

More Recurrences After Hernia Mesh Fixation With Short-term Absorbable Sutures

A Registry Study of 82 015 Lichtenstein Repairs

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Objective: To assess the effects of different mesh fixation suture materials on the risk of recurrence after Lichtenstein inguinal hernioplasty.

Design: Observational, population-based registry study.

Setting: Data from the nationwide Swedish Hernia Registry.

Patients: All 82 015 Lichtenstein inguinal hernioplasties with sutured mesh fixation in adolescents and adults (15 years or older) from January 1, 2002, to December 31, 2009, at surgical units enrolled in the Swedish Hernia Registry.

Interventions: Mesh fixation with nonabsorbable, long-term absorbable, or short-term absorbable sutures.

Main Outcome Measure: Relative risk (RR) for reoperation due to recurrence of a hernia in the same groin

during the study period, based on cumulative reoperation rates adjusted for time and confounding variables.

Results: For each study group, RR was calculated with multiregression analysis. There was no significant difference in risk for reoperation after mesh fixation with standard nonabsorbable sutures (RR, 1) or with long-term absorbable sutures (RR, 1.12; 95% confidence interval, 0.81-1.55; $P = .49$). Short-term absorbable sutures, however, more than doubled that risk (RR, 2.23; 95% confidence interval, 1.67-2.99; $P < .001$).

Conclusions: With regard to recurrence risk, long-term absorbable sutures are an excellent alternative to permanent sutures for mesh fixation in Lichtenstein inguinal hernioplasty. Short-term absorbable sutures entail an independent risk factor for recurrence and should therefore be avoided.

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THE LICHTENSTEIN INGUINAL hernioplasty with “tension-free” mesh reinforcement has become the criterion standard in inguinal hernia repair worldwide.¹⁻³ In Sweden, the Lichtenstein inguinal hernioplasty technique accounted for two-thirds of all groin hernioplasties in 2008.⁴ The procedure is one of the most standardized operations in general surgery. One

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characteristic and well-defined element of the operation is the fixation of the mesh, which, according to the originators, should be executed with nonabsorbable (ie, permanent) monofilament sutures.

Recently, it has been suggested that by substituting the mesh-anchoring sutures entirely with absorbable ones, the sur-

geon may reduce the patient's risk of developing chronic postoperative pain.⁵⁻⁹ Whether such a policy would affect the recurrence rate has, to our knowledge, not been thoroughly investigated.

Recurrence rates in modern hernia treatment depend on a wide range of risk factors unrelated to the mesh fixation. Design of a study to detect a probably small, but clinically relevant, difference in the risk for recurrence exclusively related to the mesh fixation material is thus a challenge. A randomized controlled trial may be both difficult and time-consuming to perform to answer this question.

The aim of this study was to investigate the relative risk (RR) for reoperation due to hernia recurrence in cases when the mesh is secured mainly with long-term or short-term absorbable sutures, as compared with standard nonabsorbable sutures. To examine this, we analyzed data pertaining to the reoperation rate of nearly all Lichtenstein inguinal hernioplasties per-

formed in Sweden during an 8-year period prospectively and consecutively registered in the nationwide Swedish Hernia Registry (SHR).¹⁰

METHODS

DATA FROM THE SHR

The SHR has almost complete nationwide coverage of groin (inguinal and femoral) hernioplasties in adolescents and adults. For every patient, the registration protocol mandates a number of variables to be prospectively recorded, including details regarding surgical technique (**Table 1**). The large sample size acts to minimize the risk of random error, thus ensuring good precision, even in subanalyses.

In Sweden, patient information is registered under the state-assigned personal identity numbers unique for each citizen and used for all health care and other governmental concerns.¹¹ Thus, patients can be monitored annually to adjust data according to life tables for deaths and to link recurrent hernia repairs to any previous operations.

The SHR defines *reoperation of recurrence* as any kind of hernia repair in a groin in which a hernia had previously been repaired when the patient was 15 years or older. This definition applies even in the event that the primary and recurrent hernias are anatomically different, eg, if the first repair was for an inguinal hernia and the reoperation addressed a femoral defect. More information about the SHR, including its data recording and validation, is available in earlier publications^{12,13} and on Web sites.^{4,10}

In 2002, the SHR introduced a new variable: the means by which hernia mesh is affixed (**Table 2**). The study reported here was based on SHR data for the 8 years after that addition (January 1, 2002–December 31, 2009). Inclusion criteria were Lichtenstein inguinal hernioplasty procedures in which the mesh was fastened mainly with nonabsorbable, long-term absorbable, or short-term absorbable sutures, which define the 3 study groups in this investigation.

