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## Recurrent groin hernia - Outcome after surgery

Sevonius, Dan

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# Recurrent groin hernia

Outcome after surgery

Dan Sevonius, MD



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Department of Surgery  
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DOCTORAL DISSERTATION

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To be defended in the F 3 lecture room, Main Building, Skåne University Hospital,  
Lund December 19<sup>th</sup> 2014, at 13:00

*Chairman:* Professor Christian Ingvar

*Supervisor:* Associate Professor Gabriel Sandblom

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<p><b>Background:</b> According to the Swedish Hernia Register (SHR), the reoperation rate after recurrent groin hernia is more than twice that following primary hernia repair.</p> <p><b>Aims:</b> To study the impact of method of mesh repair used in recurrent groin hernia surgery on re-recurrence as well as chronic pain and physical disability.</p> <p><b>Methods:</b> Papers 1 and 2 were based on nationwide data from the SHR 1992-2008. In Paper 1 the cumulative risk for reoperation was studied after repeated surgery for recurrent hernia. In Paper 2 the risk for reoperation was analysed in relation to the mesh method used for recurrent hernia repair, taking the previous (index) repair into account. Papers 3 and 4 were based on a cohort of 1<sup>st</sup> and 2<sup>nd</sup> recurrent repairs performed at 5 hospitals in the south-west region of Sweden 1998-2007. A follow-up was performed 2009 using the Inguinal Pain Questionnaire (IPQ) and a selective clinical examination. In Paper 3 the risk for a 2<sup>nd</sup> recurrence was studied in relation to Anterior (AMR) and Posterior Mesh Repairs (PMR) and in Paper 4 the hazard ratio for chronic pain and physical disability was studied in relation to type of mesh repair and mean surgeon's annual volume.</p> <p><b>Results:</b> Paper 1 The risk for a further reoperation increased with the number of recurrent repairs (<math>p &lt; 0.001</math>). Paper 2 Endoscopic (E-PMR) and open PMR (O-PMR) were associated with the lowest risk for reoperation when the index repair was an anterior repair (<math>p &lt; 0.001</math>) Paper 3. PMR was associated with a decreased 2<sup>nd</sup> recurrence rate compared with AMR (<math>p = 0.025</math>). An increased risk for a subsequent 2<sup>nd</sup> recurrence was seen after anterior index repair followed by an AMR (HR 3.21 (CI 1.33-7.44), <math>p = 0.009</math>) and a decreased risk after posterior index repair followed by an AMR (HR 0.08 (CI 0.01-0.94), <math>p = 0.045</math>). In the O-PMR group there was a lower 2<sup>nd</sup> recurrence rate after a Nyhus approach (2.5 %) compared to a trans inguinal approach (TIPP) (28 %) (<math>p = 0.001</math>). A mean surgeon's annual volume <math>\leq 5</math> O-PMR resulted in a higher risk for a 2<sup>nd</sup> recurrence (<math>p &lt; 0.001</math>). Paper 4 The E-PMR was associated with a lower risk for chronic pain and physical disability compared to AMR, after a previous anterior index repair (OR 0.54 (CI 0.30-0.97), <math>p = 0.039</math>). A mean surgeon's annual volume <math>&gt; 5</math> O-PMR correlated with a lower risk for chronic pain compared to an surgeon's annual volume <math>\leq 5</math> (OR 0.42 (CI 0.19-0.94), <math>p = 0.034</math>). Having a 2<sup>nd</sup> recurrent repair was associated with a higher risk for chronic pain compared to a 1<sup>st</sup> recurrent repair (OR 2.89 (CI 1.21-6.88), <math>p = 0.017</math>).</p> <p><b>Conclusions:</b> A posterior mesh repair for recurrent groin hernia surgery was associated with a lower 2<sup>nd</sup> recurrence rate compared to anterior mesh repair. A posterior mesh repair for the 1<sup>st</sup> recurrent operation is recommended after an anterior index repair and an anterior mesh repair after a posterior index operation.</p> <p>Endoscopic repairs have the lowest risk for both a 2<sup>nd</sup> recurrence and chronic groin pain and physical disability. An O-PMR performed through a Nyhus incision is preferred and the TIPP procedure should be avoided. An surgeon's annual volume <math>&gt; 5</math> O-PMR resulted in a lower 2<sup>nd</sup> recurrence rate and a lower risk for chronic pain. The risk for further recurrence increases with increasing number of groin hernia operations and the risk for chronic pain increases after a 2<sup>nd</sup> recurrent repair.</p>			
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Lund University, Sweden, 2014

# Recurrent groin hernia

Outcome after surgery

Dan Sevonius, MD



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Front cover.

Showing a direct recurrent groin hernia after a previous anterior mesh repair

Produced by Hanna Bringman

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KLIMATKOMPENSERAT  
PAPPER



*To my family*

*Catharina, Johanna, Emma  
and Enzo*

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# List of publications

This thesis is based on the following publications and manuscripts, referred to in the text by their numerals.

1. Sevonius D, Gunnarsson U, Nordin P, Nilsson E, Sandblom G. Repeated groin hernia recurrences. *Ann Surg.* 2009 Mar;249(3):516-8  
PMID:19247043
2. Sevonius D, Gunnarsson U, Nordin P, Nilsson E, Sandblom G. Recurrent groin hernia surgery. *Br J Surg.* 2011 Oct;98(10):1489-94 PMID: 21618495
3. Sevonius D, Sandblom G, Agger E, Smedberg S, Montgomery A. The impact of type of mesh repair on 2<sup>nd</sup> recurrence after recurrent groin hernia surgery. *Submitted*
4. Sevonius D, Montgomery A, Smedberg S, Sandblom G. Chronic groin pain and physical disability after recurrent groin hernia repair - Impact of anterior and posterior mesh repair. *Submitted*

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# Abbreviations

AMR	Anterior Mesh Repair
EHS	European Hernia Society
E-PMR	Endoscopic Posterior Mesh Repair
HR	Hazard Ratio
IKVL	Clinical Sciences Lund
IPQ	Inguinal Pain Questionnaire
IQR	Inter Quartile Range
O-PMR	Open Posterior Mesh Repair
OR	Odds Ratio
OSATS	Objective Structure Assessment of Technical Skills
PMR	Posterior Mesh Repair
RCT	Randomised Controlled Trials
SD	Standard deviation
SHR	Swedish Hernia Register
TAPP	TransAbdominal PrePeritoneal repair
TEP	Total ExtraPeritoneal repair
TIPP	TransInguinal PrePeritoneal repair



# Thesis at a glance

Publication	Aim	Method	Results/Conclusion
<b>Paper 1</b> Repeated groin hernia recurrences	To analyse the risk for having a further reoperation after recurrent groin hernia surgery in relation to number of previous recurrent repairs.	All recurrent groin hernia repairs registered in the SHR 1992-2006 were analysed regarding risk for reoperation in relation to number of previous repairs.	The risk for reoperation increased with each repair. Endoscopic repairs had a lower risk for reoperation compared to AMR after the 1 <sup>st</sup> and 2 <sup>nd</sup> recurrent repairs.
<b>Paper 2</b> Recurrent groin hernia surgery	To evaluate the risk for re-recurrent repair in relation to type of mesh repair after recurrent groin hernia surgery	The risk for reoperation (SHR 1992-2008) was compared for type of recurrent repair. The index repair was also taken into account.	PMR had the lowest risk for reoperation after an anterior index repair. Women benefit even more than men from a PMR.
<b>Paper 3</b> The impact of type of mesh repair on 2 <sup>nd</sup> recurrence after recurrent groin hernia surgery	To determine the 2 <sup>nd</sup> recurrence rate after 1 <sup>st</sup> recurrent repair comparing Anterior (AMR) with Posterior Mesh Repair (PMR).	Population-based study on 815 consecutive recurrent repairs at 5 hospitals in south-west Sweden. Follow-up with questionnaire and selective clinical examination.	PMR was associated with a lower 2 <sup>nd</sup> recurrence rate compared to AMR. A posterior approach after anterior index repair and anterior approach after posterior index repair is recommended.
<b>Paper 4</b> Chronic groin pain and physical disability after recurrent groin hernia repair - Impact of anterior and posterior mesh repair	To study the impact of AMR and PMR on chronic groin pain and physical disability after 1 <sup>st</sup> and 2 <sup>nd</sup> recurrent groin hernia surgery.	Population-based study on 671 1 <sup>st</sup> recurrent repairs at 5 hospitals in south-west Sweden. Follow-up with questionnaire and selective clinical examination.	Endoscopic repair was associated with less chronic pain and physical disability compared to AMR. A high surgeon's annual volume of open PMR reduces the risk for pain. The risk for pain is increased after a 2 <sup>nd</sup> recurrent repair.



# Foreword

When I started my surgical training in Karlskrona in the mid-80s, inguinal hernia repair was one of the first operations you were expected to learn. At that time, hernia repairs were non-prestigious operations intended to fill the gap in the programme between large gastrointestinal operations. Interest in hernia surgery among senior surgeons was at a low level. This was reflected when it came to surgical tutoring, which often followed the principle of “See one, do one and teach one”. I performed my first groin hernia repair in 1986 together with Dr Einar Johannesson who was the most senior surgeon on the team and also, unwillingly, responsible for the hernia surgery. When I read the surgical record from that specific operation today, I realise that I understood very little of the principles of the operation. Unfortunately I do not think that Dr Johannesson understood these principles either!

Continued training was carried out mostly on my own or together with my resident colleague and good friend, Peter Andersson. After some time we got a very clear message from Dr Johannesson “Boys, from now on you are responsible for the hernia surgery”! We accepted and he was relieved...

After studying the literature and watching a demo operation on VHS video, we started to perform the Shouldice operation. We organised the surgical training for all residents. Much focus was spent on groin anatomy and all residents trained under strict supervision. After achieving sufficient competence, they were awarded a “surgical license” to perform a primary hernia repair on their own. All recurrent groin hernias were operated with a preperitoneal mesh repair, either through a Nyhus incision or with laparoscopy (TAPP). The Lichtenstein repair was introduced in the mid-90s. In 1994 I started a local hernia quality register, which gave us the possibility to analyse our hernia surgery results on an annual basis. Based on these data we could make efforts to reduce the rate of recurrence.

Together with a young colleague, Fritz Berndsen, we performed a study comparing the recurrence rate after hernia operations performed in 1990, with operations performed in 1996, before and after the introduction of new standardised techniques, the structured surgical training and the hernia register. The 5-year recurrence rate had dropped from 28% in 1990 to 3 % in 1996<sup>1</sup>.

After this positive experience of surgical development, my mission was clear!

**Surgical education, hernia surgery and quality register!!**

(...though, I never thought of writing a thesis at that time....)





# Introduction

## History, definition and prevalence of groin hernia

The word “hernia” originates from the Greek word “hernios” meaning bulge or bud. The disorder was first defined in the cultures of Mesopotamia and Egypt around 1550 BC<sup>2</sup>. The term describes an abnormal protrusion of an organ through a weak area in the abdominal wall. In terms of a groin hernia, the contents from the abdominal cavity or preperitoneal fat protrude through a defect in the groin area.

A groin hernia is either congenital or acquired. The congenital hernia has its origin in the foetal descent of the testicles from the abdominal position through the inguinal canal<sup>3</sup>. The acquired hernia develops with age and is often associated with impaired collagen formation<sup>4</sup>.

The term “groin hernia” includes both inguinal and femoral hernia. The inguinal hernia is classified by localisation of the defect through which the hernia content protrudes. A direct or medial inguinal hernia is located medial to the epigastric vessels and the indirect or lateral inguinal hernia is located lateral to the epigastric vessels. The femoral hernia protrudes medial to the femoral vein, in the femoral canal. Femoral hernia constitutes 25 % of all groin hernias in women but only 1 % of all hernias in men<sup>5</sup>.

Forty-eight per cent of men older than 75 years are either operated for a groin hernia or have a diagnosed hernia<sup>6</sup>. More than 20 million hernia repairs are performed in the world each year<sup>7</sup>. In Sweden the incidence of groin hernia operations, on patients above the age of 15 years, is approximately 200 repairs per 100 000 inhabitants per year. This makes hernia repair the most common operation performed by general surgeons.

## Groin hernia definitions

Irreducible hernia	a hernia that cannot be reduced into the abdominal cavity
Incarcerated hernia	an irreducible hernia with acute symptoms – a clinical diagnosis
Strangulated hernia	a hernia with impaired blood circulation to the content of the hernia sac and/or bowel obstruction – an intraoperative diagnosis
Sliding hernia	a hernia containing a retroperitoneal organ, with or without its mesentery <sup>8</sup> , where the sliding organ can form part of the hernia sac

## Groin hernia symptoms

Groin hernia may be non-symptomatic or have symptoms ranging from mild discomfort to severe pain. Usually the patient notices a lump in the groin associated with a varying degree of discomfort, especially during physical exercise. Large hernias can constitute a mechanical problem for the patient. Some patients experience their hernia as a cosmetic problem. In countries with limited access to surgical healthcare, untreated groin hernia affects young individuals causing significant psychosocial stigmata<sup>9</sup>, substantial morbidity and even mortality<sup>10</sup>.

According to the annual report of the Swedish Hernia Register (SHR) 2013 an emergency hernia operation was performed in 4 % of all operations on men and in 13 % of operations on women<sup>5</sup>. The cumulative probability of strangulation for inguinal hernia has been estimated to be 2.8 % in the first 3 months after onset of symptoms<sup>11</sup>. Femoral hernias run a high risk of incarceration and emergency surgery is seven times more common compared to inguinal hernias<sup>12</sup>.

Pain localised to the groin, may be present without clear association with an existing hernia. In athletes the term “sportsman’s hernia” is often used<sup>13</sup>. Even though a traditional hernia is not obvious, a hernia repair seems to have a positive effect on the groin pain<sup>14,15</sup>. In other categories of patients, the cause of pain may be multifactorial, but is often related to musculo-skeletal conditions such as tendinitis. Physiotherapy remains the most accepted treatment for these patients<sup>16</sup>.



**Figure 1.** A bilateral inguino-scrotal hernia on a patient in Sierra Leone. Published with permission of the African Health Sciences Journal.

## Indications for surgery

The only cure for groin hernia is surgery. A truss is not a permanent solution to relieve symptoms from a groin hernia and does not prevent incarceration<sup>17,18</sup>. The aim of surgery is to reduce symptoms and to prevent acute complications and emergency surgery. Men with a non-symptomatic hernia could be considered for a “watchful waiting” strategy<sup>19</sup>, without increased risk for serious acute complications. In the long run, however many patients are operated on because of the development of symptoms<sup>20,21</sup>. A study by O’Dwyer et al showed, on the other hand, that repair of an asymptomatic hernia may be beneficial to the patient in terms of improving overall health, without affecting the rate of long-term groin pain<sup>22</sup>. Male hernia patients in Sweden are considered for surgery if they experience discomfort or pain or if their hernia has a tendency to enlarge with time.

Female patients with a hernia have an increased risk for incarceration due to the higher rate of femoral hernia<sup>23</sup>. In order to prevent emergency operations, there is a recommendation in Sweden suggesting hernia repair for all women with a diagnosed hernia, even in the absence of symptoms<sup>17</sup>. In a recent publication by Dahlstrand et al<sup>24</sup>, the awareness of a femoral hernia prior to emergency surgery was denied by 53 % of patients. The implication of that study is how important it is that those working in healthcare are informed on how to recognise these patients and make a quick and correct assessment. It also emphasises the importance of thoroughly examining the

groins, especially in women with acute abdominal pain and symptoms of gastrointestinal obstruction. Patients with signs of incarceration should be operated on without delay to prevent permanent intestinal strangulation<sup>25</sup>. Groin hernia is the most common cause of strangulation in patients with small bowel obstruction<sup>26</sup>.

# The Swedish Hernia Register – SHR

The SHR was founded and developed by Professor Emeritus Erik Nilsson (picture). The register started in 1992 with eight aligned hospitals. The aim was to become a national quality register to describe and analyse groin hernia surgery in Sweden. This was the start of a new era of structured hernia-data collection. The SHR contains data on groin hernia repairs performed in patients aged 15 years or older. During the years after the start of the SHR, several new methods of hernia repairs were introduced. At that time the Shouldice repair was the gold standard. The Lichtenstein and the laparoscopic TAPP techniques started in the early 90s and gained increasing popularity. The number of aligned hospitals has gradually increased over the years. From year 2000 until 2013 the number of hospitals affiliated increased from 53 to 86. Approximately 15 000– 16 000 groin hernia repairs are registered annually.



Over the last 13 years the register has covered around 98 % of all hernia repairs in the country<sup>27</sup>. The total number of repairs registered between 1992 and 2013 was more than 253 000. The accuracy and completeness of the recorded data are validated annually. Five independent evaluators visit 10 % of affiliated units each year to check the validity of data registered as well as to check for unregistered groin hernia operations. Since each Swedish resident has a unique personal identification number, any hernia repair on a given patient can be linked to the previous registered repair in the SHR, wherever performed in the country. This gives Sweden as a nation and the participating units a unique possibility to obtain valid data on the cumulative incidence of reoperation.

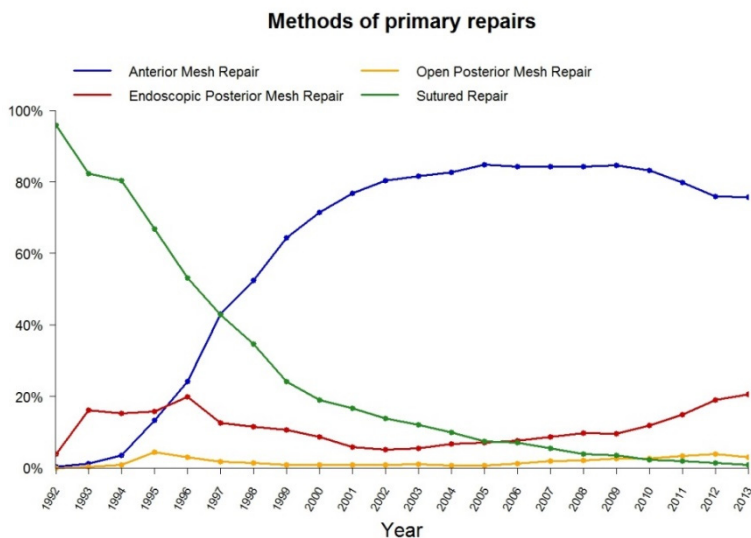
Each participating unit receives processed data annually. The units have the opportunity to analyse and compare their results with those nationwide. This has been the basis on which the participating units have begun their work to improve the quality of groin hernia surgery.

Over the years there has been a huge shift from sutured repairs towards mesh repairs (Fig. 2). In 2013, mesh repair accounted for 99.1 % of all repairs<sup>5</sup>. The five year cumulative incidence of reoperations has decreased from close to 5 % (1992-1998) to 2.5 % (2006-2013) probably due to the introduction of standardised techniques on a nationwide scale.

# Primary groin hernia repair SHR 2013

## Outcome<sup>5</sup>

- The Lichtenstein repair has the lowest cumulative risk for reoperation compared to all other methods of repair  $p < 0.001$ .
- Hernia repairs performed 2006-2013 have a lower cumulative risk for reoperation compared to hernia repairs performed 1992-1998 HR 0.70 CI 0.66-0.74,  $p < 0.001$ .
- Women have a higher cumulative risk for reoperation than men HR 1.31 CI 1.21-1.42,  $p < 0.001$ .
- Femoral hernia has the highest cumulative risk for reoperation (indirect hernia as reference) HR 2.32 CI 2.06-2.62,  $p < 0.001$ .
- Surgeons performing 6-10 primary repairs per year have a lower cumulative risk for reoperation compared to surgeons performing 1-5 repairs per year HR 0.69 CI 0.62-0.76,  $p < 0.001$ .
- Emergency repairs have a higher cumulative risk for reoperation compared to elective repairs HR 1.32 CI 1.20-1.46,  $p < 0.001$ .



**Figure 2.** Methods of repairs used in primary groin hernia surgery between 1992-2013 (SHR), based on 222 897 primary groin hernia repairs. Since the number of aligned hospitals was few during the first years, these early results may not be representative for the country as a whole.

## Register Studies

The SHR database has become a unique source to conduct population-based studies on large numbers of hernia repairs. Results from SHR studies reflect the outcome after routine hernia surgery as it is practised in the community at large<sup>28</sup>. As the outcome is not limited to centres where facilities for hernia surgery are optimised, the external validity is high and the results are not only applicable to surgeons with a special interest in hernia surgery. This is in contrast to randomised controlled trials (RCTs) that are often performed at specialised units in selected patient cohorts<sup>29</sup>. In register studies the long-term outcome (rate of reoperation for recurrence) may be studied at a lower cost compared to RCTs. The larger sizes of study cohorts also enable the analyses of rare adverse events with a higher statistical power than most RCTs<sup>30</sup>.

A potential disadvantage with register-based studies is the risk of incorrect or missed data, at least if the register is not sufficiently validated. Since the SHR applies to routine hernia surgery, the data collected must be carefully selected in order to obtain valid data from all surgeons, not only enthusiasts. The time needed for filling in the protocol must be limited in order to gain good compliance. This is carefully monitored by the steering committee of the SHR that constantly works on the protocol, as well as IT solutions for registration and giving feedback to users. So far, health-related quality-of-life has not been included in the protocol, but the steering committee is working on this as the next step in development.

Another factor to bear in mind is that the SHR only supplies data on the incidence of reoperation and not the actual rate of recurrence. Specially designed studies are needed to address issues such as chronic groin pain, health-related quality-of-life and recurrence rate<sup>31,32</sup>. Many consider register studies as a valid complement to RCTs<sup>33</sup>, and national registers have encountered an increasingly higher reputation internationally in recent years. More than 40 articles have been published based upon the SHR. This is the tenth thesis based on data from the SHR.





# Education in hernia surgery

During the first decennium of the 2000s there were large differences between hospitals in Sweden concerning the quality of education in hernia surgery. The main reason for this was that many hospitals lacked a uniform strategy for hernia surgery. Many hospitals questioned the quality of their own resident training programme. Indications for surgery and the methods of repair differed widely. Even “standardised” methods such as the Lichtenstein repair were often performed with great differences in technical performance. More than 60 % (949/1509) of repairs in women and 55 % (785/1440) of recurrent repairs were operated with an anterior mesh repair (Lichtenstein and Plug repairs) in 2009<sup>5</sup>.

## National society for hernia surgery

Hernia surgery is organised as a subsection of the Swedish Surgical Society named the SIKT (Swedish Society for Innovative Surgical Technology). Within this society there is a dedicated group working especially on the development of hernia surgery as a whole, including all types of hernia. This working group is closely attached to the steering committee of the SHR. The SIKT is also responsible for residents’ education in hernia surgery, and the spreading of information and knowledge to all hernia surgeons throughout Sweden.

