical emergency services anytime if required.

ACCESS TO PARTICIPANTS MEDICAL RECORDS

To ensure the safety of participants and to collect the research data upon trial completion, access to electronic patient files will be needed throughout the trial. Access to the electronic patient journal will be needed to get data on surgery performed, clinical outcomes, readmissions and CT-scans (descriptions). Patients will be asked to give explicit informed consent to data access for their electronic patient journal until the study period ends. Participants will be asked to give access to information in a 5-year period after inclusion. Information will be given about the intended use of the data as well as the intent to publish in international journals. Before participation in the study all eligible patients will be asked to give a written consent that the principal/coordinating investigator, local site investigators, sponsor, investigating nurse and eventual controlling authority may have direct access to patients medical records hereunder electronic patient journal in order to access patients medical data which is necessarry for study implementation and control hereunder self-control, quality control and study monitoring. Patient data will be handled in accordance with "Databeskyttelsesloven og -forordningen", the Danish adaptation of the European Union General Data Protection Regulation (GDPR). If patients are not interested in study participation, no data will be collected for the study.

Patient sensitive information

All patient sensitive data will be anonymized prior to publication. All data protection regulations and data protection law will be followed. No data will be sent to other countries.

PERSPECTIVES

One of the principles of good surgical practice is to cause as minimal surgical trauma as possible. By using mesh suture, we may substantially reduce the trauma caused by surgery. By avoiding dissection of subcutaneous tissue from underlying fascia, we preserve the perforant arteries which are usually divided and ligated. We furthermore avoid creating an artificial space between subcutis and fascia where seroma and abscesses may accrue. By reducing surgical trauma, we anticipate better QoL regarding, among others, pain, discomfort and mesh related complications such as foreign body sensations related to the surgical site. Less trauma potentially may lead to faster recovery, shorter return to work times, less use of family doctors, so we anticipate an over-all reduction in the socio-economic burden.

Our expectations are to reduce operation time by 30%, which will potentially allow us to operate on more patients per day as well as reducing waiting time to operation and thus theoretically reduce numbers of acute operations. In the planned sub-studies with longer follow-up, we will assess hernia recurrence rates to ensure that mesh suture is not inferior to planar mesh.

ETHICAL CONSIDERATIONS

Potential benefits, risks and side-effects by participation

Use of mesh suture is simple and resembles standard suture use, thus all surgeons who perform ventral hernia repair would easily be able to use the technique.

A potential concern is a potentially higher recurrence rate among patients operated with mesh suture. We will review all collected data after 3 months by a project member not otherwise involved in the project, and if early (<90 days) recurrence rates in mesh suture subgroup exceed national average reoperation rates (2%), the study will be terminated. If recurrence appears, patients will be offered standard treatment with planar mesh. It is important to mention that reoperation in case of recurrence would be easy to perform due to lack of prior extensive dissection of subcutaneous tissue and thus less fibrosis.

Patients will expectedly be subject to increased awareness regardless of whether they are randomized to the intervention group or standard treatment, as this is a known phenomenon of study participation. This may make treatment safer in both groups.

Study participants will not receive financial compensation or other benefits and will be treated according to the Helsinki declaration. Complications directly attributable to the treatment will be eligible for insurance claims from the Danish public patient insurance (“Patienterstatningen”).

PROJECT MANAGEMENT

Timeline and study feasibility

Due to high volume of small ventral hernia operations (2469 nationwide in 2023), the time frame estimated for patient inclusion is realistic and is estimated to be 1-2 years depending on the number of centers wishing to join the trial.

Data analysis plan

It is estimated that completion of statistical analyses, interpretation of results and submission for publication will take 6-12 months. The analyses from sub-studies 2 will be initiated 1 year after inclusion of the last patient and are estimated to take 6-12 months to complete including submission for publication.

