

# 1 Present State of Failure Rates (Clinical Studies and Epidemiological Database, Short- and Long-Term)

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## 1.1 Inguinal Hernia

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### Introduction

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Hernia treatment has been a challenge to surgeons for more than 2000 years. Modern hernia surgery started in Italy, more than 100 years ago, with Eduardo Bassini's presentation of a new method of repair. Bassini did not just invent a new method of inguinal hernia repair [1]; one of his major contributions was that he performed adequate audit and follow-up of patients [2]. Notable improvements in herniology after that were the development of the Shouldice technique and the introduction of prosthetic mesh.

Today many methods of repair are used, the majority including reinforcement with various mesh devices. Excellent results have been repeatedly reported from specialized hernia clinics with almost total absence of recurrences [3–5]. However, in general surgical practice, in Sweden and elsewhere, recurrent hernia still is a problem, even though the new techniques have been adopted and the outcome improved. In Sweden, with its 9 million inhabitants, each person has a personal identification number [6]; this, together with the national death register [7, 8] and the positive attitude to medical quality registers [9], makes it possible to study hernia surgery using epidemiological methods.

The aim of this chapter is to try to estimate the present failure rate following surgery for inguinal and femoral hernia by reviewing recent data from the Swedish Hernia Register.

### Background to our Epidemiological Data

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#### The Swedish Hernia Register

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The Swedish Hernia Register (SHR) [10, 11] was established in 1992 and started as a regional project, including eight hospitals, with prospective registration of all procedures for inguinal and femoral hernia surgery on people 15 years of age and older, the use of Person Numbers making it possible to link re-operations to previous operations performed within the framework of the register. The SHR has expanded each year and is now a truly “national” register with 90 units aligned (2004). Our estimation is that approximately 95% of Swedish groin hernia surgery is prospectively registered today.

Once a surgical clinic is aligned to the voluntary register, a contract outlining responsibilities concerning data collection and delivery is signed by the head of the

clinic. The aligned unit also agrees to participate in an external review (visits from SHR representatives) if the hospital is selected. External review is necessary to keep data validity high, and approximately 10% of aligned units are controlled each year. The SHR has been found to include 98% of eligible operations [12].

The aim with the register is to describe and analyze hernia surgery and to be used as a tool in improvement processes at the hospitals participating [11]. From the beginning, our register was funded by the Federation of County Councils and the National Board of Health and Welfare. Since 2001 all aligned hospitals must pay a small fee (30 SKR or approximately € 3.–) for each repair registered, to cover total costs. Recently, a decision was made to increase insight and make some of the data public on the Internet, making it possible to compare results reported from participating units. Hopefully that will stimulate Swedish hernia surgeons to further improve their results. The results of individual surgeons, however, will be reserved for internal quality audit.

## Endpoints and Definitions

The two most important outcome measures following hernia surgery are recurrence rate and chronic postoperative pain. Many variables affecting outcome may be studied in the SHR, such as method of repair, suture material, classification of anatomy and size, type of anaesthesia and postoperative complications [11]. Other quality measures such as days off work (or normal activity) following surgery, costs etc. are not as yet registered in the database, but the register can be used as a tool to identify individuals suitable for such analyses.

The focus here will be on rate of recurrence, an endpoint that is not readily available in the SHR. To be able to calculate the true recurrence rate, follow-up of all patients including a physical examination (for instance 3 years after surgery) is necessary. However, in most general surgical departments it is impossible to perform this on an annual basis because of the resources required [13]. Physical follow-up examination is optional but not mandatory for participation in the SHR.

Instead of the ultimate outcome variable recurrence rate, re-operation for recurrent hernia is used as surrogate endpoint. The definition of re-operation for recurrence is listed below. Re-operation for chronic groin pain (tension-reducing procedure including mesh removal, decompression or ligation of nerves) was added in the protocol as indication for surgery in 1999, but

numbers of such procedures registered are still so low that meaningful analyses is not yet possible.

## Processing of Data

Every year (usually in May) each surgical clinic aligned to the SHR is sent a report with its results and accumulated national data for comparison. The personal identification numbers on re-operated patients are listed to facilitate retrieval of patient files (which can be used for internal quality work, such as seminars).

Data are processed at the Register Centre once a year after certain control measures have been taken (controls of personal identification number and so-called logic controls are today included in the web-based SHR protocol). Prior to analysis, data are matched with the Swedish Cause of Death Register and dates of death are incorporated into the database [11].

An index hernia repair entered into the database is followed from date of surgery until reported date of re-operation on the operated side or, if there is no re-operation, until the person's death. The cumulative incidence for re-operation at various times after an index repair is the main measure of interest and is estimated by actuarial life table analysis. Relative risk analyses are estimated with the Cox's proportional hazards model [14], first performing univariate analyses for assumed risk variables and then selecting variables with the highest or lowest univariate risks for multivariate analysis. Statistical analyses are performed using the SPSS programme.

## Definition on Re-Operation for Recurrence in SHR Protocol

“Any hernia operation in a groin previously operated upon for hernia irrespective of type of hernia at the initial and subsequent procedure”. (However, a second operation on an adult patient following a simple hernia sac extirpation in the same groin during childhood is not defined as a recurrent groin hernia repair).

## Results

### Re-Operation as Surrogate Endpoint

To evaluate recurrence rate and chronic groin pain 3 years after hernia repair and to validate a postal questionnaire with selective physical examination as

**Table 1.1.** Variables associated with increased risk of re-operation

Indications	Methods of repair
<ul style="list-style-type: none"> <li>■ Recurrent hernia</li> <li>■ Absorbable suture material (Vicryl, Dexon)</li> <li>■ Direct hernia</li> <li>■ Postoperative complication (registered by the operating unit)</li> </ul>	<ul style="list-style-type: none"> <li>■ Shouldice</li> <li>■ Other open techniques without mesh</li> <li>■ Unspecified mesh techniques, inguinal incision</li> <li>■ Preperitoneal open techniques with mesh</li> <li>■ Plug methods</li> <li>■ Laparoscopic methods</li> </ul>

a method of follow-up, a prospective cohort study[13] was done at a hospital aligned to the SHR. The study comprised 272 repairs and the follow-up rate was 96% with a median follow-up time of 36 months. We found that the re-operation rate requires to be multiplied by a factor within the range 1.7 to 2.3 (depending on method of follow-up and definition of recurrence [15,16]) to gain the true recurrence rate. A similar conclusion was reached in a previous Swedish study[17].

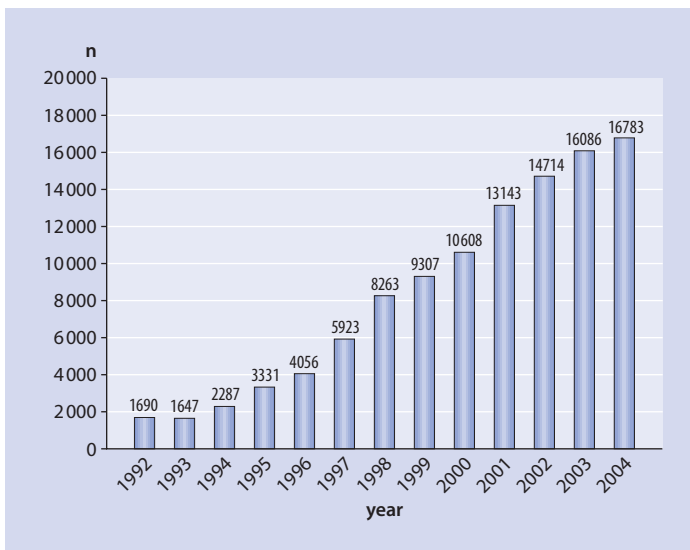
**Risk Factors for Re-Operation**

The SHR may be used to identify risk factors for re-operation for recurrent hernia [18–20]. The large numbers of operations registered make it possible to use multivariate statistics, and analyses have been done in close cooperation with a professional statistician connected to the register from the start.

