



# Rates of and methods used at reoperation for recurrence after primary inguinal hernia repair with Prolene Hernia System and Lichtenstein

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## Abstract

**Introduction** Since the introduction of tension-free mesh repair of inguinal hernia ad modum Lichtenstein (L), recurrence rates have been reduced to 1–2%. The bi-layer mesh Prolene Hernia System (PHS) is an alternative mesh with a theoretical potential to further reduce recurrence rates. However, a reoperation due to recurrence after PHS might be technically difficult since both the anterior and posterior space has been utilized.

**Methods** Data on all males 18–75 years undergoing primary inguinal hernia repair (IHR) with PHS or L between January 1999 and October 2010 was collected from the Swedish Hernia Register (SHR). Moreover, data was collected for all operations due to recurrence after primary IHR with PHS or L between January 1st 1999 and December 31st 2014.

**Results** A total of 1229 primary IHR with PHS and 78,230 with L was identified. Rates of reoperation for recurrence after PHS was significantly lower compared to L (1.5 vs. 2.7 %), [OR 0.38 (0.20–0.74)]. A medial recurrence was most common in both groups. At reoperation, an open anterior mesh repair was used in 74 % after PHS and a posterior mesh repair was performed in 58 % after L. Re-operating time was shorter, although not statistically significant in the PHS group (47 vs. 58 min,  $p = 0.29$ ). Complication rates after surgery due to recurrence did not differ between groups.

**Conclusion** The findings from this dataset suggest that recurrence rates after primary IHR with PHS might be lower and that reoperation due to recurrence after PHS is not more complicated than after L.

**Keywords** Lichtenstein · PHS · Inguinal hernia repair · Recurrence

## Introduction

Lichtenstein (L) is considered gold standard in inguinal hernia repair (IHR) [1]. Since the introduction of this tension-free mesh repair, the recurrence rate has repeatedly been reported to be as low as 1–2% within the first 2 years [1]. Besides recurrence, chronic postoperative groin pain is one important outcome variable, reported to occur in about 11–12% [2] or even higher [3]. New mesh designs and techniques are continuously being introduced with the aim to further improve results after inguinal hernia repair.

One of the most popular procedures for IHR besides L is the Prolene Hernia System (PHS<sup>®</sup>; Ethicon, Norderstedt, Germany), which is designed as a bilayer polypropylene mesh with a connector between the layers. PHS is fixated with fewer sutures than in L and in theory; this could reduce the risk of developing chronic postoperative pain. Further, recurrence rates might be reduced, since the hernia defect is covered both anteriorly and posteriorly.

On the other hand, one concern might be that since both the anterior and posterior (preperitoneal) space is used in PHS-repair, a reoperation could be more difficult and associated with increased risk of complications, which has limited its use. There are no sufficiently large published reports on reoperations due to recurrence after IHR with PHS.

The aim of the present study was to, with the use of a large cohort of patients from the Swedish Hernia Registry (SHR) [4], compare the rates of reoperation for recurrence after primary IHR with L and PHS and to evaluate if an operation due to recurrence after primary PHS repair is more complicated. Moreover, we aimed to investigate which

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surgical methods were chosen during reoperation due to recurrence.

## Methods

### The Swedish Hernia Register

The SHR was launched in 1992 and covers more than 98% of all IHR performed in Sweden [4]. Approximately 16,000 IHRs are registered at 95 centers annually on patients aged 15 years or older. Today, the database contains data from more than 240,000 operations. With the use of standardized protocols, data are registered prospectively. Yearly audits are performed to evaluate the reliability of the data. Ten per cent of all registered centers are visited annually by five independent external evaluators who assess the validity of registered data and check for unregistered IHRs [4, 5]. Data are reported annually to all participating units to enable analysis of own results over time and compare them with all other units in Sweden.

### Data collection

All data were collected from the SHR. The first IHR using PHS was registered in January 1999 and the last in October 2010. All primary unilateral IHR in males aged 18–75 with the use of PHS or L between these dates were identified. From these operations, data on age, type and size of the hernia defect (< 1.5, 1.5–3 and > 3 cm, respectively), management of the hernia sac, operating time and complications within 30 days postoperatively were collected. Moreover, the same data with the addition of information regarding the method of repair used were collected for all operations due to recurrence after a previous primary IHR with PHS or L, from January 1st 1999 to December 31st 2014.