This study was granted official approval status by the Research Ethics Committee of Stockholm University.

STATISTICS

To calculate the cumulative risk of recurrent surgery throughout the study, the primary endpoints for analysis were the date for reoperation of a hernia in the same groin or the date of death. Subsequently, the RRs for reoperation were computed for each of the 3 suture groups by Cox multiple regression analysis¹⁴ to adjust for potential confounders (Table 1). For the comparison, standard fixation was chosen as reference (RR, 1). An RR greater than 1 signified a larger risk for reoperation than for nonabsorbable sutures, whereas an RR less than 1 indicated a smaller risk. The statistics were calculated with R (open-source free software) version 2.7.2.¹⁵

RESULTS

During the study period, the SHR recorded 130 359 mesh and nonmesh repairs of groin hernias in adolescents and adults (aged 15 years or older), constituting more than 95% of all hernioplasties in Sweden. Of these, 82 015 met the inclusion criteria, (ie, Lichtenstein inguinal hernioplasty with mesh fixation by sutures) (**Figure 1**).

In the majority of the procedures, the mesh was secured with standard nonabsorbable sutures (n = 78 867). The 2 study groups with long-term absorbable (n = 1938)

Table 1. Variables in the Swedish Hernia Registry Registration Form

Demographic and preoperative patient data
10-Digit personal identity number
Body height and weight
Sex
Patient risk score (ASA classification)
Right groin, left groin, or bilateral
Emergency or elective repair
Primary or recurrent repair
If recurrent, number of previous repairs
Hernia reducible or not
Status of ipsilateral testicle
Intraoperative data
Surgical department/hospital
Expertise of main surgeon and assistant
Prophylactic antibiotics or not
Type of anesthesia
Type/location of incision
Anatomic location of hernia (lateral, medial, femoral, or any combination)
Sliding hernia or not
Type of procedure
Mesh slit or not (concerns only preperitoneal mesh)
Management of hernia sac (divided, excised, or invaginated)
Diameter of hernia defect (<1.5, 1.5-3, >3 cm)
Main suture type (in pure suture repairs) or mesh fixation material
Type of mesh
Surgical complication, type, and severity
Operation time, "skin-to-skin"
Postoperative data
Complications (including death) within 30 days
Recurrence within 30 days
Reoperation for recurrence, complication, or chronic pain

Abbreviation: ASA, American Society of Anesthesiologists.

and short-term absorbable (n = 1210) mesh fixation sutures represent less common modifications (Table 2).

The reoperation rates are listed in **Table 3** and the cumulative risks are displayed in **Figure 2**.

The RRs for reoperation are given in **Table 4**. In comparison with permanent sutures (RR, 1), mesh fixation with short-term absorbable sutures more than doubled a patient's RR for reoperation (RR, 2.23). The reoperation rates for the nonabsorbable and long-term absorbable suture groups were similar.

COMMENT

This large, population-based study was designed to detect possible risk differences for the outcome of clinical interest (recurrence), depending on the type of mesh fixation suture material used for the Lichtenstein inguinal hernioplasty. For practical reasons, we used a surrogate end point (reoperation due to recurrence). Our data demonstrate that the use of short-term absorbable sutures more than doubled the reoperation risk, whereas long-term absorbable sutures manifested no significant risk.

The follow-up period ranged from 0 to 8 years. During the study period, the cumulative reoperation curves for all 3 study groups were fairly linear and constant. Whether this pattern will prevail is yet to be seen.