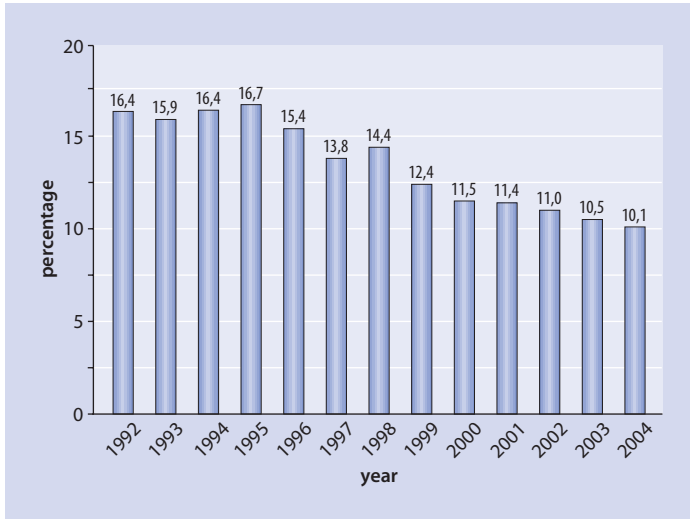
The last annual report from the SHR (available on the Internet in Swedish [21]) includes 107,838 hernia repairs done between January 1, 1992, and December 31, 2004. Variables associated with, statistically significant, increased relative risks for re-operation for recurrence can be found in Table 1.1. In two recent multivariate comparisons of anaesthetic alternatives on SHR data with local anaesthesia as reference, both general anaesthesia and regional anaesthesia were associated with decreased relative risk. Using the Lichtenstein technique as reference, all other methods of repair carried increased relative risk of re-operation.

**Operation for Recurrent Hernia**

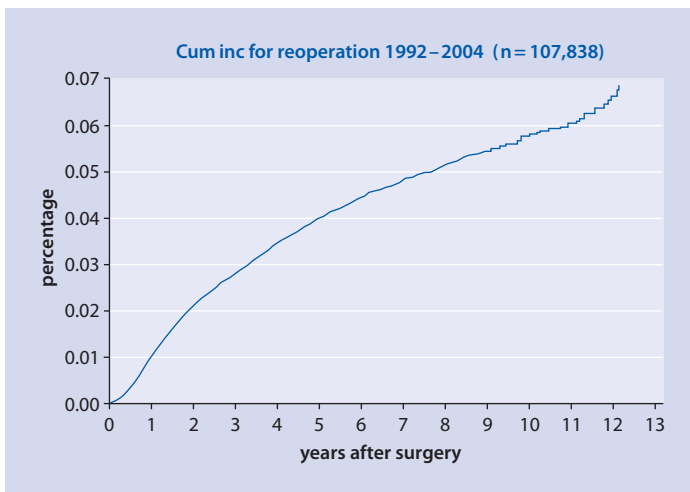
The percentage of repairs done for recurrent hernia may be used as a quality measure (but note that these figures also include surgical mistakes incurred before the start



**Fig. 1.1.** Operations per year in the SHR 1992–2004



■ Fig. 1.2. Re-operated hernias 1992 to 2004



■ Fig. 1.3. Cumulative incidence for reoperation 1992–2004 (n = 107,838)

of the SHR). ■ Figure 1.1 illustrates the growing numbers of hernia repairs included in the database; in 2004 a total of 16,090 repairs were done at the 90 units aligned. In ■ Fig. 1.2 the change in percentage of repairs done for recurrent hernia during the past 13 years is shown. As can be seen, the improvement has slowed down and has not reached statistical significance every year.

### Cumulative Incidence for Re-Operation

The cumulative incidence of re-operation for recurrent hernia is the major outcome measure. In ■ Fig. 1.3 all 107,838 hernia repairs so far regis-

tered (both primary and recurrent repairs) are included in the analysis. The cumulative incidence of re-operation 5 years after surgery was approximately 4% with no confidence intervals given in the figure.

### Discussion

Over the past 15 years great changes have taken place concerning the methods of repair used in Swedish groin hernia surgery. The Swedish Hernia Register, today comprising more than 120,000 inguinal and femoral hernia repairs, has become an important tool

in the analyses of what we have done, and where there is room for improvement in the future.

Participation in the register is voluntary for the surgical departments aligned but mandatory for individual surgeons working at those units. The register has developed to become nation wide, covering approximately 95% of Swedish groin hernia surgery. It is important to remember that repairs recorded are performed by surgeons at all levels, from specially interested consultants to trainees with various degrees of experience and supervision. The results obtained under such conditions are a measure of “effectiveness” as compared to “efficacy”, which reflects “what a method can accomplish in expert hands when correctly applied to an appropriate patient” [22]. However, there are, naturally, limitations in information reached from national epidemiological databases; register studies with multivariate analysis cannot replace randomized trials.

Results from randomized controlled studies are generally considered the highest level of evidence. In order to interpret outcomes after surgical RCTs not only the techniques tested but also inclusion/exclusion criteria, funding and surgical experience [23] have to be considered. We have to keep this in mind when we estimate the external validity of conclusions reached in RCTs. Guidelines for reporting RCTs have been published (CONSORT [24, 25]), but are not always followed. An interesting example of the importance of surgical dexterity in hernia surgery is illustrated by two RCTs published in 1998 with the Bassini repair in one arm; the recurrence rate approximately 3 years after surgery was 2% in one study [26] and 20% in the other [27]. It very clearly helps us to remember that an eponym is not an operation.

Systematic reviews and meta-analyses may increase generalizability (external validity) in findings in RCTs. Meta-analyses [28–31] in the field of hernia surgery undertaken during the past decade bring information with high scientific impact.

Data from the SHR illustrate significant improvements regarding cumulative incidence for re-operations as well as for the percentage of operations done for recurrent hernia since the start in 1992. However, recurrent hernia still constitutes a quantitative problem in our country, approximately 10% of all registered procedures being a repair for a recurrence, the speed of improvement in the last years, regarding the percentage of operations for recurrent hernia, has also decreased. Reports from the Danish Hernia Database [32] and from Germany [33] give similar (or slightly higher) figures.

In a recent Swedish randomized multicentre study by Arvidsson et al. [34] on hernia surgery there was a significant correlation between surgeon’s performance score and the recurrence rate. The importance of experienced surgeons in hernia surgery was also recently reported by Neumayer et al. [35] and by Wilkiemayer et al. [36]. Education of surgeons seems to be one important way to further improvement, and with continuing prospective registration we will follow the future outcome.

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## Discussion

**Schumpelick:** *How do you explain the high rate of recurrences in Lichtenstein repair in female compared to TEP?*

**Haapaniemi:** *You have to read our full report on that, but one important thing is that there are lots of missed female hernias. We cannot really explain why with this method. I think it was done or created for male patients from the beginning. From our material it looks as if it is not suitable for women.*

**Read:** *In regard to the excellent results of the Lichtenstein, it seems to me that the Lichtenstein operation was done more recently. In other words, it is the modern procedure. Some of your dates from the Shouldice, for instance, would be older, so it seems to me that we as surgeons probably know better than we did 10 years ago. Isn't there a little bias in your data?*

**Haapaniemi:** *It may be so. There have been great changes and perhaps it is so that it is not the same surgeons today that do the primary hernias that did the hernias 10 years ago. So it's difficult to say.*

**Read:** *It may be that you should compare some dates for the same year. In other words during the year 2003, that the Lichtenstein was this and the Shouldice was this.*

**Haapaniemi:** *We have done such an analysis but even if the figures are exactly the same, the pattern isn't the same.*

**Read:** *Oh yes, I am not denying that that is important.*

**Kehlet:** *It's an impressive amount of data and in contrast to the randomized trials. We know that the suture repairs should not be done, as you also have shown in your large epidemiological series. So my question is: why does it take so long, it's the same in Denmark, for surgeons to change their method despite the evidence? What is your experience in Sweden? Why do 25% continue to do suture repairs?*

**Haapaniemi:** *We have tried not to point out and say you have to do this, you have to do that. Our register is more*

a tool to follow what is really happening. But of course we have our annual meetings where Swedish surgeons are represented and we tell them this is the result and they can draw their own conclusions.

**Kehlet:** I can just answer that in Denmark this is public. So we have just written to the departments to say that this is on the public website. It's official that if you are doing surgery you should do it according to the evidence. But they still do it.

**Haapaniemi:** In a few weeks from now our results will also be available for every hospital on the Internet. So perhaps that will put some extra pressure on Swedish surgeons as well.

**Jeekel:** The problem is that some techniques keep on having a recurrence and some don't, as we found in our prospective randomized study of Lichtenstein versus Bassini. In our long-term follow-up we found that in the Bassini the recurrence came repeatedly for 10 years, but not with the Lichtenstein. So, what was your mean follow-up and do you have any information about the differences in recurrence rate among the techniques? Where there no recurrence rate after a suitable number of years?

**Haapaniemi:** I think with our data that these are the figures when non-specialists use these techniques. We know this from various randomized studies. You mentioned, for instance, Bassini technique. I saw randomized studies from 1998, the same technique but different studies. In one study you had Bassini with a 2% recurrence rate after 3 years and in the same year another randomised study with the Bassini arm you had 20 or 22% recurrence rate. So it's not the name of the method, it's not the eponym; it's how we do it.