### Statistics

Data are presented in numbers and percentages or median (IQR). For univariate comparison between and within groups, Chi<sup>2</sup> test, Fischer exact test, Wilcoxon signed-rank test or Mann–Whitney *U* test were used, when appropriate. Multiple logistic regression analysis was used for adjusted comparisons of complications after primary operation and rates of reoperation for recurrence. The adjustment variables for both of these were: age, ASA-class, type of hernia, size of hernia defect and management of the hernia sac. In analysis for complications with few events, i.e.,  $n \leq 9$ , only one adjustment variable (age) was used in the logistic regression model. Analysis was undertaken using Statistica<sup>®</sup> version 13 (StatSoft, Dell Software, USA) for Windows and STATA

(version 12 for Windows, College Station, TX, USA).  $p < 0.05$  was considered statistical significant.

## Results

### Primary operation

Between January 1st 1999 and October 31st 2010, a total of 1229 primary IHR with PHS and 78,230 with L were registered in the SHR, Table 1. The median length of follow-up was 131 (IQR 107–170) and 109 (IQR 80–140) months in groups PHS and L, respectively,  $p < 0.05$ ). There were slightly, however, significant higher rates of medial as well as combined lateral and medial defects encountered in patients operated with PHS Table 1. However, in both groups a lateral hernia was the most common type of defect followed by a medial hernia and these two represented together approximately 90% of all procedures. Median operation time was 16 min shorter with the use of PHS,  $p < 0.05$ . The total rates of postoperative complications within the first 30 days after primary IHR were significantly lower after PHS repair [5.7 vs. 7.1%, OR 0.65 (0.45–0.92)]. Hematoma was the most common complication in both groups followed by infection. All registered complications are shown in Table 1.

### Reoperations due to recurrence after primary inguinal hernia repair

Between January 1st 1999 and December 31st 2014, a total of 19 (1.5%) reoperations due to recurrence after primary IHR with PHS and 2084 (2.7%) after L were registered in the SHR [OR 0.38 (0.20–0.74)], Table 2.

The proportion of patients with medial defects was significantly higher at operation for recurrence after primary PHS (79%) compared to after L (46%),  $p < 0.05$ . Moreover, compared with primary operation, a medial defect was more common at reoperation in both groups.

The various methods used at reoperation for inguinal hernia recurrence are shown in Table 2. In the PHS group, an open anterior mesh technique was used in a majority of all procedures (74%) and laparoscopic (Totally Extraperitoneal repair, TEP) surgery in 5 patients (26%). In the L group, a posterior (preperitoneal) mesh repair was used in 58% of all reoperations, of which laparoscopic repair (either TEP or Transabdominal Preperitoneal repair, TAPP) was the most commonly used approach (41% of all reoperations).

The operation time for all open reoperations after L compared to PHS was significantly longer, Table 2. Operating time for open compared to laparoscopic repair after primary PHS did not differ (48 vs. 47 min,  $p = \text{ns}$ ), while an open repair was more time consuming than a laparoscopic operation (63 vs. 58 min,  $p < 0.05$ ) in group L. Operation time

**Table 1** Perioperative data in 79,459 male patients undergoing primary IHR with PHS and Lichtenstein

	PHS	Lichtenstein	OR/ <i>p</i> value
No. of operations, <i>n</i>	1229	78,230	
Age (years), median (IQR)	58.3 (48.7–65.9)	58.9 (48.6–66.4)	ns
Type of hernia defect, <i>n</i> (%)			
Lateral	682 (55.5)	41,890 (53.5)	ns
Medial	484 (39.4)*	28,609 (36.6)	<i>p</i> < 0.05
Combined	56 (4.6)*	7197 (9.2)	<i>p</i> < 0.05
Lateral + femoral	1 (0.1)	82 (0.1)	ns
Medial + femoral	0 (0)	90 (0.1)	ns
Femoral	3 (0.2)	59 (0.07)	ns
Combined + femoral	0 (0)	17 (0.02)	ns
Other	3 (0.2)	286 (0.4)	ns
Op. time (min), med (IQR)	40 (35–50)*	56 (41–73)	<i>p</i> < 0.05
Postop compl., <i>n</i> (%)	70 (5.7)*	5585 (7.1)	0.65 (0.45–0.92)
Hematoma	31 (2.5)	2196 (2.8)	0.53 (0.29–1.01)
Infection	22 (1.8)	930 (1.2)	1.37 (0.87–2.14)
Severe pain	4 (0.3)	612 (0.8)	0.41 (0.15–1.10)
Urinary retention	3 (0.2)	375 (0.5)	0.33 (0.08–1.35)
Multiple complications	1 (0.1)	322 (0.4)	0.20 (0.03–1.40)
Other (not recurrence)	9 (0.7)*	1150 (1.5)	0.44 (0.22–0.88)
Follow-up (months), median (IQR)	131 (107–170)*	109 (80–140)	<i>p</i> < 0.05

\* *p* < 0.05 vs. Lichtenstein, Mann–Whitney *U* test, Chi<sup>2</sup> test and multiple logistic regression analysis

for the most commonly used repair in recurrence after L, laparoscopic TEP, did not differ from the same procedure at operation for recurrence after PHS (47 vs. 50 min, *p* = ns).