A national meeting for general surgeons, hernia specialists and surgical residents is arranged by the SHR and the SIKT. The meeting is held annually, and reports are given on the latest evidence for various strategies in hernia surgery. This is an important meeting for the spreading of information and updating of residents and surgeons on a nationwide basis.

## National course in hernia surgery

A standardised concept for a national course in hernia surgery was demanded as part of the new curriculum of the residents’ education programme. A group of hernia surgeons were commissioned by the SIKT to design a national course in hernia surgery. A national faculty was formed and the first course was carried out in 2009. The course is now held at seven centres and is mandatory for all surgical residents in Sweden. The course curriculum is evidence-based and also includes results and information from the

SHR. The course has been a tremendous success, spreading sound and up-to-date strategies in hernia surgery to residents, and the concept has become an effective way of influencing the performance of hernia surgery in a nation-wide perspective.

Many believe that all these efforts and the work that has been performed have had positive effects on the quality of hernia surgery in Sweden, which could also be seen over time in the SHR. One example is that women were operated with a posterior mesh repair (PMR) in 70 % and PMR were used in 60 % of all recurrent repairs in 2013.

## Conditions for hernia surgery training

The conditions for surgical training have undergone tremendous changes during recent decades. The consequence of working hours regulations has been that surgical residents spend less time in the operating room and more time in structured education programmes including a broader programme for scientific and administrative education and more time in emergency care units. There have been strong demands for effective utilisation of operating room facilities and this has also affected the possibility for resident surgical training<sup>34</sup>. These circumstances have had a positive consequence on basic surgical training, which nowadays is performed in skills centres. Training is also performed in simulation-based models, which provide better conditions for structured learning of basic technical skills<sup>35</sup>. With these skills, the resident will be better prepared for further training in the operating theatre.

Even the structure of teaching practical skills has improved in recent years. The Royal College of Surgeons introduced the “Training the trainers course” in 1994<sup>36</sup>. This course presents a new concept in enhancing the effects of teaching surgical skills. The course concept was introduced in Sweden in 2006 and the principles are widely used in surgical training around the country.

Groin hernia repair is still one of the first operations the surgical resident is expected to manage on her/his own. According to the description of *Objectives in Surgical Education* formed by The National Board of Health and Welfare and The Swedish Surgical Society, it is mandatory for all surgical residents to be able to perform an anterior mesh repair in men with a primary hernia<sup>37</sup>. To facilitate the training process it is important to standardise the procedure in such a way that the same teaching principles are used regardless of where in Sweden the operation is performed. The faculty of the “National Course in Hernia Surgery” has described *The Swedish Anterior Mesh Repair in groin hernia*<sup>38</sup>. This description is divided in two main parts, *groin dissection* and *mesh repair*, which are further sub-divided into more specific parts of the operation.

The assessment of a resident’s proficiency in hernia surgery has always been based upon a subjective judgement. In Sweden it is up to the local hernia tutor to decide when the resident has achieved the goal of successfully managing the operation independently. In a study by Carlsen, a Danish group has designed a procedure-specific assessment tool

to be used for the Lichtenstein hernia repair<sup>39</sup>. The construction of the tool is based upon the OSATS<sup>40</sup> (Objective Structural Assessment of Technical Skills) developed by Reznick, to assess surgical skills in a bench model. The Danish tool to assess the Lichtenstein procedure uses a 5-point Likert scale to assess four global skills and four procedure-specific skills (Table 1). The tool has been studied using video-recorded Lichtenstein procedures and has been found reliable and valid<sup>39</sup>.

Table 1. Lichtenstein hernia repair rating scale proposed by C.G. Carlsen<sup>39</sup>  
 Published with permission from Springer/Hernia and the author.

Lichtenstein hernia repair rating scale

	1	2	3	4	5	point
Respect for tissue/ dissection technique	Unnecessary force on handling tissue. Tissue damage		Careful handling of tissue, but occasionally causes inadvertent damage.		Consistently appropriate handling of tissue. Minimal tissue damage.	
Time and motion	Many unnecessary movements. Inefficient effort		Efficient motions, but some unnecessary movements.		Clear economy of movements and maximum efficiency.	
Flow of operation	Seems unaware of next move. Frequently stops and needs corrections.		Demonstrates some forward planning, with reasonable progression of operation.		Fluent, planned course in all stages of operation. No need for corrections	
Instrument handling	Frequently use wrong or inappropriate instruments		Competent use of instruments, occasionally awkward.		Fluid moves with instruments and no awkwardness.	
Freeing the spermatic cord	Significant damage to spermatic cord or surrounding tissue		Modest damage to spermatic cord or surrounding tissue		No damage to spermatic cord or surrounding tissue	
Dissection of the hernia sac, including presentation of direct or indirect hernia	No separation of the hernia sac and inappropriate handling of peritoneal tissue.		Sufficient separation of the hernia sac and handling of peritoneal tissue		Fluent and correct separation of the hernia sac and handling of peritoneal tissue.	
Mesh fixation	Wrong placement and fixation of mesh		Sufficient placement and fixation of mesh incl. a continuous suture		Fluent and correct placement and fixation of mesh	
Wound closure	Uneven placement of sutures in the external oblique aponeurosis or skin		Sufficient placement of sutures in the external oblique aponeurosis and skin		Correct placement of sutures in the external oblique aponeurosis and skin	

**Total**

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# Recurrent groin hernia surgery

## Historical background

Recurrent groin hernia surgery has always been a challenge for surgeons. Before the era of meshes, all groin hernia repairs methods were based on the intention to restore the anatomy of the groin with various suture techniques<sup>41,42</sup>. During the 1940s and 1950s the McVay suture plasty was used for both primary and recurrent repairs<sup>43</sup>. Most repairs were performed through the trans-inguinal approach until Lloyd M. Nyhus 1959 described a preperitoneal approach through a transverse incision above the inguinal canal<sup>44,45</sup>, through which the defect was closed by suturing. It was considered especially suitable for recurrent and incarcerated hernias.

A new era of reinforced hernia repairs started after Usher introduced the polypropylene mesh (Marlex) in 1958<sup>46</sup>. It took many years until the mesh was generally accepted among surgeons. In 1988 Nyhus reported 1 % recurrence after 203 recurrent repairs where a Marlex mesh was used as a buttress of the closed defect performed through a preperitoneal approach<sup>47</sup>. This technique was proposed as “the solution” for recurrent groin hernias<sup>48</sup>. The Lichtenstein repair was introduced 1986<sup>49</sup> and the technique was also going to be used in recurrent groin hernia surgery.

## Definitions

<b>Primary groin hernia</b>	the first hernia repair in a groin.
<b>Recurrent groin hernia</b>	a hernia in a groin after a previous hernia repair, inguinal or femoral, regardless of hernia anatomy at the preceding repair.
<b>1<sup>st</sup> recurrent repair</b>	the first reoperation after a primary groin hernia repair.
<b>2<sup>nd</sup> recurrent repair</b>	the second reoperation after a primary groin hernia repair.

<b>Recurrence rate,</b>	the “true” rate of recurrent hernia after a previous hernia repair, whether or not the hernia has been re-operated. Examination or the use of interventional diagnostic methods are needed to ensure the existence of a new hernia.
<b>Cumulative incidence of reoperation</b>	the aggravated incidences of reoperation after a previous hernia repair. Non-re-operated recurrences are not included. Often used in hernia registers.

## Methods of mesh repair in recurrent hernia surgery

Repairs can be divided in two main groups, depending on the approach from which the repair is performed.

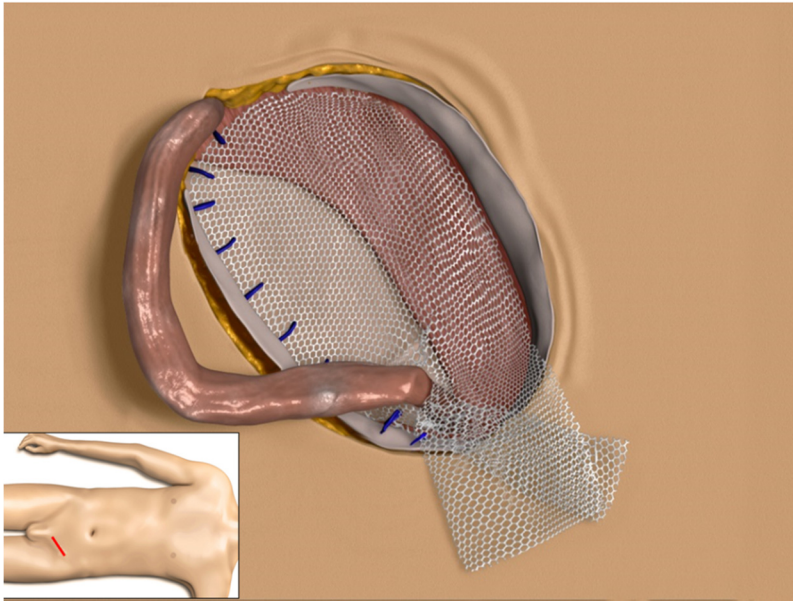
- Anterior mesh repair (AMR)** – the mesh is placed in the inguinal canal through a transinguinal approach. Repair of inguinal hernia only.
- Posterior mesh repair (PMR)** – the mesh is placed in a preperitoneal position behind the inguinal canal, through an endoscopic or open approach. Repair of both inguinal and femoral hernia.

### Anterior Mesh Repairs

*The Lichtenstein repair* was developed by Irvin Lichtenstein and popularised by Parviz Amid<sup>50</sup>. The technique was described as tension-free, and is intended to reduce the hernia and create a flat posterior wall in the inguinal canal without tension. The mesh is anchored medially and to the inguinal ligament. Over the years the technique has been subject to many modifications, both from the Lichtenstein Institute<sup>51</sup> and also among surgeons using the technique<sup>52</sup>. The modifications concern the closure of indirect defects, the use of different types of mesh (Polyester/Polypropylene, various pore size), the size of mesh, how the mesh is anchored (resorbable or non-resorbable sutures, staples, glue), repair of a combined inguinal and femoral hernia etc. The impact of these different modifications on recurrence and chronic pain has not yet been fully studied. This should be kept in mind when comparing the “Lichtenstein repair” between units and even between surgeons.

*The Swedish Anterior Mesh Repair* is a standardised description of the mesh method recommended by the faculty of the National Course in Hernia Surgery in Sweden. A description in Swedish is available at:

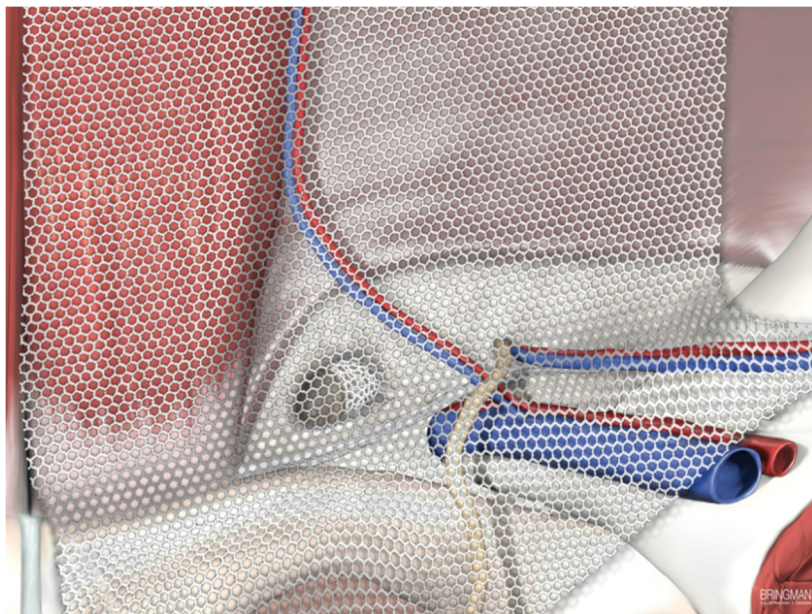
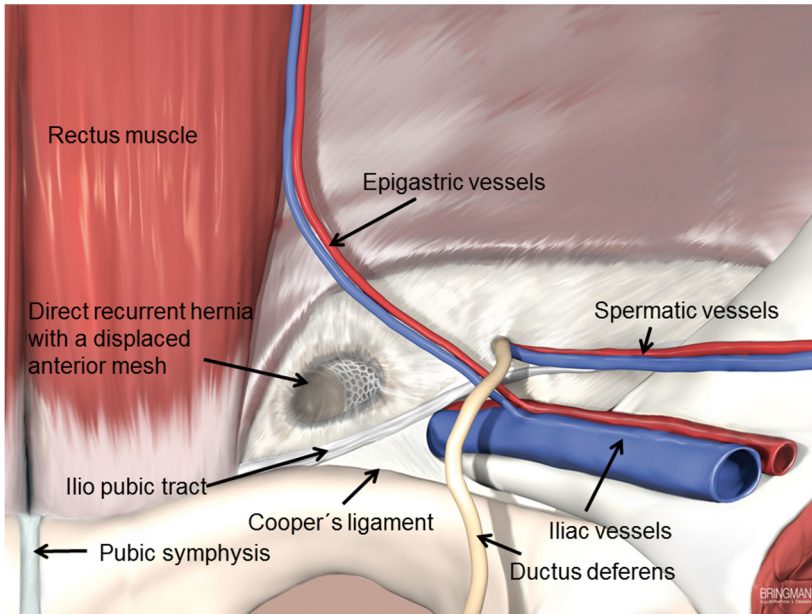
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**Figure 3.** Anterior Mesh Repair, left groin. The mesh is sutured with an overlap of the pubic tubercle and to the inguinal ligament. The Spermatic cord passes through a slit in the mesh. Illustration by Hanna Bringman.

*The Plug and Patch technique* was developed by Ira Rutkow and Alan Robbins in 1993<sup>53</sup>. A polypropylene plug was inserted into the hernia defect of the posterior inguinal wall and was combined with an onlay flat, small mesh. It was popular in Sweden during the late 1990s and early 2000s.





**Figure 4.** At the top: A preperitoneal view of the right groin showing a direct recurrent groin hernia after a previous Anterior Mesh Repair. At the bottom: A Posterior Mesh Repair . Illustration by Hanna Bringman.

## Posterior Mesh Repairs

*The Open Posterior Mesh Repair (O-PMR)* was introduced by Rive and Stoppa in 1968<sup>54</sup>. The first articles were in French. In 1975 Stoppa published the first article in English<sup>55</sup>. The preperitoneal space was accessed through a midline incision in the lower abdomen. The method was used for bilateral, recurrent hernia repair. A large Dacron® mesh was positioned to cover both groins without fixation. A recurrence rate below 1 % was reported<sup>55</sup>.

*Nyhus<sup>45</sup> and Wantz<sup>56</sup>* described the entrance to the preperitoneal space through a transverse incision above the inguinal canal. A polypropylene mesh was used and sutured to the Coopers ligament.

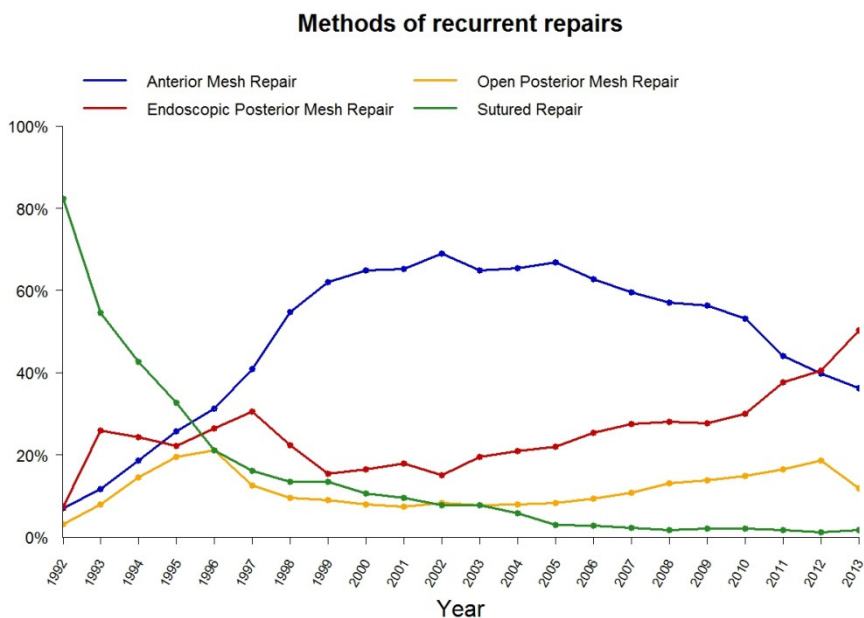
The *TIPP* procedure – *Trans Inguinal PrePeritoneal* is a third open approach to the preperitoneal space. It is performed via a transinguinal approach. This technique has been described by several authors. Kugel described a minimally invasive technique to place a non-sutured mesh in a preperitoneal position<sup>57</sup>.

The *PHS* technique – *Prolene Hernia System*, was introduced by Gilbert<sup>58</sup> in 1992. It is also performed through a transinguinal approach and the mesh used is a two layer prosthesis where one layer is placed in the preperitoneal position through an opening of the fascia transversalis and one layer is placed in an anterior position. The method was only sparsely used in Sweden.

*Endoscopic Posterior Mesh Repair (E-PMR)*. The first laparoscopic hernia repair was reported by Ger in 1982<sup>59</sup>, who plugged the hernia sac with a mesh and ligated the sac intraperitoneally. The E-PMR was introduced 1992 by Maurice Arregui who described the *TAPP (TransAbdominal PrePeritoneal repair<sup>60</sup>*. A laparoscopic approach was used. The peritoneum above the inguinal canal was opened and the hernia sac reduced into the abdominal cavity. A mesh was placed in the preperitoneal position. The mesh was anchored with staples and the peritoneum was closed. The *TEP (Total ExtraPeritoneal repair)* was described the same year by Jean-Louis Dulucq<sup>61</sup>. By entering the space behind the rectus muscle with a laparoscopic trocar, the preperitoneal space in the groin was reached without entering the abdominal cavity. Initially he called the approach “pre-peritoneoscopy”. The hernia sac was reduced from the hernia defect and a mesh was placed to cover the entire groin region.

## Methods reported in the SHR over time

When the SHR started, sutured repair was the most frequently used technique in recurrent groin hernia surgery. After the introduction of mesh in the mid-90s, the AMR, E-PMR and O-PMR techniques were more frequently used. The popularity of AMR grew rapidly towards the end of the 90s since PMR techniques were considered more difficult to learn at that time, limiting their use. Since 2012, E-PMR has become the most frequently used method of repair in recurrent groin surgery in Sweden (Fig 5)



**Figure 5.** Methods used in recurrent groin hernia repairs in the SHR 1992-2013. Based on 26 701 recurrent repairs. Since the number of aligned hospitals was few during the first years, these early results may not be representative for the whole country.

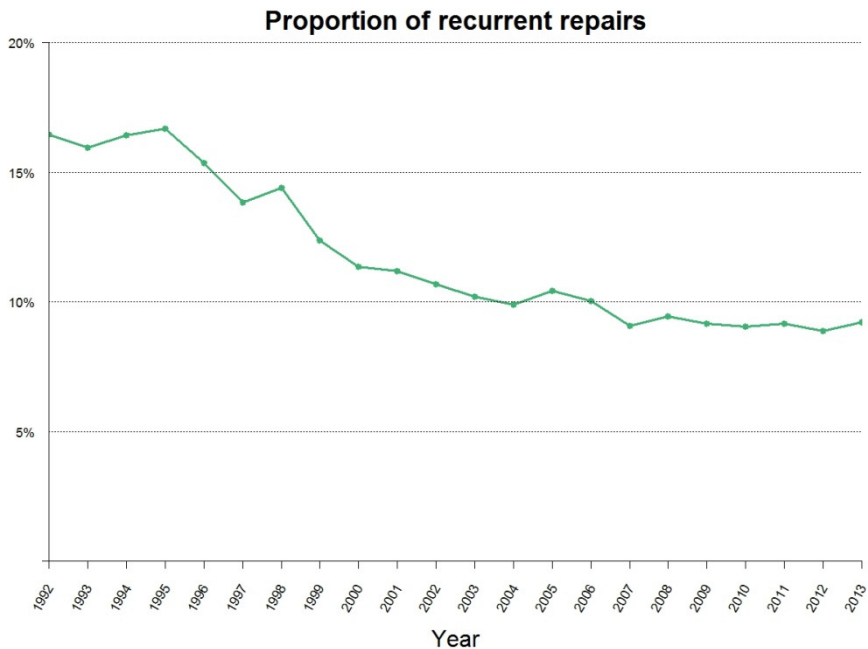
## Outcome after recurrent hernia surgery

Outcome after hernia surgery is often described in terms of the rate of recurrence and chronic pain. A major reason for embarking on this thesis was to describe and analyse the differences in outcome after primary and recurrent groin hernia surgery.

Data from the SHR can be used to describe these differences.

### Reoperation due to recurrence

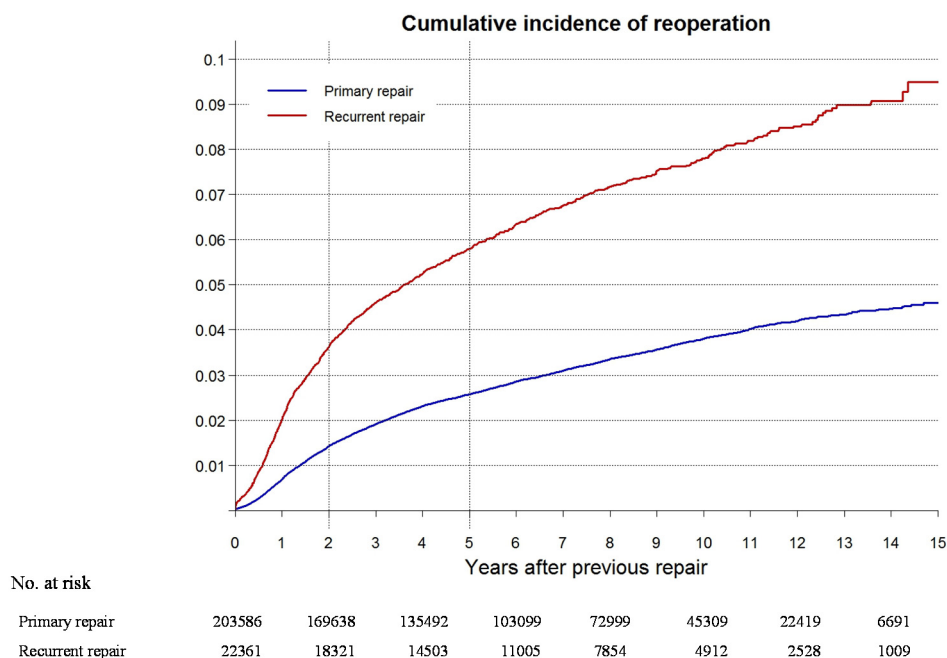
The proportion of groin hernia repairs performed on recurrent hernias was 16.4 % in 1992. The proportion has diminished over time stabilising at around 9 % since 2007 (Fig 6).