Table 2. Principal Mesh Fixation Material in Lichtenstein Repairs, 2002-2009

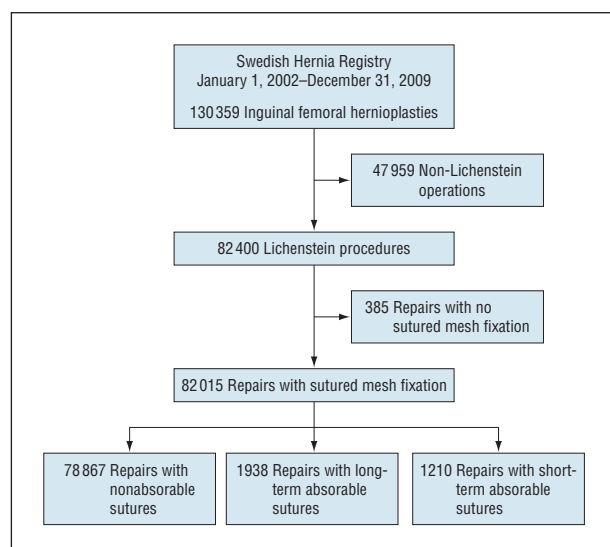
Characteristic	No.								No. (%)
	2002	2003	2004	2005	2006	2007	2008	2009	2002-2009
Nonabsorbable sutures ^a	7912	9239	10 119	10 700	10 632	9723	9828	10 714	78 867 (95.7)
Long-term absorbable sutures ^b	133	196	182	286	293	258	304	286	1938 (2.4)
Short-term absorbable sutures ^c	135	144	105	202	209	177	147	91	1210 (1.5)
Staples/tacks	2	10	9	10	10	3	8	23	75 (0.1)
Glue	NA	NA	NA	0	5	2	4	3	14 (0)
Other or unspecified	0	10	28	22	15	28	23	19	145 (0.2)
No fixation	5	2	2	2	17	13	60	50	151 (0.2)
Total	8187	9601	10 445	11 222	11 181	10 204	10 374	11 186	82 400 (100.1)

Abbreviation: NA, not applicable.

^a For example, Prolene (Ethicon, Somerville, New Jersey), Ethilon (Ethicon), Surgipro (Covidien, Mansfield, Massachusetts), Novafil (Covidien), and Dermalon (Covidien).

^b For example, PDS (Ethicon) and Maxon (Covidien).

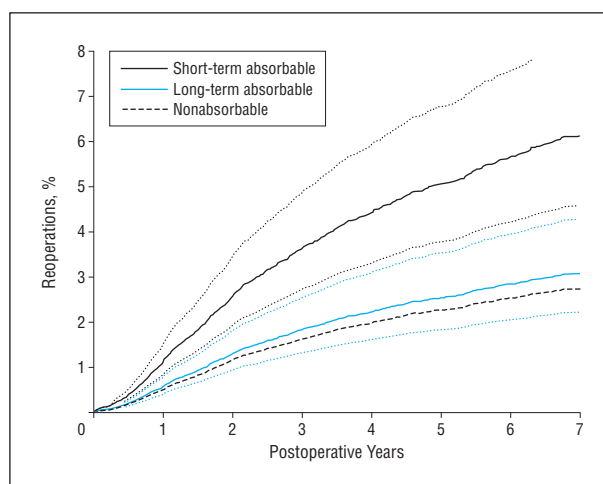
^c For example, Vicryl (Ethicon), Dexon (Covidien), and Polysorb (Covidien).

**Figure 1.** Flowchart of the study population.**Table 3. Reoperations From January 1, 2002, to December 31, 2009**

Type of Suture	No. (%)		
	Reoperation	No Reoperation	Total, No. (%)
Nonabsorbable	1428 (1.8)	77 439 (98.2)	78 867 (96.2)
Long-term absorbable	37 (1.9)	1901 (98.1)	1938 (2.4)
Short-term absorbable	50 (4.1)	1160 (95.9)	1210 (1.5)
Total	1515 (1.8)	80 500 (98.2)	82 015 (100.1)

There are 2 primary strengths of this study. First, the 3 study groups comprise almost all patients treated in Sweden with the procedure of interest during the study period. As the SHR has nationwide coverage and documents virtually every adolescent and adult inguinal and femoral hernia operation conducted in Sweden, it compiles an unselected and unbiased database.

Second, our findings are in line with results obtained from studies on abdominal wound closure, where short-term absorbable sutures have been shown to constitute an

**Figure 2.** Relative risks for reoperation due to recurrence after Lichtenstein inguinal hernioplasty between 2002 and 2009 relative to the hazard baseline (cumulative reoperations after repairs with nonabsorbable suture mesh fixation) and adjusted for the 6 most prominent other risk variables in the Swedish Hernia Registry: sex, emergency/elective repair, primary/recurrent repair, anatomic location of hernia, diameter of hernia defect, and postoperative complications. The dotted lines delineate the 95% confidence intervals.**Table 4. RR for Reoperation**

Type of Suture	RR (95% CI)	P Value
Nonabsorbable	1.00 [Reference]	...
Long-term absorbable	1.12 (0.81-1.55)	.49
Short-term absorbable	2.23 (1.67-2.99)	<.001

Abbreviations: CI, confidence interval; RR, relative risk.