All registered postoperative complications within the first 30 days after recurrent IHR are shown in Table 2. There were no differences in rates of complications after reoperation between the groups. Compared with results after the primary operation, however, complication rates were higher in patients reoperated after L, whereas this was not the case in those reoperated after PHS.

## Discussion

In the current study, results after primary operation for IHR with PHS or L as well as rates and results after operation for recurrence following the same procedures were compared. With the use of data from a large national dataset, we report that primary operation time was shorter and the number of complications was lower in patients undergoing repair with PHS compared with L. Moreover, reoperation rates due to recurrence were significantly lower after PHS repair. In patients with recurrence, a medial defect was more common in patients operated with primary PHS. As expected, an open anterior mesh repair was more frequently used for reoperation in this group, whereas a posterior mesh approach was more common after primary L repair. Operating time

or number of complications at 30 days postoperatively did not differ between patients reoperated for recurrence after primary PHS or L.

High-quality data from randomized-controlled trials comparing surgical techniques with recurrence as the primary endpoint are sparse. In the current study, data from the national hernia registry, covering close to 100% of all primary as well as recurrent IHR in Sweden, were used instead. Based on the data from 2103 patients with recurrent hernia, we found a significant lower rate of reoperation for recurrence in patients operated with PHS. This is in corroboration with data from a retrospective series including 622 patients, which in contrast to our study compared patients who were operated during two different time periods [6]. However, lower rates of reoperations for recurrence have not been able to confirm in smaller RCTs [7–14, 17], presumably reflecting that these studies were underpowered and with too short follow-up to address this. The current study covers a period of 16 years with a comparatively very long follow-up time in both groups. The risk for recurrence after IHR is known to increase over time, and any difference between groups could, therefore, theoretically have had an influence on any differences in reoperation rates. However, the follow-up time was significantly longer in the PHS group which, if anything, further supports that rates of recurrence with need of reoperation might be lower with this technique.

Similar to many other countries, an open anterior tension-free mesh repair with the L technique is considered

**Table 2** Perioperative data in 2103 male patients undergoing recurrent IHR after primary IHR with PHS and Lichtenstein

	PHS	Lichtenstein	OR/ <i>p</i> value
No. of operations, <i>n</i> (%)	19 (1.5)*	2084 (2.7)	0.38 (0.20–0.74)
Age (years), median (IQR)	62.9 (45.1–73.6)	62.4 (53.8–69.8)	ns
Type of hernia defect, <i>n</i> (%)			
Lateral	3 (15.8)*	821 (39.4)	<i>p</i> < 0.05
Medial	15 (78.9)*§	954 (45.8)§	<i>p</i> < 0.05
Combined	1 (5.2)	138 (6.7)	ns
Lateral + femoral	0	13 (0.6)	ns
Medial + femoral	0	13 (0.6)	ns
Femoral	0	96 (4.6)	ns
Combined + femoral	0	1 (0)	ns
Other	0	48 (2.3)	ns
Surgical layer <i>n</i> (%)			
Anterior mesh repair	14 (73.7)*	739 (35.5)	<i>p</i> < 0.05
Posterior mesh repair	5 (26.3)*	1201 (57.6)	<i>p</i> < 0.05
Operation method, <i>n</i> (%)			
Suture repair	0	122 (5.9)	ns
Open ant mesh rep	14 (73.7)	739 (35.5)	ns
Open post mesh rep	0	355 (17.0)	ns
PHS	0	5 (0.2)	ns
Laparoscopic repair	5 (26.3)	846 (40.6)	ns
TEP	5 (26.3)	722 (34.6)	ns
TAPP	0	124 (6.0)	ns
Other hernia repair	0	17 (0.8)	ns
Op. time (min), med (IQR)			
Open surgery	48 (35–55)*	63 (45–86)	<i>p</i> < 0.05
Lap surgery	47 (35–54)	58 (40–80)†	ns
Postop compl., <i>n</i> (%)			
Hematoma	1 (5.3)	86 (4.1)	ns
Infection	0	31 (1.5)	ns
Severe pain	0	11 (0.5)	ns
Urinary retention	0	45 (2.2)	ns
Multiple complications	0	19 (0.9)	ns
Other (not recurrence)	0	41 (2.0)	ns