**Figure 6.** The proportion of recurrent hernia repairs registered in SHR 1992-2013. Based on 253 625 repairs.

## Incidence of reoperation following primary and recurrent repairs

Even though new methods of repair have had a dramatic effect on reoperation, the cumulative incidence of reoperation after recurrent repair is more than twice as high as after primary repair according to the SHR (Fig. 7). After 5 years the incidence is 2.7 % after primary and 5.8 % after recurrent groin hernia surgery. The risk for having a reoperation after a recurrent hernia repair is more than doubled compared to primary hernia repair, HR 2.18 CI 2.06-2.32,  $p < 0.001$ . The cause of this large discrepancy has not been fully explored. Factors that could affect the outcome could be patient-related (gender, age, type of hernia, risk factors), surgeon-related (skills), complexity of the conditions at reoperation and technique-related (according to method of hernia repair). Recurrent repair is considered to be a more technically demanding procedure compared to a primary repair.



**Figure 7.** Cumulative incidence of reoperation registered in the SHR 1999-2013. Based on 203 586 primary repairs and 22 361 recurrent repairs.

## Cumulative incidence of reoperation

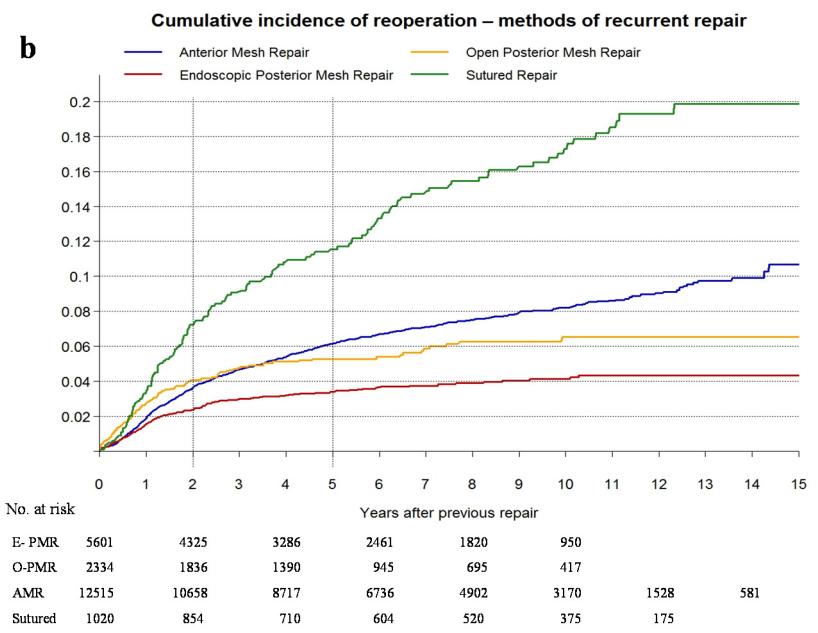
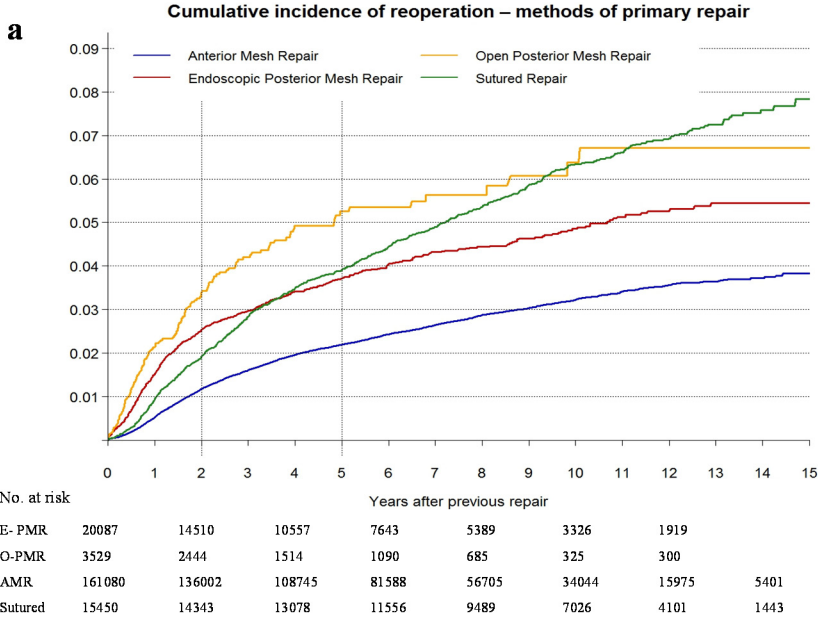
### Impact of method of repair in primary and recurrent surgery

According to the SHR, the cumulative incidence of reoperation in relation to the method of repair differs greatly between primary and recurrent groin hernia surgery.

In primary hernia surgery, the AMR is the method associated with the lowest risk for reoperation compared to all other methods of repair. In a univariate Cox proportional hazard analysis with AMR as reference category, the HR for reoperation following E-PMR was found to be 1.69 (CI 1.55-1.83), for O-PMR 2.37 (CI 2.01-2.80) and for Sutured repair 1.93 (CI 1.80-2.08) all analysis with  $p < 0.001$  (Fig.8a).

The outcome following recurrent groin hernia surgery differed from that of primary hernia repair. With AMR as reference category, the risk of a new recurrent repair is more than doubled after a sutured repair HR 2.06 CI 1.81-2.34,  $p < 0.001$ . Both PMR methods are associated with a lower risk compared to AMR. The E-PMR has the lowest risk, HR 0.58 CI 0.50-0.67,  $p < 0.001$  and the O-PMR HR 0.83 CI 0.70-0.99,  $p = 0.037$  (Fig. 8b).

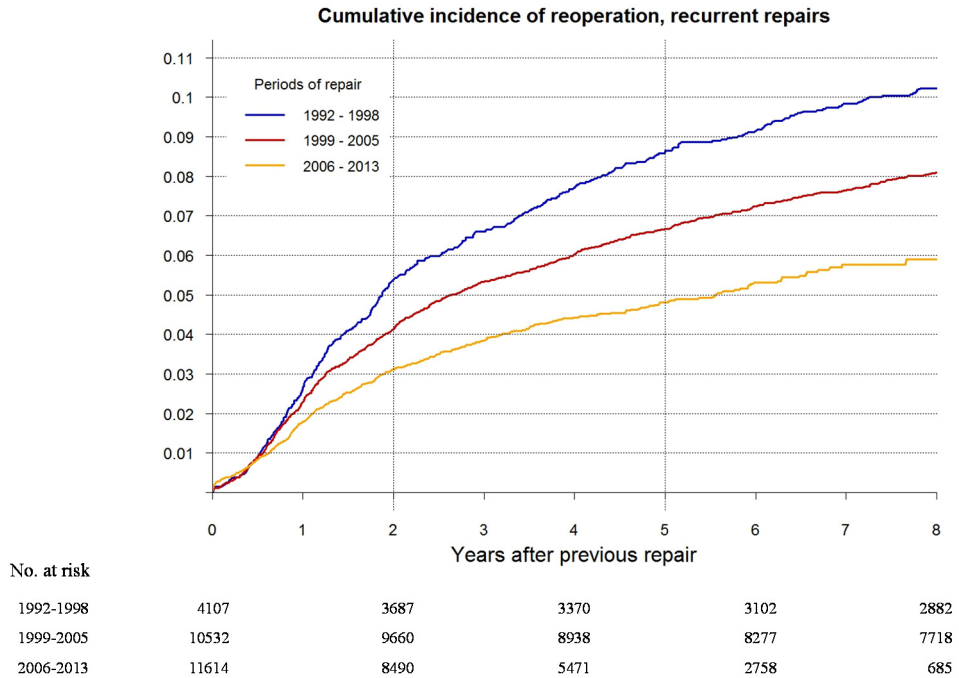
The cause of these discrepancies in outcome after PMR methods for primary and recurrent repairs is not fully understood. There is no reason to believe that a recurrent hernia is easier to operate using a PMR technique than a primary hernia. The results could reflect the learning curve among surgeons starting to perform PMR for primary hernias and that recurrent repairs are performed by surgeons specially trained in PMR methods. There is a longer learning curve for E-PMR compared to the Lichtenstein repair<sup>62</sup>. It is suggested that it requires between 50 and 100 E-PMRs to become experienced and that the first 30-50 repairs being the most critical as regard of risk for recurrence<sup>63,64</sup>.



**Figure 8 a, b** Cumulative incidence of reoperation in relation to method of repair registered in the SHR 1999-2013. **a.** Based on 200 146 primary repairs. **b.** Based on 21 470 recurrent repairs. Un-published analyses, prepared for this thesis.

## Impact of time period

The cumulative incidence of reoperation has had a clear tendency to decrease over time. In a univariate Cox proportional hazard analysis the risk for a reoperation was decreased for recurrent repairs performed 2006-2013 compared to recurrent repairs performed 1992-1998, HR 0.55 CI 0.52-0.59,  $p < 0.001$  (Fig. 9).



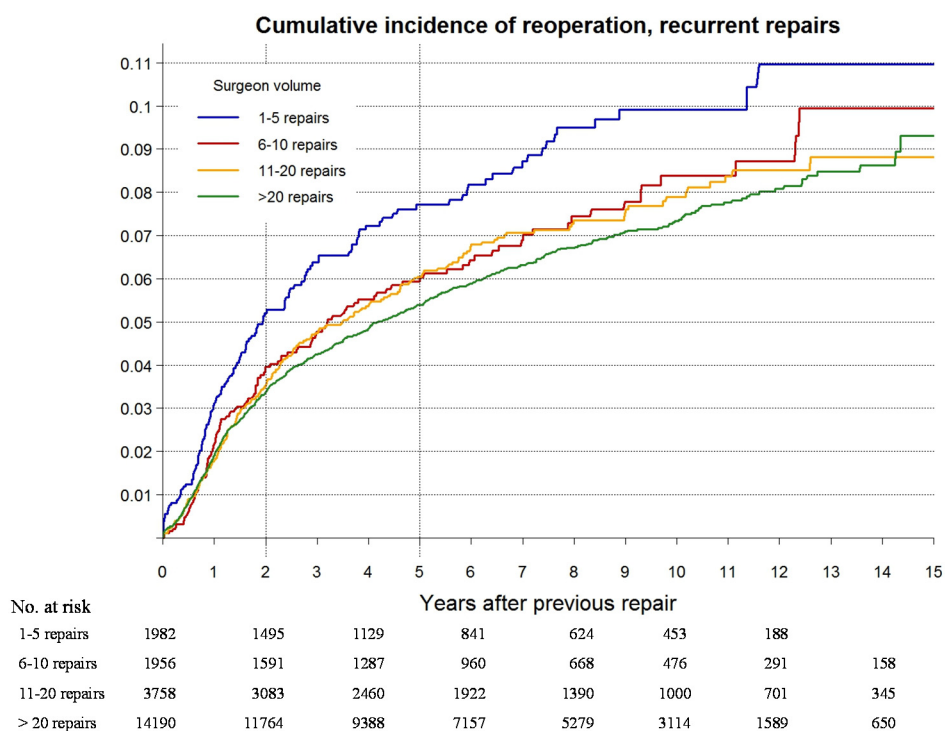
**Figure 9.** Cumulative incidence of reoperation after recurrent repairs in different time periods, registered in the SHR 1999-2013. Based on 4 107 repairs 1992-1998, 10 532 repairs 1999-2005 and 11 614 repairs 2006-2013 according to the SHR. Un-published analyses, prepared for this thesis.



## Impact of surgeon's annual volume

In the absence of a clear definition of surgeon's proficiency in hernia surgery, the surgeon's annual volume can serve as surrogate measure. Surgeons performing 6-10 *primary repairs* per year in Sweden have a lower cumulative risk for reoperation compared to surgeons performing 1-5 repairs per year (reference) HR 0.69 CI 0.62-0.76,  $p < 0.001$ <sup>65</sup>.

Surgeons performing 11-20 *recurrent repairs* per year have a lower cumulative risk for reoperation compared to surgeons performing 1-5 *recurrent repairs* (ref) HR 0.74 CI 0.61-0.90,  $p = 0.002$  (Fig. 10).



**Figure 10.** Impact of surgeon's volume on cumulative incidence of reoperation after 21 886 recurrent repairs registered in the SHR 1999-2013. Surgeon's volume 1-5 repairs (1982), 6-10 repairs (1956), 11-20 repairs (3758) and >20 repairs (14190). Un-published analyses, prepared for this thesis.

## Chronic groin pain

With the declining number of recurrences, chronic groin pain and discomfort have arisen as being the factors with greatest impact on health-related quality-of-life and ability to perform daily activities following hernia surgery<sup>32,66-68</sup>. The prevalence and the definitions of the condition vary widely in the literature<sup>69,70</sup>. Chronic pain has been defined as a pain lasting more than 3 months after surgery<sup>71</sup>. In a review by Aasvang moderate to severe chronic groin pain is reported in 10-12 % of patients, with 4 % having pain that impairs daily activities<sup>66</sup>. In a study by Poobalan et al on 351 patients, it was found that an operation for a recurrent hernia increased the risk for chronic pain 4-fold compared to primary repair ( $p=0.005$ )<sup>72</sup>. A detailed prospective study on 419 patients of which 21 % were operated on for a recurrent hernia, found a higher incidence of moderate to severe chronic pain 12 months after recurrent repair compared to primary repair (14 % vs 3 %,  $p<0.01$ )<sup>73</sup>.

Several studies indicate that intense preoperative pain increases the risk for developing chronic groin pain after hernia surgery<sup>74-76</sup>. Pain seems to diminish over time. In a study on 120 patients that reported severe or very severe pain 3 months after surgery, 71 % still reported pain 2.5 years later, but only 26 % described the pain as severe or very severe<sup>77</sup>. Even immediate post-herniorrhaphy pain intensity may correlate with the risk for chronic groin pain conditions<sup>73</sup>.

Preoperative chronic pain conditions such as headache, back pain, irritable bowel syndrome and pain from scars elsewhere in the body significantly correlated with the development of chronic groin pain in two studies<sup>76,77</sup>.

Less chronic pain is reported after endoscopic repairs compared to open tension-free repairs for primary groin hernia<sup>67,78</sup>. This is in contrast to a meta-analysis by Karthikesalingam on 4 randomised controlled trials on recurrent groin hernia, that did not show any difference in the risk for chronic groin pain between endoscopic and open repair (OR 0.91 (CI 0.14-5.88) ( $p=0.921$ ))<sup>79</sup>. In these studies however the previous hernia repair, prior to the recurrent repair, is not reported.

Methods used to quantify chronic pain have varied in the literature from merely a dichotomous “yes” or “no” answer to a question on pain<sup>80</sup> or by using a visual analogue scale (VAS)<sup>81,82</sup> or a numeric rating scale (NRS)<sup>83</sup>. To measure quality-of-life, the Short Form (36) Health Survey (SF-36)<sup>84</sup> and the Carolina Comfort Scale (CCS)<sup>85</sup> have been used.

The Inguinal Pain Questionnaire (IPQ) was designed to achieve a uniform assessment for persistent postoperative groin pain and its effect on daily activities. The instrument has been validated<sup>86</sup> and used in several studies<sup>32,68</sup> (Appendix 1). An “IPQ score” has been developed in order to quantify the combination of pain and ability to perform “everyday activities”.



**Figure 11.** Recurrent groin hernia on the right side, after a previous Anterior Mesh Repair.



**Figure 12.** Laparoscopic view of bilateral, direct groin hernias.

# Aims of the thesis

Based on a national cohort

- To describe various circumstances, that may increase the risk for further reoperation, after multiple groin hernia repairs.
- To identify risk factors for reoperation after recurrent groin hernia surgery.
- To investigate the risk for reoperation after recurrent hernia surgery, in relation to the method of previous repair.

Based on a regional cohort

- To study the impact of method of mesh repair at 1<sup>st</sup> recurrent groin hernia surgery on the risk for a 2<sup>nd</sup> recurrence.
- To analyse the impact of anterior and posterior mesh repair, on chronic groin pain and disability after 1<sup>st</sup> and 2<sup>nd</sup> recurrent groin hernia repair.



# Background

## Study 1

Although relatively infrequent, recurrent groin hernia where several repairs have previously been undertaken constitutes a major problem in hernia surgery. Repeated repair on the same groin leads to deterioration in the mechanical strength of the tissues and distortion of anatomical landmarks. Since a mesh is nowadays used for almost all recurrent repairs, a re-exploration of the groin through the same approach as the previous operation may be cumbersome because of tight adhesions between the mesh and the surrounding tissues. If the first recurrent repair is not performed with care, the situation may result in a vicious circle of repairs and recurrences. Referral of patients with complex hernia conditions to surgeons/units with a particular interest and experience in this field has been suggested as a strategy for avoiding further complications<sup>87</sup>. Low numbers and heterogeneity have made it difficult to perform large prospective studies on patients undergoing repeated groin hernia repairs due to recurrence.

The management of multiple recurrent hernias is poorly described in the literature. Identification of patients in this group, from primary repair to recurrent repairs and subsequent prospective follow-up is difficult to perform. A national register like the Swedish Hernia Register (SHR) offers the best conditions to perform a study on this group of patients.

The aim was to describe various factors that may increase the risk for further reoperations, after multiple groin hernia repairs.

## Study 2

According to the SHR the proportion of groin hernia repairs done for recurrence declined from 16.4 % in 1992 to 9.3 % in 2008<sup>5</sup>. However, treatment of recurrent groin hernia remains an important surgical problem. The risk for further reoperation after recurrent groin hernia surgery is more than double that after primary hernia repair<sup>88</sup>. The choice of surgical method for recurrent hernia repair remains controversial. Although there is general acceptance that mesh should be used for recurrent repair, there is no consensus regarding method or approach. Posterior mesh repairs (PMR) such as endoscopic (E-PMR) and open (O-PMR) may be

advantageous<sup>89-91</sup> , but favourable outcomes have also been obtained with the Lichtenstein technique<sup>92</sup>. A meta-analysis of RCTs on recurrent groin hernia surgery revealed no differences between AMR and PMR regarding re-recurrence<sup>79</sup>.

The risk of overlooking a femoral hernia is well known when performing the repair via an anterior approach, if the transversalis fascia is not opened and the preperitoneal space explored<sup>193-95</sup>.

The heterogeneous nature of recurrent hernias makes controlled trials in this field difficult particularly if the previous repair must be taken into consideration. A national hernia register makes it possible to study a large cohort of patients operated for recurrent groin hernia. A study based on the Danish Hernia Database (DHD) concluded that endoscopic repair should be recommended if the primary repair was a Lichtenstein repair<sup>96</sup>. However, outcome after O-PMR was not considered in this analysis.

The aim was to identify risk factors for reoperation after recurrent groin hernia surgery and to investigate the risk for reoperation after recurrent hernia surgery, in relation to the method of previous repair.

### Study 3

The recurrence rate after groin hernia surgery has decreased considerably over the last 20 years mainly due to the introduction of standardised techniques and mesh reinforcement. Even so, recurrent groin hernia repair still accounts for 9.2 % of all hernias registered in the SHR<sup>5</sup> 2013.

Although there are several plausible outcome measures after hernia surgery, studies from national hernia registers often focus on reoperation rates. According to the 2013 annual report from the SHR, the overall reoperation rate five years after primary groin hernia was 2.7 %, whereas the reoperation rate after recurrent groin hernia surgery was 5.8 %. The previous method of repair must also be taken into account when choosing the technique for the recurrent operation. The recommendation in the European Hernia Society (EHS) guidelines, is to adjust the technique depending on the previous repair and if possible, implant the mesh in an anatomic plane where no previous surgery has been performed<sup>97,98</sup>.

To describe the “true” recurrence rate after groin hernia surgery, complete follow-up is necessary, including clinical examination and imaging diagnostic methods if required. The “true” recurrence rate three years after hernia surgery is estimated to exceed the reoperation rate by a factor of two, due to the fact that many patients with a recurrence are never re-operated or even diagnosed<sup>99</sup>.

The referred study by Haapaniemi was based on 86 % primary hernia repairs using a postal questionnaire and selective physical examination for diagnosis of a recurrence.

This method however, has not been applied on patients operated for recurrent groin hernias.

The aim was to study the risk for a 2<sup>nd</sup> recurrence after 1<sup>st</sup> recurrent repair, comparing AMR and PMR in a populations-based regional cohort of patients in the south-west region of Sweden.

## Study 4

With the decline in the number of recurrences following hernia surgery, chronic groin pain and physical disability have become problems having greatest impact on health-related quality-of-life and ability to perform everyday activities<sup>72,80,100</sup>.

When evaluating long-term pain and physical disability after recurrent groin hernia surgery, the previous method of repair should be taken into account. The EHS's guidelines recommend using a new anatomical plane for mesh implant, avoiding a repeated repair where previous hernia surgery has been performed<sup>97</sup>. Although this may seem an obvious rationale, there are to our knowledge no studies on chronic pain after recurrent groin hernia surgery supporting this recommendation.

The aim was to study the impact of AMR and PMR on the risk for chronic groin pain and physical disability after 1<sup>st</sup> and 2<sup>nd</sup> recurrent groin hernia surgery, taking the previous operation into account, in a populations-based regional cohort of patients from the south-west region of Sweden. The Inguinal Pain Questionnaire (IPQ) was used to assess pain. To quantify the combination of pain and physical disability, the *IPQ-score* was used<sup>68</sup>.





# Patients and methods

## Overview of studies

Study	Design	Subjects
Study 1	Register-based national cohort study	16 648 recurrent repairs
Study 2	Register-based national cohort study	19 582 recurrent repairs
Study 3	Register-based regional cohort study. Questionnaire and selective clinical examination	815 recurrent repairs in 767 patients
Study 4	Register-based regional study. Questionnaire and selective clinical examination	671 recurrent repairs in 671 patients

## Study 1

All repairs for recurrent groin hernia recorded in the SHR between 1992 and 2006 were identified. Data were retrieved from the register on the method of recurrent repair, gender, and when applicable, complications and reoperation(s). The number of repairs performed in the same groin was assessed, starting with the first recurrent repair included in the register.

## Statistical methods used in Study 1

The incidence of postoperative complications was assessed with stratification for the numbers of previous repairs on the same groin. Similarly, the risk for reoperation by method of repair and the number of previous repairs was assessed using Cox proportional hazard analysis, with adjustments for gender and age.

