

Abdominal Wall Hernia

new perspectives for clinical research

Hasan H. Eker

COLOFON

The studies described in this thesis were performed at the department of Surgery, Erasmus Medical Center, Rotterdam, the Netherlands.

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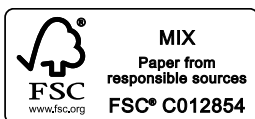
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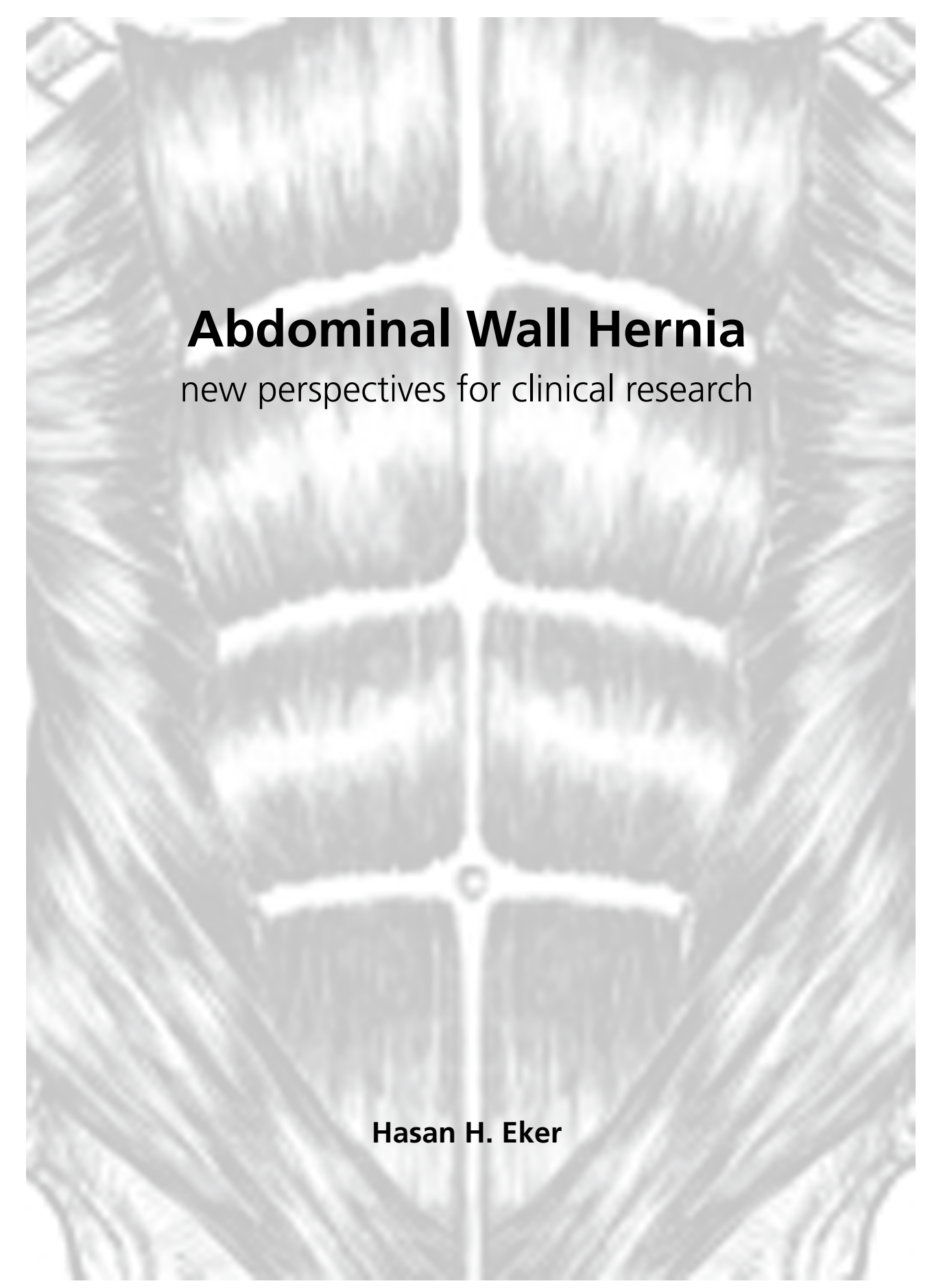
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Buikwand hernia
Nieuwe perspectieven op klinisch onderzoek

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
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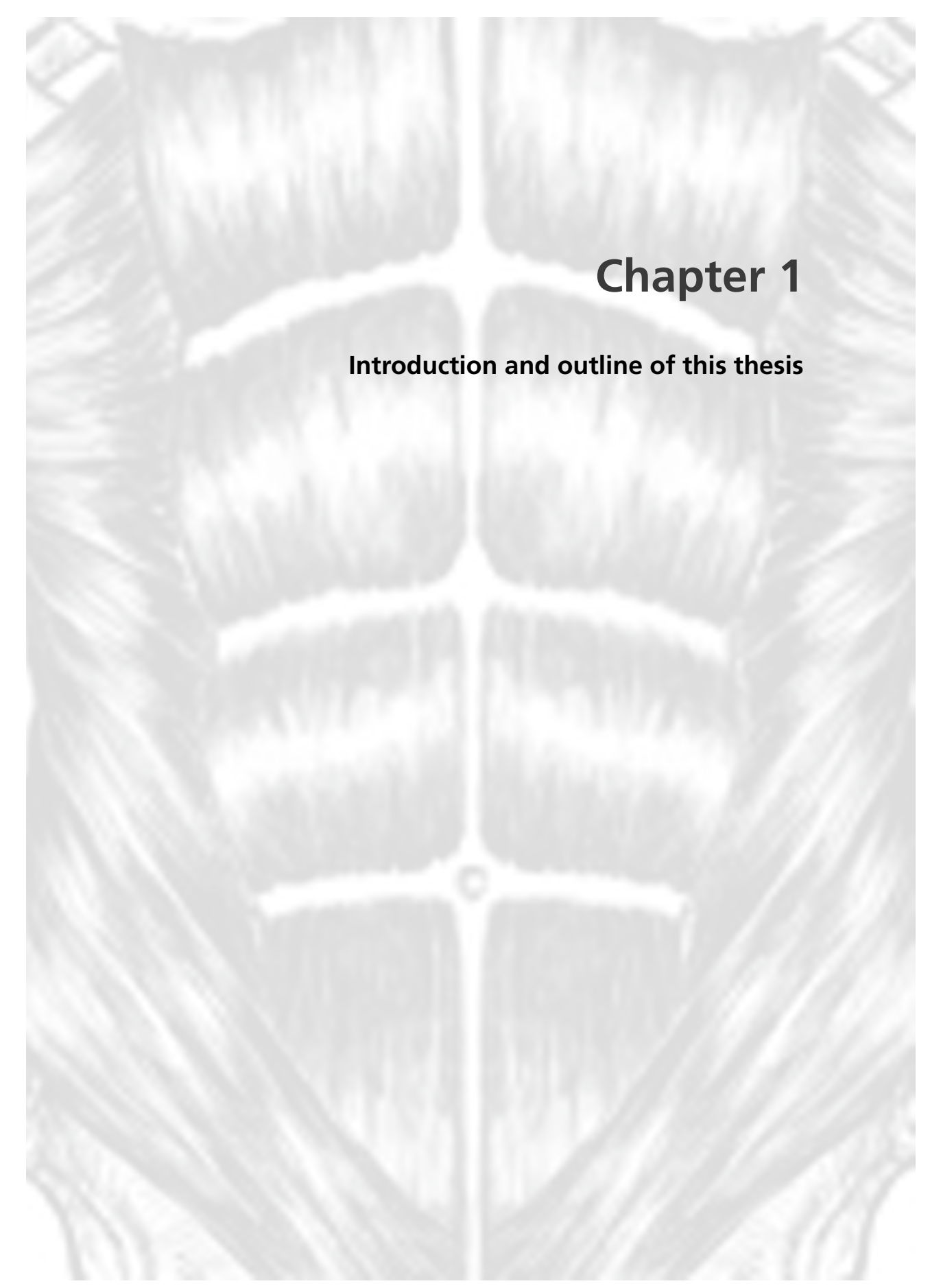
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Chapter 1

Introduction and outline of this thesis

GENERAL INTRODUCTION

Abdominal wall surgery is a broad term, covering different treatment strategies for all different types of abdominal wall hernias. For example, an inguinal hernia is a totally different entity than an incisional hernia and requires a different treatment strategy. Nevertheless, some issues and solutions are common and do apply for all types of abdominal wall hernia.

Abdominal wall surgery has undergone great evolution and transformation in the last century. Several important milestones were reached in the past few decades. The incidence of hernia recurrence was up to 60% in the long term before routine use of mesh prostheses.¹ The introduction of prosthetic mesh for reinforcement of surgical repair proved one of the true milestones with regard to the reduction of recurrences.² Meshes are not only suitable for hernia repair, but can also be used for hernia prevention in selected patient groups.³⁻⁷ However, disadvantages of prosthetic material, such as infection, adhesions, erosion, shrinkage or even meshoma also occupy surgeons' minds. Although modern mesh prostheses have been modified to include anti-adhesive layers, and consist of materials that are less prone to infection, mesh-related problems have continued to complicate hernia surgery.⁸⁻¹¹ Another milestone in the era of abdominal wall surgery was the concept of tension-free repair. The concept of tension free repair has been associated with less postoperative pain and faster recovery, especially after inguinal hernia surgery.¹² Also, tension free repair has been associated with a reduction of recurrence rates.¹³

The introduction of laparoscopic surgery in the late 20th century was a real innovation in abdominal wall surgery, since the operative possibilities increased.¹⁴ Overcoming the learning curve was an issue in the beginning stage of laparoscopy, but this new modality has created a new age in hernia surgery. Nowadays, laparoscopic preperitoneal and transabdominal procedures are performed at least as frequently as open procedures for incisional and inguinal hernia. More recent studies have shown that laparoscopic hernia repair has comparable or even superior results compared to open surgery.¹⁵⁻¹⁷ In this thesis, it has been attempted to investigate which surgical procedures should be preferred for different types of hernia, and by which factors the choice for a specific procedure is influenced.

Optimization of surgical techniques for repair of abdominal wall defects has led to a shift of focus from operative morbidity and recurrences to pain, quality of life, and even cosmesis. The endpoints of the majority of studies published in the past were classical endpoints such

as morbidity, operation time, length of hospital stay and recurrence.¹⁵⁻¹⁷ In recent years, more prospective studies with endpoints from patients' point of view as quality of life and pain have been published.¹⁸⁻²⁰ Recovery of daily activities and readmission to work were investigated after different types of hernial repair. The primary indication for repair of hernia sometimes is represented by compromised abdominal wall functioning. Recovery of abdominal wall function after abdominal wall repair, however, was not yet investigated. Another underexposed issue is body image and cosmesis before and after incisional hernia repair. Specialized questionnaires have been developed to quantify these "soft endpoints".²¹⁻²³ In this thesis, body image, cosmesis and abdominal wall function have been assessed after different types of incisional hernia repair.

OUTLINE OF THESIS

Part 1

Abdominal wall surgery continues to represent the most frequently performed type of operation in general surgery. The majority of these abdominal wall defects, being inguinal, femoral and umbilical hernias, have been associated with congenital predisposition or in more rare cases are acquired during life, as a result of life style. Incisional hernias, meanwhile, are primarily caused by surgery. Again, patient factors are of high importance with regard to the occurrence and evolution of incisional hernia. Literature, however, supports surgical closure technique of the laparotomy or lumbotomy as an independent risk factor for incisional hernia occurrence. In **Chapter 2** the incidence rates and risk factors for incisional hernia are reported in a large prospective cohort study.

The shape and position of the incision that is made for laparotomy seems to be as important as the closure technique. Many meta-analyses and systematic reviews have been written on this topic, providing a stepwise handguide for surgeons for optimal closure of the abdominal wall. Nevertheless, some patients are more prone for developing incisional hernias, like obese patients and patients with an abdominal aneurysm. These patients, therefore, require additional mesh reinforced closure. Awareness on the extraordinary high incidence of incisional hernias in patients operated for liver transplantation is much more limited. **Chapter 3 and 4** describe the incidence of incisional hernia after liver transplantation and the attempt to reduce the incidence by using different types of incisions.

Part 2

The indications and preferred technique for treatment of ventral abdominal wall hernias are multifactorial. Most of available literature on incisional hernia repair, unfortunately, does not distinguish between different types as well as location of incisional hernia. The only objective parameter published in literature is hernia defect size. Several hernia classification models have been published before, none of which have been implemented on a large scale due to the incomplete information which they provided. Under the flag of the European Hernia Society (EHS) a complete hernia classification model was developed. This is presented in **Chapter 5**.

In spite of the use of prosthetic materials and improved surgical techniques, recurrence rates after incisional hernia repair have remained unacceptably high. This is a result of the fact that main risk factors for incisional hernia occurrence, such as hernia defect size, body mass index (BMI) and collagen (e.g. aneurysm disease) cannot be influenced directly. The introduction of minimally invasive surgery at the end of the 20th century enabled surgeons with the possibility of laparoscopic incisional hernia repair. Laparoscopic incisional hernia repair provides the possibility to gain more mesh overlap, as well as full overview of the abdominal wall for possible accessory defects and reduction of incision length with less wound and mesh infection and recurrence potentially. Nowadays, minimally invasive incisional hernia repair is widely used and accepted. Literature had shown that in the short term, laparoscopic repair is superior to open repair in terms of less blood loss, fewer perioperative complications and shorter hospital stay. Long term outcomes such as recurrence rates are yet unknown. In **Chapter 6**, a level 1 randomized clinical trial is described in which laparoscopic and open ventral incisional hernia repair were compared with regard to postoperative pain and nausea, operation time, blood loss, peri- and postoperative complications, length of hospital stay and recurrence rates.

A problem that challenges surgeons frequently is burst abdomen, which in fact is an “acute hernia”, an acute defect in the abdominal wall. Despite advances in perioperative care, surgical techniques and materials, the incidence of burst abdomen has remained unchanged over the past few decades. Unlike the high incidence rate of acute hernias after abdominal surgery, literature about treatment modalities is scarce. In **Chapter 7** the different treatment options after burst abdomen are described and a review of the current, predominantly retrospective literature is provided.

In the field of hernia surgery, many different techniques have been developed for incisional hernia repair. Some of these techniques are preferred by surgeons because of the simplicity of the technique or patency concerning hernia recurrences. For the laparoscopic approach, IPOM (intra peritoneal onlay mesh) repair with a coated (composite) mesh, fixated with a double crown of tackers, is preferred by most of laparoscopic hernia surgeons. For open incisional repair, two techniques are mainly performed. The component separation technique (Ramirez) is used for “giant” hernial defects with large width of the hernial defect. For smaller defects, the “modified Rives-Stoppa” technique is the preferred technique. **Chapter 8** is an illustrated stepwise atlas for residents and surgeons who want to perform the “modified Rives-Stoppa” repair.

Although correction of inguinal hernias is one of the most common surgical procedure and over 20 million hernia repairs are performed yearly worldwide, the debate on surgical technique in inguinal hernia is still actual. Since the introduction of prosthetic mesh, tension-free mesh repair of inguinal hernia is preferred over non-mesh techniques because of reduced recurrence and pain rates. A mesh can be placed with either an open or endoscopic approach. Hernia repair according to Lichtenstein is currently the most commonly used open mesh technique and the total extra peritoneal procedure (TEP) the preferred endoscopic approach. In **Chapter 9** the long term evaluation of a prospective randomized multicenter trial regarding postoperative pain and recurrence rates of 660 patients randomised to either the endoscopic total extraperitoneal inguinal hernioplasty (TEP) or the open ‘Lichtenstein’ technique for inguinal hernia repair is presented.

Despite the fact that 20% of all patients with both liver cirrhosis and ascites develop an umbilical hernia, hernia repair in this specific group of patients remains to be a niche. For many years, surgical repair was limited to patients who developed complications such as incarceration or evisceration. Operating on these patients in an acute setting, however, has been associated with high morbidity and mortality rates. In a retrospective study, our research group already found elective repair in this group of patients superior to a “wait and see” approach. **Chapter 10** describes the results of the first prospective cohort study on elective umbilical hernia repair in this vulnerable patient group.