Table 2. Overview, project timeline

	2025				2026				2027				2028			
	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Study preparation																
Project deescription and protocol	x	x	x													
Project registrarion at North Denmark Region			x													
Co-operation agreementa and contracts			x													
Establishment of RedCap database			x													
Study																
Recruitment and treatment of patients				x	x	x	x	x	x	x	x					
Follow-up					x	x	x	x	x	x	x	x	x	x		
Analysis																
Data management												x	x	x	x	
Analysis												x	x	x	x	
Dissemination of results																
Manuscript 1													x	x		
Manuscript 2														x	x	
Manuscript 3															x	x
Writing of PhD thesis														x	x	x

DATA MANAGEMENT AND SECURITY

Study data are collected and managed using the encrypted REDCap electronic data capture tools hosted at Region Nordjylland18. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

The project will be registered in the North Denmark Region common registry for ongoing trials. When approved by the ethical board, the protocol will be made available on https://www.clinicaltrials.gov.

GOOD CLINICAL PRACTICE

The project will adhere to the ICH good clinical practice (GCP) guidelines.

PROJECT GROUP AND MANAGEMENT STRUCTURE

The project management group and study board are all employed at the coordinating center at Regionshospital Nordjylland, Hørring. Kathrine Holte will serve as the project sponsor/principal investigator and thus will be responsible for overseeing the study including financial decisions. Vitaly Gameza will serve as coordinating/principal investigator and thus will be responsible for the overall clinical implementation across research sites and the scientific goals of the study. Kathrine Holte is a clinical associate professor and consultant surgeon and a Doctor of Medical Science with many years of research experience from a variety of clinical studies. Vitaly Gameza is a medical doctor and hernia specialist.

Below, in Danish, the steering group:

Styregruppe medlem	Ekspertområde/Opgaver
Vitaly Gameza, afdelingslæge, medlem af Herniecenter Nord´s specialistgruppe, Kirurgisk afdeling, Regionshospital Nordjylland	Skrivning af protokol, praktisk ansvarlig for gennemførelse af studiet, koordinering af centre og primær investigator i Hjørring
Kathrine Holte, forskningsansvarlig overlæge, dr. med., klinisk lektor, Kirurgisk afdeling, Regionshospital Nordjylland.	Videnskabelig vejleder og garant mhp. ovenstående. > 50 publicerede artikler (H-index: 30) og stor erfaring med gennemførsel af tilsvarende projekter.
Nils Brandenburger, ledende overlæge, leder af Herniecenter Nord, Kirurgisk afdeling, Regionshospital Nordjylland.	Faglig garant for projektet og vejleder mhp. ovenstående.
Jakob Juul Christensen, videnskabelig assistent, Dansk Center for Sundhedstjenesteforskning, Aalborg Universitet.	Sundhedsøkonomiske analyser.
Frank Svendsen Jensen, cheflæge, Kirurgisk afdeling, Regionshospital Nordjylland	Organisatorisk garant for projektet
Peter Leutscher, professor, PhD, Forskningschef, Regionshospital Nordjylland.	Videnskabelig vejleder mhp. ovenstående

PUBLICATIONS AND AUTHORSHIP

All results from the trial will be published in international peer-reviewed journals independently of study outcome. Authorship will be attributed according to the International committee of medical journal editors (ICMJE) guidelines.

FINANCIAL ASPECTS AND CONFLICTS OF INTEREST

The study is investigator initiated and sponsored by the surgical department of Regionhospital Nordjylland, Hjørring and the Clinical Research Unit, Regionhospital Nordjylland, Hjørring and external funding will be sought. Any potential funding will be used to cover salary (Vitaly Gameza, project nurse) and the cost of the materials. Funding will be payed to the Department of Surgery, Regionshospital Nordjylland. None of the researchers have any economic affiliations to potential funds or other entities with economic interest in the study.

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APPENDIX 1:

Definition of SSO:

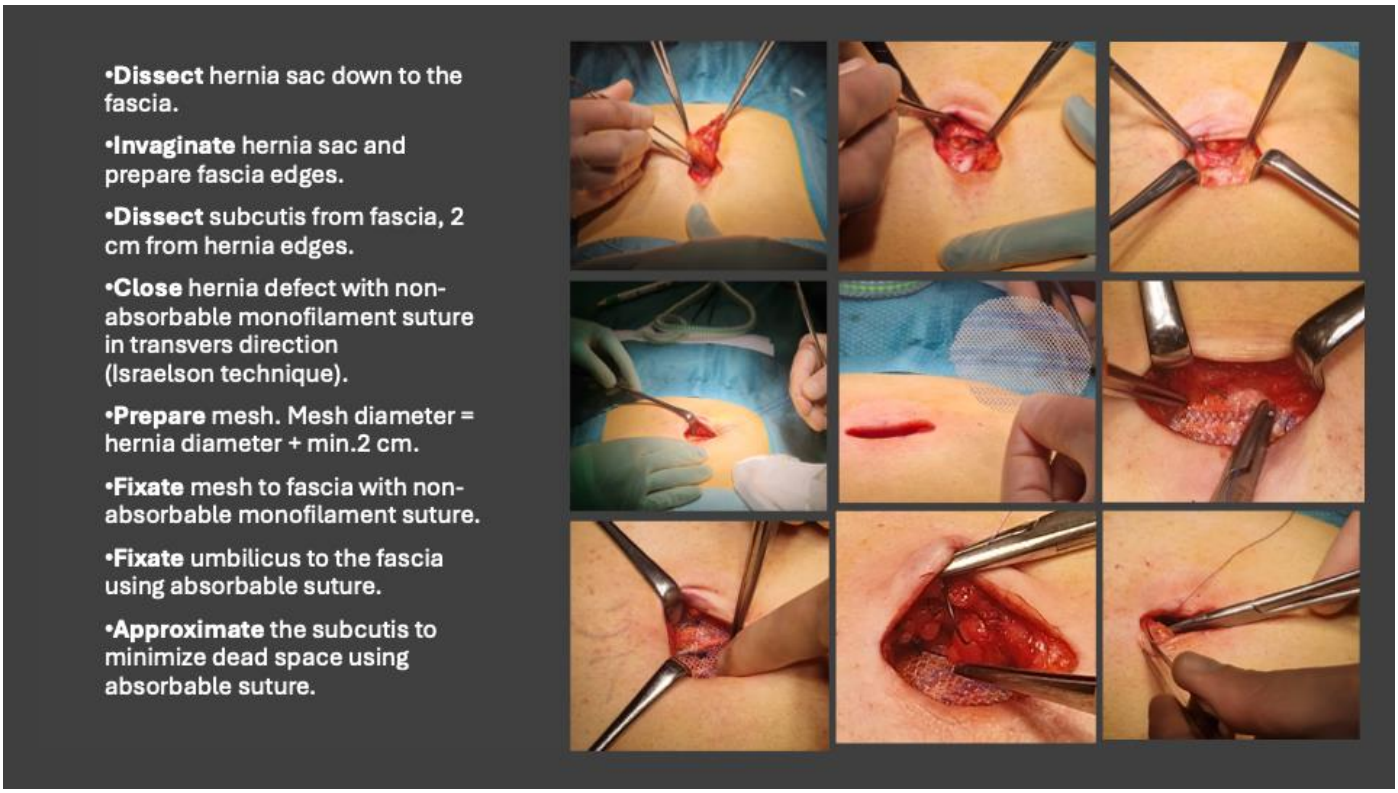
The standardized definition for surgical site infection (SSI) as defined by the Centers for Disease Control and Prevention (CDC): An infection that occurs in the part of the body where the surgery took place and includes superficial, deep, and organ space SSIs[2,13].

The standardized definition for SSO as defined by the VHWG includes any SSI as well as wound cellulitis, non-healing incisional wound, fascial disruption, skin or soft tissue ischemia, skin or soft tissue necrosis, wound serous or purulent drainage, stitch abscess, seroma, hematoma, infected or exposed mesh, or development of an enterocutaneous fistula[2]. All complications will furthermore be classified according to the Clavien-Dindo classification system.

APPENDIX 2:

See separate file Danish Hernia Database guidelines

APPENDIX 3:



APPENDIX 4:

- **Dissect** the hernia sac down to the fascia.
- **Invaginate** the hernia sac and prepare the fascia edges.
- **Place** the first stitch 5 mm from the hernia defect.
- **Close** the fascia in a transverse direction (**Israelsson technique**).
- **Ensure** counter-tension is held on the mesh-suture to avoid entanglement while pulling through.
- **Place** the final stitch 5 mm from the hernia defect and secure it with a square knot (4 throws).
- **Fixate** the umbilicus to the fascia using an absorbable suture.
- **Approximate** the subcutis to minimize dead space using an absorbable suture.