The log rank test was used to test for differences in reoperation rate according to numbers of previous repairs and operating unit. High volume units were defined as units where at least 250 repairs were performed in 2001. Differences in time elapsed since previous repair and operating time were tested with ANOVA. Differences in percentage of repairs performed as emergency procedures, prevalence of testicular atrophy and postoperative complications were tested using Kendall's tau test.

## Study 2

The study was based on all patients included in the SHR for recurrent groin hernia repair from 1992 to 2008. The analyses were based on three groups: Group 1 - the whole cohort of recurrent repairs, Group 2 - a subgroup of recurrent repairs with complete data on all variables (age, gender, hernia anatomy, method of repair and hernia size), and Group 3 - a subgroup of recurrent repairs where details of the preceding repair were recorded in the SHR. All repairs performed on a groin after previous groin hernia repair (inguinal or femoral) were considered recurrent repair, regardless of hernia anatomy at preceding and reoperation.

### Statistical methods used in Study 2

Age and gender distribution in each of the subgroups were compared to assess whether they represented a similar demographic population. Univariable and multivariable Cox proportional hazard analyses were performed on procedures in Group 2, performed before 31<sup>st</sup> December 2008. Age, gender, type of hernia, size of hernia defect and type of repair were included in the analyses. Surgery for re-recurrence was considered the endpoint. Two separate multivariable analyses were made, the first by excluding sutured repairs and the second by omitting recurrent repairs for femoral hernia. Separate Cox proportional hazard analyses were undertaken for each method of repair used at the recurrent repair using Group 3, adjusting for the variables found to significantly predict reoperation in the multivariable analysis described above, and stratified for method of repair at the previous repair. The preceding repairs were grouped together into: AMR (including Lichtenstein and plug repairs), PMR (including E-PMR and O-PMR), sutured repairs (including Bassini, Shouldice, McVay and other anterior non-mesh repairs) and others.

### Studies 3 and 4

Five hospitals in the south-west region of Sweden participated in the study, two university hospitals, one county hospital and two day-case surgery units performing elective surgery only. One of the day-case units is associated with the two university hospitals and the other with the county hospital, resulting in three separate units for registration in the SHR (referred to as A, B and C). All 1<sup>st</sup> and 2<sup>nd</sup> recurrent groin hernia repairs registered in the SHR at these units were considered for inclusion. Exclusion criteria for both studies were death before September 2008 and patients operated with a non-mesh repair. The units joined the SHR in different years; A joined in 1998, B in 2003 and C in 2000. Operations registered from the time each unit joined the SHR

until the 31<sup>st</sup> of December 2007, were eligible for inclusion. The first operation for a recurrent hernia at respective groin side for each patient registered in the SHR was considered the 1<sup>st</sup> recurrent repair and fulfilled the criteria for inclusion. The 1<sup>st</sup> recurrent hernia repair was classified into two groups; AMR and PMR. All repairs performed on a groin after previous groin hernia repair (inguinal or femoral) were considered recurrent repairs, regardless of hernia anatomy at the preceding repair and reoperation. The second reoperation, defined as the 2<sup>nd</sup> recurrent repair, was identified by searching the SHR for a new registration of a hernia repair on the specific groin.

## Follow-up

A questionnaire was sent to all patients alive in September 2008. Two reminders were sent.

The questionnaire consisted of two questions: to be answered Yes or No:

*Have you noticed a new lump in the groin after surgery?*

*Have you had any problems or discomfort after surgery?*

The patient was invited for a clinical examination if either of these questions was answered with a “Yes”. Two reminders were sent. Clinical examinations were conducted in 2009 by an independent surgeon, according to a standardised protocol (Appendix 2). Both groins were examined in patients who were operated bilaterally. Recurrence was defined as the presence of a lump or an expansile cough impulse in the operated groin. The questionnaire and the procedure for selective clinical examination have previously been evaluated<sup>99</sup>.

## The index repair

The index repair was defined as the original operation for the primary hernia. To begin with, data on the type of operative method were retrieved from a previous registration in the SHR. In case the index operation was not included in the SHR, a manual search was performed in the patients’ medical records. The repairs were classified as the “Anterior index group” that consisted of both sutured and anterior mesh repairs and the “Posterior index group” that consists of both E-PMR and O-PMR operated patients.

## Mesh methods for the 1<sup>st</sup> recurrent repair

The analysis was based on the two groups of mesh repairs, AMR and PMR. The PMR group was further sub-divided into Endoscopic Posterior Mesh Repair (E-PMR) and Open Posterior Mesh Repair (O-PMR) groups. The AMR group included patients

operated with a modified Lichtenstein technique. The E-PMR group included patients operated with Total ExtraPeritoneal (TEP) or TransAbdominal PrePeritoneal (TAPP) techniques. The O-PMR group included patients operated with an open approach for a preperitoneal position of the mesh. The O-PMR was either performed through a transverse incision above the inguinal canal (Nyhus/Wantz)<sup>47,48,56</sup>, through a midline abdominal incision (Stoppa)<sup>55,101</sup>, or through the inguinal canal (TIPP – Transinguinal PrePeritoneal)<sup>102</sup>.

## Surgeon's operating volume

Each surgeon was identified by a unique local identity code in the SHR. The mean annual volume for each surgeon was calculated for each type of mesh repair. The sum of both primary and recurrent repairs performed with each type of repair for each surgeon during the study period was estimated, until the year of the 1<sup>st</sup> recurrent repair. The number was divided by the number of years the surgeon had registered procedures in the SHR. The mean surgeon's annual volume was dichotomised in two groups,  $\leq 5$  repairs/year and  $> 5$  repairs/year, in accordance with a previous study based on the SHR<sup>65</sup>.

## Study 3

A patient could be included twice, if fulfilling inclusion criteria for both sides. Patients included were registered for baseline data at the 1<sup>st</sup> recurrent repair for age, gender, type of hernia and size of hernia defect.

### 2<sup>nd</sup> recurrence

A 2<sup>nd</sup> recurrence was considered the endpoint. This was confirmed either by registration of a 2<sup>nd</sup> recurrent repair in the SHR or at physical examination. The SHR was checked for any 2<sup>nd</sup> recurrent repairs from the time of the 1<sup>st</sup> recurrent repair until December 31<sup>st</sup> 2013. The median follow-up was calculated from the date of the 1<sup>st</sup> recurrent repair until the 2<sup>nd</sup> recurrent hernia was diagnosed (operation or clinical examination) or else until death by cross-matching with the Swedish Cause of Death Register. If none of these occurred, the patients were followed until December 31<sup>st</sup> 2013.

## Statistical methods used in Study 3

The primary endpoint was a 2<sup>nd</sup> recurrence, comparing anterior mesh repair (AMR) with posterior mesh repair (PMR) consisting of the merged group of preperitoneal mesh repairs (E-PMR and O-PMR). A subgroup analysis was performed on the E-PMR and the O-PMR groups. Age was described as mean, with standard deviation (SD). The follow-up and time between index operation and 1<sup>st</sup> recurrent repair were described as median years, with interquartile range (IQR). The Pearson Chi-Square test was used to analyse differences in the ratio of repairs in women and emergency repairs. The tests were two-sided and  $p < 0.05$  was considered significant. The Mann-Whitney U test was used to compare times between different methods of index repair and 1<sup>st</sup> recurrent repair.

Plots showing cumulative rate of 2<sup>nd</sup> recurrence were generated by the Kaplan-Meier method and differences in 2<sup>nd</sup> recurrence rates were compared using the Log rank test. Cox proportional hazard analyses were performed to estimate the risk for a 2<sup>nd</sup> recurrence for the various mesh methods, stratifying for the index hernia repair. Statistical analyses were performed using the SPSS® version 22.0 (IBM, Armonk, New York, USA).

## Study 4

The analyses were based on either of two study cohorts, one with 1<sup>st</sup> recurrent repairs only and one with both 1<sup>st</sup> and 2<sup>nd</sup> recurrent repairs, as follows.

### Study cohort 1<sup>st</sup> recurrent repair

This cohort was based on all 1<sup>st</sup> recurrent repairs. Exclusion criteria were death before follow up; patients with bilateral repairs; patients registered for a 2<sup>nd</sup> recurrent repair in the SHR during the study period; and non-mesh repairs. Entrance for each patient to the study was defined as from the date of the first operation for a recurrent hernia registered in the SHR. Each patient was included once only, with a 1<sup>st</sup> recurrent repair on either of the groins.

The 1<sup>st</sup> recurrent hernia repairs were classified in two groups; Anterior mesh repair (AMR) and Posterior (preperitoneal) mesh repair (PMR). All repairs performed on a groin after previous groin hernia repair (inguinal or femoral) were considered recurrent repairs, regardless of hernia anatomy at the preceding repair and reoperation. Included patients were registered for baseline data at the 1<sup>st</sup> recurrent repair for age, gender, type of hernia and size of hernia defect. The SHR and medical records were reviewed for information on the method of index (operation prior to the first recurrent repair) repair.

## Study cohort 2<sup>nd</sup> recurrent repair

A second reoperation, defined as the 2<sup>nd</sup> recurrent repair, was identified by searching the SHR for a new registration of a hernia repair on the specific groin during the study period. In order to compare the risk of an IPQ score > 0 between the 1<sup>st</sup> and 2<sup>nd</sup> recurrent repairs, a cohort was formed including patients re-operated for a subsequent 2<sup>nd</sup> recurrence on the same groin prior to December 31<sup>st</sup> 2007. Exclusion criteria were death before follow up; patients with bilateral repairs; and non-mesh repairs.

## Inguinal Pain Questionnaire – IPQ (see Appendix 1)

The IPQ is a validated instrument for the assessment of chronic groin pain and its impact on daily activities<sup>86</sup>. It is based on a seven-grade rating scale to assess pain linked to pain behaviour, ranging from “no pain at all” to severe pain defined as patient seeking “prompt medical advice”<sup>86</sup>. The pain intensity is assessed on three separate occasions: before surgery (estimated retrospectively); when answering the questionnaire (“pain right now”); and the maximum intensity of pain during the week before answering the questionnaire (“worst pain during the past week”). In addition there are six questions regarding difficulties in performing specific everyday activities: getting up from a low chair; sitting for more than 30 minutes; standing up for more than 30 minutes; climbing stairs; and performing sporting activities.

## IPQ score

The IPQ score was developed by Dahlstrand et al. in order to quantify the combination of the “worst pain during the past week” and the six questions on “everyday activities”<sup>68</sup>. Each positive answer to the six questions on “everyday activities” added 1 point and the degree of “worst pain during the past week” rendered a value from 0 (no pain) to 6 (prompt medical advice is sought) points. The “IPQ score” thus ranges from 0 (no pain, no disability) to 12 (maximal pain, maximal disability)<sup>68</sup>.

## Statistical methods used in Study 4

The primary endpoint was pain or physical disability of any degree (IPQ score > 0). All analyses were based on the study *cohort of 1<sup>st</sup> recurrent repairs*. The study *cohort of 2<sup>nd</sup> recurrent repairs* was used only to compare pain between 1<sup>st</sup> and 2<sup>nd</sup> recurrent repairs. The IPQ score was used as a dichotomous variable; IPQ score of 0, meaning no pain and no disability and IPQ score > 0, meaning pain or disability of any degree. Age was described as mean, with standard deviation (SD). The follow-up and time between index operation and 1<sup>st</sup> recurrent repair were described as median years, with

interquartile range (IQR). The Pearson Chi-Square test was used to analyse differences in the ratio of repairs in women and emergency repairs and to analyse differences between responders and non-responders regarding gender and method of repair. The tests were two-sided and a  $p < 0.05$  was considered significant. The Independent T-test was used for differences in age. The Mann-Whitney U test was used to compare times between various methods of index repair and the 1<sup>st</sup> recurrent repair.

In analyses on the risk for chronic pain a multivariate logistic regression analysis, with adjustments for age and gender was performed, for method of repair, mean surgeon's annual volume, acute/elective repair, complications and follow-up time. Subgroup analyses on the outcome after the 1<sup>st</sup> recurrent repair based on the method of repair at the index operation were also performed.

Statistical analyses were performed using the SPSS® version 22.0 (IBM, Armonk, New York, USA).





# Ethics

All papers included in this thesis are the result of projects approved by the Regional Research Ethics Committee in Lund, Sweden. Papers 1 and 2 are purely based on data registered in the SHR regarding previously performed surgical procedures.

In papers 3 and 4, patients were identified from the SHR. After informed consent, they were included in the study and requested to answer a questionnaire, and were invited to a clinical examination in selected cases.

The risk of harm for participating research subjects was considered low. The potential benefit for the patients was that they were offered a clinical examination if they had any discomfort after their hernia repair. They also were given the possibility to discuss their problems and receive medical advice including the offer of a new hernia operation in some cases.



# Results

## Study 1

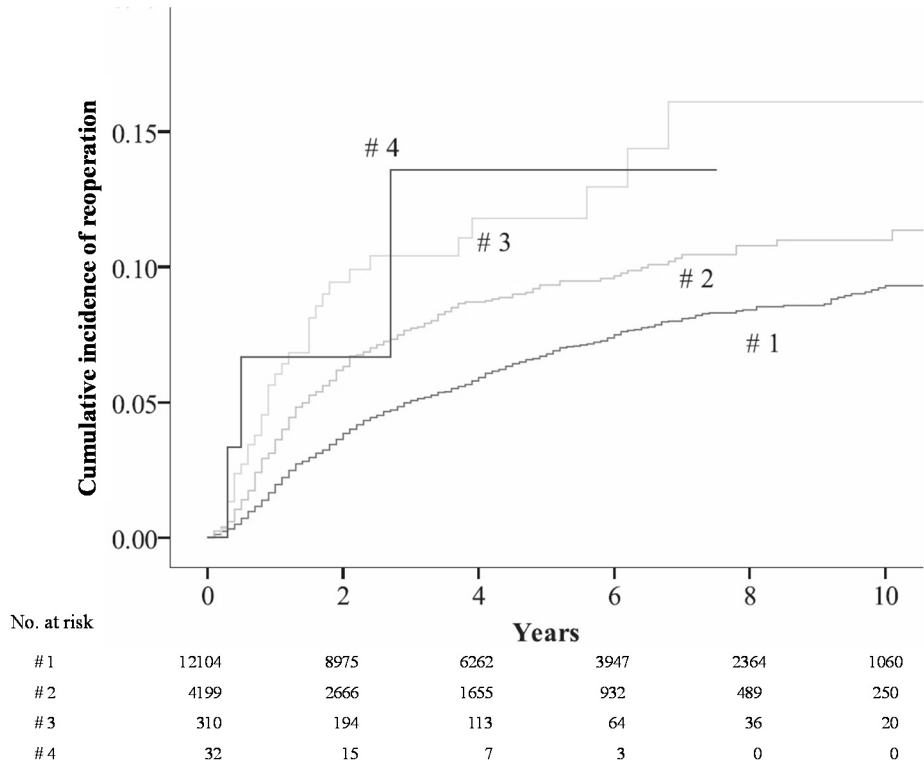
From 1992 through 2006, 142 578 hernia repairs were registered in the SHR of which 16 648 repairs were performed for recurrent groin hernia in 14 856 patients. In 12 104 repairs, the preceding operation was not recorded in the SHR. In these cases, the preceding repairs were either performed before 1992 or before the unit, at which the repair was undertaken, was aligned to the SHR, For the remaining 4 544 repairs, the preceding repair was included in the register.

The percentage of emergency repairs decreased ( $p < 0.001$ ), whereas the risk for reoperation increased with each recurrent repair (Fig. 13). The time interval between the preceding repair and reoperation decreased with increasing number of hernia repairs in the same groin ( $p < 0.001$ ). The operating time increased with each repair ( $p = 0.03$ ). The risk for developing postoperative complications or testicular atrophy was not associated with the number of recurrent repairs. In a logistic regression analysis there was no difference in risk for testicular atrophy between AMR (reference) and PMR (OR 0.96, CI 0.810-1.139,  $p = 0.643$ ).

The relative risks for reoperation following the various methods of repair, adjusted for age and gender, are presented in Table 2. With increasing number of previous repairs that had been performed, the more disadvantageous were the sutured repair techniques and the more favourable the outcome after PMR, including E-PMR and O-PMR. The risk for further reoperation was significantly lower after E-PMR than after Lichtenstein repair for the first 2 recurrent repairs (both  $p < 0.05$ ).

Five years after surgery the cumulative risk for reoperation was 7.5 % (95 % confidence interval CI, 6.9 % - 8.1 %) after the first recurrent repair, 9.7 % (CI 8.6 % - 10.8 %) after the second recurrent repair, 13.0 % (CI 8.3 % - 17.7 %) after the third repair and 16.5 % (CI 1.9 % - 31.1 %) after the fourth repair.

The risk for a repeated reoperation after the second procedure was lower when the reoperation was undertaken at a different unit compared to the unit where the previous repair was performed (Fig. 14,  $p < 0.05$ ). However was this difference not significant if adjusted for method of repair.



**Figure 13.** Kaplan-Meier plot for cumulative incidence of reoperation by number of recurrent groin hernia repair performed in the same groin. ( $p < 0.001$ ).

Table 2. Hazard Ratios for risk for reoperation in relation to number of recurrent repairs, adjusted for age and gender.

Regist Repair Nr	Licht (ref)		Sutured repairs			E-PMR			Plug repairs			O-PMR			Other		
	n		n	HR	CI	n	HR	CI	n	HR	CI	n	HR	CI	n	HR	CI
1	5 385		819	1.93	1.53- 2.45	2 424	0.79	0.62- 0.99	1 493	1.45	1.15- 1.82	931	0.81	0.58- 1.13	1 079	2.31	1.87- 2.86
2	1 589		185	1.58	1.00- 2.49	767	0.48	0.32- 0.74	614	1.24	0.89- 1.71	510	0.68	0.45- 1.03	534	1.70	1.25- 2.30
3	82		6	5.96	1.58- 22.56	73	0.46	0.12- 1.75	44	0.85	0.25- 2.84	55	0.96	0.31- 2.95	50	2.47	0.95- 6.43

Lichtenstein repair (Licht) is used as reference category. HR, Hazard Ratio, CI, 5 % confidence interval.

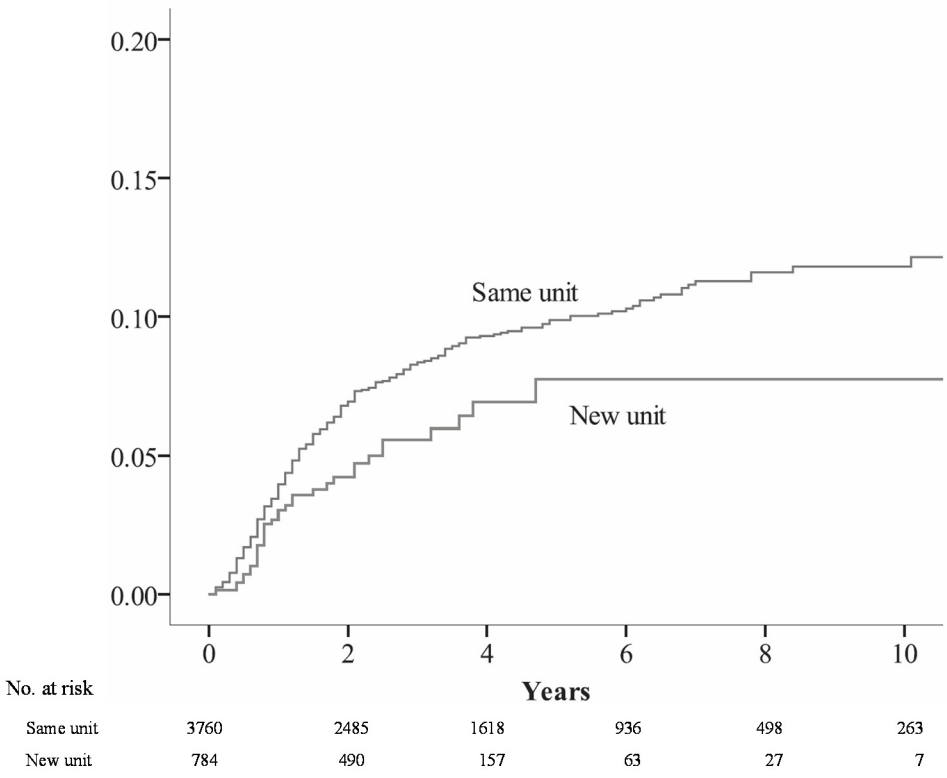


Figure 14. Kaplan-Meier plot for cumulative incidence of reoperation by unit in which the repair is performed (same as previous repair versus new unit  $p < 0.05$ ).

## Study 2

Between 1992 and 2008, a total of 174 527 groin hernia repairs were registered in the SHR. Altogether 19 582 were recurrent repairs in 17 386 patients (study Group 1). Data on age, gender, type of hernia, size of hernia defect and method of repair were available for 13 165 of the repairs (study Group 2). The preceding repair was included in the register for 5 565 of these recurrent repairs (study Group 3) (Fig. 15). For the remaining 14 017 repairs, the preceding repair had been performed before the unit became affiliated to the SHR.

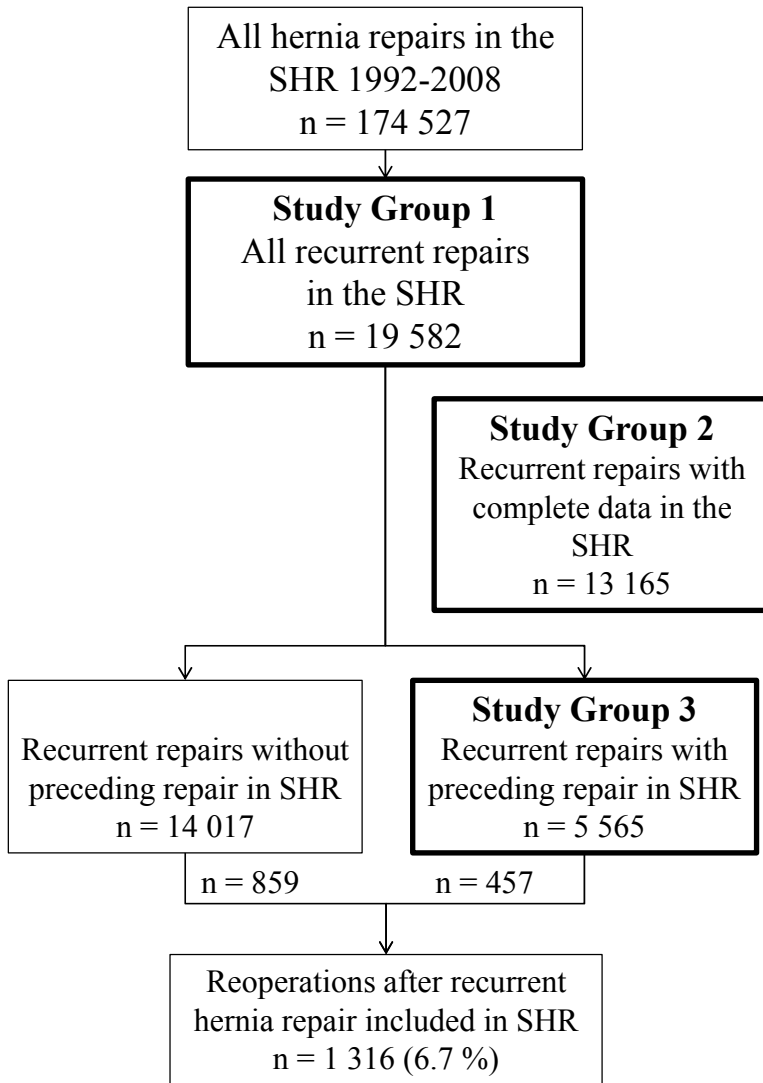
Patients in study Group 2 were slightly younger than the rest of the cohort (64.2 versus 64.8 years,  $p = 0.005$ ), but there was no difference in sex distribution. Patients in study Group 3 were also younger than the remaining cohort (62.2 versus 65.6 years,  $p < 0.001$ ) and included a higher proportion of women (9.6 versus 3.3 %,  $p < 0.001$ ).

