



Jun 04, 2025

🌐 Reoperation of Laparoscopic Inguinal Hernia Repair Using Penetrating or Non-Penetrating Mesh Fixation: A Nationwide Register-Based Cohort Study

DOI

<https://dx.doi.org/10.17504/protocols.io.kxygxq6mkv8j/v1>

Unknown Unknown¹

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Protocol Citation: Unknown Unknown 2025. Reoperation of Laparoscopic Inguinal Hernia Repair Using Penetrating or Non-Penetrating Mesh Fixation: A Nationwide Register-Based Cohort Study. **protocols.io**

<https://dx.doi.org/10.17504/protocols.io.kxygxq6mkv8j/v1>

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Protocol status: Working

We use this protocol and it's working

Created: June 03, 2025

Last Modified: March 17, 2026

Protocol Integer ID: 219480

Keywords: reoperation risk in laparoscopic groin hernia repair, based cohort study inguinal hernia repair, reoperation of laparoscopic inguinal hernia repair, elective laparoscopic groin hernia repair in adult, following elective laparoscopic groin hernia repair, laparoscopic groin hernia repair, laparoscopic inguinal hernia repair, reoperation in the same groin, hernia size, danish hernia database, subgroup analyses by hernia size, data from the danish hernia database, penetrating mesh fixation, reoperation risk, hernia type, reoperation rate, term outcomes such as reoperation, association between mesh fixation method, mesh fixation, same groin, performed surgery, crude reoperation rate, time to reoperation, reoperation, mesh fixation method, using penetrating, based cohort study, cohort study

Abstract

Inguinal hernia repair is one of the most frequently performed surgeries worldwide. The choice between penetrating and non-penetrating mesh fixation may influence long-term outcomes such as reoperation. This is a protocol for a nationwide, register-based cohort study that will use data from the Danish Hernia Database (1998–2025) to assess the association between mesh fixation method and reoperation rates following elective laparoscopic groin hernia repair in adults.

Patients will be grouped by hernia type (medial, lateral, pantaloon, femoral, and combined inguinal-femoral). The primary outcome is reoperation in the same groin.

Crude reoperation rates will be calculated with 95% confidence intervals. Kaplan-Meier plots and log-rank tests will illustrate time to reoperation. Cox-regression models adjusted for age and sex will estimate hazard ratios, with checks for proportional hazards and linearity. Sensitivity analyses will incorporate hernia size and mesh weight from 2015–2024. Subgroup analyses by hernia size and type will further refine risk estimates.

This study aims to provide long-term, real-world evidence on how fixation technique affects reoperation risk in laparoscopic groin hernia repair.



Guidelines

This will be a retrospective cohort study utilizing data from the Danish Hernia Database from January 1998 to January 2025. This study will report according to the REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) guideline. Information regarding patient characteristics, including gender and age, will be retrieved from the database for adjustments in our statistical analysis. Participants will include men and women ≥ 18 years at primary operation undergoing an elective laparoscopic groin hernia repair where mesh is fixated with either non-penetrating or penetrating fixation technique. Exclusion criteria will be if the participants are no longer resident in Denmark, the primary operation is not registered in the Danish Hernia database. Furthermore, insufficient data on fixation method, operation method, and patient data regarding age at operation time will also be excluded. In this study, two interventions will be compared. The first intervention is penetrating mesh fixation. All types of brands of absorbable tacks, permanent tacks, permanent staplers, permanent suture, and lastly absorbable suture will be pooled for assessing primary analysis. The second intervention is non-penetrating mesh fixation. This includes all brands of glue (fibrin sealant and synthetic glue), and self-gripping mesh. Non-penetrating mesh fixation intervention group will be compared to penetrating mesh fixation intervention group. All laparoscopic operation techniques will be grouped due to very little difference in short and long-term outcomes. We will assess the primary outcome reoperation for recurrence.

Materials

SPSS version 29.0 (IBM, Armonk, NY, USA) for statistical analysis.

Statistical Method

- 1 Statistical analysis will be performed using SPSS version 29.0 (IBM, Armonk, NY, USA). Continuous data will be reported as mean with standard deviation for normally distributed variables or median with interquartile range for non-normally distributed variables. Normality of continuous variables will be assessed visually using histogram, QQ plot, and Shapiro-Wilk test. To compare between the two intervention groups, Mann-Whitney-U will be performed. Categorical variables will be compared using frequencies and comparing in between groups we will perform a Chi2 test.