**Jeekel:** But we found no recurrence at all in the course of 10 years after Lichtenstein versus the randomized other arm, where we found recurrence up to 10 years. So, do you have any information that, for example, with the Lichtenstein you don't have any recurrence rate after 1, 2, or 3 years?

**Haapaniemi:** No, I can't answer that question right now. But it seems that it's not so.

**Schumpelick:** But are there different time courses for recurrence in different methods?

**Haapaniemi:** I understand what you mean, but I cannot answer that question now. Perhaps you can come back to this later this week.

**Schumpelick:** Is there any method without recurrence?

**Haapaniemi:** No.

**Schumpelick:** O.k. I think that is the answer.

**Kurzer:** I'd like to endorse what Prof. Kehlet said. It has troubled me for a long time why certain surgeons persist with an operation that the evidence in the literature says is no good. There has been a recent paper from Poland

that, with some others, looked at factors that will make surgeons change their practice. Published evidence in the literature doesn't seem to make the ordinary general surgeon change his practice. Fitzgibbons said in his opening remarks, what do I hope to learn from this conference? My feeling is that what we should all learn that it is our duty as surgeons from individual countries to go back to our countries and think about how we are going to educate our colleagues; there is a lot of evidence now that the way we will do it is simply by showing other people, making ourselves available, having workshops. The general surgeons will change their practice if they are shown what to do, if they are shown the evidence of their mistakes. The Swedish databases have shown that when you give surgeons feedback about their mistakes and their errors and their recurrences they will change their practice. I think that this is something we should learn from this conference. It's not enough that we learn how to stop recurrence but we have to learn how to teach our colleagues and as "experts" I think it's our duty to go back to our countries because every person in this room knows that hernias recur because they are not done properly in the main and, as Haapaniemi just said, you can call an operation what you want, you can hear a surgeon say "I do an Lichtenstein" you can go and watch him but I have heard Amid say this: "I watch the people do the operation, they call it a Lichtenstein but it is simply not a Lichtenstein operation". So we have to take on a role as teachers and go back and educate our colleagues in our home countries.

**Schumpelick:** Comment on that?

**Haapaniemi:** No, I do agree. I think it's the way to go, to improve their education.

**Verhaeghe:** Another answer to your question about recurrences after TEP in the female, it is probably the same problem for TEP techniques and GRPVS. I mean that the important point is the parietalization of the cord. On women it's very difficult to perform because the teres uteri ligament is more adhesive to the peritoneum and on the male it's easy to stick, so for women often the prosthesis may not stay in place.

**Chan:** For any surgery people come over to see how we operate, and I have somebody who has been there for 1 week, for example, and I go back to see how he operates and I find he is doing very well after 1 week; he is actually doing the real Shouldice technique.

**Schumpelick:** Dr. Chang, but you are a well-equipped and well-educated Shouldice hospital. You have recurrences of operation done by yourself. Is that so?

**Chang:** Yes!

**Schumpelick:** Me too! There must be more than only technical differences.

**Chang:** Yes, we have around 1% recurrences. For primary hernias it will be a little bit lower; as you can see in my first paper in 1987. We saw the recurrence rate go up the more recurrences you do. But then we learned how to put in another mesh, which is underneath the muscle.

We go down to the level of the cooper ligament. I think we did it a little bit better now than at former times. But we are learning, too. We changed our thinking in 1987 when we started to say we can't do all primary hernia with suture.

## 1.2 Incisional Hernia

K.M.F. ITANI

### Introduction

Although the rate of ventral incisional hernia (VIH) is about 4% [1], the reported incidence varies from 0.5 to 11% [2, 3]. Recurrence of the hernia is among the more problematic adverse outcomes following incisional hernia repair [4, 5] with progressively higher rates of recurrence after repeated repairs [5, 6]. Repeat recurrence rates after initial repair has varied between 4 and 54%, regardless of the surgical technique used [7–9]. This variability in recurrence rate is due, at least in part, to methodological factors involved in the design of these studies (e.g., heterogeneous study populations and varying study design, end points, and length of follow-up), technical factors involved in the conduct of the operation (e.g., use of autogenous tissue or prosthetic grafts), and patient-related factors (e.g., characteristics of the hernia and co-existing chronic illnesses [7].

### A Population-Based Analysis of Incisional Hernia Repair

In 2003, Flum and colleagues published their findings on a total of 10,822 patients undergoing VIH repair extracted from an administrative database in the state of Washington [10]. Of patients undergoing VIH repair, 12.3% underwent at least one subsequent re-operative VIH repair within the first 5 years after initial repair (23.1% at 13 years follow-up). The 5-year re-operative rate was 23.8% after the first re-operation, 35.3% after the second and 38.7% after the third (■ Fig. 1.4). The use of synthetic mesh in incisional hernia repairs increased from 34.2% in 1987 to 65.5% in 1999. When controlling for age, sex, comorbidity index of the patient, year of the initial procedure, and hospital descriptors, the hazard for recurrence was 24.1% higher if no mesh was used compared to the hazard if mesh was used (■ Fig. 1.5). After similar adjustments, no differences were found

in the hazard of re-operation based on the era of the operative repair [10].

Several important and definitive conclusions can be drawn from this population-based study.

1. Recurrence is not limited to the first 2–5 years after VIH repair but continues over the course of follow-up.
2. Recurrence after each subsequent repair is higher.
3. The use of a mesh in VIH repair decreases recurrence.
4. The rate of recurrence has not changed in time despite newer technology and material.

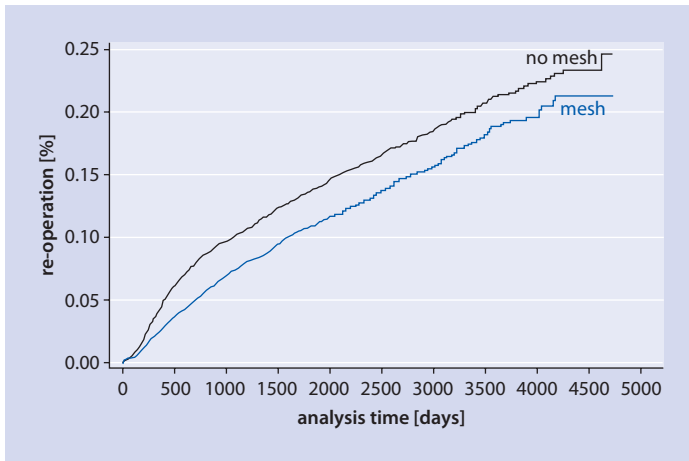
### Effect of Repair Technique on Recurrence

#### Conventional Non-Prosthetic Ventral Incisional Hernia Repair

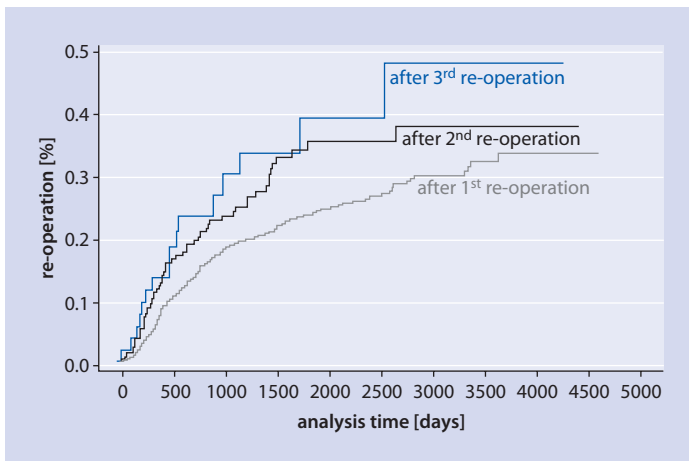
Primary repair of ventral incisional hernia without prosthesis can be divided into simple or complex repairs. Simple repairs include edge approximation, vest over pants repair, advancement procedures, a Darn repair, as well as multiple modifications of the above. Complex repair includes components separation, abdominal wall partitioning, the use of tissue expansion-assisted closure, as well as multiple modifications of the above. A summary of the largest series of primary repairs reported in the literature is presented in ■ Table 1.2. Recurrence rates have varied from a minimum of 25% to a maximum of 54% with a mean follow-up of 1.1 years to 7 years.

The components separation technique, which was first popularized by Ramirez [18], has a recurrence rate of 2–11% in series of 7–26 patients reported between 1994 and 2001. In a more recent publication by DeVries, the recurrence rate was 32% [19].