Of 4 039 E-PMRs, 3 043 (75.3 %) were performed as TEP and 996 (24.7 %) as TAPP. The 1 835 O-PMRs were performed through a transverse incision above the inguinal canal (Nyhus) in 997 repairs (54.3 %), through a transinguinal preperitoneal approach (TIPP) in 231 (12.6 %) and through a midline incision (Stoppa) in 147 procedures (8.0 %). The incision was not recorded in 460 (25.1 %) of the PMRs.

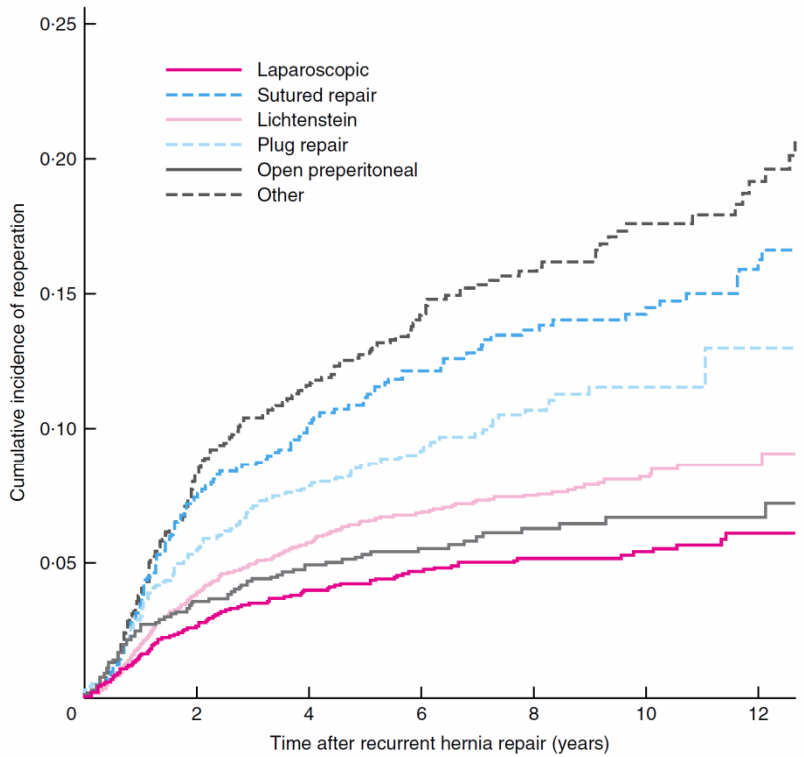
### Study Group 1

Follow-up was 5.3 (3.8) years (mean (SD)). In 6.7% (1 316 of 19 582) a reoperation for a re-recurrence was recorded in the SHR (Fig 15). A Kaplan Meier plot describing the cumulative incidence of reoperation for the various methods of repairs in Study Group 1 is presented in Fig. 16.





**Figure 15.** Flowchart on recurrent groin hernias registered in the SHR 1992-2008, showing Study Groups 1-3. The total reoperation rate was 6.7 %.



No. at risk	0	2	4	6	8	10	12
Laparoscopic	4035	3129	2249	1572	1086	746	328
Sutured repair	1064	868	705	578	466	356	241
Lichtenstein	8334	6399	4376	2723	1404	699	228
Plug repair	2450	1954	1440	970	497	151	11
Open preperitoneal	1831	1401	1045	766	544	363	194
Other	1852	1415	1061	766	500	301	182

**Figure 16.** Cumulative incidence of reoperation after recurrent groin hernia repair based on 19 566 procedures in the SHR (Study Group 1). Of the 19 582 recurrent repairs, 16 procedures were not included because the date of recurrent repair was prior to the date of the previous repair.

## Cox proportional hazard analyses in Study Group 2

Univariable and multivariable Cox proportional hazard analyses of factors predicting reoperation after recurrent hernia repair in Study Group 2 are presented in Table 3. As defect size was not included during the first years of the register, there is a predominance of patients treated more recently. Accordingly, a relative small number of patients undergoing sutured repair was included in the multivariate analysis.

The Cox proportional hazard ratio analyses showed a significantly higher risk for a subsequent reoperation for sutured, Lichtenstein, plug and O-PMR repairs with E-PMR as reference category, adjusted for patient age and type of hernia (Table 3).

In a separate subgroup analysis with stratification by gender and adjustments for type of hernia and age, the risk for a subsequent reoperation was found to be 2.27 (CI 1.27-4.05) ( $p = 0.005$ ) for women and 1.64 (CI 1.43-1.88,  $p = 0.001$ ) for men following an AMR compared to PMR as reference.

The reoperation rate was significantly higher after AMR (Lichtenstein and Plug) repair compared to PMR as reference, in a subgroup analysis that excluded sutured repairs and was adjusted for age, gender, hernia defect size and type of hernia (HR 1.32 (CI 1.06-1.65,  $p < 0.015$ ).

In a separate analysis, omitting recurrent repairs of a femoral hernia and adjusting for the same co-variables, the PMR gave a significantly lower risk for reoperation than AMR (HR 0.78 (CI 0.62-0.98,  $p=0.031$ ).

**Table 3.** Cox proportional hazard analysis of variables predicting reoperation after recurrent groin hernia repair, based on 13 165 repairs with complete information available for all variables (Study Group 2).

	No of patients*	Univariable analysis		Multivariable analysis	
		Hazard Ratio†	p	Hazard Ratio†	p
Age (years)					
< 65.82	6581 (50.0)	1.0 (ref)		1.0 (ref)	
> 65.82	6584 (50.0)	0.85 (0.73-0.99)	0.037	0.82 (0.71-0.96)	0.007
Gender					
M	12 472 (94.7)	1.0 (ref)			
F	693 (5.3)	1.13 (0.82-1.55)	0.466		
Type of hernia					
Lateral	4 515 (34.3)	1.0 (ref)		1.0 (ref)	
Medial	6 585 (50.0)	1.44 (1.21-1.72)	< 0.001	1.44 (1.21-1.73)	< 0.001
Femoral	590 (4.5)	1.55 (1.08-2.23)	0.017	1.22 (0.84-1.78)	0.285
Combined	1 209 (9.2)	1.42 (1.08-1.88)	0.013	1.54 (1.16-2.03)	0.003
Other	266 (2.0)	2.33 (1.53-3.54)	< 0.001	1.89 (1.23-2.89)	0.003
Size of hernia (cm)					
< 1.5	2 637 (20.0)	1.0 (ref)			
1.5 – 3	6 832 (51.9)	0.94 (0.77-1.14)	0.520		
> 3	3 696 (28.1)	1.03 (0.83-1.28)	0.766		
Method of repair					
E-PMR	2 587 (19.7)	1.0 (ref)		1.0 (ref)	
Sutured	350 (2.7)	2.37 (1.54-3.64)	< 0.011	2.55 (1.66-3.93)	< 0.001
Lichtenstein	6 457 (49.0)	1.46 (1.14-1.86)	0.002	1.53 (1.20-1.95)	0.001
Plug	1 897 (14.4)	2.21 (1.68-2.89)	< 0.001	2.31 (1.76-3.03)	< 0.001
O-PMR	1 192 (9.1)	1.30 (0.91-1.85)	0.149	1.36 (0.95-1.94)	0.091
Other	682 (5.2)	3.02 (2.19-4.15)	< 0.001	3.08 (2.22-4.29)	< 0.001

Values in parentheses are \*percentages and †95 % confidence interval. E-PMR – Endoscopic Posterior Mesh Repair, O-PMR – Open Posterior Mesh Repair

## Cox proportional hazard analyses in Study Group 3

Hazard ratios for each method of recurrent repair, adjusted for type of hernia, gender, age, and stratification for type of preceding repair, are shown in Table 4. By using data from patients with full details on both the recurrent and previous repair, the hazard ratios for reoperation was compared for the type of preceding repair, with PMR (E-PMR and O-PMR) as reference category and adjusted for type of hernia, gender and age were 2.30 (CI 1.61-3.27,  $p < 0.001$ ) for sutured repair; 2.06 (CI 1.47-2.90,  $p < 0.001$ ) for Lichtenstein repair; and 2.13 (CI 1.38-3.38,  $p=0.001$ ) for other repair.

In a separate analysis adjusting for the same variables, E-PMR and O-PMR combined as a single category (PMR), were found to be associated with a lower risk for reoperation than AMR when the previous repair had been an anterior repair ( $p < 0.001$ ), but no method of repair differed significantly from the other following a preceding PMR (hazard ratio 2.17 CI 1.69-2.79).

At reoperation in Study Group 3, a femoral defect was found in 353 recurrent repairs for which a defect other than an isolated femoral defect had been recorded at the previous repair. Whereas PMR was used in 21 612 (12.4 %) of 174 527 repairs in the entire cohort, it was used in only 11 (3.1 %) of 353 repairs where a femoral defect was found at subsequent repair ( $p < 0.001$ ).

**Table 4.** Hazard ratio of reoperation after recurrent repair, adjusted for type of hernia, gender and patient age, and stratified for method of previous repair, based on 5 565 operations with information of previous method of repair (Study Group 3).

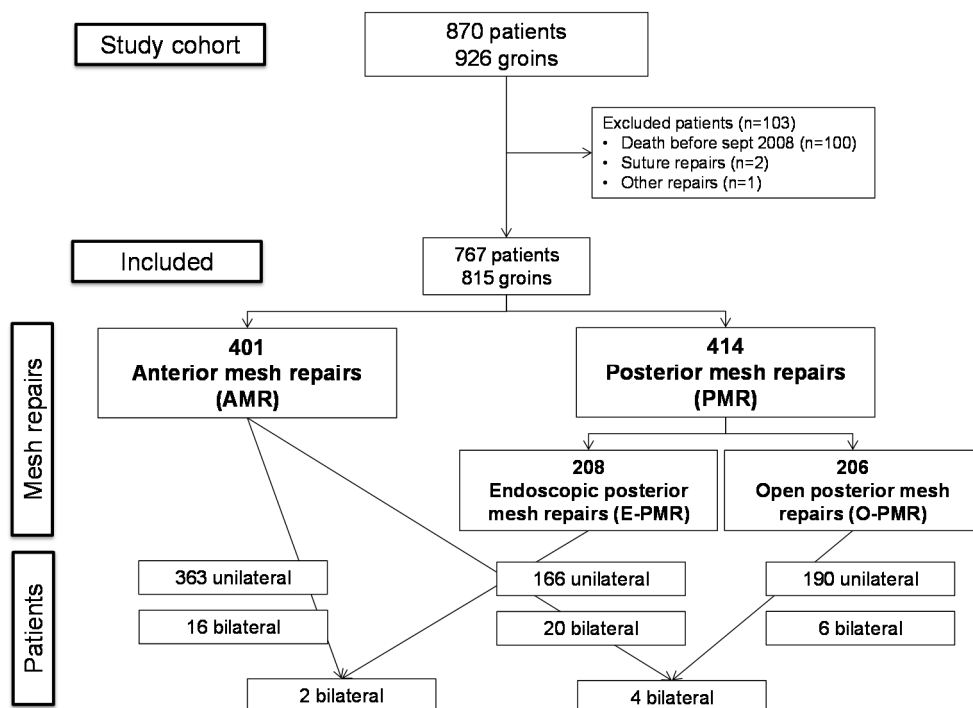
	Type of previous repair							
	Sutured		AMR		PMR		Other	
	n*	Hazard ratio†	n*	Hazard ratio†	n*	Hazard ratio†	n*	Hazard ratio†
<b>Recurrent repair</b>								
<b>E-PMR</b> (n=1 166)	247 (18.9)	1.0 (ref)	750 (26.4)	1.0 (ref)	84 (9.0)	1.0 (ref)	85 (17.8)	1.0 (ref)
<b>Sutured</b> (n=222)	70 (5.3)	5.34 (2.47-11.55)‡	78 (2.7)	3.96 (1.82-8.63) ‡	45 (4.8)	1.98 (0.44-8.98)	29 (6.1)	0.69 (0.08-6.30)
<b>Lichtenstein</b> (n=2 144)	527 (40.3)	2.43 (1.30-4.55)‡	936 (32.9)	2.80 (1.75-4.47) ‡	519 (55.4)	1.24 (0.37-4.23)	162 (33.9)	1.63 (0.52-5.08)
<b>Plug</b> (n=800)	122 (9.3)	2.12 (0.93-4.83)	470 (16.5)	3.33 (2.02-5.49)‡	144 (15.4)	1.86 (0.50-6.90)	64 (13.4)	2.97 (0.91-9.69)
<b>O-PMR</b> (n=759)	220 (16.8)	1.44 (0.68-3.06)	392 (13.8)	1.82 (0.99-3.34)	80 (8.5)	0.33 (0.03-3.25)	67 (14.0)	1.47 (0.39-5.53)
<b>Other</b> (n=474)	123 (9.4)	4.14 (2.00-8.57)‡	215 (7.6)	4.50 (2.58-7.86)‡	65 (6.9)	1.25 (0.25-6.28)	71 (14.9)	4.26 (1.36-13.32) ‡
<b>Total</b> (n=5 565)	1309 (100)		2 841 (100)		937 (100)		478 (100)	

Values in parentheses are \*percentages and †95 % confidence intervals. ‡p < 0.05 versus reference category (Cox proportional hazard analysis).

AMR –Anterior Mesh Repair (Lichtenstein and Plug), PMR –Posterior Mesh Repair ( Endoscopic and Open Posterior Mesh Repair), Other –repairs that could not be classified.

## Study 3

During the study period, 926 recurrent groin hernia repairs were performed in 870 patients. A total of 103 patients were excluded according to Figure 17.



**Figure 17.** Flow chart of inclusions and exclusions. Unilateral repairs were performed on 719 and bilateral on 48 patients. Six patients had bilateral repairs with a combination of different methods and 42 had bilateral repairs with the same method on both sides.

Altogether, 815 recurrent groin repairs in 767 patients were included in the analyses. Unilateral operations were undertaken in 719 patients and 48 were operated bilaterally within the study protocol. Of these operations, 401 were AMRs and 414 PMRs, of which 208 were E-PMRs (182 TEP and 26 TAPP) and 206 were O-PMRs.

The median follow-up after the 1<sup>th</sup> recurrent operation for the whole material was 9.1 years (IQR 3.6) subdivided into groups as follows: AMR 10.0 years (IQR 4.8), and PMR 8.7 years (IQR 3.0), and for PMR subgroups: E-PMR 8.3 years (IQR 2.6) and O-PMR 9.2 years (IQR 3.4).

Emergency surgery was performed in 48 of the 815 groin operations (5.9 %). The rate of emergency repairs was for Unit A 19/339 (5.6%), Unit B 15/219 (6.8%) and Unit C 14/257 (5.4%) with no difference between the units ( $p=0.58$ ). The AMR was used more frequently than PMR in the emergency setting, 33 and 15 repairs respectively ( $p=0.005$ ). Emergency recurrent repairs were not associated with a higher rate of a 2<sup>nd</sup> recurrence compared to elective recurrent repairs, 4/48 (8.3 %) and 63/767 (8.2 %) respectively ( $p=0.98$ ).

## Questionnaire

The questionnaire was sent to 767 patients, of whom 48 patients underwent surgery in both groins for a 1<sup>st</sup> recurrent groin hernia, yielding a total number of 815 groins operated. The questionnaire was answered by 509 patients (66%), representing patients who had been operated in a total number of 523 groins. A total of 141 patients (28%) indicated a new lump or other discomfort in the groin. Physical examination was undertaken in 97 of 141 patients (69 %). The remaining patients chose not to be examined.

## Index operation

Data on the index operation were available for 674 of the procedures (83 %) of which 139 (17 %) repairs were registered in the SHR and 535 (66 %) were retrieved from patients medical records. Of these, 560 repairs were performed prior to December 2001 (83%). The anterior group consisted of 534 sutured repairs and 87 anterior mesh repairs and the posterior group consisted of 29 E-PMRs and 12 O-PMRs. Twelve repairs could not be classified as anterior or posterior repair (Table 8). The median time from the index operation to the 1<sup>st</sup> recurrent operation was 10.0 years (IQR=17.0) for all index repairs. The corresponding time for suture repair was 13.0 years compared to 2.0 years for mesh repair (AMR 2.0 years and PMR 3.0 years) ( $p<0.001$ ).

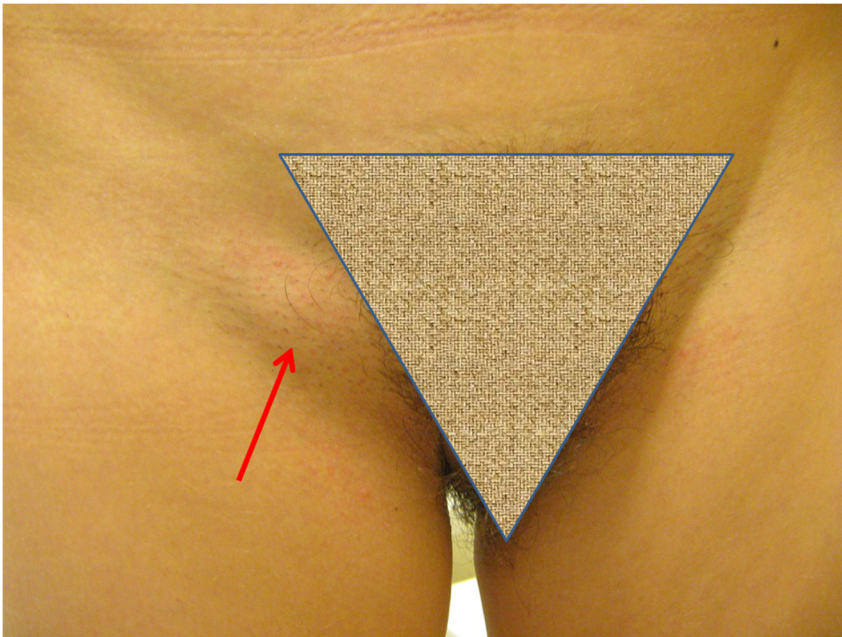


## Gender differences

Twenty-nine repairs (3.6 %) were performed on women. The women were operated with a PMR, (E-PMR or O-PMR), in 24 of the 29 repairs (83 %) with a statistical difference compared to AMR ( $p=0.001$ ). Of these 29 repairs, a femoral hernia was found in 12 repairs (41.4 %). The index repair was identified in 27 out of the 29 repairs in women (93 %). An anterior index repair was reported in 21 repairs. At the 1<sup>st</sup> recurrent repair, a femoral hernia was found in 10 of these 21 index repairs (47.6%).

Men were operated with a PMR in 390 of 786 repairs (49.6 %) and a femoral hernia was found in 24 of the 786 repairs (3.1 %). A total of 20 femoral hernias were found at the 1<sup>st</sup> recurrent repair in men, after 600 anterior index repairs (3.3 %).

There was no difference in 2<sup>nd</sup> recurrence rate between women and men, 1 out of 29 repairs (3.4 %) and 66 of 786 repairs (8.4 %) respectively (Log rank test  $p=0.461$ ).

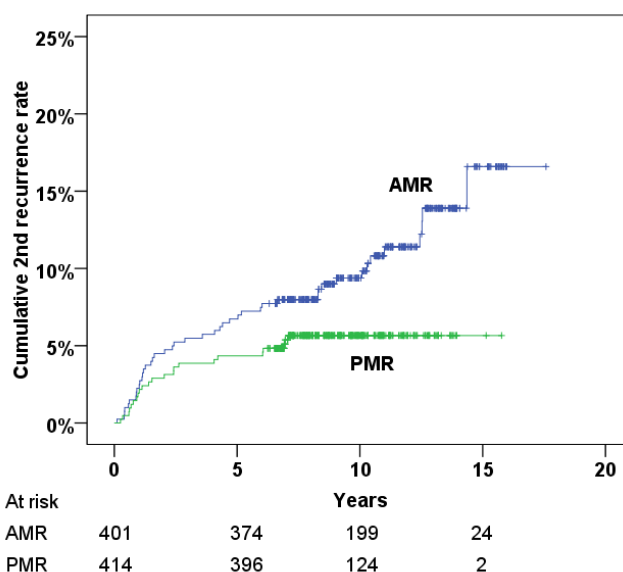


**Figure 18.** A visible femoral hernia in a woman. The hernia is localised below the inguinal ligament in the right groin.