Adjusted¹⁴ for other significant risk factors: sex, emergency/elective repair, primary/recurrent repair, anatomic location of hernia, diameter of hernia, postoperative complications.

independent risk factor for incisional hernia formation and long-term absorbable sutures do not.¹⁶⁻²⁰ In addition, research on nonmesh groin herniorrhaphy has demonstrated that short-term absorbable sutures raise the recurrence risk, whereas long-term absorbable sutures do not.²¹⁻²³

One may consider a weakness of our study to be uneven distribution of the 3 groups, with less than 4% of

the procedures divided into the 2 absorbable suture groups (Figure 1). Notwithstanding these modest percentages, these groups collectively comprise 3148 repairs performed by several hundred surgeons. Therefore, we consider the risk that individual practices of attending surgeons will manifest as statistical outliers and skew the overall results to be minimal.

Given that this study was not a randomized controlled trial, it provides only a descriptive account of surgical outcomes documented for nearly the entire patient population of a single country. As such, it makes no attempt to control for or even declare the reasons underlying decisions to deviate from standard use of non-absorbable suture fixation. Thus, biased patient selection is a possibility that might confound determination of the recurrence risk. However, multiregression analysis adjusts for essential disparities between study groups concerning other risk factors.

A strength of the Lichtenstein inguinal hernioplasty procedure, in contrast to other methods of hernia repair, is that it enables even nonexpert surgeons to repair groin hernias with few recurrences.^{4,24-28} In recent years, however, the issue of chronic postoperative pain has been addressed. Several authorities in the field of hernia surgery have argued that posthernioplasty pain should be a greater cause for concern than should recurrence rates.²⁹⁻³¹ Tissue-penetrating anchoring of mesh is recognized to be a plausible cause of chronic discomfort.³¹⁻³⁶ Removal of the permanent fixation material can thus sometimes be an effective remedy.^{5,6,8} Further studies regarding whether absorbable mesh fixation may reduce the incidence of persistent postoperative pain need to be performed. It is nevertheless important that measures with the intention to reduce the risk for chronic pain do not increase the recurrence risk.

When launched in 1992, the primary objective of the SHR was to assess variables associated with recurrence risk. Since then, the chronic postoperative pain issue has achieved increasingly more attention worldwide. As shown in Table 1, the SHR has not routinely recorded data concerning chronic pain beyond 30 days. Therefore, we regret that the SHR at this time does not possess data suitable to assess causal relationships between mesh fixation and chronic pain. However, for some time, the SHR has made efforts to develop a new pain evaluation protocol that is simple enough to be accepted by Swedish surgeons for use in their daily practice and, at the same time, complex enough to be scientifically useful and valid. A pilot study with a test protocol is currently being conducted in a limited number of hospitals.

To our knowledge, there have been no previous studies investigating whether a shift from permanent to absorbable mesh fixation will increase the recurrence rate after a hernioplasty. We hypothesized that for some patients, the mesh fixation material will play a crucial role in the long-term outcome of their hernioplasty. Still, the abundance of other plausible recurrence risk factors, some of them potentially more influential than the choice of suture material, makes it difficult to determine which one was the principal factor for hernia recurrence in each case. Many might consider a randomized controlled trial to be the most appropriate study design to assess the importance of mesh fixation suture material; however, that would

necessitate an enormous number of patients and several years of observation time, entailing an economically and logistically formidable, if not impossible, project. We chose, therefore, to conduct a registry study rather than a randomized controlled trial because recurrence constitutes a rare event, one furthermore influenced by many risk factors. We believe that a study based on data derived from a large nationwide registry has better prerequisites for cost-effectiveness and valid statistical inference.³⁷ In a recent commentary in the *Archives*,³⁸ advantages of national registry studies were noted: very large patient samples increase study power and facilitate multivariate analysis, and the broad range of physicians involved in treatment strengthens the external validity (generalizability) of the results (ie, the outcome is likely to reflect what may be expected in routine practice).

Large numbers of cases, such as the 3 groups studied here, are sine qua non for adequate multiregression. There were very few less-frequent alternatives for mesh fixation (glue, staples/tacks, other/unspecified, or no fixation) in the SHR, and the number of reoperations was even smaller. Therefore, these rarities recorded in the SHR may not yet be considered adequate for appropriate statistical inference regarding reoperation risk.