■ Fig. 1.4. Failure rates after re-operation on a cohort of 10,822 patients in the State of Washington [10]



■ Fig. 1.5. Progression to re-operative repair, by use of mesh in a cohort of 10,822 patients in the State of Washington Patients [10]

### Conventional Ventral Hernia Repair with Prosthesis

Three categories of repair have been described in the repair of VIH with prosthesis: direct fascial attachment (simple or Usher techniques), the onlay mesh (Sandwich technique, Chevrel technique), and the sublay mesh popularized by Flament, Rives, and Stoppa. Various modifications and combinations of the above techniques have been described. The recurrence rate after the onlay repair has varied from 5.5–14.8% with a mean follow-up of 1 to 6.7 years (■ Table 1.3). Various types of prosthetics and repairs are reported in these series. The recurrence rate after the sublay prosthetic technique has varied from 1 to 23% at a mean follow-up of 1.7–6.7 years (■ Table 1.4).

In a prospective randomized trial of open primary VIH repair vs. repair with sublay mesh, the recurrence rate was 43 and 24% after 3 years, respectively, [17]. The 10 year cumulative rate of recurrence rose to 63% after suture repair and 32% after mesh repair in the same patients [35].

It is clear from the presented data that, irrespective of the technique, the use of mesh to repair VIH reduces recurrence rates in all series by about half.

The sublay mesh technique as described by Flament, Rives, and Stoppa has also been associated with the lowest recurrence rate (5.93%) in the hands of its originator [36]. Although the European Society of Hernia Surgery has adopted the sublay mesh repair as the standard open repair, the complication rate as-

**Table 1.2.** Recurrence rate with simple repair of ventral incisional hernias

Author, country	Year	No. of patients	Follow-up [years]	Recurrence rate [%]
Langer, Sweden [5]	1985	72	7.0	31
George, U.K. [11]	1986	81	1.1	46
Van der Linden, Netherlands [12]	1988	47	3.3	55
Read, USA [8]	1989	169	5.0	25
Manninen, Finland [13]	1991	57	4.5	34
Hesselink, Netherlands [14]	1993	231	2.9	36
Geçim, Turkey [9]	1996	109	3.6	45
Luijendijk, Netherlands [15]	1997	68	Varying	54
Paul, Germany [16]	1997	111	5.7	53
Anthony, USA [7]	2000	48	3.8	54
Luijendijk, Netherlands [17]	2000	97	2.2	46

**Table 1.3.** Recurrence rate with onlay prosthetic repair of ventral incisional hernias

Author, country	Year	No. of patients	Prosthesis	Follow-up [years]
Chevrel, France [20]	1986	50	Mersilene/Prolene	1–20
Molloy, USA [21]	1991	50	Marlex	4
Kennedy, USA [22]	1994	40	Goretex	4
Liakakos, Greece [23]	1994	49	Marlex	8
Küng, Switzerl.[24]	1995	47	Marlex	6
Vestweber, Germany [25]	1997	36	Prolene	3
Leber, USA [26]	1998	118	Marlex	6.7

sociated with this type of repair remains high and is associated with a steep learning curve. When originally reported by Stoppa in 1985 on 247 patients, the recurrence rate was 18.5% [37] dropping to 5.93% in 1998 [36].

### Laparoscopic Ventral Incisional Hernia Repair

Laparoscopic VIH repair has revolutionized the care of patients with these problems. Laparoscopy is accepted as a more rational technique for repair of a

**Table 1.4.** Recurrence rate with sublay prosthetic repair of ventral incisional hernias

Author, country	Year	No. of patients	Prosthesis	Follow-up [years]	Recurrence [%]
Adloff, France [27]	1987	130	Mersilene	3	5
Stoppa, France [28]	1989	368	Mersilene	5	15
Amid, USA [29]	1996	75	Marlex	varying	1
Schumpelick, Germany [30]	1996	82	Marlex	5.3	7
Sugerman, USA [33]	1996	98	Marlex	1.7	4
Temudom, USA [34]	1996	50	Prolene	2	4
Leber, USA [26]	1998	82	Marlex Prolene or Mersilene	6.7	20
Feleshtinskii, Ukraine [33]	1999	57	Polyuretan or Marlex	1–5	2
Petersen, Germany [34]	2000	50	Gore-Tex or Prolene	1.5	10
Luijendijk, Netherlands [18]	2000	84	Marlex or Prolene	2.2	23

**Table 1.5.** Recurrence rate after laparoscopic repair of ventral incisional hernias

Author	Year	No. of patients	Recurrence [%]	Follow-up [months]
Toy [38]	1998	144	4.4	7
Chowbey [39]	2000	202	1.6	35
LeBlanc [40]	2001	100	9.3	23
Berger [41]	2002	150	5.4	28
Henniford [42]	2003	850	4.7	20
Carbajo [43]	2003	270	4.4	44
Rosen [44]	2003	100	17	30

VIH than for repair of an inguinal hernia, because an abdominal procedure and general anaesthesia are requirements for VIH repair whether by an open or

a laparoscopic technique, while an inguinal hernia can readily be repaired using local anaesthesia without a laparotomy. The technique of laparoscopic VIH

repair has been standardized with the use of intra-peritoneal polytetrafluoroethylene mesh. In addition, the peritoneal sublay method that is used during laparoscopic ventral herniorrhaphy is based on the Stoppa technique for open ventral herniorrhaphy. Some few controversies continue to exist regarding technique such as the extent of mesh overlap and the placement of transabdominal mesh fixation, all of which might affect recurrence. All reports since the introduction of the laparoscopic technique in 1992 consist of retrospective reviews of personal series or prospective collection of data on a cohort of patients undergoing this procedure.

Recurrence rate has varied between 1.6 and 9.3% at 0.6 to 3.6 years mean follow-up (■ Table 1.5). This will amount to a mean recurrence rate of 4.9% at a mean follow-up of 27 months. In a meta-analysis of eight studies comparing open to laparoscopic repair, no conclusion could be made regarding recurrence due to the short follow-up and lack of standardization [45]. A prospective randomized trial comparing a standard open mesh repair to a standard laparoscopic repair is currently underway in the United States [46].

### Other Technical Factors Contributing to Recurrence

Other technical factors within each category of repair have been shown to contribute to recurrence. These include the type of mesh used, type of suture (tacking alone versus tacking and transabdominal suture fixation in the laparoscopic repair), mesh overlap and details of the specific techniques as perfected by its originator and which made it a success in the hands of experts. In addition, one should not ignore the associated learning curve with any procedure; although the learning curve was best described with the laparoscopic technique, it applies as well to the various open techniques.

Each of these issues is mentioned here, but will be the subject of a complete discussion in other chapters.

### Patient Risk Factors for Recurrence

Despite the frequency with which incisional hernias complicate the postoperative course of patients undergoing laparotomy, they remain relatively poorly studied. There are only a limited number of studies assessing the impact of various patient-related factors on long-term outcome. In general, previous studies have been retrospective reviews of an institution's experi-

ence over a prolonged period of time (10–20 years). The cohort examined is often heterogeneous as patients with ventral hernias at various sites and from a myriad of prior operations are often considered together. Furthermore, the results of repeated repairs are often included with those of the initial attempt, thus confounding the accurate definition of recurrence risk. The impact of various patient-related factors such as chronic illness has received relatively little attention in these previous studies and will be addressed in a more complete discussion in subsequent chapters of this book.

### Conclusion

Several conclusions can be made from the above discussion.

1. Mesh repair of VIH is superior to suture repair and will reduce recurrence by half.
2. Repair of recurrent VIH is associated with higher recurrence rates for each subsequent repair.
3. The type of open-mesh repair seems to favour the sublay technique. Other types of repair in the hands of experts can match the sublay repair with similar recurrence rates.
4. The laparoscopic repair of VIH is gaining popularity and is currently under study in a prospective randomized trial.
5. To appropriately assess recurrence after VIH, long follow-up of at least 5 years is required.

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## Discussion

**Jeekel:** Consider the Luijendijk study that we published in the *New England Journal of medicine* 2000, after that a long-term follow-up was published in the *annals of surgery* and recently in the *annals* and then you see that the recurrence rate is much higher at 10 years follow-up. So then the mesh result had a 32% recurrence rate and in the primary closure it was 67%. It is amazing, so high. So that means that you need a long-term follow-up as you say, for a good study. So on what should we then agree? Should we say, we no longer trust on data with a follow-up of less than 4, 5 years, or do we, as you may do, extrapolate. What should we do? Another small question is that in the incidence of incisional hernia you see so many differences. I think in the literature you find between 5 and 20% incidence of incisional hernia. In Holland when we calculated a number of years ago it was 15%. Is there a difference in races, in countries, in Caucasians people versus, Chinese or what ever?