Part 3

For decades, classic endpoints for studies in the era of hernia surgery have been “hard endpoints”, like recurrence, complications or costs. These endpoints have primarily been chosen from the point of the surgeons’. To understand which endpoints actually matter from patients’ point of view, one must first understand what motivates patients to undergo surgery. Thereafter, it has to be

understood how surgery and postoperative recovery are experienced by them. As a result, these hard and soft endpoints, have impact on patients' daily activities and quality of life in the short and longterm. Standardized questionnaires are available to measure health related quality of life (QoL) preoperatively and during follow-up. In **Chapter 11** the results of a randomized controlled trial (RCT) on QoL after open or endoscopic inguinal hernia repair are described. Thereafter, in **Chapter 12**, QoL is measured between open and laparoscopic incisional hernia repair. Having a primary or recurrent incisional hernia is believed to have impact on the QoL of patients. In a specific group of patients, that are prone to develop an incisional hernia after burst abdomen, the impact of having an incisional hernia on QoL is investigated in **Chapter 13**.

One of the main motives for both patients and surgeons to perform incisional hernia repair is reported to be cosmesis. In spite of the relevance of cosmesis to this patient population, none of the current literature on ventral hernia repair had cosmetic outcome as endpoint. Patients' self-image can be investigated by means of the Body Image Questionnaire (BIQ), which was developed by Dunker et al and has been used in several studies. The first study to report results on body image and cosmetic results after laparoscopic or open incisional hernia repair is reported in **Chapter 14**.

Other motives for performing ventral hernia repair have been reported to be lower back pain and pain of the abdominal wall. Hernia defects, especially when located in the midline, often cause lateralization and disfunction of the rectus muscles, impairing the balance between trunk flexor and extensor muscles. Anatomical reconstruction of the abdominal wall during incisional hernia repair could enhance or even improve the strength of the trunk flexor muscles. In **Chapters 15 and 16**, strength of the trunk flexor muscles is measured with the Biodex® dynamometer during isokinetic movement, and flexor musculature thickness with ultrasound. Anatomical reconstruction of the abdominal wall was compared to tension-free repair.

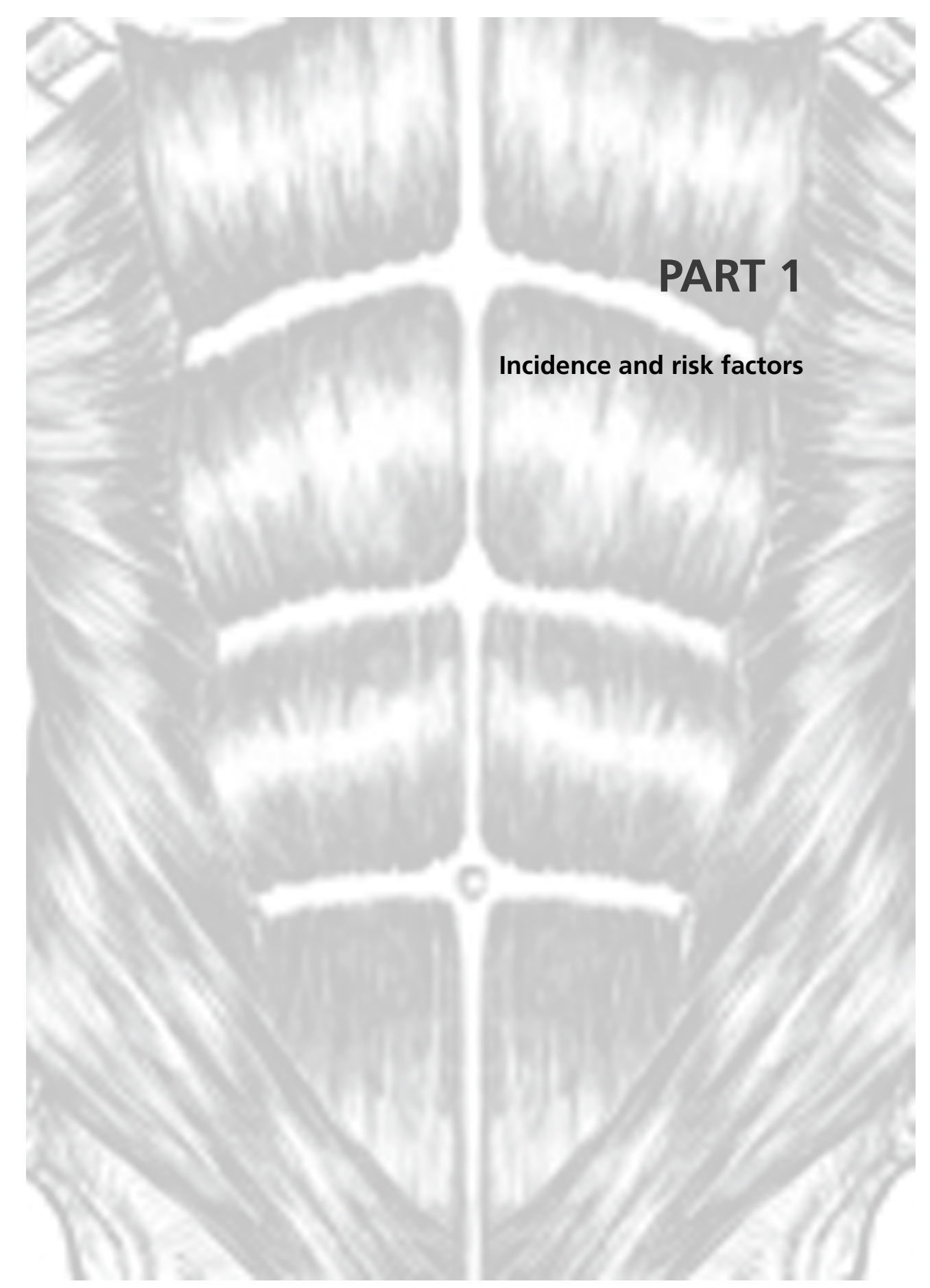
Finally the results of the studies described in this thesis are summarized and discussed in **Chapter 17**.

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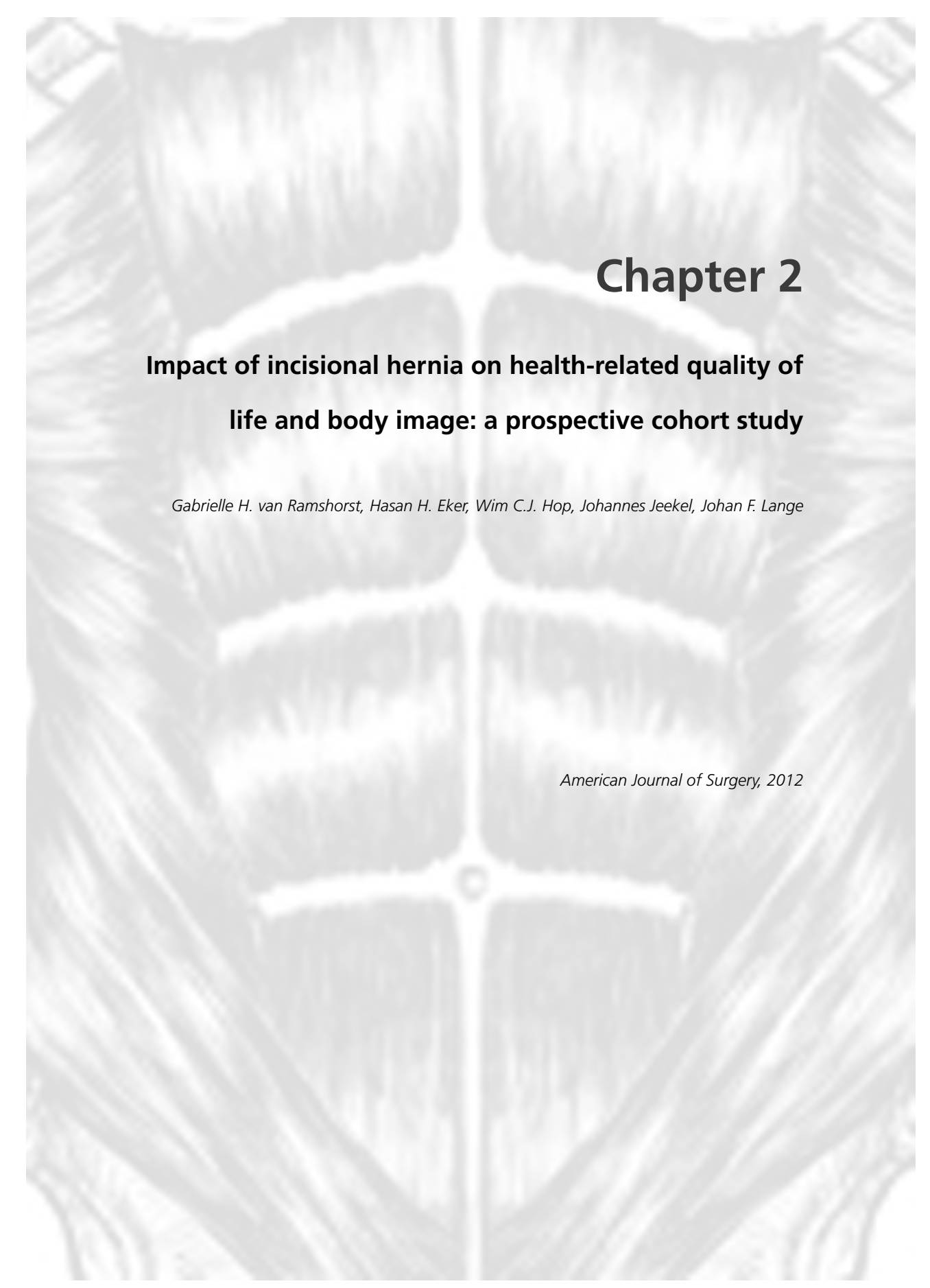




PART 1

Incidence and risk factors





Chapter 2

Impact of incisional hernia on health-related quality of life and body image: a prospective cohort study

Gabrielle H. van Ramshorst, Hasan H. Eker, Wim C.J. Hop, Johannes Jeekel, Johan F. Lange

American Journal of Surgery, 2012

ABSTRACT

Background: We investigated the impact of incisional hernia (IH) on quality of life and body image.

Methods: Open abdominal surgery patients were included in a prospective cohort study performed between 2007 and 2009 in an academic hospital. Main outcomes were incidence of IH after approximately 12 months and Short-Form 36 and body image questionnaire results.

Results: There were 374 patients who were examined after a median follow-up period of 16 months (range, 10 –24 mo). Seventy-five patients had developed IH (20%); 63 (84%) were symptom-atic. Adjusted for age, sex, and Charlson Comorbidity Index score, patients with IH reported significantly lower mean scores for components physical functioning ($P=.033$), role physical ($P=.002$), and physical component summary ($P=.010$). A trend toward significance was found for general health ($P=.061$). Patients with IH reported significantly lower mean cosmetic scores ($P=.002$), and body image and total body image scores (both $P=.001$).

Conclusions: Patients with IH reported lower mean scores on physical components of health-related quality of life and body image.

Keywords: Incisional hernia; Ventral hernia; Quality of life; Body image; Surgical site infection; Obesity; Cosmesis

INTRODUCTION

Incisional hernia (IH) is a frequent complication of open abdominal surgery with an incidence ranging between 3% and 20%.¹⁻⁵ In subgroups, such as patients with obesity or abdominal aneurysms, incidences have been reported of up to 26% to 39%.⁶⁻¹⁵ Few reports exist on the impact of IH on health-related quality of life, especially on groups of patients who have not been selected already for hernia repair.

Patients with IH can present with various symptoms such as pain, discomfort, limitation of daily activities, cosmetic complaints, skin problems, or incarceration with or without strangulation of the hernia content.¹⁶⁻¹⁸ The natural course of incisional hernia and changes in the proportion of symptomatic patients over time are unknown. Most patients with IH undergo surgery electively, and a minority of patients present with acute incarcerations requiring emergency repair.¹ The absolute risk of incarceration in patients with IH is unknown but estimates as low as 1% are made in the literature.¹⁸ However, reoperations for IH have been associated with recurrence rates of up to 63% for suture repair and up to 32% with mesh repair.¹⁹⁻²² The purpose of this study was to investigate IH-associated symptomatology, health-related quality of life, and body image.

MATERIALS AND METHODS

Between 2007 and 2009 a prospective cohort study was performed in which 967 eligible patients who underwent open abdominal surgery were included. Primary outcome for this study was surgical site infection according to the criteria as documented by the Centers for Disease Control and Prevention and abdominal wound dehiscence.²³ Approval for the study was obtained from the Institutional Review Board. Inclusion criteria included minimum age of 18 years, open abdominal surgery, or converted laparoscopic procedure. Exclusion criteria were laparoscopic surgery, inguinal/umbilical hernia, and day surgery. Informed consent was obtained from all study participants. Surgeons were asked to complete 2 questions: the first question was regarding fascia quality ("Was the fascia strong/easily torn/infected?") and the second question was regarding the closure procedure ("Was fascia closure performed tension free/under tension/with mesh?") on the day of surgery. Abdominal wounds were inspected following our protocol on a daily basis (including weekends and holidays) by 2 research fellows from postoperative day 2 until discharge to observe for presence of surgical site infection and abdominal wound dehiscence. In the primary study, 30-day follow-up evaluation after discharge was completed in 827 of 967 patients (85.4%): 643 (77.9%) at the out-patient clinic, 170 (20.6%) by telephone, and 14 (1.7%) by letter/e-mail. In addition, patient charts, discharge letters, electronic files, and registered wound complications were reviewed at least 3 months after discharge.

This follow-up study, which was not included in the original study design, was performed approximately 12 months after surgery between February 2009 and February 2010. The primary outcome of this study was the incidence of clinically detectable incisional hernia. The latter was defined as a palpable defect in the abdominal wall of the incision used for the surgery performed during the initial study period, resulting in herniation of abdominal contents. Secondary outcomes were health-related quality of life and cosmesis as measured with the Medical Outcomes Study Short Form 36 (SF-36) and body image (BIQ) questionnaires. Inclusion criteria for participation in the follow-up study included participation in the primary study, mental competence, and ability to complete the questionnaires. All 967 patients were invited for clinical evaluation after approximately 12 months after exclusion of deceased patients who were identified through national administrative data. All patients were requested to provide separate informed consent for this follow-up study. In each patient, the physical examination was performed by an independent physician in both a supine and erect position, in rest and during the Valsalva maneuver.

The SF-36 consists of 36 items that allow measurement of 8 health domains including physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health. In addition, physical and mental health are scored with the SF-36 physical component summary and SF-36 mental component summary, respectively. SF-36 scores range from 0 to 100, with higher scores implicating a better quality of life.

The BIQ, previously described and used by Dunker et al, consists of a body image score and a cosmetic score.^{24,25}

For each item of the body image score, 1 to 4 points are awarded, resulting in a total score between 5 and 20. The cosmetic score ranges between 3 and 24 points. Again, higher scores represent higher satisfaction.

Four additional questions were added to the questionnaires, as follows: (1) "Do you find it bothersome if others, such as your partner or persons you are living with, see your abdomen nude?" (possible answers: not at all/a bit/quite a bit/yes, extremely); (2) "My body does not look as good as before my surgery" (possible answers: totally disagree/ agree a little/quite agree/ totally agree); (3) "Have you felt more inhibited to initiate/maintain sexual relation(s) since your surgery?" (possible answers: not at all/a bit/quite a bit/yes, extremely/not applicable); and (4) "Has there been a change in sexual activity in the period after your surgery?" (possible answers: much less active/a bit less active/equally active/a bit more active/much more active/not applicable). Risk factors for IH were analyzed in univariate analysis using the chi-square test or the Mann-Whitney *U* test for categoric or continuous data, respectively. Multiple linear regression was used to evaluate the impact of IH on SF-36 and body image scores. Comorbidity was scored using

the Charlson Comorbidity Index (CCI), a weighted score as described by Charlson et al.²⁶ One point was given for myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, connective tissue disease, ulcer disease, stroke or transient ischemic attack, and diabetes. Two points were given for hemiplegia, moderate or severe renal disease, diabetes with end organ damage, any tumor, leukemia, and lymphoma. Three points were given for moderate or severe liver disease and 6 points were given for a metastatic solid tumor and acquired immune deficiency syndrome. A higher CCI score indicates an increased severity of patient condition. Possible effects of age, sex, and comorbidity (represented by CCI) were taken into account by using these variables as covariates in the analyses. *P* values less than .05 were considered statistically significant.