The exact date of a recurrence is an unsuitable end point in hernia studies because it can only be arbitrarily defined and still rarely be pinpointed. Even in prospective trials, the diagnosis (of recurrence) is always made in retrospect. Therefore, the recurrence date is not recorded in the SHR or in hernia studies. Instead, since the SHR registers both the primary and recurrence operation dates, we selected the day of reoperation as the primary end point. This enabled precise calculation of the reoperation rate, which we consider an adequate surrogate factor for recurrence rate.

From the patient's perspective, a recurrent hernia evolves in the following manner: anatomic recurrence, clinical manifestation, diagnosis, and potential reoperation. This evolution varies per individual and may span from hours to decades. This might be one of several plausible explanations for the observation in Figure 2 that the reoperation curves continue to separate long after one would expect the absorbable sutures to be gone. Furthermore, reoperation is not performed on a significant number of recurrent hernias, which sometimes are not even diagnosed. Thus, the recurrence rate will always be higher than the reoperation rate. At any given time, the true rate of clinically detectable recurrences can be estimated to be approximately 3 times higher than the SHR reoperation rate.³⁹

The delay from recurrence to reoperation is most likely dependent on factors similar for all 3 study groups. When comparing the alternative fixation materials, it is therefore reasonable to assume the calculated RR for a reoperation to be approximately the same as the true RR for a recurrence (in this case, as compared with standard nonabsorbable sutures).

CONCLUSIONS

In most cases, all 3 types of suture material worked well for the mesh fixation after the limited follow-up time. Still,

for some patients, short-term absorbable sutures seemed to constitute an independent cause of failure. At this time, we have no clinical method to detect preoperatively the group of patients for whom the choice of fixation material may make a difference. Furthermore, so far there is no scientific evidence to recommend short-term absorbable sutures to alleviate the risk for chronic postoperative pain.

To minimize hernia recurrence following the Lichtenstein inguinal hernioplasty, we recommend either non-absorbable or long-term absorbable sutures for the mesh fixation in all cases and advise against short-term absorbable sutures.

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Author Contributions: Dr Novik had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Novik, Nordin, Skullman, and Dalenbäck. *Acquisition of data:* Novik and Nordin. *Analysis and interpretation of data:* Novik, Nordin, Skullman, Dalenbäck, and Enochsson. *Drafting of the manuscript:* Novik and Dalenbäck. *Critical revision of the manuscript for important intellectual content:* Novik, Nordin, Skullman, Dalenbäck, and Enochsson. *Statistical analysis:* Nordin. *Obtained funding:* Novik and Skullman. *Administrative, technical, and material support:* Novik, Nordin, Skullman, Dalenbäck, and Enochsson. *Study supervision:* Novik, Nordin, Dalenbäck, and Enochsson. **Financial Disclosure:** None reported.

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INVITED CRITIQUE

Surgical Registries

Effective, but How to Pay for Them?

Registries such as the nationwide SHR are powerful tools to evaluate adoption of practices and their effectiveness. Surgical registries are of particular importance as technical aspects and patient factors can be analyzed together to determine the effectiveness of an operation. Novik et al reported that during an 8-year study period, 1.5% of Lichtenstein inguinal hernias had mesh fixation with short-term absorbable suture. Although there was no significant increase of that practice during the observation period, mesh fixation with short-term absorbable suture had a greater than 2-fold hazard of reoperation due to hernia recurrence. Mesh fixation methods have been implicated as a potential cause of chronic groin pain following inguinal hernioplasty. In trying to improve outcomes for patients, surgeons adopted an unexpectedly less effective practice. Without a nationwide registry, this finding may have taken much longer to become apparent.

For registries to be effective, they must contain complete and accurate data and mechanisms for systematic follow-up and audits of the data. The barriers for implementing surgical registries in the United States are obvious: consensus about what to measure; who will be responsible for collecting, entering, and auditing the data; and how follow-up information will be collected. The costs

and barriers are minor in comparison with costs associated with randomized controlled trials. Furthermore, registries serve as natural experiments. Surgeons are innovative and adopt new techniques or products, often without the necessary evidence to support effectiveness or potential harm. Registries provide a rational collective experience of innovation and allow for critical, objective assessments. Some treatments will need evaluation via clinical trials, but registries can direct areas of further study, as well as provide a broader patient population to determine effectiveness. Surgical societies, third-party payers, and industry need to come together to fund these endeavors.

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