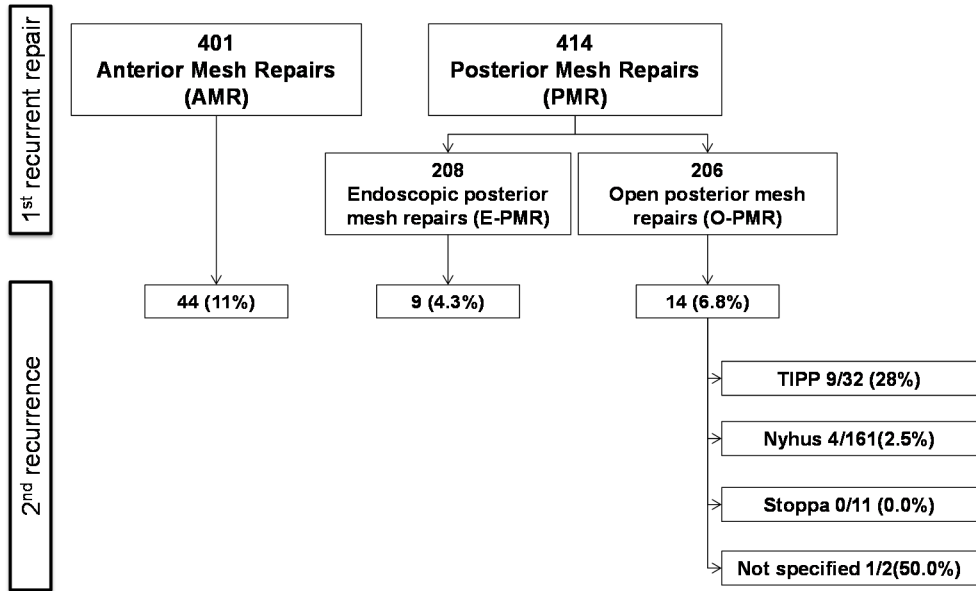
## 2<sup>nd</sup> recurrence in relation to method of mesh repair

A 2<sup>nd</sup> recurrence was found in 67 out of 815 1<sup>st</sup> recurrent groin hernia repairs (8.2 %). Fifty-two of these repairs (78%), in 52 patients, were registered in the SHR for a 2<sup>nd</sup> recurrent repair and 15 2<sup>nd</sup> recurrences (22%) were found in 15 patients at clinical examination.

Altogether a 2<sup>nd</sup> recurrence was found in 44 of 401 (11.0%) in the AMR group and in 23 of 414 (5.6 %) in the PMR group. The AMR group was compared to the PMR group in a Kaplan-Meier analysis with a Log rank test showing a lower rate of a 2<sup>nd</sup> recurrence for the PMR group ( $p=0.025$ ) (Figure 19). A 2<sup>nd</sup> recurrence was discovered in 14 of the 206 (6.8%) in the O-PMR group and in 9 of 208 (4.3%) in the E-PMR group ( $p=0.276$ ) (Figure 20). A subgroup analysis was performed on the O-PMR group for the different approaches through which the repairs were performed (Figure 20). The proportion of TIPP in the O-PMR group was 32 out of 206 repairs (15.5 %). Nine of 32 TIPPs had a 2<sup>nd</sup> recurrence (28%). The corresponding figures for repairs performed through a transverse incision (Nyhus), was 4 out of 161 (2.5 %). The difference between TIPP and Nyhus was tested in a Log rank test. ( $p=0.001$ ). There was no difference in the rate of 2<sup>nd</sup> recurrence for patients who had bilateral 1<sup>st</sup> recurrent repairs compared to patients with unilateral repairs ( $p=0.917$ ).



**Figure 19.** Kaplan-Meier plot presenting the cumulative rate of 2<sup>nd</sup> recurrence after 1<sup>st</sup> recurrent groin hernia repairs comparing Anterior Mesh Repairs (AMR) and Posterior Mesh Repairs (PMR) ( $p=0.025$ ).



**Figure 20.** Flow chart showing the distribution of 2<sup>nd</sup> recurrences for the various methods of 1<sup>st</sup> recurrent repairs. The O-PMR group is subdivided due to the different incisions through which the repairs were performed; TIPP (Trans Inguinal PrePeritoneal), Nyhus (transverse incision above the inguinal canal), Stoppa (midline abdominal incision), not specified. Numbers of 2<sup>nd</sup> recurrences are given in relation to the total number of repairs. The 2<sup>nd</sup> recurrence rate after Nyhus approach was significantly lower compared to the TIPP ( $p < 0.001$ )

## 2<sup>nd</sup> recurrence in relation to index method of repair

The impact of the index operation on the rate of 2<sup>nd</sup> recurrences was studied using a univariable Cox proportional hazard analysis. The anterior index group was a mixture of 534 sutured repairs and 87 anterior mesh repairs and the Posterior index group from 29 endoscopic and 12 open posterior mesh repairs. Of the known 674 previous repairs, 12 repairs were excluded, since they could not be classified as either anterior or posterior repair. An increased hazard ratio 3.21 (CI 1.33-7.44, p=0.009) for a subsequent 2<sup>nd</sup> recurrence was seen after an anterior index repair followed by an AMR compared to an E-PMR. A decreased hazard ratio 0.08 (CI 0.01-0.94, p=0.045) for a subsequent 2<sup>nd</sup> recurrence was seen after a posterior index repair followed by an AMR, compared to an E-PMR (Table 5).

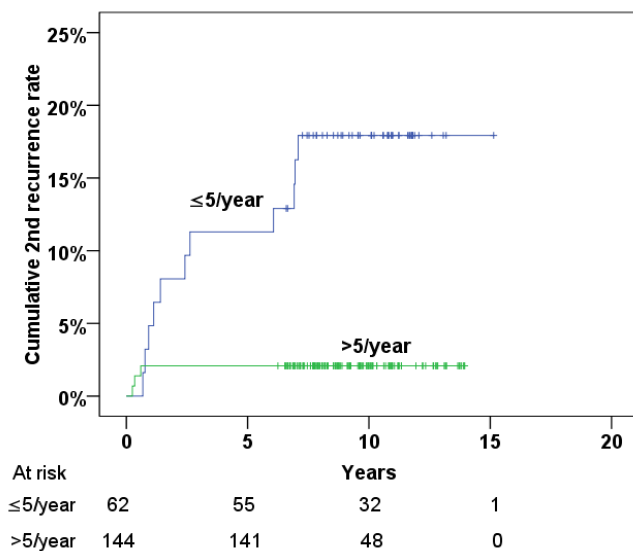
**Table 5.** Cox proportional hazard ratio of 2<sup>nd</sup> recurrence after the three different methods of 1<sup>st</sup> recurrent repair, depending on the index method of repair. E-PMR was defined as reference category.

	Index method of repair					
	Anterior (n=621)			Posterior (n=41)		
Method of 1 <sup>st</sup> Recurrent repair	n	Hazard Ratio (CI)†	p	n	Hazard Ratio (CI)†	p
E-PMR	179	Ref 1.0	-	5	Ref 1.0	-
AMR	263	3.21 (1.33-7.44)	0.009	29	0.08 (0.01-0.94)	0.045
O-PMR	179	1.75 (0.65-4.73)	0.271	7	0.45 (0.04-5.17)	0.525

E-PMR - Endoscopic Posterior Mesh Repair, AMR - Anterior Mesh Repair, and O-PMR - Open Posterior Mesh Repair. P < 0.050 versus reference category (Cox proportional hazard analysis). Values within parentheses show †95 % Confidence Interval.

## 2<sup>nd</sup> recurrence in relation to the surgeon's annual volume

The 2<sup>nd</sup> recurrence rate for each method for the 1<sup>st</sup> recurrent groin hernia repair was analysed in relation to the mean surgeon's annual volume. In the AMR and E-PMR groups there was no difference in rate of 2<sup>nd</sup> recurrence between the surgeon's annual volume,  $\leq 5$  repairs and  $> 5$  repairs (AMR  $p=0.622$  and E-PMR  $p=0.204$ , Log rank test). For the O-PMR group (Figure 21) the 2<sup>nd</sup> recurrence rate was higher if the mean surgeon's annual volume was  $\leq 5$  repairs ( $p<0.001$ , Log rank test).



**Figure 21.** Kaplan Meier plots presenting rate of 2<sup>nd</sup> recurrences after Open Posterior Mesh Repair (O-PMR) for 1<sup>st</sup> recurrent groin hernia repairs, with mean surgeon's annual volume of  $\leq 5$  repairs and  $> 5$  repairs ( $p<0.001$ ).

## Study 4

### Study cohort 1<sup>st</sup> recurrent repair

During the study period 9 720 hernia repairs were performed at the five hospitals of which 926 (9.5 %) were recurrent groin hernia repairs performed in 870 patients. A total of 199 patients were excluded according to Figure 22. Altogether 671 unilateral, 1<sup>st</sup> recurrent repairs were included in the analysis. Of these repairs, 329 were AMRs and 342 PMRs, of which 161 were E-PMRs (139 TEP and 22 TEP) and 181 O-PMRs.

The three SHR units had different strategies for recurrent groin hernia operations. Unit A performed 62.3 % of all AMRs, Unit B performed 80.1 % of all E-PMRs and Unit C performed 60.2 % of all O-PMRs.

The median follow-up from the 1<sup>st</sup> recurrent operation for the whole cohort was 9.3 years (IQR 3.0). The median follow-up times for the groups were: AMR 10.3 years (IQR 5.0), E-PMR 8.3 years (IQR 2.0) and O-PMR 9.5 years (IQR 3.0). A multivariate logistic regression analysis was used to compare the risk for chronic pain and physical disability (IPQ score > 0) in relation to the length of follow-up after the 1<sup>st</sup> recurrent repair. The risk did not differ between patients with follow-up times, < 10 years and ≥ 10 years (reference), (OR=1.14 (CI 0.76-1.72), p=0.517).

Emergency surgery was performed in 42 out of 671 patients (6.3 %). The AMR was used more frequently in the emergency setting compared to the PMR, 28 and 14 repairs respectively (p=0.018). The risk for pain or physical disability of any degree (IPQ score > 0), did not differ between emergency and elective recurrent (ref) repairs in a multivariate regression analysis (OR 1.16 (CI 0.46-2.93) (p=0.745)).

A total of 28 repairs (4.2 %) were performed on women. The women were operated with a PMR, (E-PMR or O-PMR), in 23 out of the 28 repairs (82 %) with a statistical difference compared to AMR (p=0.001).

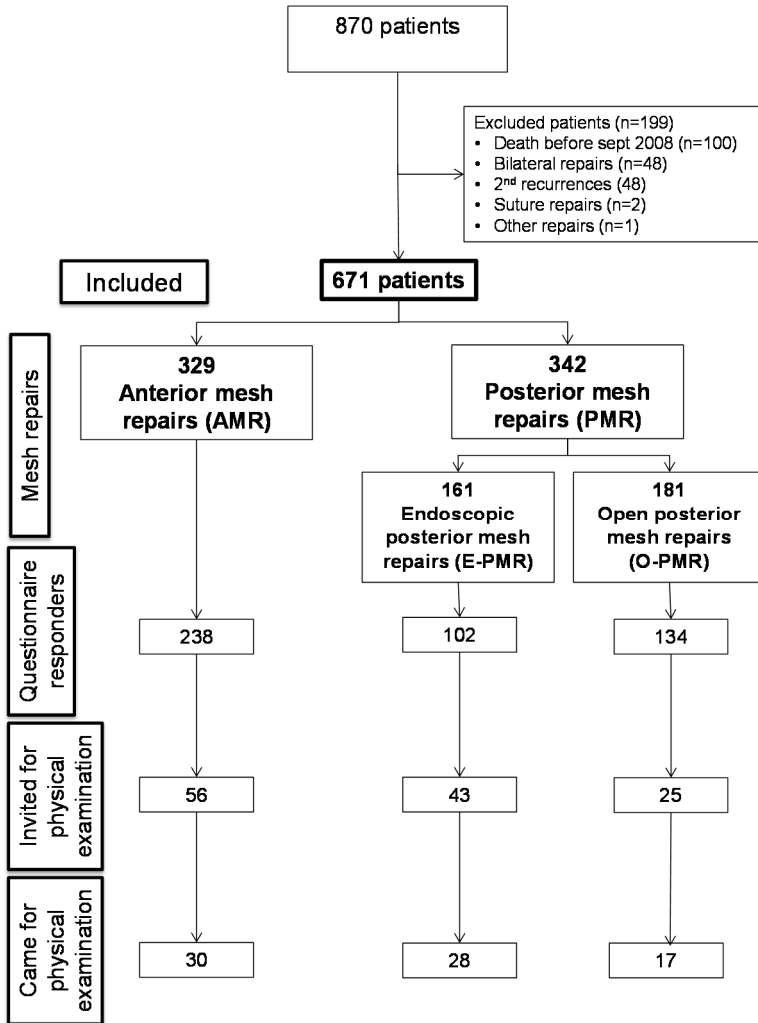


Figure 22. Flowchart of inclusion and exclusions, study cohort of unilateral 1<sup>st</sup> recurrent repairs. Four hundred seventy-four patients answered the questionnaire and 75 were examined clinically.

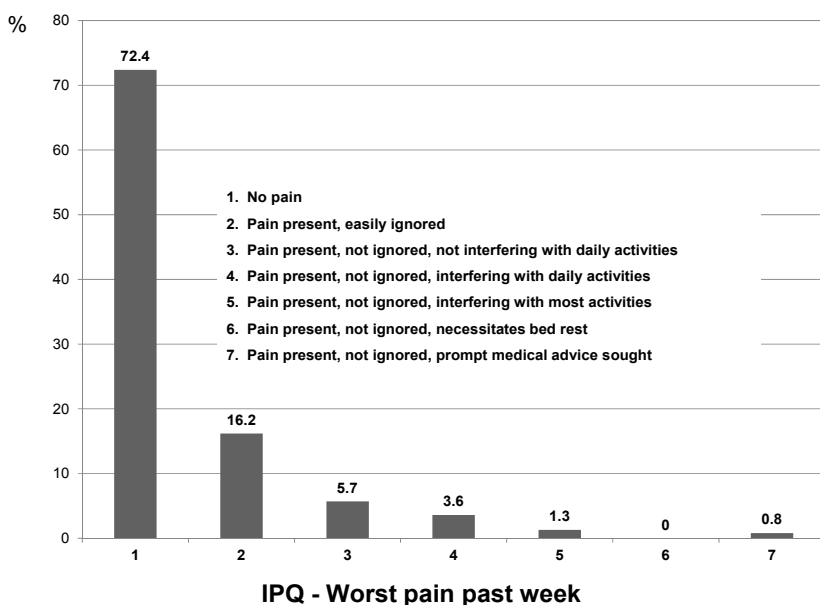
## IPQ and clinical examination

The IPQ was sent to 671 patients, of whom 474 answered (70.6 %). In 343 out of 474 (72.4 %) “No pain at all” was described. A total of 27 out of the 474 patients (5.7 %) had a pain-score between 4 and 7, implying pain that could not be ignored and at least interfered with daily activities (Figure 23).

A total of 124 patients (26 %) stated a new lump or other discomfort in the groin and were offered a clinical examination and 75 (60 %) of these attended after two reminders.

The 197 patients (29.4 %) that did not answer the IPQ (non-responders) were analysed and compared with the 474 patients who answered the IPQ (responders). There was no difference in mean age between the groups, responders 64.0 (SD 12.8) and non-responders 63.7 (SD 14.5) ( $p=0.816$ ). Fewer women answered the IPQ 13/28 (46 %) compared to men 461/643 (71.7%) ( $p=0.004$ ) and the number of IPQ answers from the E-PMR group was 102/161 (63.4 %) compared to AMR 238/329 (72.3 %)  $p=0.061$ .

Of the 75 patients examined clinically, 48 (64 %) were found to have radiating pain or increased sensitivity in the groin, interpreted as signs of a nerve lesion (Table 6). A 2<sup>nd</sup> recurrence was found in 10 of the 75 clinically examined patients (13.3 %).



**Figure 23.** Distribution of 474 answers to the Inguinal Pain Questionnaire in respect of “worst pain past week”



**Table 6.** Baseline characteristics on IPQ score (combination of “Worst pain past week” and “everyday activities”), ranging from 0 (no pain, no disability) to 12 (maximal pain and disability) for 474 patients answering the IPQ.

IPQ Score	No clinical examination n=399	Clinical examination n=75		Total n=474
		Patients without signs of nerve lesion n=27 (36.0)	Patients with signs of nerve lesion n=48 (64)	
0	309 (77.4)	13 (48.1)	13 (27.1)	335 (70.7)
1	52 (13.0)	5 (18.5)	10 (20.8)	67 (14.1)
2	15 (3.7)	2 (7.4)	11 (22.9)	28 (5.9)
3	10 (2.5)	3 (11.1)	8 (16.6)	21 (4.4)
4	2 (0.5)	1 (3.7)	0	3 (0.6)
5	3 (0.8)	0	3 (6.3)	6 (1.3)
6	4 (1.0)	0	1 (2.1)	5 (1.1)
7	1 (0.3)	1 (3.7)	1 (2.1)	3 (0.6)
8	3 (0.8)	1 (3.7)	1 (2.1)	5 (1.1)
9	0	1 (3.7)	0	1 (0.2)
10	0	0	0	0
11	0	0	0	0
12	0	0	0	0

Values within parentheses show %

## Index operation

Data on the index operation were available for 558/671 (83 %) of the patients, including 108 (16 %) repairs registered in the SHR and 450 (67 %) retrieved from patients medical records. Of the 558 index repairs, 446 repairs were performed prior to January 2001 (80%). The anterior index group consisted of 443 sutured repairs and 75 anterior mesh repairs and the posterior index group consisted of 18 E-PMRs and 11 O-PMRs. Eleven repairs could not be classified as anterior or posterior repairs.

The median time from the index operation to the 1<sup>st</sup> recurrent operation was 11.0 years (IQR=16.0) for all index repairs. The time for suture repair was 14.0 years (IQR=13) compared to mesh repair 2.0 years (IQR=3) (AMR 2.0 years (IQR=3) and PMR 3.0 years (IQR=5) ( $p < 0.001$ ).

## IPQ score

An IPQ score > 0, representing any groin pain or physical disability, was reported by 139 of the 474 patients answering the IPQ (29.3 %) (Table 6). The risk of having signs of nerve lesion found at clinical examination in patients with an IPQ score > 0 compared to patients with an IPQ score of 0 was OR 2.50 (CI 0.93-6.71),  $p = 0.069$ . If patients who responded that they did not have persistent symptoms were assumed to lack signs of nerve lesion, the same analysis gave a strong association between signs of nerve lesion at clinical examination and the IPQ score (OR 7.99 (CI 4.03-15.83),  $P < 0.001$ ). Neither gender, age, method of recurrent mesh repair or surgeon's volume could predict an IPQ score > 0 in univariate logistic regression analysis.

## 1<sup>st</sup> recurrent repair in relation to index repair

Out of the 474 patients who answered the IPQ, data were available for 389 index repairs (82 %), of which 371 were anterior and 18 posterior index repairs. When taking the index repair in to account, and comparing the methods of 1<sup>st</sup> recurrent repair, a decreased risk for an IPQ score > 0 was seen after an anterior index repair followed by an E-PMR compared to AMR (OR 0.54 (CI 0.30-0.97,  $p = 0.039$ ) (Table 7). The group of patients where the index repair was performed with a posterior approach was too small to allow statistical analysis.

**Table 7.** Method of 1<sup>st</sup> recurrent repair as risk factor predicting IPQ score >0, after anterior and posterior index repair in 389 patients.. Logistic regression analyses adjusted for age and gender.

1 <sup>st</sup> Recurrent repair	Anterior index repair n=371			Posterior index repair n=18		
	n	Odds Ratio (95% CI)	p	n	Odds Ratio (95% CI)	p
AMR (ref)	158	1	-	16	1	-
O-PMR	121	0.91 (0.55-1.51)	0.717	2	-	-
E-PMR	92	0.54 (0.30-0.97)	0.039	0	-	-

AMR-Anterior Mesh Repair, O-PMR-Open Posterior Mesh Repair, E-PMR-Endoscopic Posterior Mesh Repair

## Surgeon's volume and surgical approach

The risk for an IPQ score > 0 after a 1<sup>st</sup> recurrent groin hernia repair was analysed in relation to the mean surgeon's annual volume for the different surgical techniques used (Table 8). There was no difference in risk of an IPQ score > 0 between the surgeon's annual volume for the AMR and E-PMR groups. However for the O-PMR group there was a lower risk of having an IPQ score > 0 if the mean surgeon's annual volume was > 5 repairs (OR 0.42 (CI 0.19-0.94, p=0.034) (Table 8).

**Table 8.** Mean surgeon's annual volume, on method of 1<sup>st</sup> recurrent repair, as risk factor for an IPQ score >0. Logistic regression analyses adjusted for age and gender.

	≤ 5 repairs/year (ref)		> 5 repairs/year		p
	n	Odds Ratio	n	Odds Ratio (95% CI)	
<b>1<sup>st</sup> recurrent repair</b>					
All Repairs	91	1	383	0.65 (0.40-1.06)	0.088
AMR	41	1	197	0.96 (0.46-2.04)	0.924
O-PMR	37	1	97	0.42 (0.19-0.94)	0.034
E-PMR	13	1	89	0.92 (0.22-3.82)	0.913

AMR-Anterior Mesh Repair, O-PMR-Open Posterior Mesh Repair, E-PMR-Endoscopic Posterior Mesh Repair

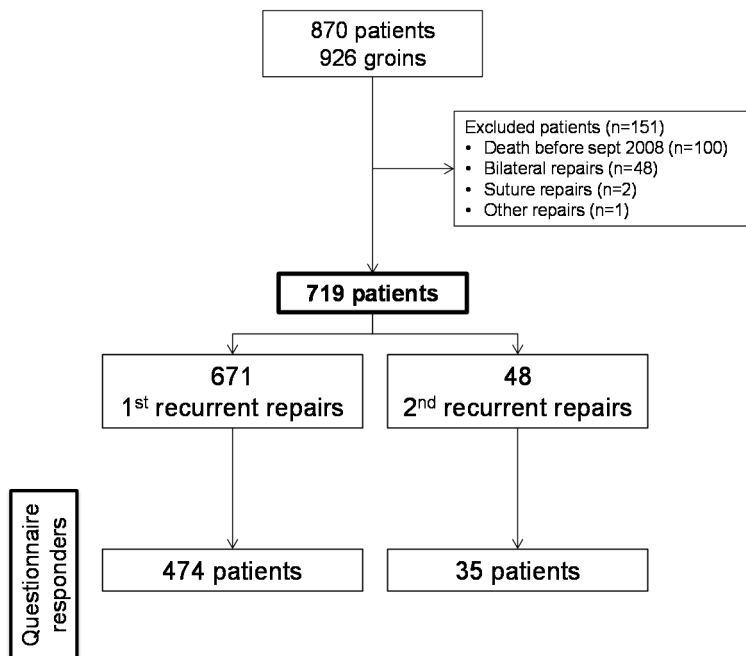
The O-PMR group was also analysed regarding the risk of an IPQ score > 0 in relation to the surgical approach used for the preperitoneal mesh repair. The transverse incision above the inguinal canal (Nyhus) was used in 113 patients and compared with a group of 21 "other O-PMR techniques" (17 TIPP and 4 Stoppa). The Odds Ratio of an IPQ score > 0 was 2.58 (CI 0.97-6.87), p=0.057) for "other O-PMRs" compared to the "Nyhus" approach.