RESULTS

Of all 967 included patients, 374 patients provided informed consent and were examined. The remaining 593 patients were deceased (n 176), incompetent (n 1), emigrated/untraceable (n 11), nonresponders despite repeated attempts (n 244), or refused participation (n 161). The median follow-up period was 16 months (range, 10–24 mo). Seventy-five patients developed IH (20%); 63/75 (84%) were symptomatic and 51/75 (68%) considered these symptoms as complaints. The mean hernia defect size was 53.9 cm² (range, 1–504 cm²). Symptoms reported by patients with IH included bulging (n 50), pain/discomfort (n 45), and cosmetic complaints (n 8). None of the patients reported episodes of incarceration or strangulation. Eight patients with IH were wearing supportive corsets. Eight patients underwent surgery for IH, 2 of whom had developed recurrences.

Baseline and clinical characteristics of patients at the time of the initial surgery were compared for patients with and without IH (Table 1). Risk factors for IH were body mass index (*P*=.006) and surgical site infection (overall *P*<.001).

Table 1 Patient and clinical characteristics for patients with and without IH at time of primary surgery

Variable	Patients with IH (n 75)	Patients without IH (n 299)	Total (n 374)	P value
Age, mean SD, y*	61 ± 12 (45–75)	56 ± 13 (36–72)	57 ± 13 (39–72)	.006
50 y (%)	12 (12)	87 (88)	99	
50–64 y (%)	36 (22)	126 (78)	162	
65 y (%)	27 (24)	86 (76)	113	
Sex				.003
Male (%)	58 (25)	175 (75)	233	
Female (%)	17 (12)	124 (88)	141	
Body mass index, kg/m ² , mean SD*	27.7 ± 4.6 (22–35)	25.5 ± 4.7 (20–31)	25.9 ± 4.8 (20–32)	.001
20	3 (10)	27 (90)	30	
20–25	21 (14)	125 (86)	146	
25–30	27 (21)	99 (79)	126	
30	23 (37)	40 (63)	63	
Unknown	1 (11)	8 (89)	9	
ASA class				.080
I (%)	4 (9)	42 (91)	46	
II (%)	38 (20)	148 (80)	186	
III (%)	31 (23)	106 (77)	137	
IV (%)	1 (25)	3 (75)	4	
V (%)	1 (100)	0 (0)	1	
Smoking	31 (21)	120 (79)	151	.850
Comorbidity, mean SD†	3.4 ± (3.0)	2.6 ± 2.5	2.8 ± 2.6	.032
Emergency surgery (%)	19 (23)	64 (77)	83	.464
Type of surgery				.162
Abdominal wall (%)	4 (15)	23 (85)	27	
Esophagus (%)	10 (24)	32 (76)	42	
Gastroduodenal (%)	1 (17)	5 (83)	6	
Pancreas (%)	6 (25)	18 (75)	24	
Small intestine (%)	8 (42)	11 (58)	19	
Colorectal (%)	8 (16)	43 (84)	51	
Kidney (%)	12 (13)	81 (87)	93	
Gall bladder/bile duct (%)	2 (11)	16 (89)	18	
Liver (%)	15 (28)	39 (72)	54	
Vascular (%)	7 (26)	20 (74)	27	
Other (%)	2 (15)	11 (85)	13	
Type of incision				.185
Median (%)	42 (22)	148 (78)	190	
Subcostal (%)	15 (19)	64 (81)	79	
Transverse (%)	0 (0)	17 (100)	17	
Other (%)‡	18 (20)	70 (80)	88	
Surgical site infection				.001
Superficial (%)	23 (28)	58 (72)	81	
Deep (%)	11 (48)	12 (52)	23	
Organ/space (%)	5 (38)	8 (62)	13	

ASA American Society of Anesthesiologists class. *Values present the range (10th–90th percentile).

†Charlson comorbidity Index score calculated at follow-up evaluation. ‡Includes gridiron and semilunar lower-abdominal incisions.

Surgeons' questionnaire answers were available in less than 85% of all patients and, therefore, not entered in univariate analysis. Surgeons' description of fascia closure were available for 83% (312 of 374) of patients and proved a significant risk factor for IH development ($P=.024$). IH occurred in 18.5% (52 of 281) of patients with tension-free closures, 43% (9 of 21) of patients with closures under tension, and 15% (2 of 13) of patients with mesh closures.

Surgeons' description of fascia quality was available for 82.9% (310 of 374) of patients and was not a significant risk factor for IH development ($P=.584$). IH occurred in 20% (59 of 294) of patients with strong fascia, 9% (1 of 11) of patients with easily torn fascia, and 25% (1 of 4) of patients with infected fascia.

Not allowing for the effects of age, sex, or comorbidity, patients with IH showed significantly lower scores for the SF-36 components physical functioning ($P=.012$), role physical ($P=.002$), and physical component summary ($P=.008$) (Table 2). Patients with IH reported significantly lower scores on all components of the body image questionnaire (Table 3).

Table 2: Mean Short Form 36 scores and standard deviations (SD) for patients with and without incisional hernia (IH)

Short Form 36 component	Patients with IH			Patients without IH			P-value
	N	Mean	SD	N	Mean	SD	
Physical functioning	73	64.5	23.8	289	71.6	24.0	0.012
Role physical	73	39.7	38.8	283	57.4	43.3	0.002
Bodily pain	73	68.6	25.5	287	72.7	26.0	0.152
General health perceptions	73	53.4	21.8	285	58.2	22.6	0.120
Vitality	72	60.5	17.7	286	59.1	21.2	0.956
Social functioning	73	74.0	23.7	287	75.8	24.9	0.371
Role emotional	72	68.1	42.0	282	71.7	39.9	0.523
Mental health	72	75.0	16.3	286	74.9	17.8	0.875
Change	73	76.0	24.5	289	73.0	27.2	0.502
Physical Component Summary	69	59.7	18.6	263	66.3	20.7	0.008
Mental Component Summary	67	69.5	14.4	271	70.0	17.9	0.493

Table 3: Mean Body Image questionnaire scores with standard deviations (SD) for patients with and without incisional hernia (IH)

Body Image Questionnaire	Patients with IH				Patients without IH				P value ^a
	N	Mean	SD	Scale	N	Mean	SD	Scale	
Are you less satisfied with your body since the operation?	73	2.9	1.1	1-4	289	3.2	0.9	1-4	0.011
Do you think the operation has damaged your body?	73	2.6	0.9	1-4	288	3.0	0.9	1-4	0.001
Do you feel less attractive as a result of your operation?	73	3.0	1.1	1-4	289	3.3	0.9	1-4	0.024
Do you feel less feminine/masculine as a result of your operation?	72	3.5	0.9	1-4	289	3.7	0.7	1-4	0.062
Is it difficult to look at yourself naked?	73	3.3	1.0	1-4	287	3.6	0.8	1-4	0.037
Body Image score (5-20)	72	15.3	4.0	5-20	286	16.8	3.5	5-20	0.002
On a scale of 1 to 7, how satisfied are you with your scar?	73	3.8	2.0	1-7	287	4.4	2.0	1-7	0.024
On a scale from 1 to 7, how would you describe your scar?	73	3.8	1.5	1-7	287	4.1	1.4	1-7	0.055
Could you score your own scar on a scale from 1 to 10?	72	6.0	2.2	1-10	285	6.6	2.1	1-10	0.021
Cosmetic Score (3-24)	72	13.6	5.0	3-24	282	15.1	4.9	3-24	0.023
Total Body Image Score (8-44)	71	28.8	7.8	8-44	280	31.8	7.7	8-44	0.002

^aMann-Whitney U test

Adjusted for age, sex, and comorbidity, patients with IH reported significantly lower scores on the SF-36 components physical functioning ($P=.033$), role physical ($P=.004$), and physical component summary ($P=.010$) (Table 4). No significant differences were found for other SF-36 components, although a trend was found toward statistical significance for the general health component ($P=.061$).

Adjusted for age, sex, and comorbidity, patients with IH reported significantly lower body image scores ($P<.001$), cosmetic scores ($P=.002$), and total body image scores ($P<.001$) (Fig. 1). Median scar scores (scale, 1–10) were 6 for patients with IH and 7 for patients without IH ($P=.019$). Length of follow-up evaluation did not significantly influence SF-36 or BIQ scores (all $P>.05$). No differences were found for the SF-36 and BIQ between patients with IH who had undergone repeat surgeries and those who had not ($P>.05$).

Table 4: Effects of incisional hernia on Short Form – 36 (SF-36) and Body Image Questionnaire components; data shown are differences between the hernia and non-hernia groups after adjustment for age, gender and Charlson Comorbidity Index (CCI) score

Questionnaire	Mean difference (95% CI)	P-value
Physical functioning	-6.8 (-13.0 to -0.5)	0.033
Role physical	-16.4 (-27.5 to -5.2)	0.004
Bodily pain	-5.2 (-12.0 to 1.6)	0.135
General health	-5.6 (-11.4 to 0.3)	0.061
Physical Component Summary	-7.3 (-12.8 to -1.7)	0.010
Vitality	0.1 (-5.2 to 5.5)	0.961
Social functioning	-3.0 (-9.5 to 3.4)	0.353
Role emotional	-3.7 (-14.5 to 7.0)	0.498
Mental health	-0.6 (-5.2 to 4.0)	0.805
Mental Component Summary	-1.5 (-6.2 to 3.1)	0.515
Change score	3.7 (-3.3 to 10.7)	0.297
Body image score	-1.8 (-2.7 to -0.8)	<0.001
Cosmetic score	-2.0 (-3.3 to -0.7)	0.002
Total body image score	-3.8 (-5.8 to -1.8)	<0.001

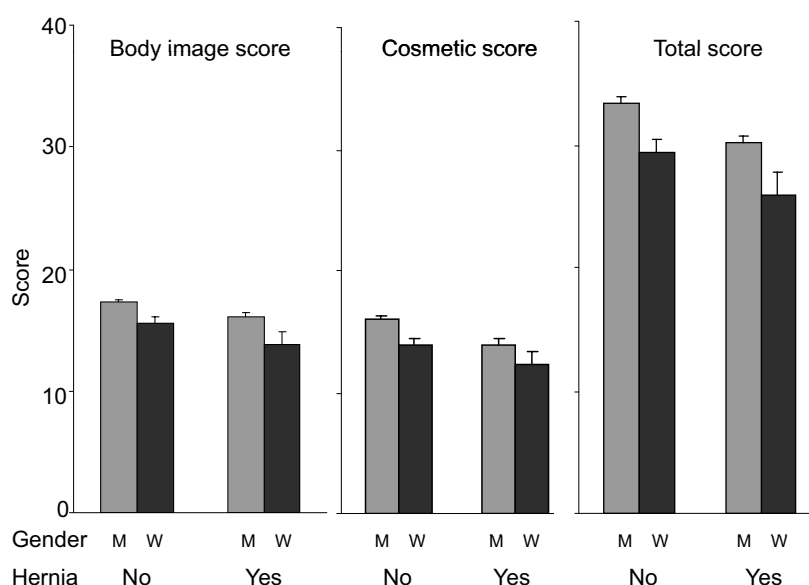


Figure 1 Data shown are age and Charlson Comorbidity Index score-adjusted mean values (with standard errors) for the body image score, cosmetic score, and total score according to presence of hernia and sex. The differences between the presence and absence of hernia are significant (all $P < .002$). Also, women generally had lower mean scores (all $P < .001$).

Patients with IH “quite agreed” or “totally agreed” significantly more often with the statement “My body does not look as good as before my surgery” than patients without IH (47% vs 31%; $P=.02$). Although patients with IH did not report higher inhibition toward initiating or maintaining sexual relations since the primary surgery, patients with IH were significantly more often sexually inactive than patients without IH (45% vs 27%; $P=.004$). Both these differences remained significant after adjustment for age, sex, and comorbidity. No significant differences were found between patients with and without IH with regard to exposure of the abdomen in front of others ($P=.080$).

After adjustment for age, sex, and comorbidity, patients with IH and complaints, as compared with patients with IH without complaints, reported significantly lower (ie, worse) mean scores for total body image score (difference, -4.6 ; $P=.020$) and the SF-36 items of physical functioning (difference, -14.6 ; $P=.017$), bodily pain (difference, -15.3 ; $P=.019$), physical component summary (difference, -10.4 ; $P=.035$), vitality (difference, -10.7 ; $P=.017$), social functioning (difference, -15.7 ; $P=.007$), and change score (difference, -15.7 ; $P=.009$). No significant differences were identified between both groups for cosmetic score (borderline at $P=.053$), body image score (borderline at $P=.056$), and SF-36 items role physical ($P=.070$), general health ($P=.757$), role emotional ($P=.280$), mental health ($P=.829$), and mental component summary ($P=.125$). The presence of bulging was correlated significantly with pain/discomfort ($P=.001$).

COMMENTS

Follow-up evaluation of a prospectively studied patient cohort revealed that IH occurrence has significant impact on health-related quality of life and body image. A high proportion of the patients with IH experienced complaints (68%), and the vast majority (84%) reported symptoms. These are high rates compared with the studies by Pollock and Evans²⁷ and Hesselink et al,²⁰ who reported complaints in 2 of 17 (12%) and 51 of 96 (53%) patients, respectively. Body mass index and surgical site infection were risk factors for IH. After adjustment of the SF-36 results for age, sex, and comorbidity, mean physical component scores were significantly worse for patients with IH compared with patients without IH. After these adjustments, significance was lost for the component general health ($P=.061$). Although patients with IH were significantly more often sexually inactive, it is unclear whether this was based on physical limitations or, for example, absence of a sexual partner. In patients with symptomatic IH, not only physical components (physical functioning, bodily pain, physical component summary), but also mental components (such as vitality and social functioning) proved worse than in patients with asymptomatic IH. A limitation of the current study was that SF-36 questionnaires were not issued at the time of

inclusion in the primary study, which inhibits comparison of preoperative and postoperative SF-36 outcomes. Also, postoperative quality of life may have been influenced by confounders in the association with IH for which no adjustments were made, such as severity of illness at inclusion or malnourishment.

Few reports exist on quality of life and SF-36 scores in particular of patients with IH. Thaler et al²⁸ found significantly worse SF-36 scores in a nonrandomized study for the domains physical functioning, general health, social functioning, mental health, and mental component summary for 16 patients with IH compared with 83 patients without IH after laparoscopic or open colectomy. Mussack et al²⁹ compared SF-36 preoperative scores of 24 patients with IH who underwent laparoscopic hernia repair with 24 patients who underwent open hernia repair. Their patients reported physical functioning and general health perception scores comparable with scores reported by patients with IH in our study. Our patients reported worse scores for role physical, but all other SF-36 scores were higher than the preoperative scores for the patients from the study by Mussack et al.²⁹

Cheatham et al³⁰ reported that patients with massive IH who await abdominal reconstruction experience significantly decreased physical, social, and emotional health. As far as we are aware, no reports exist on the value of the SF-36 in the treatment decision process. A questionnaire among hernia specialists revealed that pain and limitations of daily activities were regarded as the most important indications for repair.³¹

Body image was impaired significantly in patients with IH, especially in patients with symptomatic IH. Body image has not been granted considerable attention by surgeons in the past, but eventually may harm patients' sense of self-worth. Results of the aforementioned questionnaire among hernia specialists confirmed that cosmetic complaints were regarded as the least important motive for surgical repair.³¹ Cosmetic complaints were reported by 8 of 75 patients only, but this may present an underestimation in light of the low BIQ scores. In addition, the lack of improvement in cosmetic results after IH repair in a large proportion of patients is discouraging from a patient's perspective.¹⁹

Surgical site infection (or wound infection) is by far the most frequently reported risk factor for incisional hernia.^{32–34} Although this correlation between surgical site infection and IH has been described by many, occurrence of surgical site infection seldom has been chosen as the primary outcome. In our primary study, however, surgical site infection was the primary outcome and therefore, very detailed and well-documented information was available on the incidence and degree of infection in this patient group. In 53% of patients surgical site infections had preceded the formation of incisional hernia compared with 26% in the patients without incisional hernia, comparable with the findings of Veljkovic et al.³⁴ Additional analysis concerning the impact of

various degrees of infection on the occurrence of IH was possible as a result of the available, prospectively registered data. The infection percentage of 53% in our patients with IH was in the same range as published by Bucknall et al,³⁵ who found that 48% of their patients (41 of 84) had developed wound infections before IH formation. Obesity has been reported as an independent risk factor by many investigators, especially if body mass index exceeded 30 kg/m².^{2,9,32,35} In a series of gastric bypass patients published by Christou et al,³⁶ IH occurred in 14% of patients without wound infection compared with 35% of patients with wound infection. Besides the risk factors body mass index and surgical site infection, other variables such as closure method and the ratio of suture length to wound length, have been reported as relevant risk factors by other investigators.^{32–35,37} Closure was almost without exception performed with slowly absorbable sutures in a continuous, mass-closure fashion; including the type of suture in the analysis therefore was considered irrelevant. It was note-worthy that the incidence of IH was significantly higher in patients in whom the fascia, according to the surgeon, was closed under tension. Unfortunately, the ratio of suture length to wound length was not measured in our study and therefore could not be included in the analysis.