**Itani:** These are very good comments and questions. You might know when we planned the inguinal hernia trial with the NDA the budget for this study was six million dollars and for a follow-up of 2 years. So you can imagine what the budget for a study would be for a follow-up of 5 years or even 10 years. So I think it is impossible to go to 5 years without having a budget of millions of dollars. I think the way to do it is to go to population-based studies such as the Flum study in order to understand the progression of the disease. I think that we have enough evidence now to show that 75–80% of the recurrences are going to occur in the first 5 years but that you will continue having recurrences beyond that, as long as we keep that in mind. For your second question regarding races, I don't think it has been studied anywhere in the literature and nobody knows what the exact answer to that is. In any study that we perform, whenever it is a prospective randomized control studies such as the VA study, we take race into consideration but we have a higher proportion of one race over the other so that it would be inappropriate or statistically impossible to reach a good conclusion about race difference.

**Jeekel:** Doing laparoscopic surgery, just one remark: We will close our laparoscopic versus open randomized study in 2 months I think and then we shall have some answers.

**Amid:** In all the reported randomized studies the issue is open versus laparoscopic repair. But what is meant by open? There are many different types of open and there is not only one kind of laparoscopic. Do you have any idea?

**Itani:** That's another very important point, Dr. Amid, and you know those few studies that I've shown you, small studies that have looked at open versus laparoscopic. The VA trial that we've just started standardized the open repair with all details and particular attention was paid to each single issue within the repair in order to come up with an evaluated conclusion about the repair. But as you might know, even if you adopt one repair over the other, you will have proponents of that repair and you will have detractors as well that will tell you should have used a different one because it is better.

**Amid:** So the consensus of the previous meeting in Suvretta was that Rives was superior to the other types of open repair. Would it be possible to get the same consensus in this meeting, because it is very important to see which open repair we have to do?

**Schumpelick:** I think we will come to that topic again, but I would like to comment on that. We have done a prospective randomized study of eight centres in Europe, now published in the *British Journal of Surgery*, and in three centres we have no recurrence at all, in five centres a large number of recurrences; it is a question of technique. There is no question that the technique is a very important point and you can use different techniques in open approach but there will still be a biological reason we don't understand at the moment; we can talk about this in the coming days.

**Franz:** I agree with your conclusion that the majority of recurrences of primary incisional hernias are probably forming early and, as group of scientific surgeons being scared away from a long-term follow-up that may be required to get better numbers, certainly a physical exam as deterrent factor of surrogates could be used or radar imaging studies or ultrasound, for example, to detect these defects early. There are recent reports in the literature showing that a gap in the fascial closure occurring even in the first month with great accuracy will predict a downstream hernia rate. In your VA trial perhaps you consider surrogate markers for the defects such as ultrasound.

**Itani:** A very good question. If there is any question we do recommend a radiological study such as an ultrasound or CT scan to look more carefully at whether a recurrence is there. We did not adopt surrogate endpoints in our study at the VA. However, I would like to also caution you because you are introducing now a new parameter whereby if your radiologist is not properly trained to detect these small recurrences, they are going to be missed and you will have to standardize among radiologists reading these studies and maybe have one or two radiologists reading all the studies from all the centres in order to come up with a valid surrogate endpoint rather than saying that

each centre can have one radiologist reading the studies. I don't think you will have a good standardization that way.

**Franz:** *To the use of the ultrasound, we provide exactly that service at the University of Michigan and when the team is dedicated, it is amazing how accurate they can be with defining what you are going to see in the operating room, but it does require their extreme interest.*

**Miserez:** *I would like to expand to the previous speaker. We need more standardization. Conferences like this need to work on standardization and especially if you talk about recurrences with the laparoscopic technique we should not forget postoperative bulging and diastases as an important point also to register and to measure because for some this is kind of pseudorecurrence with a lot of complaints for the patients, so we should not forget this.*

**Deysine:** *I congratulate you, this is progress. There is a problem with standardization. You are talking about VA programs that train first- to fifth-year residents in surgery with different skills. So you are comparing the first year to the fifth, which is totally different. There was an article published showing an improvement from the first to the fifth year in the recurrence rate of inguinal hernias. However the attendants taking care of those residents were the same. So there is a fault in the training program*

*and in the teaching program that permits a first-year resident operating with an attendant to have a very high recurrence rate.*

**Itani:** *Very, very good point. Actually excellent point. Dr. Fitzgibbons and I were on that publication that looked at PJV level and recurrence rate and your comments are very well taken. We have adopted a much stricter approach with ventral incisional hernia because the operation itself is more complex than inguinal hernia repair and the attending physicians are very involved in that trial and making sure that they are doing the right thing.*

**Read:** *I would like to make one short comment. I think we should stop calling this operation the Rives or the Rives-Stoppa procedure. Rives did some pioneering work in this area in the early 1970s. Stoppa did further work in the next decade. But this operation is the Flament operation because he has struggled with it for the last 25 years. As Fitzgibbons says, this is the Flament operation. It is the Flament operation and he is with us today and I think he should get all the credit.*

**Flament:** *I am a very faithful man so I don't want to forget the people who were behind me. As my boss told me, when you work on a heritage, you can take the heritage for yourself but you must not forget the people who succeeded before you. It is Rives-Stoppa.*

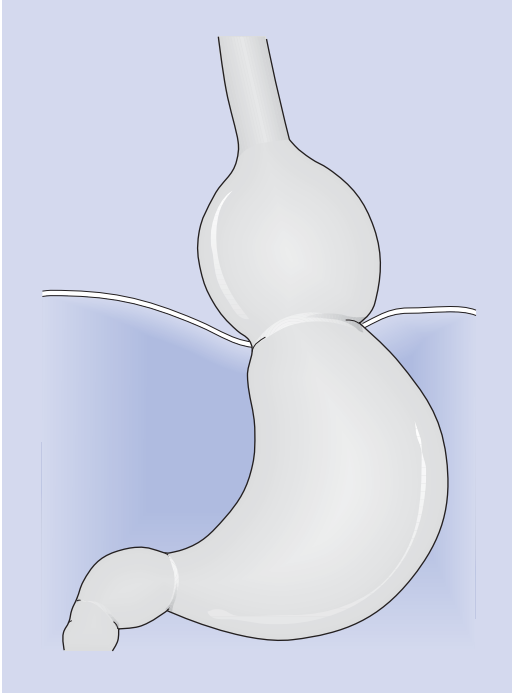
### 1.3 Hiatal Hernia

R. POINTNER, F.A. GRANDERATH

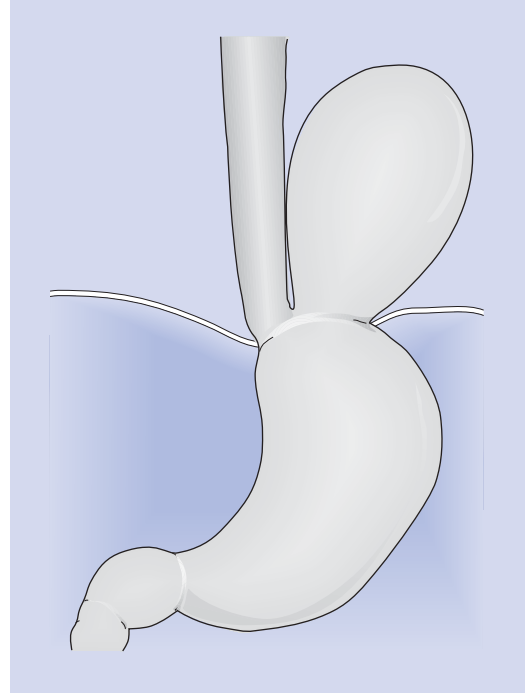
In 1951 Philip Allison [1] emphasized the association between esophagitis and hiatal hernia, and hiatal hernia became synonymous with gastro-esophageal reflux disease. Soon thereafter, attention shifted to the lower esophageal sphincter, and investigators related sphincter function to the presence of GERD. It became evident that in patients with hiatal hernia the altered geometry at the cardia could potentially affect lower esophageal sphincter function. Recently, much work has been done to elucidate the effect of the hiatus hernia in the pathophysiology of reflux disease and we are now beginning to understand this complex relationship. A hiatus hernia disrupts the anatomy and physiology of the normal antireflux mechanism. It reduces lower esophageal sphincter length and pressure and impairs the augmenting effects of the diaphragmatic crura. The presence of a hiatus hernia is supposed to be associated with symptoms of gastro-esophageal reflux and

increased prevalence and severity of reflux esophagitis, although there are no data available regarding whether patients are more impaired by symptoms corresponding to the insufficiency of lower esophageal-sphincter pressure or hiatal hernia. The fact that esophagitis and reflux were deemed a predictable consequence of hiatus hernia became untenable with the observations that not all patients with hiatus hernias had reflux disease and that not all patients with esophagitis had concomitant hernias and that simple repair of a hiatus hernia did not resolve GERD. Although this fact is well known in only a few papers dealing with recurrences of large hiatal hernias, a differentiation between radiological recurrences and symptom recurrence due to postsurgical anatomical changes or GERD-related problems is worked out.