## Postoperative complications

A postoperative complication was registered in the SHR in 63 of 671 (9.4 %) patients in the entire study cohort of 1<sup>st</sup> recurrent repairs. Among the 474 patients with an IPQ answer, 42 patients (8.9 %) were registered in the SHR for a postoperative complication. A registered complication did not increase the risk for an IPQ score > 0 compared to patients not having a complication (OR 0.80 (CI 0.39-1.66, p=0.554).

## Study cohort 2<sup>nd</sup> recurrent repair

The cohort included 719 patients of which 509 completed the IPQ (70.8 %) (Figure 24). A total of 48 patients were operated with a subsequent 2<sup>nd</sup> recurrent repair prior to 31<sup>st</sup> December 2007. This group was compared with 474 patients without a 2<sup>nd</sup> recurrent repair, regarding the risk of having an IPQ score > 0 during the same time period. Patients having had a 2<sup>nd</sup> recurrent repair had a higher risk for an IPQ score > 0 (OR 2.28 (CI 1.14-4.57), p=0.020).



**Figure 24.** Flowchart of inclusion and exclusion of the study cohort of 2<sup>nd</sup> recurrent repairs to compare the risk for pain and disability with the cohort of 1<sup>st</sup> recurrent repairs.



# Discussion

## Studies 1 and 2

Both studies are based on national data from the Swedish Hernia Register and focus on risk factors predicting repeated recurrent groin hernia operations and risk factors affecting the cumulative incidence of reoperation after recurrent groin hernia surgery. To our knowledge, no prospective studies on the management of hernias after multiple repairs have previously been published. These studies represent the largest population-based cohort studies on recurrent groin hernias in the literature.

These studies present the outcome after routine, recurrent groin hernia surgery as performed in Sweden over more than twenty years. During this time period there was a dramatic change in methods of repair used in recurrent groin hernia surgery. This, of course, must be kept in mind when interpreting the results.

## Reoperation after recurrent hernia repair

These studies show that Endoscopic Posterior Mesh Repair for recurrent groin hernia surgery is associated with the lowest cumulative incidence of reoperation. Both studies suggest that posterior mesh repair, whether endoscopic or open, should be preferred after previous hernia repair employing an anterior approach. The outcome after open posterior mesh repair following a previous posterior index repair was favourable, although not significantly different from results obtained with endoscopic techniques. The recommendation in the EHS guidelines to use a new anatomical plane for mesh implantation compared to the previous repair, is supported by this study as regard PMR after a previous anterior repair. If these guidelines are to be followed, an AMR should be used after a previous posterior repair. The results from this study do not support this recommendation, since neither Lichtenstein nor plug repairs were associated with a lower risk for reoperation compared to PMR techniques.

The relative advantage of endoscopic methods of repair following anterior repair has been shown in previous studies<sup>103,104</sup>. However, previous studies have lacked the statistical power to compare the outcome following previous posterior repair. Assuming similar reoperation rates at 5 years after surgery as in the present study (4.7 % for E-PMR and 6.9 % for Lichtenstein repairs), a controlled trial would require more than

4 000 patients to achieve an 80 % chance of detecting a significant difference between the two procedures.

The age and sex distribution in Study 2, varied slightly between the different groups. The differences in age may be explained by the shorter follow-up of patients in Groups 2 and 3, owing to the lack of complete data for all variables during the first years of registration. These differences should not be considered to limit the validity of this study. The SHR provides data on the outcome after hernia surgery as it is practised in the community, without selection of any specific patient group or focus on specialised units.

The study also indicates that women with a recurrent hernia benefit even more than men from a PMR. This was due to the higher incidence of femoral hernia in women, which may be overlooked if the recurrent repair is performed through an anterior approach. These results are in accordance with other studies<sup>94,105</sup>.

Even if all femoral hernias were excluded from the analysis, the PMR methods were still associated with a significantly lower risk for reoperation than AMR. This might indicate a mechanical advantage of the posterior position of the mesh compared to an anterior mesh position, for recurrent inguinal hernia, and not just being related to the risk of overlooking a femoral hernia.

Previous studies have suggested that E-PMR is the method of choice for preperitoneal access<sup>96,103,106</sup>. The outcome after O-PMR however is almost equivalent (Table 3). Beets et al found in a RCT study, a lower recurrence rate after bilateral O-PMR (1.9 %) compared to the TAPP procedure (12.5 %) ( $p < 0.04$ )<sup>104</sup>. In Study 2, the majority of the Open Posterior Mesh Repairs were performed through a transverse incision above the inguinal canal according to the described approach by Nyhus<sup>47</sup> and Wantz<sup>107</sup>. A smaller number of repairs were performed using a midline incision, as described by Stoppa<sup>55</sup>, or through a transinguinal approach<sup>108</sup>. This study has not analysed the impact of the various approaches in the O-PMR group on the risk for reoperation, which could affect the outcome of the whole O-PMR group. The choice between E-PMR and O-PMR is often a matter of local tradition and surgeon's preference.

## Repeated groin hernia surgery

The risk for further reoperation increased with the number of previous repairs performed on the same groin. The correct choice of repair in patients with a recurrent groin hernia is important since the more repairs that are performed, the more advantageous the PMR becomes. The difference between E-PMR and the Lichtenstein repair was statistically significant for the first two recurrent hernia repairs ( $p < 0.05$ ). Repairs without mesh had the worst outcome<sup>109</sup>, and the condition and outcome worsened with each succeeding unsuccessful repair. Operating time also increased, with increasing number of recurrent repairs.

The risk for a further recurrent repair was lower when reoperation was undertaken at a different unit to that where the previous repair was performed. This confirms the importance of the unit's gathered competence in recurrent groin hernia surgery, to prevent patients operated for multiple recurrent repairs ending up in a vicious circle of further repeated repairs. Basically this reflects the surgeon's expertise in both anterior and posterior mesh repairs, in order to customise the choice of mesh repair for each individual patient.

The incidence of testicular atrophy or absence at recurrent hernia repair was 4.2 % for all repairs. It did not rise as much as would have been expected considering the potential trauma to the testicular circulation during repeated explorations in the same groin. This could be explained by incomplete registration of complications and perhaps an underestimation of testicular atrophy when patients were assessed prior to the re-recurrent repair.

As multiple recurrences are relatively rare and constitute a heterogeneous group, it is impossible to perform a randomised controlled trial on these patients. Hence, the best evidence for this group of patients is obtained from large, population-based register studies<sup>28,110</sup>.

The results presented here are based only on repairs included in the SHR. The number of repairs performed on each patient may thus be an underestimation since some patients underwent hernia repairs before the first repair was registered in the SHR. This may have diluted the effect of previous repairs in this study. When assessing the outcome after recurrent hernia repair the approach used in the previous repair must be considered, not only the number of previous repairs. In Study 1, the preceding repair was not recorded in the SHR in 12 104 cases. As most of these repairs were performed before 1992, they can be assumed to be sutured repairs in most cases<sup>27</sup>.

In Studies 1 and 2, the same patient may have been included twice if operated bilaterally. This could have caused a minor bias when risk factors for reoperation were analysed, since a risk factor related to the patient may have played a role in the recurrences in both groins.

Although a difference in outcome was seen if the repair was undertaken at a different unit than the previous, there was no difference in reoperation rate between large (> 250 repairs/y) and small volume units (<250 repairs/y). This underlines the importance of having the surgical expertise to meet the challenges of recurrent groin hernia surgery, as a large unit volume alone is not sufficient to guarantee high quality.

Primary hernia repairs can usually be managed according to standardised routines, but the management of recurrent hernia requires an approach that must be adapted to the specific circumstances of each patient, including age, gender, type of previous repair, type of hernia and size of defect<sup>111</sup>. This implies that units managing recurrent repairs must have suitable equipment, staff and surgeons experienced in performing both anterior and posterior mesh repairs.



The difference in risk for reoperation if the repeated repair is performed at the same or new unit does not remain significant if adjusted for method of repair. In other words the quality of repair may be sufficient even if it is performed at the same unit, as long as an adequate method of repair is applied. The E-PMR and O-PMR techniques has however not been performed at all units operating groin hernia in Sweden. Centralisation is sometimes proposed as an option that may solve the problem of providing the most suitable method of repair for each patient<sup>112</sup>. Another option would be a national focus to improve education and training in PMR methods at the national level, preferably using the endoscopic technique.

These studies focused on reoperation for re-recurrence as the major endpoint. There are, however, equally important factors to be considered in recurrent groin hernia surgery, such as chronic pain. The technical difficulties when dissecting through scarred tissue, where the usual anatomical landmarks are distorted, may lead to nerve damage and an increased risk for persistent pain. By approaching the recurrent hernia from the preperitoneal space, these problems may be avoided<sup>113</sup>. Whether or not the E-PMR and the O-PMR methods of recurrent groin hernia repairs can reduce the risk for chronic pain is addressed in Study 4.

## Studies 3 and 4

These studies were based on regional cohorts of patients who had undergone surgery for recurrent groin hernia. A follow-up was conducted using the IPQ and selective clinical examination in order to determine the *prevalence of a 2<sup>nd</sup> recurrence* and *chronic groin pain and physical disability* after 1<sup>st</sup> and 2<sup>nd</sup> recurrent groin hernia surgery.

### Study 3

#### Risk for a 2<sup>nd</sup> recurrence

Study 3 indicates that a 1<sup>st</sup> recurrent groin hernia should preferably be operated with a mesh repair in the previously non-touched space on the groin, in order to minimise the risk for a 2<sup>nd</sup> recurrence. This is in accordance with the EHS guidelines<sup>97</sup>. Endoscopic methods of repair were associated with the lowest rate of 2<sup>nd</sup> recurrence and anterior mesh the highest. These results are in accordance with the randomised study by Kouhia<sup>103</sup>, but in contrast to the latest review articles<sup>79,114</sup>, which could not find any differences in re-recurrence between endoscopic and Lichtenstein repair. A Cochrane review from 2003 was also inconclusive regarding the rate of recurrence when comparing endoscopic and anterior mesh methods of repair<sup>115</sup>. Most studies on recurrent groin hernia compare endoscopic and tension-free anterior repairs and do not include open posterior mesh repairs. National data from the SHR 2012, show that 18 % of recurrent repairs were O-PMRs<sup>5</sup>. The proportion in the current study was 25 %. The study shows that open posterior mesh repairs as a group, is equally as favourable as endoscopic repairs. In sub group analyses however the TIPP technique does not seem to be as favourable as the Nyhus technique, which had the lowest recurrence rate of all PMR methods.

#### Method of repair in relation to index operation

A posterior mesh repair is the method of choice if the index operation, prior to the 1<sup>st</sup> recurrent repair, is an anterior repair. These findings are consistent with previous register studies<sup>96,116</sup>. In this study most index repairs were anterior suture repairs that are now considered outdated.

For a relatively small group of patients who had a 1<sup>st</sup> recurrent repair after a previous posterior repair, this study shows a lower risk of a 2<sup>nd</sup> recurrence if an anterior mesh repair is used. Although not proven in previous studies, this is in line with the recommendations in the EHS guidelines<sup>97,98</sup>. To use the untouched anatomical space in the groin appears favourable after having a recurrence in order to diminish the risk

of having a 2<sup>nd</sup> recurrence. This seems logical, since the untouched space is more easily accessed, and more resembles the circumstances of a primary hernia repair. In this study 42 % of the recurrent operations, were performed through a previously used space. Most recurrences follow an anterior approach, performed when the Shoudice procedure was the gold standard. To repair a recurrence in the same space after a sutured repair seems more feasible compared to a former mesh repair. We did not, however, make this group distinction since the numbers of index mesh repairs were few. The results are overwhelming with a more than three-fold higher risk for having a new recurrence when the same anterior space was used compared to an E-PMR.

The number of patients with a former suture repair will diminish over time, but still these patients will be common. The median time to develop a 1<sup>st</sup> recurrence was 10 years in this study. Our results indicate that recurrence appears earlier if the index operation was a mesh repair compared to a suture repair. This is in contrast to a study by Magnusson et al, who reported early recurrence after suture and endoscopic repairs compared to AMR<sup>17</sup>. Early recurrence, however, is often considered a result of technical failure.

## Approach in Open Posterior Mesh Repair (O-PMR)

This study reveals large differences in 2<sup>nd</sup> recurrence rate after different O-PMR techniques, when correlated to the surgical approach. If the mesh was placed in the preperitoneal position through a transverse incision above the inguinal canal (Nyhus/Wantz) the 2<sup>nd</sup> recurrence rate was lower than all other mesh methods (2.5 %). With a transinguinal approach (TIPP) the 2<sup>nd</sup> recurrence rate came close to 30 %. These results may reflect the fact that these operations are often performed through scar tissue after previous anterior repairs, which makes dissection and placement of the preperitoneal mesh more difficult. The TIPP procedure should thus be avoided in recurrent groin hernia surgery. The Kugel herniorrhaphy was not used in the current study, though other studies have shown results comparable with endoscopic techniques<sup>57,118</sup>.

## Gender aspects

Groin hernia repairs in women constitute 9 % of all hernia repairs registered in the SHR 2013. In this cohort of recurrent repairs the corresponding figure was 3.6 %. The proportion of women operated with a PMR was 83 %, which must be considered high from a nationwide perspective. The corresponding figure for men was 49.6 %. There was no significant difference in 2<sup>nd</sup> recurrence rates between men and women.

The first annual report from the SHR that reported methods of repair in men and women separately was in 2008. Of the 1340 repairs in women that year, 761 (56.8 %)

were performed with an AMR (Lichtenstein and Plug repairs). This clearly indicates the need for a change in the operative management of hernia in women. This was supported by other studies that showed the advantage of the TEP procedure in detecting femoral hernia in women<sup>119</sup> and large register studies have confirmed that PMR in women is associated with a lower risk for reoperation than AMR<sup>93,94</sup>.

In the current study, a femoral hernia was found in 41.4 % of repairs in women and in 3.1 % in men at the 1<sup>st</sup> recurrent hernia repair. These figures indicate a higher prevalence of femoral hernia at recurrent repairs compared to primary repairs. This is confirmed by non-published national data from the SHR 2004-2013, showing that men were found to have a femoral hernia in 0.9 % (1187/133627) of primary repairs and in 3.9 % (546/13980) of recurrent repairs. The corresponding data for women were 23.5 % (2953/12580) of primary repairs and 42.1 % (343/814) of recurrent repairs.

When the index operation was an anterior repair, a femoral hernia was found at the 1<sup>st</sup> recurrent repair in 47.6 % of women and in 3.1 % of men. This indicates a high risk for a missed femoral hernia when performing anterior repair, if not taking specific actions to exclude the presence of a femoral hernia.

These data support the use of PMR methods in women for both primary and recurrent groin hernia repair and in men with recurrent hernia.

## Impact of surgeon's annual volume

The impact of the surgeon's proficiency on outcome after hernia surgery has to our knowledge only been addressed in primary inguinal hernia surgery<sup>120</sup>. In the absence of a scientific definition of surgeon's proficiency in hernia surgery, the surgeon's annual volume may serve as surrogate. This study indicates a lower risk for a 2<sup>nd</sup> recurrence, if the mean surgeon's annual volume was higher than five open posterior mesh repairs. This however, was not the case for anterior mesh or endoscopic repairs. Regarding endoscopic repairs, the low risk for a 2<sup>nd</sup> recurrence could be explained by the fact that even the "low volume surgeons" who performed recurrent hernia surgery, were well trained long before the units started their registrations in the SHR. This was not the case for surgeons performing a low-volume of O-PMRs, who in the majority of cases, only occasionally performed hernia surgery. It could be suspected that the O-PMR was used in order to avoid a re-operation through an anterior approach. The fact that the anterior mesh repairs are associated with the same risk for recurrence, regardless of surgeon volume, could indicate that an adverse effect of a re-operation through scarred tissue in the anterior space cannot be avoided even by a high volume surgeon. Even with stratification for annual volume, there may have been a selection bias in the choice of method.

## Methodological considerations

A weakness of the study is that the clinical examination was performed in 2009 although 2<sup>nd</sup> recurrent repairs were included from the SHR until December 31<sup>st</sup> 2013. This means that clinically diagnosed 2<sup>nd</sup> recurrences that were not re-operated in this interval have been overlooked. An additional weakness is the incompleteness of answers to the questionnaire and of clinical follow-up. The study detected 67 2<sup>nd</sup> recurrences of which 15 (22 %) were found after having a 66 % response rate to the questionnaire and 69 % of patients having had a clinical examination after indicating a new lump or other discomfort. It is hard to draw any conclusions what this incompleteness means in number of missed 2<sup>nd</sup> recurrences. It could be assumed that the majority of patients with a symptomatic 2<sup>nd</sup> recurrence would most likely answer after several reminders and offers to become clinically examined. Our data suggests that the 2<sup>nd</sup> recurrence rate could be estimated by multiplying the reoperation rate registered in the SHR, with a factor of at least 1.3 (67/52). In the study by Ekelund et al, this factor was 2.7<sup>90</sup> and in the study by Haapaniemi 2.3<sup>99</sup>.

A strength of the study was the high level of completeness, including previous and subsequent repairs, which made it possible to analyse the impact of the index repair. This study has also supplemented the data taken from the SHR with a postoperative follow-up procedure to detect non re-operated 2<sup>nd</sup> recurrences. The study reflects the outcome after routine recurrent groin hernia surgery performed in the first decade of the 2000s. This is in contrast to the randomised controlled trials<sup>103,104,121</sup>, that were mainly conducted in the 1990s and included small numbers of patients.

Ekelund et al<sup>90</sup> reported a cumulative increase in 2<sup>nd</sup> recurrence rate from 6 % after one year to 19 % five years after the TAPP and 6.5 % after one year to 18 % five years after the Lichtenstein repair. These frequencies are high but at that time the meshes were smaller, which could have contributed to the high 2<sup>nd</sup> recurrence rate. A cumulative recurrence rate was also noted by us in the AMR group being 8% after five years and 17% after 15 years. This is in contrast to the PMR group that reached a plateau of 5% after 7 years, suggesting this technique to be a good choice for a long-lasting repair.

## Study 4

### Chronic pain and physical disability

The current population-based study shows a very high incidence of chronic pain and/or physical disability remaining after a median of nine years after recurrent groin hernia surgery. A total of 29 % of patients stated persistent pain or disability and 6% stated pain that could not be ignored and that affected everyday activities.

These results are difficult to compare with other studies since they generally lack a long follow-up time especially for patients having had a recurrent operation. This study underlines the importance of keeping chronic pain in mind as being a major factor influencing health-related quality-of-life in patients undergoing recurrent groin hernia surgery. In a recent meta-analysis by Yang et al, on randomised controlled trials comparing different surgical techniques for recurrent groin hernia repair, the overall rate of chronic pain was 10.3 %<sup>122</sup>. These results are difficult to compare with those of the current study, since the definition of pain as well as length of follow-up varies widely.

There are to our knowledge no studies on recurrent groin hernia surgery describing the interference of pain on daily activities. A study on chronic pain after primary groin hernia surgery, using the IPQ, reported the same rate of pain interfering with daily activities (6 %) <sup>32</sup> as does the current study after recurrent hernia surgery. Poobalan et al, reported a 4-fold increased risk ( $p=0.005$ ) for chronic pain after recurrent hernia surgery compared to primary hernia surgery<sup>72</sup>. In a prospective study on 88 patients operated for a recurrent hernia, there was a higher incidence of moderate and severe chronic groin pain 12 months after operation compared to primary repairs (14 vs 3 %,  $p<0.01$ )<sup>73</sup>

### Chronic pain in relation to follow-up time

Repeated surgical trauma to the groin tissue and the risk for nerve lesions associated with recurrent groin hernia surgery should be considered when performing recurrent hernia surgery. Even if chronic pain seems to diminish to some extent during the first years after a hernia repair<sup>90,123,124</sup>, it may limit the patient's ability to perform daily activities and affect health-related quality-of-life<sup>67</sup>. Since this study was based on a very long-term outcome with a median follow-up of nine years, with only 1 % of patients having a follow-up shorter than 5 years, it is difficult to compare these results with those of other studies. The current study shows the same prevalence of pain and physical disability, measured using the IPQ score, in patients with a follow-up less than 10 years as those with a longer follow-up. This indicates that the problems did not seem to diminish with time in the present cohort.

## Chronic pain in relation to method of repair

When comparing different types of mesh repair technique and the risk for chronic pain after recurrent groin hernia surgery, the preceding (index) repair must be taken into account. The results from this analysis underline the importance of the index repair. In a univariate logistic regression analysis, not taking the index repair into account, the method of the 1<sup>st</sup> recurrent mesh repair was not a predictor of pain. In this study 95.4 % of index repairs were anterior repairs. For this large cohort of patients, the E-PMR had a significantly lower risk for chronic pain and physical disability compared to AMRs. To our knowledge no other large follow-up study has provided data on chronic pain and disability after recurrent hernia surgery taking the index repair into account.

The advantages of endoscopic techniques is supported by the latest meta-analysis on primary groin hernia surgery, that showed fewer patients with chronic pain after endoscopic compared to Lichtenstein repairs; 5.6 % versus 15.5 %, (OR 0.33 (CI 0.17-0.68),  $p=0.002$ )<sup>122</sup>. This however is in contrast to some other studies that could not demonstrate any differences in chronic pain between E-PMR and AMR<sup>79,115</sup>.

There were too few posterior index repairs to be able to draw any conclusion on what approach to recommend for this small group of patients with a recurrence. The recommendations in the EHS guidelines to use the untouched plane for mesh implantation in a recurrent groin hernia could therefore not be supported by this study on this small group of patients<sup>97</sup>.

The Nyhus approach was the most commonly used technique for open preperitoneal mesh placement. Although not significant, the Nyhus approach had a lower incidence of chronic pain compared to all other incisions (Stoppa and TIPP). No recommendation for open preperitoneal techniques can be made based on the results of this study.

## Impact of surgeon's annual volume

The impact of the surgeon's proficiency on outcome after hernia surgery has, to our knowledge, only been addressed in primary inguinal hernia surgery<sup>120</sup>. In the absence of a scientific definition of surgeon's proficiency in hernia surgery, the surgeon's annual volume may serve as surrogate. This study indicates a lower risk for chronic pain and physical disability, if the mean surgeon's annual volume is higher than five open posterior mesh repairs. This however, was not the case for anterior mesh or endoscopic repairs. Regarding endoscopic repairs, the low risk for pain could be explained by the fact that even the "low volume surgeons" who performed recurrent hernia surgery, were well trained long before the units started their registrations in the SHR. This was not the case for surgeons with a low annual volume of O-PMRs, who in most cases only occasionally performed hernia surgery. It may be that the O-PMR was chosen to avoid

a reoperation via an anterior approach. The fact that the anterior mesh repairs have the same risk for pain regardless of surgeon's volume, could imply that adverse effects of reoperation through scarred tissue in the anterior space cannot be avoided even by a high-volume surgeon. Even with stratification for annual volume, there may have been selection bias in the choice of method.