No significant differences were found for SF-36 or BIQ in the subgroup of patients with IH who had undergone surgery, including 2 patients who had developed recurrences, versus patients who had been treated conservatively. This may be a type 2 error owing to the small patient numbers. Also, differences might become detectable after a longer period of follow-up evaluation. Most patients present with IH within the first few years after surgery, but IH also can develop after longer periods, which warrants long-term follow-up evaluation of our patient population.^{20,27,38–40} Long-term follow-up evaluation also may give us the opportunity to evaluate changes in quality-of-life scores after repair.

Patient follow-up evaluation was challenging in our study, as is the case for most quality-of-life studies. The high mortality rate in our patient group can be explained by the large proportion of oncologic patients (eg, pancreatic and esophageal cancer), causing significant drop-out at a median follow-up period of 16 months. We did not receive any reports on hernia-related deaths. Also, we considered physical examination essential to detect incisional hernia instead of, for instance, using a postal or telephone survey.

Because our hospital functioned as a tertiary referral center for a large proportion of our patients, many of them considered the transfer time too long and refused participation.

In general, minimally invasive surgery might be preferred to open abdominal surgery to prevent IH. If this is not an achievable option, the ratio of suture length to wound length and surgical site infection are the risk factors that can be influenced by surgeons most easily. Moreover, preventive use of mesh could be useful in high-risk patient groups (eg, obese and aortic aneurysm

patients), and a randomized clinical trial on this topic currently is being conducted with our international trial group partners.

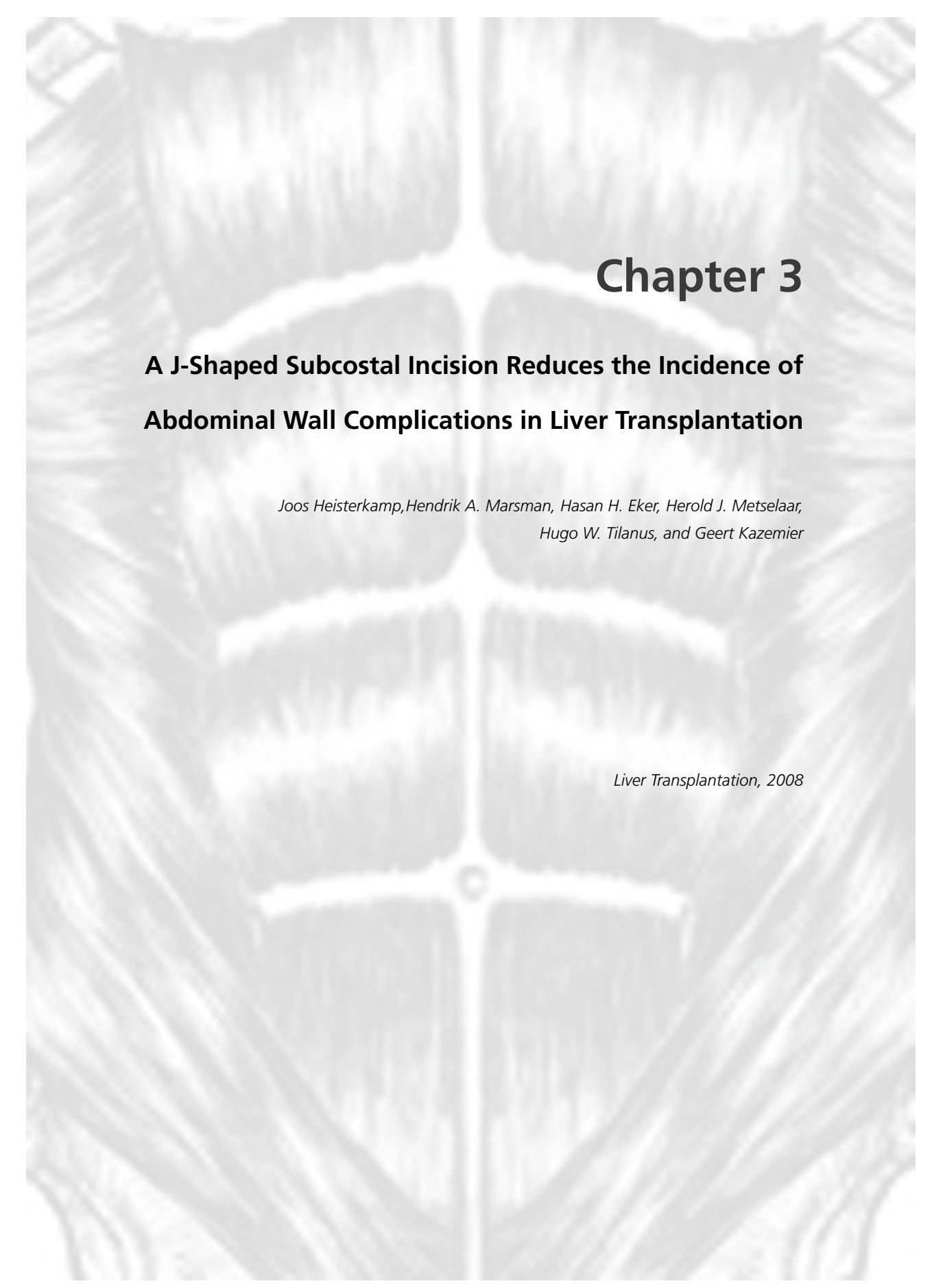
In conclusion, the vast majority of patients with IH in this cohort was symptomatic. Patients with IH experience a lower health-related quality of life on physical components and worse body image.

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Chapter 3

A J-Shaped Subcostal Incision Reduces the Incidence of Abdominal Wall Complications in Liver Transplantation

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A novel J-shaped incision for liver transplantation was introduced in attempt to reduce the wound-related complication rate while maintaining comparable access. Some 58 consecutive patients with the classic Mercedes incision were compared with the following 60 consecutive patients with a J-shaped incision. Nine of 60 patients (15%) with a J-shaped incision were converted to an extensive incision. The duration of surgery did not differ between both groups, and relaparotomy rates were comparable in both groups (45% versus 31%, P 0.487) whereas the early wound-related morbidity was significantly reduced in the J-shaped incision group (3% versus 19%, P 0.009), as well as incisional hernia rate (7% versus 24%, P 0.002, corrected for different length of follow-up). Other factors such as previous surgery, ascites, abdominal drainage, retransplantation, and indications for transplantation did not differ between both groups and were not predictive of wound-related morbidity or incisional hernia. We therefore conclude that a J-shaped incision should be the incision of choice in liver transplantation. This new, seemingly minor modification reduces wound infections, fascial dehiscence, and incisional hernia.

Liver transplantation has become a routine treatment modality for end-stage liver diseases. Surgical, anesthesiological, critical care, and immunological innovations have led to a dramatic reduction in postoperative morbidity and mortality. Optimization of surgical technique may even further reduce morbidity. Wound-related and incision-related complications such as wound infections and incisional hernias are common after liver transplantation and they imply considerable morbidity and even mortality.¹⁻⁸

From a series studying partial hepatectomy, it is known that access to the left and right hepatic lobe can be sufficient through a right subcostal incision with a medial extension to the xyphoid process (J-shaped or hockey stick-shaped incision; herein referred to as a J-shaped incision).² This incision has been reported to reduce wound infections and incisional hernias after partial liver resection and it is occasionally mentioned for liver transplantation but has yet to find its way into the textbooks.^{3,4} The objective of this study was to determine the feasibility of liver transplantation through a J-shaped subcostal incision and compare wound-related complications and hernia incidence using this incision with those obtained using a typical, classical, bilateral subcostal incision, possibly with a midline extension—the Mercedes incision.

PATIENTS AND METHODS

Study Group

Data were analyzed from patients undergoing transplantation from August 2002 through February 2008. From May 2004, the J-shaped incision was used for 61 consecutive transplantations, only allowing extension of the incision at the surgeon's discretion. Internationally-accepted indications for liver transplantation were applied for cadaveric and living donor liver recipients. As neither the indications, surgical team (always consisting of 2 experienced surgeons and a resident), operative techniques (except the incision), immunosuppression, or length of follow-up changed throughout the study period, the control group consisted of the last 61 consecutive patients undergoing transplantation before May 2004. Those patients were identified from a prospectively-managed database. Patients with intraoperative mortality (unrelated to the incision) from both groups were excluded from this study.

Conversion of the J-shaped incision to the Mercedes incision was defined as passing the *linea alba*, thus extending a monosubcostal incision into a bisubcostal incision. Patients were followed routinely by hepatologists and nurse practitioners at least every 3 months. Patients with a suspected incisional hernia were all investigated at the surgical outpatient department. All patients had at least 3 years of follow-up. Patients with discomfort as well as cosmetic complaints were considered for surgical correction of the hernia, regardless of the diameter of the hernial ring.

Surgical Procedures

The extensive incision (ie, the Mercedes incision) consisted of a bisubcostal incision with a mediocranial extension to the xyphoid process. The left and right lateral extensions were variable. Closure was performed as a single-layer mass closure with a running absorbable monofilament loop (PDS 0; Ethicon, Johnson & Johnson, Amersfoort, The Netherlands) for the fascia and musculature, by tying the suture from the medial extension to the suture of the bisubcostal closure, finished with an intracutaneous running absorbable monofilament suture (Monocryl 4.0; Ethicon) for the skin. The J-shaped incision consisted of a right subcostal incision with a mediocranial extension to the xyphoid process. The right lateral extension was variable but comprised transection of the oblique abdominal musculature. Closure was performed as a single-layer mass closure with a running absorbable monofilament loop (PDS 0) for the fascia and musculature and an intracutaneous running absorbable monofilament suture (Monocryl 4.0) for the skin. Examples of both incisions are depicted in Fig. 1.

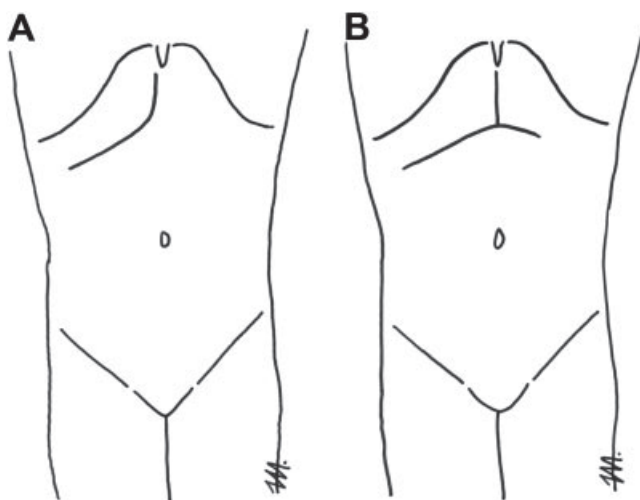


Figure 1. (B) The classic Mercedes incision and (A) the J-shaped incision.

Antibiotic prophylaxis consisted of cefazolin (1500 mg) with an additional dose of metronidazole (500 mg) in case of a planned hepaticojejunostomy. Known pathogens from previous cholangitis was covered with antibiotics accordingly. During surgery, exposure was maintained with a table-mounted retractor system in all patients. Passive abdominal drainage at the end of the operation was only performed for patients with considerable preoperative ascites. The vena cava-preserving technique without a venovenous or portocaval bypass was used in all patients for both cadaveric and living-related donor grafts.

Study Parameters and Statistical Analysis

Data were retrieved from a prospectively-managed database and were analyzed on an intention-to-treat basis. Incision-related morbidity such as conversion to a classic Mercedes incision, wound infection (according to World Health Organization criteria), fascial dehiscence, and incisional hernia were primary outcome factors. Possible confounders such as previous incisions, duration of surgery, ascites during the initial transplantation, use of drains, and use and number of relaparotomies (including retransplantations) were studied using The Statistical Package for Social Science version 11 for Windows (SPSS Inc, Chicago, IL). To correct for the difference in length of follow-up between the 2 groups, a Cox regression analysis was performed using S-plus.

Aside from the abdominal wall-related outcomes, other quality parameters for the transplant program such as duration of hospitalization and graft and patient survival were studied. A difference with a *P* value 0.05 was considered significant.

RESULTS

Study Group

Both groups comprised 61 consecutively operated patients. In the Mercedes incision group, 3 patients died intraoperatively and in the J-shaped incision group, 1 died intraoperatively (0 related to the incision), leaving 58 and 60 patients, respectively, for evaluation in both groups. Median laboratory Model of End-Stage Liver Disease scores at transplantation were comparable between groups (Mercedes group, 17; J-shape group, 18; *P* 0.23). In both groups, patients with large polycystic liver (3/58 [5%] versus 2/60 [3%]) and with autoimmune hepatitis with preoperative steroid use (4/58 [7%] versus 3/60 [5%]) received transplantation. The median surgical time did not differ between the groups: 271 minutes (range, 180-559 minutes) for patients in the Mercedes incision group versus 284 minutes (range, 172-590 minutes) in the J-shaped incision group (*P* 0.243). In both groups a drain was left postoperatively in comparable proportions: 43% versus 49% (*P* 0.448). The relevant demographics are shown in Table 1.

Nine out of 60 patients (15%) with a J-shaped incision were converted to a classic Mercedes incision. The reasons for conversion are given in Table 2.

Table 1. Demographics of Both Groups

	J-Shaped (n 60; %)	Incision Technique Mercedes (n 58; %)	P Value
Indication			0.12
Other	55 (92)	53 (91)	
Polycystic	3 (5)	2 (4)	
Autoimmune	2 (3)	3 (6)	
Conversion	9 (15)	NA	NA
Previous laparotomy	6 (10)	4 (7)	0.23
Reoperation			0.87
Once	10 (17)	14 (26)	
Twice	11 (19)	10 (19)	
Retransplantation	4 (6)	2 (4)	0.9265
Requirement of blood products	68%	59%	0.32
Abdominal drain	28 (47)	21 (39)	0.15

NOTE: No statistically significant differences were present, when applicable.
Abbreviation: NA, not applicable.

Table 2. Reasons for Conversion of a J-Shaped Incision to the Classic Mercedes Incision

Reason for Conversion	Number of Patients (n 9)
Bleeding from extensive abdominal wall collateral veins	1
Dimensions of graft	2
Necessity of venous conduit from superior mesenteric vein	1
Splenomegaly with need to ligate splenic artery	1
Colonic distension with need for right colectomy	1
Previous bisubcostal incision with incisional hernia	3

NOTE: The number of patients converted was 9 out of 60 (15%).

Outcome

In-hospital wound-related morbidity was significantly higher in the Mercedes incision group (19% versus 3%, P 0.09). There were fewer incisional hernias during follow-up in the J-shaped incision group: 4 out of 60 (7%) versus 14 out of 58 (24%) in the Mercedes incision group (P 0.002). When corrected for difference in length of follow-up (median, 42 months versus 38 months, respectively; P 0.19) with a Cox regression analysis, this difference persisted. All but 1 patient diagnosed with an incisional hernia were operated on successfully using open or laparoscopic mesh repair.

The duration of hospitalization, graft and patient survival, and number of relaparotomies (including retransplantations) did not differ between groups. The type of incision was the only factor associated with in-hospital wound complications and incisional hernia, whereas previous

incisions, duration of the operation, ascites, abdominal drainage, relaparotomies (including retransplantations), and conversions from subcostal to classic extensive incision were not.

DISCUSSION

In this study, a reduced incision for orthotopic liver transplantation was studied; the early and late abdominal wall-related complications in the reduced incision group were compared to those complications in a group of patients who underwent the same procedure through a classic Mercedes incision. It was found that a J-shaped incision leads to less early and late abdominal wall complications without disadvantages during hepatectomy and implantation of the graft.