Participants

- 2 Groin hernia primary elective laparoscopic repair
 - 2.1 Groin hernia: Divided into five cohorts: Inguinal lateral, Inguinal medial, Inguinal pantaloon, Femoral, Combined (femoral and inguinal). Exclusion of hernia if: repair for no hernia or inguinal hernia not further specified.
 - 2.2 Primary: Only primary repairs will be included. Exclusion: If the first operation registered in the Danish hernia database is classified as a reoperation.
 - 2.3 Elective: All elective and not specified primary repair statuses will be included. Exclusion: All acute primary operations.
 - 2.4 TAPP repair: Either as a classic laparoscopic repair or a robot-assisted TAPP repair or laparoscopic not specified. Exclusion: All open repairs and TEP repairs.
 - 2.5 Participants: exclude all emigrated since many come back to Denmark for having their groin hernia surgery, making the follow-up time incorrect in the analysis.

Interventions

- 3 Penetrating and non-penetrating mesh fixation
 - 3.1 The primary repair must have enough details for it to be classified as penetrating or non-penetrating fixation, otherwise, the groin will be excluded. It is acceptable if specific tack name or material is not listed.



- 3.2 Penetrating mesh fixation: permanent tacks, absorbable tacks, permanent staples, permanent suture, and absorbable suture.
- 3.3 Non-penetrating mesh fixation: glue (cyanoacrylate and fibrin sealant) and self-adhesive/-gripping mesh.

Outcome

- 4 Reoperation in the same groin side.
 - 4.1 Definition: operation in the same groin twice. There must be a minimum of one day between the repairs. Reoperation is included regardless of operation type, hernia type or size, or mesh fixation choice.
 - 4.2 Reoperation performed on the same day will be interpreted as a double registration of one repair, and the first registered repair will be chosen as the primary repair.

Missing Outcome Data

- 5 For patients having a second operation (either a contralateral repair or a reoperation for a recurrence), about 10% are only available in Lands Patient Registeret. In about half of these, the side of the groin is registered. For the remaining second repairs, we are unaware if patients have received a contralateral repair or a reoperation for a recurrence. For these approximately 5% of repairs, we will conduct random missing data imputation, with a weighted distribution based on the distribution of left, right, bilateral in the rest of the cohort.

Statistical Significance

- 6 $p \leq 0.05$ considered statistically significant.

Main Analyses

- 7 5 cohorts (medial, lateral, pantaloon, femoral, inguinal+femoral)
 - 7.1 Crude rates: % (number/total) of reoperation in penetrating and non-penetrating mesh fixation with exact 95% CI.



- 7.2 Kaplan Meier plot + the log-rank test (p-value) Illustrate the cumulated re-operation rate + visually get an idea if there are proportional hazards.
- 7.3 Multivariate Cox-regression Our Cox regression will depend on a linearity between each continuous variable and log(hazard) Proportional hazards: Categorical covariates log (-log(survival) plot Continuous covariates: include time-dependent variable in Cox model. The endpoint will be time until reoperation, death, or data extraction. Linearity of continuous covariates with log hazard (visual binning of include age2 as a variable in the Cox regression to test for linearity) We will adjust for confounders/effect modifiers: Age (continuous) Sex

Sensitivity Analysis

- 8 Sensitivity analysis on all five hernia types comparing penetrating versus non-penetrating:
- 8.1 We will re-run the Cox-regression, now including these covariates: Age (continuous) Sex Size of hernia <3 and 3 Due to the Danish hernia database introduced mesh weight in 2015, we will restrict this analysis from 1 January 2015 to 31 December 2024. Mesh weight: light (<45 g/m²), medium (45–65 g/m²), or heavy weight (>65 g/m²). We will attempt to identify the weight by researching the brand.

Subgroup Analysis

- 9 Penetrating versus non-penetrating depending on hernia size
- 9.1 Four analyses: medial size 3, medial size <3, lateral size 3, lateral size <3 The hazard ratios and 95% CI will be presented in a summary Table.
- 9.2 For each of the four comparisons Multivariate Cox-regression The same model control as the main analyses We will adjust for confounders/effect modifiers: Age (continuous) Sex

Sensitivity on Subgroups

- 10 Multivariate Cox-regression, adjusting for age (continuous), sex, and mesh weight (three categories).

Number of Hospitals Using the Different Mesh Materials



- 11 This will be presented narratively to get an overview of how widespread the use of the different fixation methods are (without adjusting for it in the analyses). How many surgeons have used: penetrating tacks, absorbable tacks, staples, permanent sutures, absorbable sutures, glue, self-adhesive mesh. Report minimum number in the text. From 2016 and onwards.