There is no exact definition of a hiatus hernia, as the "normal" hiatus is well described in regard to its



■ Fig. 1.6. Type-I hiatal hernia



■ Fig. 1.7. Typ-II hiatal hernia

function but not to its size regarding the anatomy. A hiatus hernia is defined as a proximal displacement of the proximal part of the stomach through the diaphragmatic hernia. There are two different ways to describe a hiatal hernia, the endoscopic and radiological:

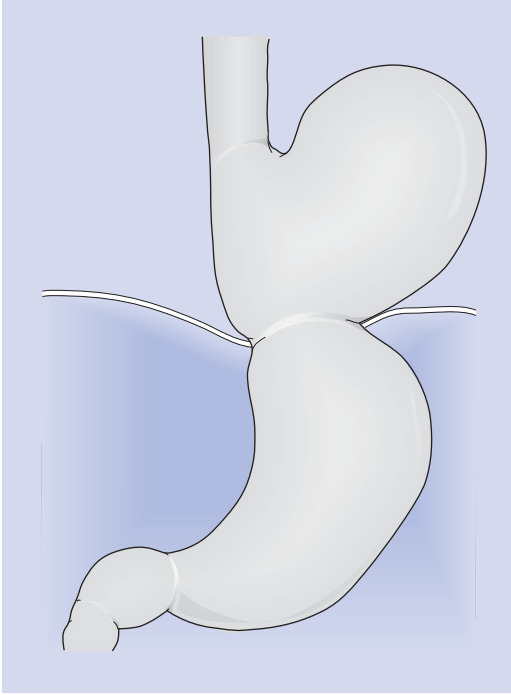
- Endoscopically, a hiatal hernia is present when the Z-line can be identified above the crural ring with the folds of gastric mucosa between the crura and the Z-line. The distance between the Z-line and the crura indicates the size of the hiatal hernia. The current practice of diagnosing a hiatus hernia and measuring its size using the centimetre markings on the endoscope is inaccurate. There is no standardization regarding the degree of air insufflation or at which phase of respiration the measurement is made.
- Radiologically the hiatal hernia is specified in three major types:
  - Type I: The sliding hiatus hernia: the gastro-esophageal junction migrates through the hiatus (■ Fig. 1.6).
  - Type II: The para-esophageal hiatus hernia (PEH): the gastric fundus herniates through the hiatus with the gastro-esophageal junction maintaining its normal intra-abdominal position (■ Fig. 1.7).

- Type III: represents a combination of type I and type II: the gastric fundus and gastro-esophageal junction herniate through the hiatus into the thorax (■ Fig. 1.8).
- Type IV: this is a type-III hernia with the addition of other organs herniating through the hiatus into the thorax.

The examination technique for diagnosis of hiatal hernias is standardized for neither the endoscopic nor the radiological approach, therefore the size of hiatal hernias depends on different and not standardized examination techniques. There are few published data on the correlation between upper endoscopy and barium studies in the diagnosis of hiatus hernia [2, 3]. Upper GI endoscopy significantly underestimates the size of hiatus hernias compared with barium studies. At present, neither radiology nor endoscopy is an accurate method of measuring hiatus hernia size.

For restoration of normal hiatal anatomy, the knowledge of contents of the hernial sac as well as the distance between Z-line and the diaphragmatic crura is necessary. The most important fact for restoration is the knowledge of the length of the pillars and the width of the maximum distance between the pillars. Measur-





■ Fig. 1.8. Type-III hiatal hernia

ing these distances, the size of the hiatal surface area (HSA) can be calculated as the only exact parameter for dividing individuals into patients with normal, small and large hiatal hernias [4].

The precise etiology of large or para-esophageal hernias (PEH) is unknown. The current theory is that large and para-esophageal hernias result from progression of sliding hiatal hernias. Sliding hernias are more common in younger patients and more common than para-esophageal hernias. Increased intra-abdominal pressure, enlarging of the diaphragmatic hiatus and stretching of the phreno-esophageal membrane are key factors in large hiatal hernia formation.

Complications of gastric incarceration or volvulus have been described by Skinner and Belsey [5] with a grade of severe complications in 30% of asymptomatic patients treated conservatively for para-esophageal hernia. Recently, Allen [6], who followed 23 PEH-patients for a medium of 78 months documented a very low incidence, and Stylopoulos [7] created a decision analytical model to determine if asymptomatic patients with large hiatal hernias benefit from elective hiatal repair. For asymptomatic patients, a higher risk for surgery is calculated in the paper of Stylopoulos, and this study

adds support to the conservative treatment approach towards asymptomatic PEH.

In 1951 Philip Allison [1] reported very enthusiastically on 33 patients operated over a 5 year period with 30 of them having excellent short-term results. Twenty-two years later, he was courageous enough to report his long-term results and recurrence rates of almost 50% to the American Surgical Association meeting in 1973 [8]. Supported by a grant from the American Surgical Association, he reviewed 421 of his 553 surgically treated patients, of whom 118 were dead and the condition of 14 was unknown. This study of Philip Allison, one of the pioneers of hiatal hernia surgery, is the only one with a nearly complete follow-up of patients in the long-term run for open hiatal surgery. After radiological re-examination of these 421 patients, in cases with presence of a supradiaphragmatic gastric pouch, irrespective of the pouch size, a surgical intervention was indicated for determination of recurrence.

By these rigid standards, radiological recurrence was found in 33% of former para-esophageal hernias and in 49% of former sliding hernias. An important aspect is that recurrences increased steadily with the years after operation.

In the group of patients operated by Allison, there were 27 recurrences in the first year, 28 between 1 and 5 years, 15 between 5 and 10 years and 11 after 10 years. Similar results were found in the group of the other surgeons in this trial. Beneath this high recurrence rate, Philip Allison made clear that a lot of patients were completely free of symptoms but were found to have radiological recurrence, pointing out that there is no correlation between radiological recurrence and symptom recurrence. Over the next decades, no radiologically controlled mid-term or long-term results of hiatal hernia surgery were published, until Hashemi [9] followed 54 patients with type-III hiatal hernias for a medium of 27 months, 27 of them having undergone laparoscopic hiatal hernia repair and 27 open hiatal hernia repair.

The symptomatic outcomes were similar in both groups, with excellent or good outcomes in 76% of the patients of the laparoscopic repair and in 88% after an open repair. A recurrent hernia was present in 12 of the 41 patients (29%) who returned for a follow-up video esophagogram; 42% (9 of 21) of the laparoscopic group had a recurrent hernia compared with 15% (3 of 20) of the open group. Five years later, a similar study was published by Ferri [10], comparing 25 patients with para-esophageal hernia after an open approach with 35 patients after a laparoscopic

hernia repair. No significant difference in general or disease-specific quality of life was documented. Radiographical follow-up was available for 78% open and 91% laparoscopic repairs, showing anatomical recurrence rates of 44% and 23%, respectively. These data are exactly contrary to those published by Hashemi [9] 5 years before. Although the data for the open transabdominally and laparoscopic approaches are contradictory in both papers, the overall recurrence rate in the two studies is exactly the same, 30%! These 30% recurrences were detected also by Jobe [11]. He evaluated the long-term effectiveness of the laparoscopic management of giant type-III hiatal hernia in 52 patients at a mean of more than 3 years. Esophagograms revealed a recurrent hernia in 32% (11 of 34) of patients of whom 36% (4 of 11) were asymptomatic. Of these 11 recurrences, 4 occurred within the first 2 years, 3 between the second and fourth year and 4 between years 4 and 7. According to the increasing rate of recurrences, the rate of patients presenting no adverse symptoms dropped from 91% 3 months postoperatively to 81% 3 years postoperatively. These results were confirmed by Targarona [12] in 2004 in a study of mid-term analysis of safety and quality of life after the laparoscopic repair of para-esophageal hiatal hernia in 46 patients he had operated on. Eight patients (21%) had postoperative gastro-intestinal symptoms in a follow-up of more than 6 months. Barium swallow was performed in 30 patients (81%) and showed a recurrence in 6 of them (20%). However, follow-up of the patients with recurrent hernia was significantly longer than that of the patients without recurrence, suggesting that the risk of recurrence is highly correlated with time. In his study, Targarona pointed out that the quality of life of patients postoperatively reached normal values and did not differ significantly from the standard values for the Spanish population of similar age and with similar comorbidities. Successfully operated patients reached a gastro-intestinal quality-of-life index value comparable to standard population; however, symptomatic patients had significantly lower gastro-intestinal quality-of-life index scores than the asymptomatic or the X-ray-recurrent group.