Patient-related factors associated with an increased risk of wound-related complications or hernias did not differ between the 2 groups in this study, other than the type of incision used. Two mechanisms could be responsible for the reduced wound infection and hernia rate in the J-shaped incision group. First, a reduced wound length has been reported to reduce the risk of wound infection, thereby reducing the risk of fascial dehiscence and incisional hernia.^{9,10} The second explanation for the difference may be the fact that with a J-shaped incision the avascular linea alba is not crossed and thus does not need to be reconstructed. Although the midline incision is widely practiced, it is known for its higher frequency of incisional hernia compared to paramedian or transverse abdominal incisions.¹¹⁻¹³ It has been reported that the advantage of reducing incisional hernia is lost when the midline is crossed,¹⁴ which is in support of the findings in this study. This fact would contraindicate the use of a bilateral subcostal incision, which is a very common and alternative incision for the Mercedes incision. No randomized comparisons are available to substantiate a difference of a monolateral versus a bilateral subcostal incision. A disadvantage of the J-shaped incision may be the extra traction applied through the table-mounted retractor, with subsequent local ischemia, potentially increased risk of infection, and delayed or in-adequate fascial healing.

Theoretically, the J-shaped incision may lead to reduced access and exposure. However, in this study, operative times were comparable in both groups. The majority of the extensions from the J-shaped incision to the classic Mercedes incision were to increase access because of rare recipient-related factors. The size of the graft or the need for vascular reconstruction dictated conversion in the other cases. In case a greater exposure is necessary a conversion is easily accomplished. Conversion of a J-shaped incision to a bisubcostal incision, however, leads to the Mercedes incision with 3 edges. Therefore, we suggest that if additional complex procedures in the inframesocolic compartment are expected, increasing the possibility of a bisubcostal incision, one might start with a monosubcostal incision without extension to the upper midline preventing ending up with a Mercedes incision.

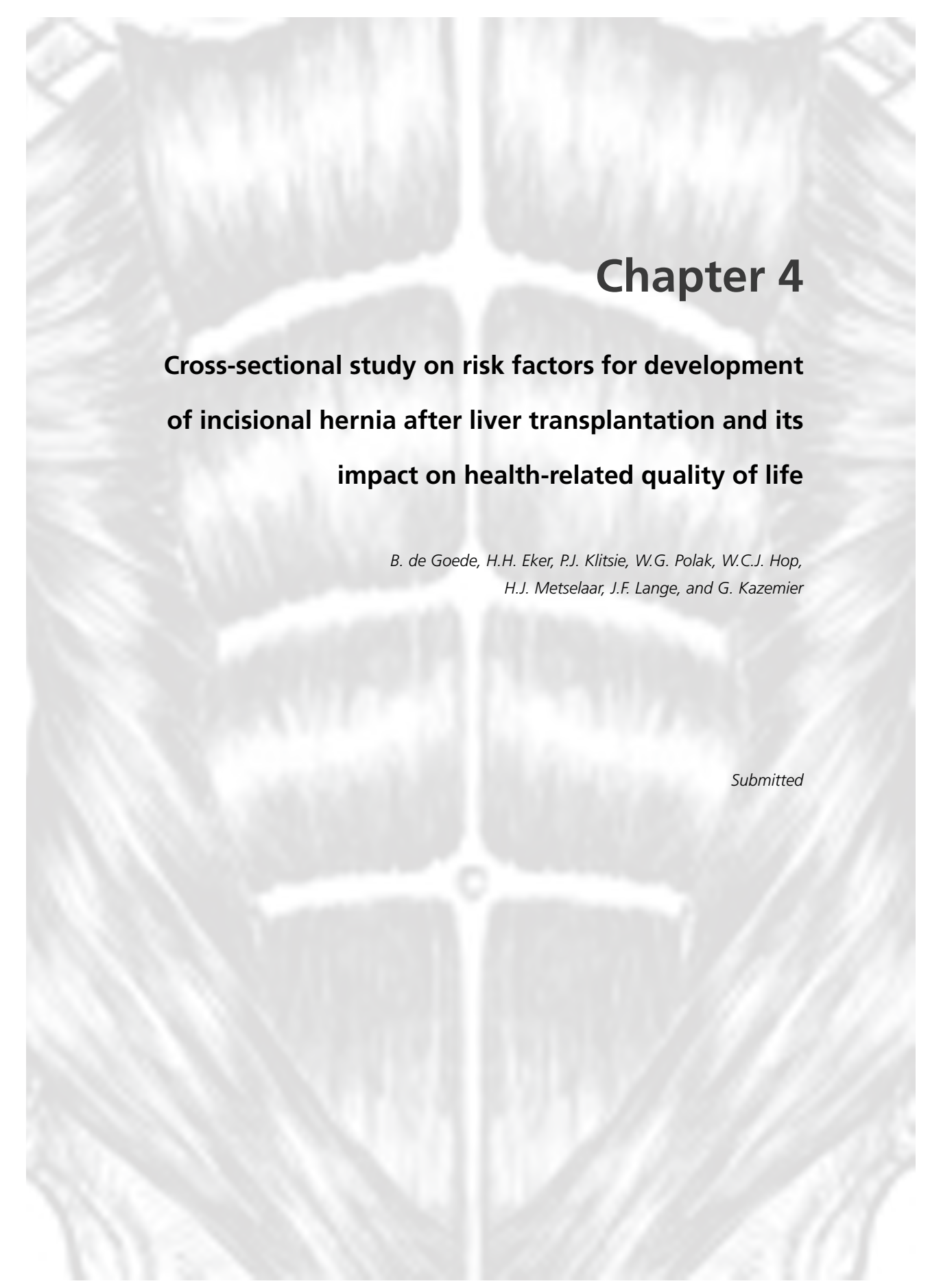
It has been reported that abdominal drainage increases the risk of wound infection¹⁵; although that association was not statistically significant in our study, this factor could not have been responsible for the differences as a comparable proportion in both groups of patients received a drain. Although the costs associated with wound related complications were not studied it is very well conceivable that a reduced rate of wound infection will lead to lower overall costs, although one may argue whether these costs are substantial in the total package of organ transplantation. Nevertheless, *primum non nocere* (ie, first do no harm), may also be applied to the length of the incision, suggesting a new adage: less is more.

Prevention is the best treatment for incisional hernia and we therefore conclude that a J-shaped incision should be the incision of choice in liver transplantation.

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Chapter 4

Cross-sectional study on risk factors for development of incisional hernia after liver transplantation and its impact on health-related quality of life

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Submitted

ABSTRACT

Background Improved survival after liver transplantation (LT) has made incisional hernia a more relevant late surgical complication. This cross-sectional study aimed to analyze the incidence of incisional hernia, to determine potential risk factors for incisional hernia development, and to assess the impact of incisional hernia on health-related quality of life (HRQoL) in patients after LT.

Methods Patients who underwent LT at the Erasmus University Medical Center through a J-shaped incision with a minimum follow-up of 3 months were included in this cross-sectional study. Patients transplanted through a different incision were excluded. Patients underwent their follow-up at the outpatient clinic. Short form 36 (SF-36) and body image questionnaire (BIQ) were used for the assessment of HRQoL.

Results A total of 140 patients were included. The mean follow-up period was 33 (SD 20) months. Sixty patients (43%) were diagnosed with an incisional hernia at the outpatient clinic. A multivariate analysis revealed surgical site infection (OR 5.27, $p = 0.001$), advanced age (OR 1.05, $p = 0.003$), and prolonged ICU stay (OR 1.54, $p = 0.022$) to be independent risk factors for incisional hernia development after LT. Patients after LT with an incisional hernia scored significantly worse on the components: physical role functioning ($p = 0.020$), vitality ($p = 0.003$), social functioning ($p = 0.003$), emotional role functioning ($p = 0.003$), mental health ($p = 0.028$), mental component summary ($p = 0.001$) and were significantly less satisfied with their perceived body image ($p = 0.003$ and $p = 0.016$) and cosmesis ($p = 0.022$).

Conclusions Patients who undergo LT have a high incidence of incisional hernia, which has considerable impact on HRQoL. Development of incisional hernia seemed to be related to surgical site infection, advanced age and prolonged ICU stay.

INTRODUCTION

Liver transplantation (LT) has evolved from a life saving operation with high mortality in the 70's and 80's of the past century to a standardized procedure with a reported 1-year survival rate of over 90%, depending on the initial indication.¹⁻² During this evolution, focus has shifted from preventing peri-operative mortality and major complications to managing long-term side effects of immune suppressive therapy and improving quality of life after LT.³⁻⁶

With improved long-term survival after LT, incisional hernia has become a frequently diagnosed and clinically more relevant complication with incidences varying between 1.7 and 34.3%.⁷⁻¹⁶ Incisional hernias form not only an aesthetic problem, but they may reduce quality of life and can lead to serious morbidity due to incarceration or strangulation.¹⁶⁻¹⁸ Therefore, prevention of this late complication has become increasingly important. Many causative factors for incisional hernias have been identified retrospectively in patients after LT: recipient's age, male sex, body mass index (BMI), indication for transplantation and underlying liver disease, pulmonary complications, wound infections, number of reoperations, immunosuppressive regimen, and incision type.^{14, 16, 19-20} Prospective data on independent risk factors for incisional hernia development after LT are scarce and none have evaluated the impact of incisional hernia after LT on health related quality of life (HRQoL).

Traditionally, the classic 'Mercedes Benz star' incision or 'rooftop' incision was predominantly used to perform LT. More recently, smaller incisions like a subcostal incision with or without a mediocranial extension ('J-shaped' or 'hockey-stick' incision) are preferred increasingly, since they have been proven to provide adequate access for LT with presumed less abdominal wall trauma, resulting in a reported lower incidence of incisional hernia.^{1, 11, 21-22} However, the optimal incision type for LT, which combines optimal access with a low incisional hernia incidence, remains unclear. Earlier studies, reporting on incisional hernia development after LT often include patients operated through different incisions, which hampers interpretation of results.¹⁵⁻¹⁶

The aim of this cross-sectional study is to assess the incidence of clinically detectable incisional hernias, to evaluate the risk factors for incisional hernia development, and to determine the impact of incisional hernia on HRQoL in patients who all underwent LT through a J-shaped incision.

METHODS

A cross-sectional study was performed including patients who underwent LT between January 2004 and November 2010 at the Erasmus University Medical Center. All patients who underwent LT through a J-shaped incision with minimum follow-up of 3 months and who signed informed consent were included in the study. Patients were excluded if they underwent LT through a different incision.

Patients characteristics and clinical data were collected prospectively in the search for potential risk factors, including: age, sex, underlying liver disease, cardiovascular diseases (cardiac arrhythmia, ischemic heart disease or other cardiovascular disease), chronic obstructive pulmonary disease (COPD), diabetes mellitus (DM), abdominal wall hernia (incisional hernia, umbilical and/or inguinal hernia) or earlier surgery through a right subcostal or median laparotomy in medical history, Body Mass Index (BMI) at time of LT, Child-Turcotte-Pugh (CTP) score at time of LT, Model of End-stage Liver Disease score based solely on laboratory findings at time of LT (labMELD), intraoperative presence of ascites, procedure time of LT, intra-operative blood loss, length of hospital stay, length of postoperative intensive care unit (ICU) admission, immunosuppressive regimen, postoperative complications including wound complications, surgical site infection, pneumonia, biopsy proven acute graft rejection, and number of relaparotomies.

The J-shaped incision, consisting of a right subcostal incision combined with a mediocranial extension towards the xyphoid, was used primarily to get access to the abdominal cavity in all patients. Extension of the incision was allowed at surgeon's discretion. Routinely, a table-mounted abdominal wall retractor (Thompson Surgical Instruments, Incorporated, Traverse City, MI, USA) was used during the entire procedure. At completion of the procedure the abdominal wall fascia was closed through a two-layer mass closure technique with two running slowly absorbable monofilament suture loops (PDS 0, Ethicon). The skin was closed using intracutaneous running absorbable monofilament sutures (Monocryl 4.0, Ethicon). Thirty minutes preoperatively, a single dose Cefazolin (1500 mg) was administered as antibiotic prophylaxis unless another antibiotic regimen was prescribed because of earlier infections in the patient's recent medical history. An additional dose of Metronidazole (500 mg) in case of expected bilioenteric reconstruction. Only when patients had considerable ascites at the first exposure of the abdominal cavity, passive abdominal drainage was performed after LT. No T-tubes or stents were used during the biliary reconstruction. All biliary reconstructions were duct-to-duct unless primary sclerosing cholangitis or another disease was present affecting the extrahepatic bile duct. In these patients a bilio-enteric reconstruction was created, using a Roux-en-Y loop. Relaparotomies were always done primarily through the same incision created during LT. Postoperatively, dual or triple immunosuppressive therapy consisting of low dose steroids, and Tacrolimus and/or Mycophenolate Mofetil (MMF),

was used during three months. All patients were withdrawn from steroid therapy except patient with an underlying immune regulated liver disease.

All patients with a minimum follow-up period of 3 months were invited at the outpatient clinic for a physical examination by an experienced surgeon to assess the incidence of incisional hernia after LT. An incisional hernia was defined as a palpable defect in the abdominal wall of the incision used for LT, performed during the initial study period, resulting in a herniation of abdominal contents. If a patient was diagnosed with an incisional hernia, data on hernia location, hernia size and if corrected data on recurrence were collected. If an incisional hernia correction was performed, a flat heavyweight polypropylene mesh was used if no gross contamination was present at the time of correction. This mesh was placed in the pre-peritoneal plane preferably. Antibiotic prophylaxis was administered to prevent infection of the prosthesis.

To compare HRQoL in patients after LT with an incisional hernia to those without, patients were asked to fill in quality of life (SF-36 and BIQ) questionnaires prior to physical examination. The SF-36 consists of 36 items that allow measurement of eight health domains, including: physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health. In addition, physical- and mental health are scored with the SF-36 physical component summary and SF-36 mental component summary, respectively. SF-36 scores range from 0 to 100, with higher scores implicating a better quality of life.

The BIQ consists of eight items evaluating body image and cosmesis after surgery, and two items evaluating self-confidence. The body image scale measures patients' perception of and satisfaction with their own body and it explores patients' attitude towards their bodily appearance (items 1, 2, 3, 4, 5); each item can be awarded 1 to 4 points (1 = "no, not at all" to 4 = "yes, extremely"). The cosmetic scale assesses the degree of satisfaction of the patient with respect to the physical appearance of the scar (items 6–8); item 6 ranges from 1 ("very unsatisfied") to 7 ("very satisfied"), item 7 ranges from 1 ("revolting") to 7 ("beautiful") and item 8 is a scoring scale from 1 to 10, with higher scores implicating more satisfaction. Two items (9, 10) evaluate self-confidence of the patient *before* and *after* LT; both items will be awarded 1 to 10 points (1 = "not very confident" to 10 = "very confident")

Statistical analysis

SPSS (version 15.0) was used for statistical analysis. Chi-square test, Mann-Whitney U-test and independent sample t-test were used for categorical, continuous variables and analysis of quality of life. Univariate and multivariate analysis of various factors were performed with logistic regression to determine HRQoL, putative and independent risk factors for incisional hernia occurrence. In multivariate analysis, risk factors were corrected for length of follow-up; SF-36 components and

BIQ questions were corrected for age and gender. Values were considered statistically significant at p-values less than 0.05.

Results

Between January 2004 and November 2010, LT was performed in 249 patients. Hundred-nine patients were screened but did not meet the inclusion criteria: 48 were transplanted through a different incision, 40 patients died during follow-up, and 21 patients did not want to participate in the study. A total of 140 patients were included in the study. Patient characteristics and clinical data are set out in table 1. No differences in baseline characteristics were observed in participants (n = 140) and non-participants (n = 61).

Table 1. Patient characteristics and clinical data

	Total (n = 140)		Total (n = 140)
Sex*		Preoperative ascites*	93 (66)
Male	90 (64)		
Female	50 (36)	Procedure time LT (min)***	441 (254-822)
Advanced age (years)**	49 (12)	Blood loss (litre)***	3.2 (0.1-25.0)
Body mass index (at LT)**	26 (4)	Duration hospital stay (days)***	20 (10-77)
Follow-up (months)**	33 (20)	Duration ICU stay (days)***	4 (2-70)
Liver disease*		Relaparotomy*	53 (38)
Hepatitis	41 (29)		
Alcoholic	30 (21)	Immunosuppressive regimen*	
HCC	33 (24)	Dual	29 (21)
Cryptogenic	13 (9)	Triple/quadruple	111 (79)
Autoimmune PCS, PBS	44 (31)		
Acute liver failure	20 (14)	Acute graft rejection*	30 (21)
Budd-Chiari syndrome	1 (0.7)		
Other	10 (7)	Surgical site infection*	28 (20)
Child Pugh Score*		Diabetes*	45 (32)
A	24 (17)		
B	57 (41)	Cardiovascular disease*	42 (30)
C	59 (42)		
		COPD*	12 (9)
labMELD***	15 (6-40)		
		Other hernia in medical history*	47 (34)

*Data between parentheses are percentages; **values are mean (s.d.); ***Data shown are median (range). PSC, primary sclerosing cholangitis; PBC, primary biliary cirrhosis; labMELD, Model of End-stage Liver Disease, only based on laboratory variables; COPD, Chronic obstructive pulmonary disease; Other hernia in medical history includes: inguinal-/umbilical hernia/acute dehiscence.