## Chronic pain after 1<sup>st</sup> and 2<sup>nd</sup> recurrent repair

A previous study has shown that the risk for further reoperation increases with the number of previous repairs<sup>89</sup>. The relationship between chronic pain and number of previous repairs has to our knowledge not previously been studied. In a separate cohort analysis, patients operated for a 2<sup>nd</sup> recurrent hernia repair had a higher risk for developing chronic groin pain and physical disability compared to patients operated for a 1<sup>st</sup> recurrent repair. It seems logical that the risk for chronic pain increases with increasing number of repairs.

## Methodological considerations

A weakness of the study is its retrospective design resulting in the absence of IPQ data registered before the 1<sup>st</sup> recurrent repair. The results must be interpreted with some caution since the source of pain and functional disability may have been created at the index operation or may not have been related to groin hernia at all.

In all multivariate analyses, adjustment was made for age and gender. There may still, however, be residual confounding factors. Length of follow-up did not have a significant impact on outcome, but we cannot exclude that there may be other factors that differed between the groups. Although the response rate was high, the non-responders and patients who did not complete the follow-up may have differed from the rest.

The strength of the study was the high level of completeness, including previous and subsequent repairs, which made it possible to analyse the impact of the index repair. The IPQ questionnaire as well as the items and procedure for selecting patients for clinical follow-up have been evaluated in previous studies<sup>68,86,99</sup>. All data in the SHR have a high national coverage and in-data are regularly validated, which limits the risk of selection bias. As the SHR is population-based, the results represent the outcome of hernia surgery as practised in the community at large in contrast to local case series and randomised controlled trials.





# Conclusions

- With increasing number of recurrent hernia repairs on the same groin, the risk for reoperation is increased. Endoscopic repair is associated with the lowest risk for reoperation in repeated groin hernia surgery.
- Anterior Mesh Repair is associated with a higher risk for reoperation compared to Posterior Mesh Repairs (Endoscopic and Open) in recurrent hernia surgery. Women benefit even more than men from a Posterior Mesh Repair, due to the high incidence of femoral hernia in recurrent repairs.
- The previous, index operation must be taken into account when performing recurrent groin hernia surgery. After an index anterior operation, a Posterior Mesh Repair is recommended and after an index posterior operation, an Anterior Mesh Repair is recommended.
- An Open Posterior Mesh Repair in 1<sup>st</sup> recurrent groin hernia, performed through a Nyhus approach has a lower risk for a 2<sup>nd</sup> recurrence compared to the transinguinal approach. A mean surgeon's annual volume > 5 Open Posterior Mesh Repairs reduces the risk of a 2<sup>nd</sup> recurrence compared to a surgeon's volume ≤ 5 repairs.
- After 1<sup>st</sup> recurrent hernia repair, 29 % of patients complain of chronic groin pain or physical disability and 6 % have pain that affects everyday activities. After an index anterior repair, Endoscopic repair was associated with a lower risk for pain and physical disability compared to Anterior Mesh Repair. Patients operated for a 2<sup>nd</sup> recurrent repair had a higher risk for chronic pain and physical disability compared to patients operated for a 1<sup>st</sup> recurrent repair. A mean surgeon's annual volume > 5 Open Posterior Mesh Repairs, reduces the risk for pain compared to a surgeon's volume ≤ 5 repairs.



# Future perspective

## Biological aspects on hernia

The fundamental mechanism behind hernia formation in adults is the loss of mechanical strength in the abdominal wall muscles and fasciae. There is evidence that genetic and extracellular matrix disorders may predispose patients to hernia formation<sup>125</sup>. An increase in Type III collagen in relation to Type I collagen<sup>126</sup> has been shown to increase the risk for hernia development. An impaired collagen metabolism is caused by a defect in collagen gene regulation<sup>127</sup>. This knowledge has led us to the use mesh techniques in 99 % of all groin hernia repairs performed in Sweden. There are also data suggesting that groin hernia is most likely an genetic disease, even though a clear inheritance pattern not yet has been described<sup>128</sup>.

Although it is an intriguing thought that in the future we might be able to prevent hernias through medical regulation of the patient's collagen metabolism, surgery will in the foreseeable future remain the only treatment to cure groin hernia.

## Mesh in hernia surgery

The advantage of lightweight compared to heavyweight mesh regarding reduced chronic pain, has been shown in many studies<sup>129,130</sup>. This seems to be the case for both open and endoscopic surgery. These meshes do not appear to be associated with a higher risk for recurrence compared to heavyweight meshes. There is today no evidence for the use of biological mesh in groin hernia surgery. The further development of mesh is hard to predict. The “perfect mesh” should have good biocompatibility with minimal tissue reaction whilst creating sufficient strength in the tissues to prevent recurrence, and, moreover, be produced at a low cost. Such a mesh has not yet seen the light of day!

In order to diminish the risk for chronic pain, the trend in both endoscopic and open hernia surgery is to avoid “traumatic” fixation of the mesh<sup>131</sup>. The use of glue<sup>132</sup> and “self-gripping” meshes<sup>133</sup> has become popular. Reported results are promising but they should however be interpreted with caution due to a relatively short follow-up time.

## Technique in groin hernia surgery

National registers are an invaluable source of data to follow the quality of groin hernia surgery, but they need to be further developed to include long-term quality-of-life also. It is possible to study large cohorts of patients and to gather results rapidly when new techniques are lounged.

The golden opportunity for successful hernia surgery is when the first hernia operation is performed on a patient. All efforts should be made to minimise the risk for having a recurrent hernia and chronic pain problems!

There is reason to believe that minimally invasive techniques such as the TEP procedure will gain more acceptance and be used more frequently in elective groin hernia surgery. In the hands of trained and skilled surgeons, the outcome after endoscopic repairs regarding risk for recurrence and short and long-term pain, seems better than all other methods of repairs used today<sup>134,135</sup>. To be able to operate the majority of elective groin hernias with endoscopic methods would require the formation of specialised centres where dedicated surgeons and trained staff perform large volumes of endoscopic repairs and take the responsibility for education. In contrast to this development stands the option to perform the Anterior Mesh Repair in primary groin hernia in men. The advantage of this technique is that it may be performed under local anaesthesia and at a lower cost<sup>136</sup>. Open hernia surgery will still remain a cornerstone in emergency hernia surgery, and this is dependent on adequate training in elective hernia surgery.

Hopefully there will be a more customised mix of open and endoscopic hernia surgery. The studies in this thesis have shown that the Endoscopic and Open Posterior Mesh Repair techniques should be preferred for recurrent hernia in both men and women after an index anterior repair. Other studies have shown an advantage of endoscopic techniques for women planned for primary hernia repair. The Anterior Mesh Repair could be used for primary hernia operation in men and for recurrent hernias after previous posterior mesh repair.

## Education in hernia surgery

The growing interest in endoscopic techniques as a whole will probably result in educational changes in surgical training including more focus on the endoscopic hernia techniques.

Nationally coordinated education programmes have the power to set a high national standard of education in hernia surgery. Courses should be held at different levels to guarantee quality of hernia surgery in general as well as in units specialised in more complex hernia surgery. A basic course for surgical residents which focuses on groin and abdominal wall anatomy and open hernia surgery and a post graduate course focused on more advanced hernia surgery and new tailored techniques, will lead to a high quality of care in hernia surgery nationwide. The possibility to train both open and endoscopic<sup>137</sup> hernia surgery in simulation-based models, will hopefully be further developed in order to shorten the learning curve.

# Populärvetenskaplig sammanfattning

## Vad är ljumskbräck och hur vanligt är det ?

Bräck är en försvagning i bukväggen genom vilken bukhinnan och bukinnehåll kan bukta ut så att en knöl kan kännas. Bräck i ljumskan kan vara medfödda eller utvecklas med stigande ålder då vävnaden försvagas. Ljumskbräcken kan indelas i två typer: *inguinala* och *femorala* (lårbräck). De inguinala är lokaliserade ovan och de femorala nedan ljumskvecket. De inguinala bräcken är vanligast och endast 3 % är femorala. Bräck hos män är 10 gånger vanligare än hos kvinnor. De manliga bräcken är oftast inguinala emedan kvinnor i drygt 25 % har femoralbräck. Symtom från bräck kan variera från lättare obehag till svår smärta som kan uppkomma om bräcket blir inklämt, vilket kräver ett akut omhändertagande. Risken för inklämning är störst för de femorala bräcken.

Bräck indelas ofta i *förstagångsbräck* och *återfallsbräck*. Nio procent av alla ljumskbräcksoperationer i Sverige är för *återfallsbräck*, vilket innebär att patienten är opererad minst en gång för bräck i samma ljumskan.

## Operation av ljumskbräck

Bräck kan bara botas genom operation. Operationen syftar till att eliminera symtom från bräcket samt att förhindra akut inklämning. I Sverige utförs årligen mellan 15 000-16 000 ljumskbräcksoperationer på personer över 15 års ålder. Det är det vanligaste ingreppet som utförs av kirurger.

Operationen syftar till att ta bort den utbuktande bukhinnan samt bukinnehåll från det försvagade området och förstärka detta område för att undvika återfall av bräcket. Vid drygt 99 % av alla operationer i Sverige används ett nät för att åstadkomma denna förstärkning. Operationen kan utföras med två olika placeringar av nätet. Antingen opereras nätet in framför det försvagade området i ljumskan, *främre nätplastik* eller genom att nätet placeras på baksidan av det försvagade området, *bakre nätplastik*. Den *främre nätplastiken* görs genom ett snitt i ljumskan och kan endast åtgärda inguinala bräck och den *bakre nätplastiken* kan utföras med titthålsteknik alternativt genom ett snitt och kan åtgärda både inguinala och femorala bräck.

## Svenskt Bräck Register (SBR)

I början av 1990-talet började svenska kirurger intressera sig för att studera kvaliteten av bräckkirurgin. Detta sammanföll med att nya operationstekniker introducerades och att nät som förstärkning i ljumskan började användas allt oftare.

SBR är ett nationellt kvalitetsregister som startades 1992 med avsikt att samla in och analysera uppgifter om utförda ljumskbräckoperationer i landet med målsättning att delge dessa resultat till deltagande kliniker i syfte att förbättra kvaliteten av bräckkirurgin. Numer registreras ca 98 % av alla operationer för ljumskbräck som utförs i Sverige. SBR innehåller idag uppgifter om drygt 250 000 ljumskbräckoperationer.

Eftersom alla svenska medborgare har ett personnummer, finns en unik möjlighet att följa upp alla opererade patienter, oberoende var i landet operationerna utförs. Eftersom många andra länder saknar denna möjlighet, har SBR fått en unik internationell ställning, inte minst ur ett vetenskapligt perspektiv. Mer än 40 vetenskapliga artiklar och 10 avhandlingar (denna inräknad) är baserade på data från SBR.

### Återfall av tidigare opererat ljumskbräck

Ett av de kvalitetsmått som ofta används inom bräckkirurgin, är andelen patienter som får återfall efter operation av ljumskbräck. Från SBR kan alla deltagande enheter få uppgift om hur många av deras patienter som genomgått en omoperation efter tidigare bräckoperation. Denna andel har minskat dramatiskt under de senaste 15 åren. Faktorer som förbättrat resultaten efter ljumskbräckoperation är till exempel, användandet av nätförstärkning, nya standardiserade operationsmetoder, förbättrad utbildning och inte minst ett ökat intresse och förhöjt status bland kirurger.

Ett annat och mycket viktigt kvalitetsmått är risken att drabbas av kroniska smärtor och besvär från den opererade ljumskan. Tidigare studier har visat att andelen som får långvariga besvär efter operation av ett *förstagångsbräck* är betydligt större än andelen som får återfall. Andelen patienter som får kroniska besvär efter operation av *återfallsbräck* är bristfälligt utrett. Denna information finns inte i SBR, utan kräver att patienter genomgår en efterundersökning

## Avhandlingens bakgrund och syfte

Risken för en patient att behöva genomgå en omoperation på grund av återfall av bråck, är mer än dubbelt så stor efter operation av ett *återfallsbråck* jämfört med ett *förstagångsbråck*. Fem år efter operation av ett *förstagångsbråck*, har 2.7 % av bråcken blivit omopererade på grund av återfall. Efter operation för *återfallsbråck* har 5.8 % blivit opererade för ännu ett återfallsbråck. Orsaken till denna skillnad är inte vetenskapligt klarlagd.

Syftet med avhandlingen var att identifiera faktorer som påverkar risken för nytt återfall av bråck samt risken för kronisk smärta, efter operation av återfallsbråck. Målsättningen var att, med ledning från detta avhandlingsarbete, kunna ge kirurger praktiska råd om hur patienter med återfallsbråck skall opereras för att minimera risken för nytt återfall och kronisk smärta efter operation.

### Delarbete 1 och 2

Båda studierna analyserar alla återfallsbråck i Sverige som registrerats i SBR under åren 1992-2008. Dessa studier är till antalet inkluderade operationer av återfallsbråck de största publicerade materialen i litteraturen.

**Delarbete 1** visar att risken för ytterligare omoperation för återfallsbråck ökar med antalet tidigare utförda ljumskbråcksoperationer i samma ljumske. En bakre nätplastik innebar en lägre risk för omoperation jämfört med en främre nätplastik.

Risken för omoperation var lägre om patienten opererades på en annan enhet än den enhet som utförde den föregående operationen. Detta kan bero på att man saknade kompetens att utföra en bakre nätplastik på den enhet där patienten genomgick föregående operation.

**Delarbete 2** visar att en bakre nätplastik med titthålsteknik har den lägsta risken för omoperation. Om föregående operation var en främre ljumskbråcksoperation, hade de bakre nätplastikerna en lägre risk för omoperation jämfört med en främre nätplastik. Studien visar att kvinnor som opereras för återfallsbråck skall opereras med en bakre nätplastik, eftersom de i större utsträckning än män har femoralbråck.

### Delarbete 3 och 4

I dessa studier ingår patienter som opererats för återfallsbråck i Malmö, Lund, Landskrona, Helsingborg och Ängelholm under åren 1998-2007. Data från SBR har inhämtats och analyserats. Patienterna har dessutom fått besvara frågor om huruvida de återfått en knöl i ljumskan och om de hade några besvär i den opererade ljumskan. De har också fått besvara en omfattande enkät om ljumsksmärta. De patienter som



angav en ny knöl eller besvär från den opererade ljumsken, kallades för undersökning av läkare. **Delarbete 3** har studerat risken att få ännu ett återfall och **delarbete 4** har undersökt risken för kronisk smärta och försämrad fysisk förmåga.

**Delarbete 3** visade att en bakre nätplastik utförd med titthålsteknik eller genom öppen operation via ett snitt ovan ljumsken hade den lägsta risken för återfall. Studien visade betydelsen av att ta hänsyn till vilken operationsmetod som använts vid första ljumskbräckoperationen. Risken för ett nytt återfall var mindre om återfallsbräck efter tidigare främre ljumskbräcksplastik, opererades med en bakre nätplastik. Om den första bräckoperationen var en bakre nätplastik, innebar en främre nätplastik en lägre risk för återfall jämfört med en ny bakre nätplastik. Detta är inte visat i tidigare studier.

Drygt 40 % av alla kvinnor med återfallsbräck hade ett femoralbräck, vilket endast kan åtgärdas med en bakre nätplastik.

Om återfallsoperationen utförs av en kirurg som utför en årlig medelvolym större än 5 öppna bakre nätplastiker, är risken för återfall mindre än om kirurgen utför mindre än 5 öppna bakre nätplastiker.

**Delarbete 4** visar att 29 % beskriver en kronisk smärta i ljumsken eller försämrad fysisk förmåga efter operation av återfallsbräck. Sex procent av patienterna anger en smärta som inte kan ignoreras och påverkar dagliga aktiviteter.

För de patienter som opereras för återfall efter en tidigare främre ljumskbräckoperation, var risken för kronisk smärta och försämrad fysisk förmåga lägre efter en titthålsoperation jämfört med en främre nätplastik.

Om återfallsoperationen görs av en kirurg som utför en årlig medelvolym större än 5 öppna bakre nätplastiker, är risken för kronisk smärta och försämrad fysisk förmåga mindre än om operatören utför mindre än 5 öppna bakre nätplastiker.

Patienter som genomgår en andra operation för återfallsbräck, har en högre risk för kronisk smärta och försämrad fysisk förmåga jämfört med dem som opererats en gång för ett återfallsbräck. Det är därför av största vikt att patienter som opereras första gången för ett återfallsbräck, får ett optimalt kirurgiskt omhändertagande för att minimera risken för ytterligare återfall och därmed risken för kronisk smärta.

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# Errata

- In Paper 2, on page 1492, in the legend to Table 1, it should be:  
...based on 13 165 repairs for which...”
- In the Paper 2, on page 1491, it should be:

The reoperation rate was significantly higher after anterior mesh repair than after the posterior approach in a subgroup analysis that excluded sutured repairs and adjusted for age, gender, defect size and hernia anatomy. In a separate analysis, omitting recurrent repair of a femoral hernia and adjusting for the same co-variables, posterior mesh repair had a significantly lower risk for reoperation than anterior mesh repair. The outcome after both analyses was in accordance with the outcome for the whole cohort (Table 1)



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# Appendix 1

## Inguinal Pain Questionnaire

1. Date of completion:	
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<p>2. Estimate the pain you felt in the groin before the surgery.</p> <p>3. Estimate the pain you feel right now in the groin on the same side as the operation.</p> <p>4. Estimate the worst pain you felt in the operated groin during this past week.</p>	<ol style="list-style-type: none"> <li>1. No pain</li> <li>2. Pain present, but can easily be ignored</li> <li>3. Pain present, cannot be ignored, but does not interfere with everyday activities</li> <li>4. Pain present, cannot be ignored, interferes with concentration on chores and daily activities</li> <li>5. Pain present, cannot be ignored, interferes with most activities</li> <li>6. Pain present, cannot be ignored, necessitates bed rest</li> <li>7. Pain present, cannot be ignored, prompt medical advice sought</li> </ol>
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5. If you answered "no pain" to question 4 try to remember when the pain in the operated groin disappeared after the operation	1. The pain in the operated groin disappeared within 1 month after the operation	2. The pain in the operated groin disappeared 2-3 months after the operation	3. The pain in the operated groin disappeared 4-6 months after the operation	4. The pain in the operated groin disappeared 7-12 months after the operation	5. The pain in the operated groin disappeared 13-24 months after the operation	6. The pain in the operated groin disappeared recently
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To be answered by those who have had pain during the preceding week:

6. How often have you felt pain in the operated groin during the past week?	1. Once	2. 2-5 times	3. Every day	4. Every day and also during night time	5. I have had pain the whole week, both day and night
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7. How long have the episodes of pain in the operated groin lasted in the past week?	1. 1 min to 1 hour	2. 1 to 5 hours	3. The whole day	4. Day and night	5. The pain has lasted the whole week, day and night
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8. Do you find it difficult to get up from a low chair due to the pain in the operated groin?	<ol style="list-style-type: none"> <li>1. No</li> <li>2. Yes</li> <li>3. I don't know</li> <li>4. Not applicable</li> </ol>
9. Do you find it difficult to sit down for more than half an hour due to the pain?	
10. Do you find it difficult to stand up for more than half an hour due to the pain?	
11. Do you find it difficult to go up or down stairs due to the pain?	
12. Do you find it difficult to drive a car due to the pain?	
13. Has the pain limited your ability to exercise or perform sports?	

14. Have you on any occasion during the past week taken pain killers for the pain in the operated groin?	<ol style="list-style-type: none"> <li>1. No</li> <li>2. Yes</li> </ol>
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15. To what extent has the pain in the groin limited your working capability in the last 2 months?	1. I have not needed to take sick leave	2. The pain made me take 1-7 days of sick leave	3. The pain made me take sick leave for 1-4 weeks	4. The pain has made me take sick leave for the entire past two months	5. I have a disability pension because of the pain in the groin	6. I am not working for other reasons.
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**To be answered by everybody:**

16. Estimate the severity of pain that you feel right now in the groin opposite to the operated side	<ol style="list-style-type: none"> <li>1. No pain</li> <li>2. Pain present, but can easily be ignored</li> <li>3. Pain present, cannot be ignored, but does not interfere with everyday activities</li> <li>4. Pain present, cannot be ignored, interferes with concentration on chores and daily activities</li> <li>5. Pain present, cannot be ignored, interferes with most activities</li> <li>6. Pain present, cannot be ignored, necessitates bed rest</li> <li>7. Pain present, cannot be ignored, prompt medical advice sought</li> </ol>
17. Estimate the worst pain that you have felt in the groin opposite to the operated side during this past week	

To be answered by male patients: Have you experienced testicular pain on the same side as the operated groin since the operation?	<ol style="list-style-type: none"> <li>1. No</li> <li>2. Yes</li> </ol>
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# Appendix 2

## Protocol clinical examination

**Protocol**

**Pers. id nr:** \_\_\_\_\_ - \_\_\_\_\_

**Name:** \_\_\_\_\_

### Clinical examination of groins

**Date:** \_\_\_\_\_

**Performed by Dr.** \_\_\_\_\_

Examination of                      Right side    Left side    Bilat

Palpable recurrence                      Right side  Yes                       No

Palpable recurrence                      Left side  Yes                       No

Non-palpable recurrence                      Right  Yes                       No

If Yes state side                      Right side    Left side

Diagnostic method                      Herniography    U-sound    MR/CT

Laparoscopy    Other

Patient's comments

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Doctor's comments

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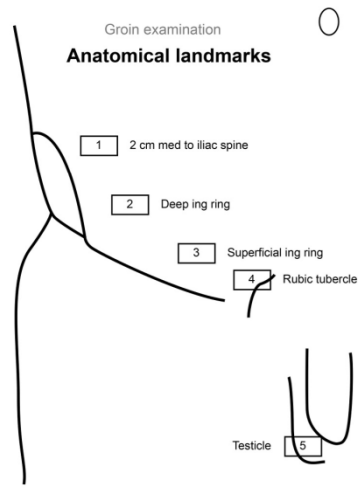
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## Clinical examination of groins

- NP = No pain  
 T = Tenderness  
 HT = Hypoesthesia, on touch  
 HN = Hypoesthesia, with needle  
 HE = Hyperesthesia  
 RP = Radiated pain



Right side:

	NP	T	HT	HN	HE	RP
1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Testicular atrophy

Varicocele

Tenderness adductor tendon

Pain on adduction of hip

Pain on rotation of hip

Left side:

	NP	T	HT	HN	HE	RP
1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Right  Yes  No

Left  Yes  No

Right  Yes  No

Left  Yes  No

Right  Yes  No

Left  Yes  No

Right  Yes  No

Left  Yes  No

Right  Yes  No

Left  Yes  No