\* *p* < 0.05 vs. Lichtenstein, † vs. open surgery, § < 0.05 vs. primary IHR, Mann–Whitney *U* test, Wilcoxon signed-rank test, Chi<sup>2</sup> test and multiple logistic regression analysis

gold standard for unilateral primary IHR in Sweden. The PHS repair involves a preperitoneal dissection and due to its bilayer design, the repair will be strengthened with an anterior, posterior as well as a plug technique. In accordance with our findings, previous studies have reported some advantages in primary IHR with PHS compared to L in terms of shortened operating time and/or reduced postoperative pain [8, 11, 15, 16]. In the current study, postoperative complication rates were lower after primary PHS repair than after L. This is in contrast to what was reported in a meta-analysis by Sanjay et al. [10], showing that PHS was associated with a higher complication rate compared to L. One possible explanation could be that earlier reports

included in the meta-analysis contain data collected while participating surgeons had not passed their learning curve.

The proportion of medial defects encountered at reoperation for recurrence was significantly higher in the PHS group. One possible explanation could be that the overlapping of the pubic tubercle by the mesh at primary operation could be insufficient with the use of PHS due to the smaller size of the anterior sheet compared to what is usually used during Lichtenstein repair and since only a few sutures are used for fixation.

During reoperation for recurrence after IHR, the dissection of an “untouched layer” is usually preferred. As expected, the choice of surgical approach for reoperation differed between the groups. An open anterior mesh technique

was more frequently used (74%) after PHS recurrence whereas a preperitoneal mesh repair was chosen in 58% of all IHR after L recurrence. In the latter group, laparoscopy accounted for 41% of all procedures of which TEP was most commonly used. Interestingly, five patients with recurrence after primary PHS were reoperated with laparoscopic TEP, and in none of these any postoperative complications were reported.

Operating time at the reoperation with open approach was significantly shorter after primary PHS, while laparoscopic operation did not differ in this respect between groups in the current study. Although the study might have been underpowered to address this with certainty, the findings if anything suggest that reoperation due to PHS recurrence is not more complicated compared to reoperation after L. This is also supported by the finding that complications after reoperation for L recurrence were more common than after primary operation whereas there was no corresponding difference encountered for PHS.

### Limitations

The current study design, a retrospective cohort study, has limitations including the risk of underreporting data, incomplete data collection, lack of confounder information and possible missing information on data quality. It is also important to point out that the register contains solely data for recurrent IHR surgery and not the actual relapse incidence, which could be assumed to be higher. However, the patients included in the analysis in this study are those in which the recurrent hernia was of sufficient clinical relevance to justify reoperation. Another weakness of our study is that the surgeon's level of competence/experience (specialist or resident) was under-reported. It could not be excluded that those who operated primary IHR with PHS as well as recurrence after the same procedure were experienced and hernia dedicated surgeons while L is a procedure that most surgeons perform, also during surgical training.

The main strengths are the large size of the cohort with long follow-up time, that data have been collected independently and that selection bias could be minimized by the use of a complete study population on a national basis.

### Conclusion

The aim of this study was to investigate rates of reoperation due to recurrence after primary IHR with a PHS and to evaluate if these operations were more complicated than a reoperation after L recurrence. Our hypothesis was that an operation due to recurrence after PHS repair could be more complicated than after L, since both the anterior and posterior space already have been used. Based on our data, we

were not able to confirm this. On the contrary, our data suggest that there might be lower rates of reoperation for recurrence after primary IHR with PHS than after L while there is no longer operating time or higher complication rates.

Due to the fact that PHS is more expensive compared to L, is associated with more extensive dissection and since there previously was no proof of any advantages in terms of outcome, the technique is nowadays almost abandoned and not recommended by the World Guidelines from HerniaSurge [18]. The need of reoperation due to other factors such as pain or complications after IHR using PHS should, therefore, be an important issue to address in future studies.

### Compliance with ethical standards

**Conflict of interest** JM declares no conflict of interest, UG declares no conflict of interest, JN declares no conflict of interest, and AT declares no conflict of interest.

**Ethical approval** The study (NCT02424604) was approved by the regional ethics committee (Dnr 2015/351-31/1).

**Human and animal rights** This article does not contain any studies with animals performed by any of the authors.

**Informed consent** For this type of study, formal consent is not required.

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