The mean follow-up period was 33 (SD 20) months. All 140 patients underwent physical examination of the abdominal wall at the outpatient clinic. Sixty patients (43%) were diagnosed with a clinically detectable incisional hernia after physical examination. Twenty-one of those 60 incisional hernias (35%) were located in the subxyphoidal part of the incision, 18 (30%) were located in the middle part of the incision, and 9 (15%) were located laterally. In 12 patients (20%) the incisional hernia was located at more than one location. The mean diameter of the incisional hernia was 3.4 cm (SD 5.5).

Thirteen of the 60 patients (22%) who developed an incisional hernia underwent hernia repair during follow-up. Three patients of those 13 were operated for acute wound dehiscence and one for acute wound dehiscence with strangulation of small bowel. Eight patients were operated electively and one in an emergency setting due to incarceration of small bowel. Twelve patients (92%) underwent incisional hernia correction using mesh. Nine patients (69%) suffered from a recurrent incisional hernia and two patients developed infection of the mesh. In both cases the infected mesh had to be removed.

Univariate analysis demonstrated advanced age ($p = 0.02$), high preoperative BMI ($p = 0.012$), prolonged ICU stay ($p = 0.022$), surgical site infection ($p = 0.004$), and hernia in the medical history ($p = 0.036$) to be putative risk factors for incisional hernia development after LT. Sex ($p = 0.133$), follow-up time ($p = 0.076$), pre-transplant MELD score ($p = .$), relaparotomy frequency ($p = 0.057$), immunosuppressive regimen ($p = .$), and biopsy proven acute graft rejection ($p = 0.078$) were not identified as risk factors for incisional hernia occurrence after LT. (Table 2)

Multivariate logistic regression analysis after adjustment for follow-up duration revealed surgical site infection (OR 5.27, 95% CI 1.94 to 14.35; $p = 0.001$), advanced age (OR 1.05, 95% CI 1.02 to 1.09; $p = 0.003$) and prolonged ICU stay (OR 1.54, 95% CI 1.06 to 2.22; $p = 0.022$) to be independent risk factors for incisional hernia development in patients who underwent LT through a J-shaped incision.

A total of 122 patients (87%) completed quality of life questionnaires. Patients with an incisional hernia scored significantly lower (i.e. experienced worse quality of life) on the SF-36 components: physical role functioning ($p = 0.026$), vitality ($p = 0.004$), social functioning ($p = 0.002$), emotional role functioning ($p = 0.005$), mental health ($p = 0.042$) and mental component summary ($p = 0.001$). (Table 3)

Table 2. Univariate analysis: putative risk factors for incisional hernia development

	Patients with IH (n = 60)	Patients without IH (n = 80)	p - value
Follow-up (months)**	37 (19)	31 (20)	0.076
Sex*			
Male	43 (72)	47 (59)	0.113
Female	17 (28)	33 (41)	
Advanced age (years)**	51 (10)	47 (14)	0.020
Body mass index (at LT)**	26 (5)	25 (4)	0.012
labMELD***	11 (6-40)	11 (6-40)	0.423
Surgical site infection*	19 (32)	9 (11)	0.004
Relaparotomy*	28 (47)	25 (31)	0.057
Duration ICU stay (days)***	5 (2-70)	4 (2-46)	0.022
Immunosuppressive regimen*			
Dual	13 (22)	16 (20)	0.772
Triple/quadruple	47 (78)	64 (80)	
Acute graft rejection*	8 (13)	22 (28)	0.078
Other hernia in medical history*	26 (43)	21 (26)	0.036

*values are mean (s.d.); **data between parentheses represent percentages; ***data shown are median (range). IH, incisional hernia; labMELD, Model of End-stage Liver Disease, only based on laboratory variables; Other hernia in medical history includes: inguinal-/umbilical hernia/acute dehiscence.

Table 3. Mean SF-36 scores and SD for patients with and without an incisional hernia

Short form 36 component	Patients with IH			Patients without IH			p - value* (p - value)	
	N	Mean	SD	N	Mean	SD		
Physical functioning	54	65.9	26.2	65	73.2	28.0	0.053	0.204
Role physical	51	43.6	42.4	60	62.9	42.6	0.026	0.020
Bodily pain	53	72.3	26.7	65	79.2	24.2	0.149	0.113
General health perceptions	54	52.5	23.2	65	58.0	22.8	0.139	0.197
Vitality	54	51.9	22.6	65	63.5	18.9	0.004	0.003
Social functioning	54	66.9	26.5	66	80.1	23.3	0.002	0.003
Role emotional	50	68.7	44.9	61	90.7	26.1	0.005	0.003
Mental health	54	73.5	18.3	65	79.9	17.0	0.042	0.028
Physical component summary	50	41.4	11.5	59	44.8	10.9	0.138	0.137
Mental component summary	50	48.2	11.7	59	54.9	8.4	0.001	0.001

*Mann-Whitney *U* test (univariate); p-values after adjustment for age and gender are shown between parentheses; SF 36, short form 36; SD, standard deviation; IH, incisional hernia

Patients with an incisional hernia scored significantly more points (i.e. experienced more bodily damage due to the transplantation) on the BIQ question: *"Do you think the surgery has damaged your body?"* and scored significantly lower (i.e. were less satisfied) on the question: *"how satisfied are you with your scar?"* ($p = 0.007$ and $p = 0.036$, respectively). (Table 5) Within the group of patients with an incisional hernia, no difference in HRQoL was observed with regard to the location of the diagnosed incisional hernia. Multivariate analysis on SF-36 components and BIQ questions, after adjustment for age and gender, did not change the results significantly, except for the BIQ question: *"Do you think the surgery has damaged your body?"*. After adjustment for age and sex, patients with an incisional hernia scored significantly more points (i.e. had more difficulty looking at their body naked). (Table 4)

Table 4. Mean BIQ scores with SD for patients with and without an incisional hernia

Body image questionnaire	Patients with IH				Patients without IH			
	Scale	N	Mean	SD	Scale	N	Mean	SD
Body image								
<i>Are you less satisfied with your body since the surgery?</i>	1-4	51	1.9	1.1	1-4	63	1.6	0.8
<i>Do you think the surgery has damaged your body?</i>	1-4	51	2.0	0.8	1-4	62	1.6	0.6
<i>Do you feel less attractive as a result of your surgery?</i>	1-4	50	1.7	0.9	1-4	63	1.5	0.7
<i>Do you feel less feminine/ masculine as a result of your surgery?</i>	1-4	51	1.4	0.8	1-4	62	1.2	0.6
<i>Is it difficult to look at yourself naked?</i>	1-4	51	1.6	0.9	1-4	63	1.3	0.6
Cosmesis								
<i>On a scale from 1 to 7, how satisfied are you with your scar?</i>	1-7	51	4.5	1.9	1-7	63	5.2	1.9
<i>On a scale from 1 to 7, how would you describe your scar?</i>	1-7	51	4.2	1.5	1-7	62	4.7	1.4
<i>Could you score your own scar on a scale from 1 to 10?</i>	1-10	55	6.1	2.7	1-10	75	6.2	3.4
Self-confidence								
<i>How confident were you before your operation?</i>	1-10	54	6.7	2.8	1-10	75	5.9	3.4
<i>How confident were you after your operation?</i>	1-10	55	6.0	3.0	1-10	76	5.9	3.5

*Mann-Whitney U test (univariate); p-values after adjustment for age and gender are shown between parentheses; BIQ, body image questionnaire; SD, standard deviation; IH, incisional hernia

DISCUSSION

This cross-sectional study shows that patients who undergo LT through a J-shaped incision have a high incidence of incisional hernia and that those patients experience diminished HRQoL as compared to those patients who do not develop an incisional hernia. It also shows that recurrence rates after mesh-repaired incisional hernia are very high and that incarcerated incisional hernias occur frequently in this fragile group of patients. These results underscore the importance of this late complication in patients after LT. Liver transplantation patients, however, are often not considered to be at typically high risk for incisional hernia development in contrast to patients with obesity or abdominal aneurysms.²³⁻²⁹ Poor preoperative nutritional status, long duration of the operation, poor immunologic status due to postoperative immunosuppressive medication and the underlying liver disease in patients undergoing LT could all attribute to this.

Other studies show much lower incidences of incisional hernia after LT.^{12-13, 20, 22} It is known, however, that physical examination alone to diagnose incisional hernias often underestimates incisional hernia incidences, particularly when incisional hernias are asymptomatic.³⁰ If those incisional hernias are without symptoms, it can be imagined that patients are often not examined with specific focus on incisional hernias at the outpatient clinic. Diagnosing abdominal wall hernias retrospectively without physical examination, but through questionnaires or from medical records, has been shown to be even more unreliable groin hernias³¹. Incisional hernias after LT are however reported with growing incidence in recent years, reflecting improved survival after LT and greater awareness probably.^{11, 14-16, 21}

A very recent retrospective study reported a high overall incidence of incisional hernia after LT also.¹⁶ They described an incidence of 32.4%. The authors identified early use of mammalian target of rapamycin inhibitors as most important independent risk factor for incisional hernia development after LT. The current cross-sectional study, however, reports an even higher incidence of incisional hernia without use of this immunosuppressive regimen. Montalti et al. identified besides rapamycin, MELD scores greater than or equal to 22 and male sex as independent risk factors for development of incisional hernia after LT.¹⁶ The current study however identified surgical site infection, advanced age and prolonged ICU stay as risk factors related to incisional hernia development after LT. This is more in line with previous studies, investigating risk factors for incisional hernia development after abdominal surgery for other indications.^{14, 20, 22}

Infection of the surgical site is considered to be an important risk factors contributing to the development of incisional hernia in non-transplant patients.^{18, 32-33} This study provides evidence that surgical site infections are the most important risk factor for the development of incisional hernias in transplantation patients as well. Negative effects of immunosuppressive therapy after

LT on patients' immune system can contribute to the high incidence of surgical site infections and therefore increased incidence of incisional hernias due to disturbed and delayed wound healing in the early postoperative period after LT.^{3, 14} The study by Montalti et al. found that the use of immunosuppressive therapy was indeed associated with a higher incidence of incisional hernias.^{14, 16} Intensity of immunosuppressive therapy however could not be verified as an independent risk factor for the development of incisional hernia after LT in the current study. The high incidence of PSC found in the current cohort can also have contributed to the high incidence of surgical site infections as PSC is a known risk factor for SSI after LT due to the frequent presence of infected bile and the need for bilioenteric anastomoses in these patients.³⁴⁻³⁶

Aging is also associated with a decline in many functions of the immune system.³⁷ It has been argued that changes in the immune system may lead to more surgical site infections.³⁸ However, changes in the immune system leading to infection in patients with advanced age are not fully understood.³⁷⁻³⁸ The current study found indeed advanced age to be an independent risk factor for incisional hernia development in patients after LT. This has also been suggested, but not as independent risk factor, in an earlier study by Gomez et al.¹⁹

Malnutrition, with an incidence of up to 40% in the ICU, is found to be associated with impaired immune function, impaired ventilatory drive, and weakened respiratory muscles, leading to prolonged need for ventilatory support in critically-ill patients.³⁹ This might explain the association found in the current study between prolonged ICU stay and incisional hernia development after LT. Muller et al have also suggested this association in an earlier report.¹

Although most incisional hernias in this study were asymptomatic, HRQoL on both SF-36 and BIQ revealed impaired outcomes for patients with an incisional hernia after LT compared to those without an incisional hernia. Patients after LT with an incisional hernia experienced worse HRQoL on the SF-36 components: physical role functioning, vitality, social functioning, emotional role functioning, mental health, mental component summary and reported to be less satisfied on several BIQ questions on body image and cosmesis. The highest impact on HRQoL following the SF-36 was observed for the component 'role emotional', which scored 22 points lower on a 0 – 100 scoring scale in the presence of an incisional hernia in patients after LT. Patients suffering from an incisional hernia reported to be less satisfied with their scar; they scored significantly lower on a 1 – 7 item scale compared to those without an incisional hernia. This negative impact of incisional hernias after LT on HRQoL underscores the importance of prevention of this complication.

In the current study, only patients operated through a J-shaped incision were included. The optimal incision to perform an LT is much debated.^{11, 16, 22} A J-shaped incision is often named as the optimal incision as it combines minimal abdominal wall trauma with sufficient access

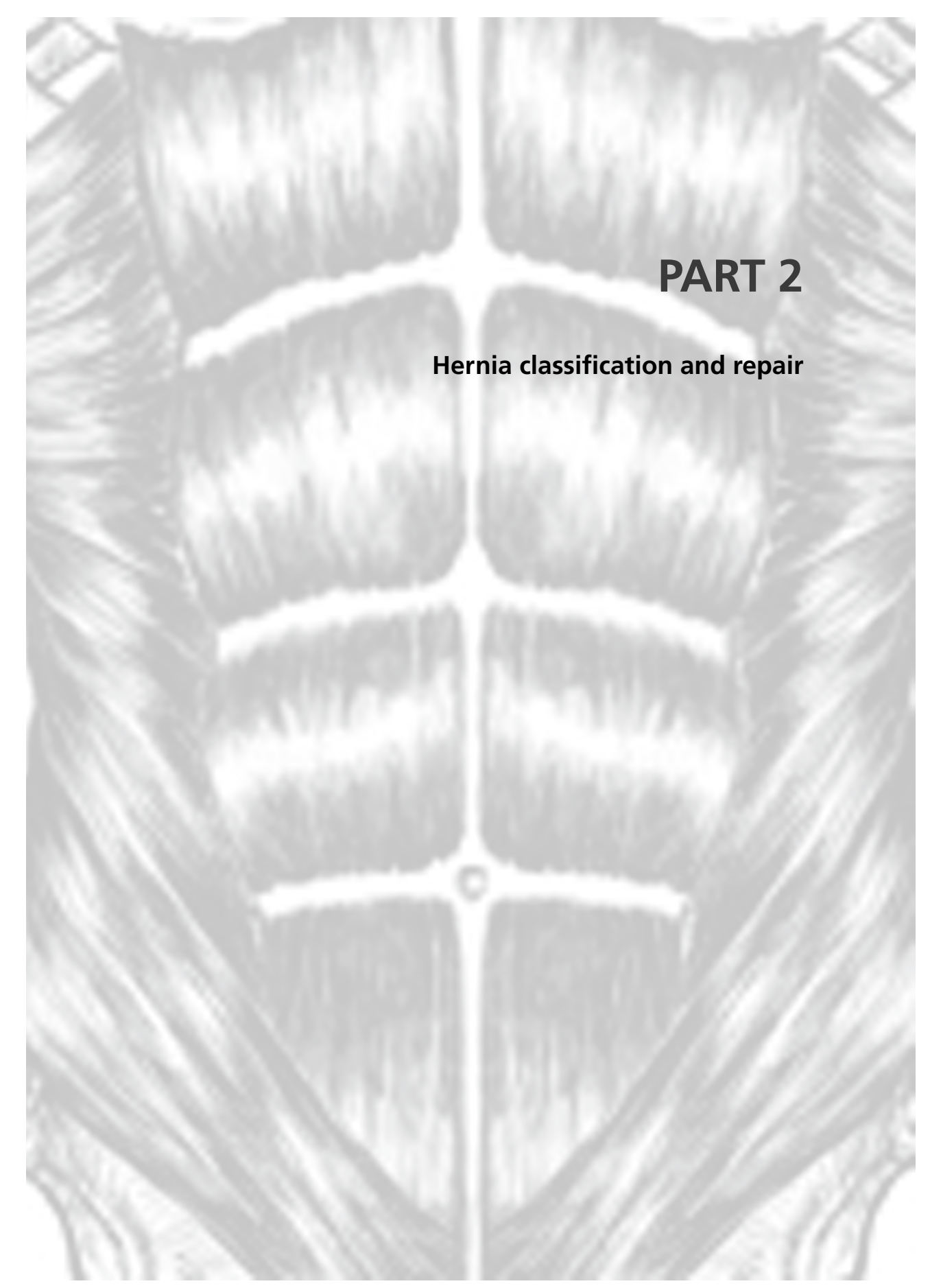
to the abdominal cavity to safely perform an LT. This small incision, however, may also have contributed to the high incidence of an incisional hernia because of increased mechanical strain on the wound with wound retractors, necessary to provide adequate access.¹ The optimal incision type, that combines optimal access to the suprahepatic inferior vena cava, liver hilum and both liver lobes with prevention of long-term complications, such as incisional hernias after LT, remains to be determined, just like the optimal closing technique. Randomized controlled trials on incision types, closure techniques, and prophylactic mesh use and studies with focus on prevention of surgical site infections are needed to tackle this often underestimated complication after LT.