The main object of Targarona's study was to assess the incidence of recurrences of hiatal hernia repair and to investigate its correlation with the patients' postoperative quality of life. One interesting finding was that a number of patients with recurrent radiological hernia remained asymptomatic, whereas, as shown also by Jobe [11], increase of adverse symptoms or low quality of life index is not obviously correlated with anatomical recurrence.

Going through the literature of laparoscopically performed hiatal hernia repairs (■ Table 1.6), there is general agreement that a wrap has to be constructed and should hold the stomach intra-abdominally. Whereas the majority of authors prefer a Nissen fundoplication, about 50% of them anchor the stomach intra-abdominally in addition to the wrap by performing a gastropexy. The incorporation of a fundoplication has gained popularity, since it became evident that most of patients with giant hernias report symptomatic reflux pre-operatively. If, and this should be oblique, 24-h pH monitoring and esophageal manometry is performed on these patients, abnormal reflux and incompetence of the lower esophageal sphincter pressure can be demonstrated in almost all of these patients.

Only regarding the utility of performing a gastropexy is controversy likely to remain. Up to now, there are no randomized trials validating the use of a gastropexy in preventing hiatal hernia recurrences. All published studies (see ■ Table 1.6) have demonstrated that complete sac excision and the reduction of viscera into the abdomen is unalterable, as shown by Edye [19]. In his study patients treated without sac-excision experienced a recurrence rate of 20% versus no recurrence in the sac-resection group. The closure of the hiatus is the most essential step in hernia repair. Assessing the failures and problems of antireflux surgery, it is well known that the majority of complications and failures leading to redo surgery in 80% are related to problems of the hiatal closure [20].

Most authors prefer crural closure with simple non-absorbable sutures posteriorly to the esophagus. Buttressing the hiatal closure, typically with a mesh onlay, is advocated if the crura are not of sufficient girth and adequate suture purchase is not possible. Tension-free hiatal closure using prosthetic material seems superior to simple closure, if the gap between crura is excessive and undue tension is placed on the sutures [21].

By now, it is impossible to compare open and laparoscopic results. For both procedures only a few studies are available which routinely include esophagograms to identify asymptomatic recurrences. Based on the only available long-term investigation with a nearly complete follow-up in X-ray documentation, one must conclude that for the open approach recurrence-rates have been increasingly high [8]. For the laparoscopic approach the follow-up time is too short to compare these studies with the long-term study of Philip Allison. Nevertheless, anatomical recurrence rates vary between 15 and 43% (■ Table 1.7) with a clear

Table 1.6. Laparoscopic hiatal hernia repair

Author	No. (con-version)	WRAP			Gastro-pexie	Collis	Sac excision	Crural closure		
		Nissen	Toupet	Hill				Sutures	Pledgets	Mesh
Perkidis [13]	53 (2)	52	1	–	24/53 (45%)	–	Yes	Post.	–	–
Mattar [14]	136 (3)	136	–	–	–	6 (5%)	Yes	Post.	136	–
Jobe [11]	52 (0)	–	–	52	–	–	Yes	Post.	>4 cm	–
Khaitan [15]	31 (6)	19	6	–	13/25 (52%)	–	Yes	Post.	15	–
Diaz [16]	119 (3)	108	6	–	48/116 (41%)	6 (5%)	Yes	Post.	116	6 (5%)
Andujar [17]	166 (2)	127	23	–	14/166 (8%)	1	Yes	Post.	–	–
Smith [18]	94 (8)	92	–	–	92/94 (98%)	6 (6%)	Yes	Post. Prae.	–	–

Table 1.7. Recurrence rates after laparoscopic hiatal hernia repair

Author	No.	Follow-up [months]	X-ray (% of N)	Recurrences	Redo	Satisfaction (exc./good)
Perkidis [13]	53	18 (2–54)	46/53 (87%)	7/46 (15%)	0	49/53 (92%)
Mattar [14]	136	40 (12–82)	32/125 (25%)	14/32 (43%)	1	25/28 (90%)
Jobe [11]	52	37 (2–84)	34/52 (65%)	11/34 (32%)	2 (+4)	32/37 (86%)
Khaitan [15]	25	25	15/25 (60%)	6/15 (40%)	0	Not done
Diaz [16]	116	8 (6–12)	66/96 (69%)	21/66 (32%)	3 (2,6%)	Not done
Andujar [17]	166	15	120/166 (72%)	34/120 (28%)	10 (8,3%)	Not done
Smith [18]	94	27 (3–93)	47/94 (50%)	11/47* (23%) 10/86 (12%)	10 (12%)	*= asympt. *=sympt. (before X-ray)

sign that recurrence rates increase with time. These high recurrence rates for the open as well as for the laparoscopic approach necessitate further consideration

to ameliorate the results of hiatal hernia repair. One of these new concepts could be the application of meshes at the hiatus [21].

Although the recurrence rate of hiatal hernia repair is extremely high, we know little about the effect of diaphragmatic stressors on recurrent hiatal hernia. Kakarlapudi and Filipi [22] investigated the correlation between the various diaphragmatic stressors and anatomical disruption of the diaphragmatic closure. They conducted a retrospective analysis utilizing a standardized diaphragm stressor questionnaire for the study group and a control group of 50 patients without hiatal hernia recurrence. Only vomiting and weight lifting were significant, using a logistic regression to determine the significant predictors of hiatal hernia recurrence.

Beside these stressors there is discussion about the existence of a so-called short esophagus and whether this entity might influence recurrence rates. There is also discussion, whether decreased adhesion formation due to a wide use of ultrasonic devices can increase the recurrence rates.

Looking at the radiographical features of recurrences, exact descriptions of the new and recurrent pictures are required. Terms like “sliding” hernia or “para-esophageal” hernia in patients with recurrences are incorrect, leading to misinterpretations, and can by no means have influence on the indication for surgery. For recurrences, we need other characteristics, since a patient with a wrap around the distal esophagus can experience neither a „sliding,“ nor a “para-esophageal” hernia.

Recapitulating, a high incidence of 30–50% of anatomical recurrences has been demonstrated with routine postoperative radiological studies for both the open and laparoscopic approach. Half of these patients remain asymptomatic, whereas a group of patients of unknown incidence is symptomatic without showing anatomical recurrence.

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## Discussion

**Frantzides:** *What you point out is exactly what we see in the literature. We saw the high recurrence rates of hiatal hernia repairs. A colleague here said: „What is it, that we have to change with our technique? “ You pointed, that there is up to 40% recurrence rate and we are still wondering why but we are doing the same thing: Placing a few stitches on the crura, expecting that this would be the best treatment. Of course this topic is near to my heart. I’ve been working on this for 20 years and I was very disappointed when I saw that you didn’t mention our work, that is the only prospective, randomised study up to now. I’ve shown that if you use mesh the recurrence rate should be much less. Actually our study, was a 9-years study published in *The Annals of Surgery* 2000 with a medium follow-up of 3.5 years. We’ve shown that the use of mesh should result in 0 recurrence of hiatal hernia. I recognize that mesh is something we are very leery to use around the hiatus. There are reports of erosions especially with prolene mesh. With PTFE we haven’t seen that. So I would like to hear your comments. In this forum it is evident that we need to change a lot of things. As said by others before we have to send a message out about when you operate: If there are symptoms, if it is para-esophageal or sliding? When is it time to make decision? The placement of the mesh will be discussed in another forum.*

**Pointner:** *Thank you Dr. Frantzides. I know your work and I’ll mention your work in the afternoon. You*

*know we use meshes as you do and I think that meshes should be used in the correction of this region and they are very important but that’s the topic for this afternoon.*

**Fitzgibbons:** *I can ensure you that we see a lot of redoes and we see plenty of erosions of PTFE into the oesophagus after the hiatus was repaired with Gore-Tex. And we think that material in this area is nonsense because we have seen many of them.*

**LeBlanc:** *I think this is a problem that we see in all the other hernia repairs. There is no standardized technique: Where do we have to place the sutures, what type of knots and which instruments should be used and even which meshes should be used and where should they be placed? So there is no standardization of any of that. We haven’t seen any erosion but we certainly have seen a lot of redoes without the use of mesh. So I’m proposing to use the mesh, particularly for the redo, but I think we need to standardize the operation just like all the others. But I guess we will never eliminate recurrences.*

**Pointner:** *You are right, there is no standardization of the operation and we don’t know which technique – but one thing is clear to me: we have a recurrence rate of about 30% for open and laparoscopic procedures and the recurrence rate for patients with meshes is very, very low. We have to talk about which mesh, which shape of mesh, but we see that we have a lower recurrence rate but that’s the topic for this afternoon.*

## 1.4 Results of Unpublished Studies

M.G. SARR

### Introduction

When asked to write this chapter on Results of Unpublished Studies, I thought my task to be very easy and very short (indeed, very, very short!): unpublished studies are unsubstantiated and therefore not peer-reviewed; thus, these “studies” are neither substantiated nor reliable, and thus my report is over! However, many physicians, both the serious and the pedantic, talk of results (often their own) of unpublished trials, so several questions arise. Who does this? What are these studies? Why do these “studies” get discussed? And finally, what are the perils of this non-science? The following discussion represents my thoughts

on this topic as it deals with the subject of the management of hernia disease.