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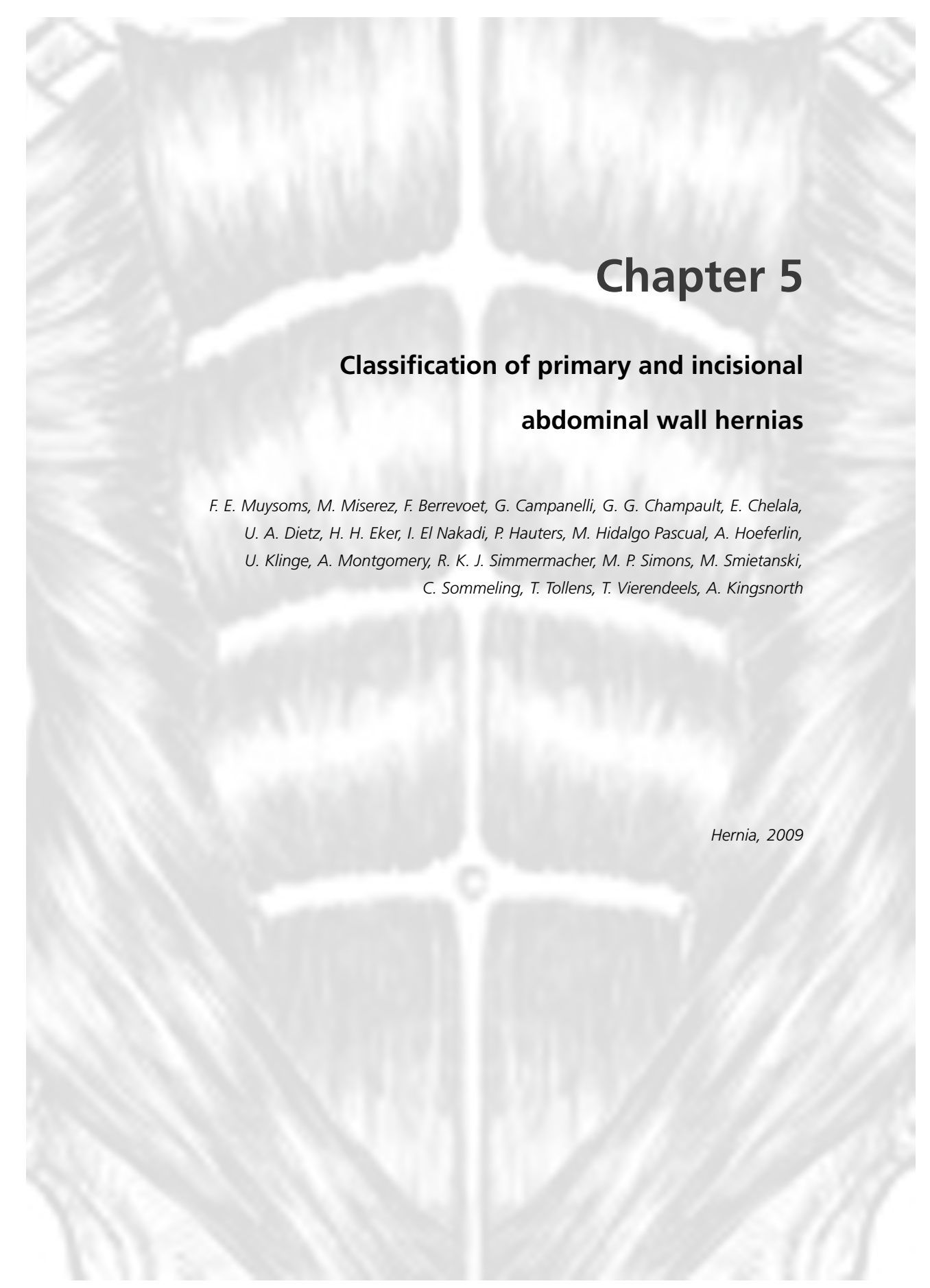
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PART 2

Hernia classification and repair





Chapter 5

Classification of primary and incisional abdominal wall hernias

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Hernia, 2009

ABSTRACT

Purpose A classification for primary and incisional abdominal wall hernias is needed to allow comparison of publications and future studies on these hernias. It is important to know whether the populations described in different studies are comparable.

Methods Several members of the EHS board and some invitees gathered for 2 days to discuss the development of an EHS classification for primary and incisional abdominal wall hernias.

Results To distinguish primary and incisional abdominal wall hernias, a separate classification based on localisation and size as the major risk factors was proposed. Further data are needed to define the optimal size variable for classification of incisional hernias in order to distinguish subgroups with differences in outcome.

Conclusions A classification for primary abdominal wall hernias and a division into subgroups for incisional abdominal wall hernias, concerning the localisation of the hernia, was formulated.

Keywords Abdominal wall hernia Classification Incisional hernia Ventral hernia Umbilical hernia Epigastric hernia

INTRODUCTION

At the 29th Congress of the European Hernia Society in Athens in May 2007, Andrew Kingsnorth, the president of the EHS, stressed that a classification of ventral and incisional hernias is important because at this moment we are comparing “apples and oranges” in the different studies that are published and presented at meetings.¹

Already in 2000, Schumpelick stated that a classification of incisional hernias, like we have for groin hernias, is urgently needed. “Despite the magnitude of the problem, we do not have a classification that is simple, reproducible and internationally accepted”.²

Since 2000, several authors have proposed classifications for incisional hernias, but none of them are widely used in the literature on incisional hernias.²⁻⁵

MATERIALS AND METHODS

Methodology

Several members of the EHS board and some invitees gathered at the initiative of the Belgian Section for Abdominal Wall Surgery (BSAWS) and the Dutch Hernia Society (DHS) for 2 days to discuss the development of an EHS classification for primary and incisional abdominal wall hernias.¹

During an initial discussion, the existing proposals were briefly presented by one of the participants. Thereafter, a decision was taken concerning the purpose of a classification and the scope of this consensus meeting. Some of the participants saw it mainly as a search for a simple classification.

¹ At the initiative of the first author, Filip Muysoms, current president of the Belgian Section for Abdominal Wall Surgery (BSAWS), and in collaboration with Rogier Simmermacher [member of the Dutch Hernia Society (DHS) and Secretary for Educational of the European Hernia Society (EHS)] and with Marc Miserez (member of BSAWS and Secretary Scientific Research of the EHS), a consensus meeting on the classification of primary and incisional abdominal wall hernias was organised. The BSAWS and the DHS are the National Chapters of the EHS, respectively from Belgium and The Netherlands. A first preparatory meeting took place with members of both Chapters during a whole day session in La Hulpe, Belgium, on 4 April 2008. This was followed by a second meeting in Brussels, Belgium, on 16 September 2008.

As participants to the consensus meeting, held in Ghent, Belgium, on 2–4 October 2008, we invited the board members and past presidents of the EHS (A. Kingsnorth, G. Campanelli, G.G. Champault, A. Hoeflerlin, S. Mandala, M. Miserez, R.K.J. Simmermacher, M. Smietanski, J.B. Flament and M. Hidalgo), the board members of the BSAWS (F.E. Muysoms, F. Berrevoet, E. Chelala, I. El Nakadi, P. Hauters, C. Sommeling, T. Tollens and T. Vierendeels) and the board members of the DHS (H.H. Eker and M.P. Simons). In addition we invited some other European experts (U.A. Dietz, U. Klinge and A. Montgomery) who by publications and organisation of national registries have shown major interest in hernia classification.

Because it was supported by and originated from the EHS, this classification could have a greater application in hospitals and in the surgical literature than the previous proposals published originating from one centre. Others were more in favour of an open structured approach, in which “scientists” would gather a maximum number of data sets in a prospective registry. With this registry, it was hoped to discover the most valuable and important risks factors for recurrence in order to direct future guidelines and therapeutic choices. It was decided to focus first on a simple, reproducible classification, because getting results out of the registry may take many years. A classification was proposed as such, including localisation of the hernia and the size of the hernia defect as decisive for the outcome, not going into its use to direct therapeutic choices for the present time. During the last session of the meeting, the development of a large, broad and open structured European registry was initiated.

Currently existing classifications

Chevrel and Rath³ proposed a classification for incisional hernias in 2000. This classification is attractive, because it is simple, and the data required to reach the classification are readily obtained. Three parameters were utilised. Firstly, the localisation of the hernia of the abdominal wall: divided into median (M1–M4) and lateral (L1–L4) hernias. Secondly, the size of the hernia: it was postulated that the width of the hernia defect is the most important parameter (greater than hernia defect surface, length of the hernia or size of the hernia sac), which was divided into four groups (W1–W4). As a third parameter of this classification, subgroups were made for incisional hernias and recurrences: the number of previous hernia repairs was recorded as (R0, R1, R2, R3,...). Although apparently easy to use, this classification has not been commonly used in the literature.

In his book on hernia surgery, “Hernien”, Schumpelick described a classification that divided incisional hernias into five classes.² The size of the defect, the clinical aspect of the hernia in lying and standing position, the localisation of the incision and the number of previous repairs were used for this classification.

Korenkov et al.⁴ reported on the results of an expert meeting on classification and surgical treatment of incisional hernia, but no detailed classification proposal resulted from this meeting. Ammaturo and Bassi⁶ suggested an additional parameter to the Chevrel classification. The ratio between the anterior abdominal wall surface and the wall defect surface predicts a strong abdominal wall tension when closing the defect, with possible abdominal compartment syndrome development, and thus might influence the choice of surgical technique.

Recently, Dietz et al.⁵ proposed another alternative classification of incisional hernias in which variables like body type, hernia morphology and risk factors for recurrence were included and recommendations made for surgical repair based on the different types. It is based on a self-

explanatory taxonomy and is intended to tailor the repair to the body type and risk factors of the individual patient.

The Swedish Abdominal Wall Hernia Registry presented their data collection sheet for incisional and ventral hernias at the EAES congress in Stockholm in June 2008, which forms the basis for a classification and includes many prognostic relevant variables. For this reason Agneta Montgomery was invited to the consensus meeting to present the method of classification used in Sweden.

Purpose of a classification

The primary purpose of any classification should be to improve the possibility of comparing different studies and their results. By describing hernias in a standardised way, different patient populations can be compared. The secondary purpose of a classification would be to collect results of different surgical techniques from the literature and develop evidence-based therapeutic guidelines using the classification. When a classification would become generally accepted, future studies might use the subgroups within the classification in their prospective registries and within the inclusion criteria for prospective studies.

Scope of the classification: primary ventral hernias versus incisional ventral hernias

The first decision to take was whether the classification would involve primary ventral hernias and incisional ventral hernias in one classification or if two separate classifications were preferable. A consensus was reached on the decision to separate the two entities, since in the authors' opinion primary ventral hernias have a different aetiopathology compared with incisional abdominal wall hernias resulting from failure of a previous incision. The group reached agreement on separating non incisional hernias, "primary abdominal wall hernias" (also known as "ventral"), and the other "incisional abdominal wall hernias". A recurrent hernia after a primary abdominal wall hernia treatment will then fall into the incisional hernia group. To avoid confusion, the word "primary incisional hernia" should not be used.

There was a consensus to exclude "parastomal hernias" from this classification. Although they are by definition incisional hernias, they make up a distinct group, with specific properties and treatment options.

Format of the classification

In 2007 the EHS published a simple classification for groin hernias.⁷ We agreed that a classification for primary abdominal wall hernias and incisional hernias should preferably be in a similar format to the EHS groin hernia classification. This would involve the development of a grid format for the classification, although this may place restrictions on the number of variables that can be used in this classification.

Variables for classification

When proposing a classification, it is important to determine the most suitable variables to include in the classification. However, it is important to keep a classification simple and practical to use. In Table 1 the potential variables are listed, as well as their use in previously proposed classifications. It is impossible to take all these variables into account for a practical classification, so a decision on inclusion or exclusion of various parameters was made.

Classification of primary abdominal wall hernias

For the primary abdominal wall hernias, there was agreement on the use of localisation and size as the two variables to use.

Localisation of the hernia

Two midline (epigastric and umbilical) and two lateral hernias (Spigelian and lumbar) are identifiable entities with distinct localisations.

Size of the hernia

Primary abdominal wall hernias are usually more or less round or oval shaped. Therefore, the size can be described with one measurement. Width and length will be more or less comparable most of the time. We agreed to use the "diameter" of the primary abdominal wall hernia as the second variable. Cutoff values of 2 and 4 cm were chosen to describe three subgroups according to size: small, medium and large.

Taxonomy

For the primary abdominal wall hernias, the choice was made for nominative description: epigastric, umbilical, small, medium and large.

Classification table

In Table 2 the grid format for classification of primary abdominal wall hernias is proposed.

Table 1 Possible variables to use for classifying primary and incisional abdominal wall hernias and their use in previous classifications

PRIMARY OR INCISIONAL ABDOMINAL WALL HERNIAS	VARIABLES FOR CLASSIFICATION OF		Chevrel & Rath [3]		Korenkov et al. [4]		Shumpelick [2]		Ammarturo & Bassi [6]		Swedisch registry		Dietz et al. [5]	
	Size of the hernia defect: surface area, length, width		Width		Width or length		Maximal size		Width		Width and length		Width and length	
Size of the hernia sac														
Number of hernia defects							X				X			
BMI of the patient											X		X	
Ratio anterior abdominal wall surface/ wall defect surface									X					
Ratio between the abdominal volume / the volume of the hernia sac														
Primary versus incisional hernias														
Recurrent hernias (number of previous repairs)			X		X		X		X		X		X	
Previous mesh implantation											X			
Indication for primary operation of the incisional hernia											X			
Type and localisation of the incision											X			
Symptoms of the hernia											X			
Reducibility of the hernia											X			
Localisation of the hernia			X		X		X		X		X		X	
The anatomy of the patient in the subcostal area: sternocostal angle													X	
Risk factors for hernia recurrence													X	

Table 2 European Hernia Society classification for primary abdominal wall hernias

E H S Primary Abdominal Wall Hernia Classification		Diameter cm	Small <2cm	Medium ≥2-4cm	Large ≥4cm
Midline	Epigastric				
	Umbilical				
Lateral	Spigelian				
	Lumbar				

Classification of incisional abdominal wall hernias

Definition of incisional hernia

It was decided to use the definition proposed by Korenkov et al.⁴: “Any abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging”.

Choice of variables used to classify

The task of developing a good classification for incisional hernias is much more difficult than for groin hernias or for primary abdominal wall hernias because of their great diversity. On the other hand, because of this diversity a classification is highly desirable in this group of hernias. The question remains as to whether a simple classification can cover the complexities of the great diversity of incisional hernias and their different variables.

There was a consensus that the localisation of the hernia on the abdominal wall and the size of the hernia defect are essential for classifying. There was less agreement on the inclusion of the number of previous hernia repairs as a variable for classifying. Including more variables (Table 1) in the classification will make it more complex and less practical. Other variables and risk factors will be part of the above-mentioned registry, but for the present, will not be part of a simple classification.

Localisation of the hernia

The abdomen was divided into a medial or midline zone and a lateral zone.

Medial or midline hernias

The borders of the midline area are defined as: (1) cranial: the xyphoid

(2) caudal: the pubic bone

(3) lateral: the lateral margin of the rectal sheath

Thus, all incisional hernias between the lateral margins of both rectus muscle sheaths are classified as midline hernias.

The Chevrel classification uses three midline zones.³ Our group agreed that hernias close to bony structures have separate subgroups. They pose specific therapeutic approaches and have an increased recurrence risk. An easily memorable classification from M1 to M5 going from the xiphoid to pubic bone was proposed (Fig. 1). Therefore, we define 5 M zones:

- (1) M1: subxiphoidal (from the xiphoid till 3 cm caudally)
- (2) M2: epigastric (from 3 cm below the xiphoid till 3 cm above the umbilicus)
- (3) M3: umbilical (from 3 cm above till 3 cm below the umbilicus)
- (4) M4: infraumbilical (from 3 cm below the umbilicus till 3 cm above the pubis)
- (5) M5: suprapubic (from pubic bone till 3 cm cranially).