### Who Does This?

Who would refer to unpublished studies as dictum or truth? Well, we all do, or at least most of us do. We talk of our own experience (usually a flawed surrogate of a “study”), not disingenuously, but rather based on our believed memory, i.e. our experience. Yet how often our memory fails us – we forget much morbidity and even mortality, though we may have suffered

equally with the patient and their family. Indeed, some memories of complications are just too painful – after all, we often remember the good and protect ourselves psychologically from remembering the bad. I tend to believe that many of us practice this invisible and unknowing selective memory, not out of malice or disinformation, but rather because we may believe strongly and honestly in what we do and how we do it; the important lesson is that we acknowledge this potential fallacy and recognize it for what it is, and keep an open mind such that we try to either prove our “experience” to be correct or, equally important, prove it to be wrong, and then change our practice according to evidence-based studies.

Other possibilities, however, also occur. Ego is often blind. “I’ve done about 300 of these operations.” When I hear this type of a boast, I usually divide the number immediately by a factor of two (or greater depending on the presumed “head size” of the boaster, i.e. here the “presumer” is the boaster himself/herself!). This calculation seems especially pertinent when the boaster is discussing (long-term) morbidity and mortality! I have no scientific data to support my impressions and thus I also write without data, but I always question any non-published, self-aggrandizing “personal experience” when delivered with undeserved authority.

Still another possibility is ignorance. “I’ve never had a recurrent hernia.” Well, it might be true that Surgeon A has never had to repair a recurrent hernia, but that does not mean, necessarily, that none of his (the term “his” from now on will be gender-neutral!) herniorrhaphies have recurred. You don’t see what you don’t look for! Maybe his patients with a recurrence are asymptomatic, maybe they don’t want to tell him because of their respect for him or they believe he will be embarrassed, or more likely, they have gone to another surgeon for repair because Surgeon A failed the first time to fix it. Again: “You don’t see what you don’t look for.” Therefore, Surgeon A may be well-meaning and not untruthful, but just ignorant of his results.

### What Are These Unpublished Series?

We have all heard about these series: “I’ve done 300 of these complicated, huge, multiply recurrent hernias.” Remember the divide by 2 (or greater) rule! “My infection rate (or recurrence rate) is zero,” or “I’ve never had a wound infection (or a recurrence).” Right! We have all hopefully learned the lesson of recurrent incisional hernia by the long-term studies from The Netherlands and the Washington State Medical database showing

not only an (unbelievably but documented!) high recurrence rate but also the relentless, steady increase year-by-year, not just in the first year or two [1–3]. One can argue about personal experience, but an evidence-based approach is dissociated from emotion, no matter how fervent one might be about his “beliefs” – they remain “beliefs” until proven to be facts. While surgeon A is hopefully in the minority of the rest of us evidence-based surgical scientists, nevertheless surgeon A, especially if a well-renowned leader in his university hospital or community, can promulgate quite a bit of disinformation – “tissue repairs of inguinal hernias have low recurrence rates” – try and argue this point with an enlightened, evidence-based surgeon in Denmark [4]!

### Why Do These Unpublished Studies Get Discussed?

There are a multitude of reasons that emanate from many of the points raised above. “My repairs are better,” or “It can’t happen to me.” Divine ignorance. Or in the well-meaning but ignorant surgeon – we never looked, or the follow-up is too short, or the patients seek out another surgeon. Remember, hernias don’t recur in the operating room (!) and, admittedly, the infection rate of a herniorrhaphy wound is zero as the patient leaves the operating room and will remain so (in the surgeon’s mind) until he looks objectively for a wound infection or a recurrence. Finally, while ideally all operative procedures (in our case herniorrhaphy procedures) should be studied in an evidence-based manner, i.e. well-designed class-I data with long-term follow-up preferably by a double-blind, randomized controlled study, such studies are expensive, difficult to design, impossible to have accepted by the local or national community of all potential participating surgeons, and take a lot of time. Because all of our procedures/approaches cannot fully be confirmed by such studies, we need to continue to question our practices continually and not rely on these unpublished studies.

### What Are the Perils of Unpublished Studies?

Beware of the phrase, “in my experience!” Remember the problems with anecdotal “experience”, e.g. the scare of port-site recurrence (of colon cancer) after laparoscopic colectomy. Similarly, the implications of validating an operation based on too short a follow-up rings so true when one attempts or continues to justify the practice of repairing incisional hernias with

autogenous suture repairs [1, 2]. Another trap we as surgeons also fall into is the belief in “expert testimony”, often the expert is our mentor, whom so many of us “worship.” Similarly, our often unwavering support and loyalty toward institutional tradition has also too often clouded our judgment; for instance, at my institution, talk of the Mayo repair of umbilical hernias still lingers in some hallways! Progress continues; new operations are designed; techniques change; we need to maintain an open mind (albeit a critical open mind) – witness the fate of our ancestors who said that laparoscopic gall-bladder removal will never catch on. Along these lines, however, we also need to remain cognizant of what we don’t know, e.g. duodenal ulcer disease and *Helicobacter pylori*; or pre-1990 the lack of a prosthetic material for repair of direct inguinal hernias, or maybe even the avoidance of prosthetic-based repair for any incisional abdominal wall hernia! We need to learn more about the biology of hernia development and repair, thus, the Suvretta Symposium!

How, then, do we approach the future in the field of herniology when class-I evidence is absent? We will be approached (undoubtedly and hopefully) by industry with new devices, new products, new techniques etc! This is good, this is opportunity, and we need to embrace such a partnership! But we need to question animal models, avoid relying on sensationalism or expert testimony and accept case reports and anecdotal “experience” for what they are, i.e. preliminary observations. Moreover, we need to support study of these advances and to compare them to our (documented) gold standards. Change is (often) good, change is (often) an opportunity, but change must be justified or at the very least accepted with a critical eye and with “The Data!”

## The Future

While no one can predict the future, many new programs in the healthcare field are reassuring and offer potential optimism. The proliferation of quality-control initiatives, both at the local (hospital-based) and national level, such as proliferation of participation in National Study of Quality Improvement (NSQIP), the voluntary participation in the Danish herniorrhaphy database, the multi-centre trials in Germany, France, the Netherlands, Sweden and finally in the United States through the Veterans Administration (VA) hernia trials – here is the future of an evidence-based practice. We need to partner with industry, foundations, insurance providers, universities, and the government to evaluate

best practice in herniorrhaphy; indeed, this may even be the lack of the need for herniorrhaphy, i.e. watchful waiting [5]! And hopefully through meetings like this Suvretta conference, we will be able to educate our peers in the biology of hernias.

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## Discussion

**Bendavid:** *I really enjoyed your paper and it is true that you have touched on a point that we all have experienced – the fact that every organization actually needs a maverick, and unfortunately this can be very difficult. A good story that I have heard also is: Mark Ravitch was being interviewed once and the topic was division of nerves and, as you certainly know, Dr. Amid does triple neurectomies and a lot of us have done neurectomies for the past 20 years, all of them as routine operations. And the answer of Mark Ravitch to the question “What would happen if your resident cut the nerve?” was “You mean my former resident!” Thanks for the good talk.*

**Sarr:** *Just the topic of vagotomy. “Should we ever do a vagotomy now?” that’s hearsay from 20 years ago.*

**Schumpelick:** *Dr. Sarr, say something about your unpublished opinion: can we always treat a hernia successfully?*

**Sarr:** *Can we always treat a hernia successfully? I think no. I think some of them are too big. We can operate on them – but do we really help them? The small ones we should be able to fix as long as we are not ignorant in our knowledge (i.e. primary suture repairs); but as we work with a lot of ignorant surgeons, and many of us are ignorant, it is basic practice that we really have to do just that. But I think there are some hernias we can’t fix and some we shouldn’t fix. Based on no data!*