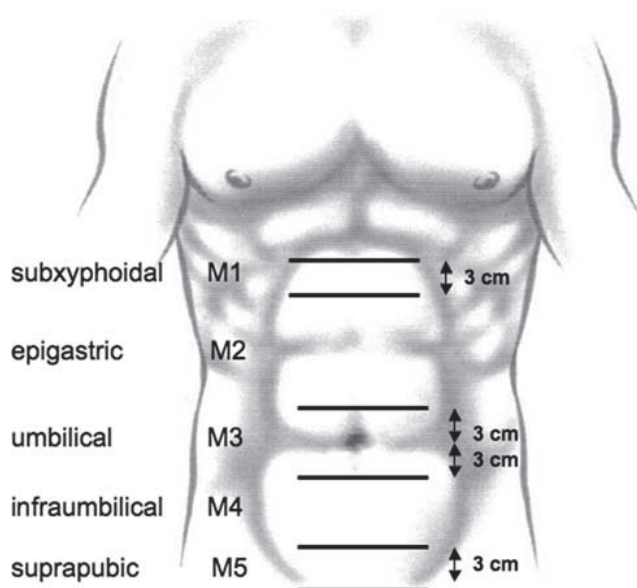


Fig. 1 To classify midline incisional hernias between the two lateral margins of the rectus muscle sheaths, five zones were defined

Several questions arose from this classification:

- (1) How should hernias extending over more than one M zone be classified? No consensus was reached on this. One proposal was to allocate hernias to the M zone that is generally considered as the more difficult or more representative for the hernia. They are, in order of importance: first subxyphoidal (M1) and suprapubic (M5), then umbilical (M3) and finally epigastric (M2) and infraumbilical (M4). This would avoid making further subgroups (e.g. M1-2/M1-2-3/M2-3-4). So a hernia extending from M1 over M2 to M3 (thus from subxyphoidal to the umbilicus) would be classified as M1 (thus as a subxyphoidal hernia). A hernia extending from M2 over M3 to M4 (thus from epigastric to infraumbilical) would be classified as M3 (thus as an umbilical hernia). No consensus was reached on this. It was decided to mark every zone in which the hernia was located when using the grid for incisional hernias.
- (2) How should incisional hernias with multiple defects be classified? Different hernia defects caused by one incision will be considered as one hernia. If the different defects were caused by two different incisions, they should be considered two different hernias.

Lateral hernias

The borders of the lateral area are defined as (Fig. 2).

- (1) cranial: the costal margin
- (2) caudal: the inguinal region
- (3) medially: the lateral margin of the rectal sheath
- (4) laterally: the lumbar region.

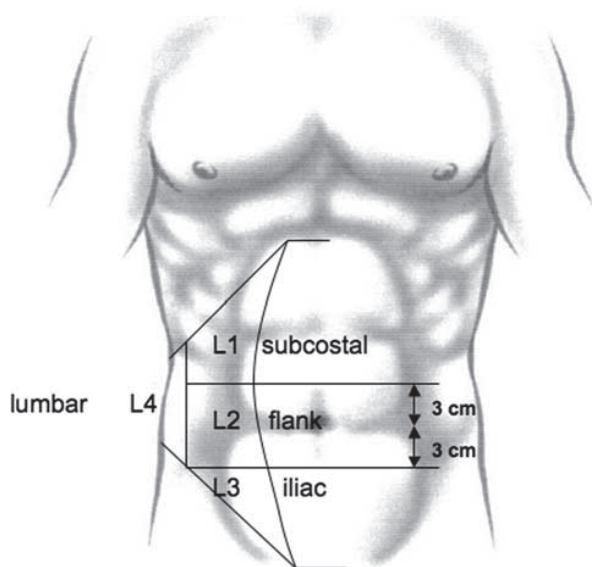


Fig. 2 To classify lateral incisional hernias, four zones lateral of the rectus muscle sheaths were defined

Thus, four L zones on each side are defined as:

- (1) L1: subcostal (between the costal margin and a horizontal line 3 cm above the umbilicus)
- (2) L2: flank (lateral to the rectal sheath in the area 3 cm above and below the umbilicus)
- (3) L3: iliac (between a horizontal line 3 cm below the umbilicus and the inguinal region)
- (4) L4: lumbar (latero-dorsal of the anterior axillary line)

Taxonomy

Once subgroups had been defined, it was important to give them a name. Some of the experts were in favour of using simple coded notations similar to the Chevrel classification: M1, M2, M3,... L1, L2,... W1, W2,... Others preferred a descriptive name: umbilical, supraumbilical, subcostal,... The advantage of a nominative description over a coded description is that it is more self-explanatory and comprehensible. No real consensus was reached over this topic, and a combination of coded and nominative descriptions is proposed.

Much discussion took place concerning the best word to describe the area on the lateral side of the abdomen below the subcostal region and above the iliac region. It was agreed that the word "transverse" as used in the Chevrel classification was not satisfactory. Finally, it was agreed to call this area the "flank".

Size of the hernia

In contrast to primary abdominal wall hernias, incisional hernias come in many different sizes and shapes. So the size of an incisional hernia is not easily captured in only one variable or measurement. For classification in the two-dimensional grid format, it is essential to bring the variable "size of the hernia defect" in one quantitative or semi-quantitative measure. Chevrel solved this problem by choosing the width of the hernia defect as the one parameter to classify, stating that the width is the most important measurement of size to determine the difficulty of successfully repairing the hernia [3].

There was a consensus that the width of the hernia defect alone was insufficient to describe the hernia defect size adequately. We agreed that width and length should be used. This means that for a "grid format" both width and length have to be combined in one measurement.

The width of the hernia defect was defined as the greatest horizontal distance in cm between the lateral margins of the hernia defect on both sides. In case of multiple hernia defects, the width is measured between the most laterally located margins of the most lateral defect on that side (Fig. 3).

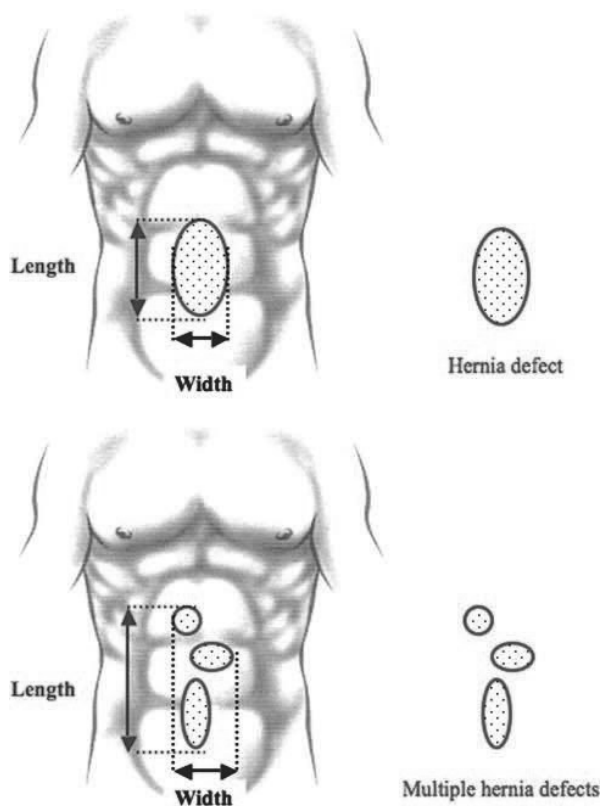


Fig. 3 Definition of the width and the length of incisional hernias for single hernia defects and multiple hernia defects

The length of the hernia defect was defined as the greatest vertical distance in cm between the most cranial and the most caudal margin of the hernia defect. In case of multiple hernia defects from one incision, the length is between the cranial margin of the most cranial defect and the caudal margin of the most caudal defect (Fig. 3).

Hernia defect surface can be measured by combining width and length in a formula for an oval, thus trying to make an estimation of the real surface in cm^2 . This option was not withheld, because many incisional hernias are not oval shaped, and many hernias have multiple defects, making the correct estimation of hernia defect size difficult.

Because no consensus was reached on the variable "size of the hernia defect", it was not possible to make a "grid format" for an EHS classification for incisional abdominal wall hernias. Instead, the grid could be made for the localisation variable with space to note width and length correctly in cm. A semi-quantitative division, taking only the width as measurement for the size, was

accepted to be included in the classification table. To avoid confusion with primary abdominal wall hernias (small, medium and large), a coded taxonomy was chosen ($W1 < 4$ cm; $W2 \geq 4$ –10 cm; $W3 \geq 10$ cm) instead of a nominative one.

Previous hernia repairs

Several participants in the meeting considered that if an incisional hernia is a recurrence after previous repair of a hernia—either incisional or primary—then this variable should be included in the classification. The number of previous hernia repairs was not considered of enough importance to include in the table. A simple yes or no answer was chosen.

Classification table

In Table 3 the format for classification of incisional abdominal wall hernias is proposed.

Table 3 European Hernia Society classification for incisional abdominal wall hernias

E H S				
Incisional Hernia Classification				
Midline	subxiphoidal	M1		
	epigastric	M2		
	umbilical	M3		
	infraumbilical	M4		
	suprapubic	M5		
Lateral	subcostal	L1		
	flank	L2		
	iliac	L3		
	lumbar	L4		
Recurrent incisional hernia?		Yes O No O		
length:		width:		cm
Width	W1	W2	W3	
	<4cm	≥ 4 –10cm	≥ 10 cm	
	O	O	O	

CONCLUSION

The goal of the consensus meeting, i.e. to make a definitive EHS classification of incisional hernias in a grid format, as has been done for inguinal hernias, was not realised. However, a classification for primary abdominal wall hernias and a division of subgroups of incisional abdominal wall hernias, concerning the localisation of the hernia, was formulated. Because no consensus was reached on a single size variable in incisional hernias, a simple classification grid was not possible.

Nevertheless, the participants in this meeting believe that, besides a more “scientific” registry (including risk factors, treatment and outcome data), a simple classification is urgently needed. This classification may provide enough information to establish incisional hernia registries and may be used to compare studies on treatment and outcome of incisional hernia repair. It has shortcomings, because of the large diversity and heterogeneity of incisional hernias, but it is a mandatory condition to improve the quality of reporting results in the field of incisional hernia surgery.

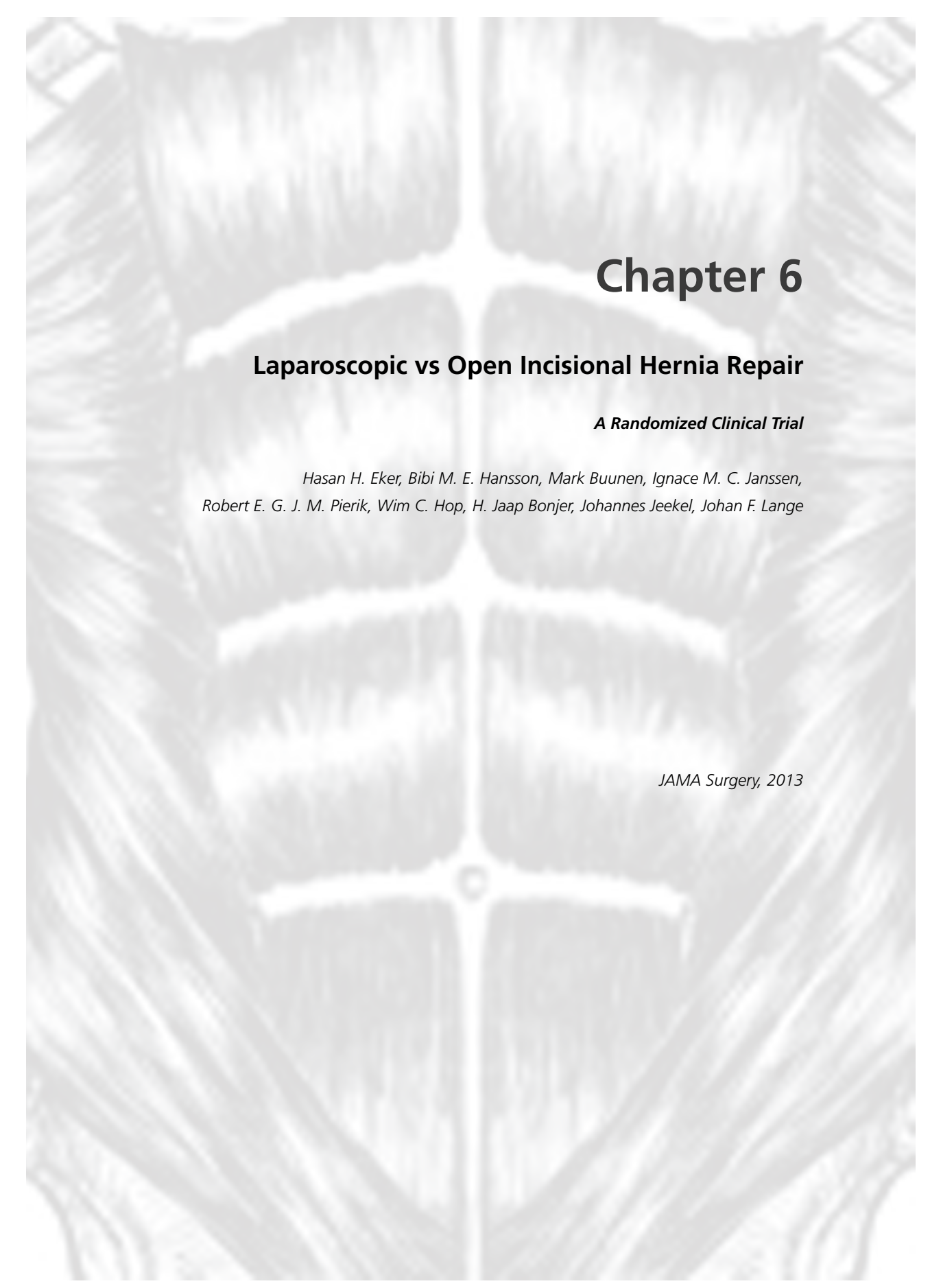
Therefore, we must use the momentum created by this first consensus meeting on classification of primary and incisional abdominal wall hernias. The current proposal should be tested and validated in our surgical practices. This will provide a basis for a new consensus meeting to try to define subgroups based on the size of the hernia defect.

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Chapter 6

Laparoscopic vs Open Incisional Hernia Repair

A Randomized Clinical Trial

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ABSTRACT

Importance: Incisional hernia is the most frequent surgical complication after laparotomy. Up to 30% of all patients undergoing laparotomy develop an incisional hernia.

Objective: To compare laparoscopic vs open ventral incisional hernia repair with regard to postoperative pain and nausea, operative results, perioperative and postoperative complications, hospital admission, and recurrence rate.

Design: Multicenter randomized controlled trial between May 1999 and December 2006 with a mean follow-up period of 35 months.

Setting: All patients were operated on in a clinical setting at 1 of the 2 participating university medical centers or at the other 8 teaching hospitals.

Participants: Two hundred six patients from 10 hospitals were randomized equally to laparoscopic or open mesh repair. Patients with an incisional hernia larger than 3 cm and smaller than 15 cm, either primary or recurrent, were included. Patients were excluded if they had an open abdomen treatment in their medical histories.

Intervention: Laparoscopic or open ventral incisional hernia repair.

Main Outcome Measures: The primary outcome of the trial was postoperative pain. Secondary outcomes were use of analgesics, perioperative and postoperative complications, operative time, postoperative nausea, length of hospital stay, recurrence, morbidity, and mortality.

Results: Median blood loss during the operation was significantly less (10 mL vs 50 mL; $P = .05$) as well as the number of patients receiving a wound drain (3% vs 45%; $P .001$) in the laparoscopic group. Operative time for the laparoscopic group was longer (100 minutes vs 76 minutes; $P = .001$). Perioperative complications were significantly higher after laparoscopy (9% vs 2%). Visual analog scale scores for pain and nausea, completed before surgery and 3 days and 1 and 4 weeks postoperatively, showed no significant differences between the 2 groups. At a mean follow-up period of 35 months, a recurrence rate of 14% was reported in the open group and 18%, in the laparoscopic group ($P = .30$). The size of the defect was found to be an independent predictor for recurrence ($P .001$).

Conclusions and Relevance: During the operation, there was less blood loss and less need for a wound drain in the laparoscopic group. However, operative time was longer during laparoscopy. Perioperative complications were significantly higher in the laparoscopic group. Visual analog scores for pain and nausea did not differ between groups. The incidence of a recurrence was similar in both groups. The size of the defect was found to be an independent factor for recurrence of an incisional hernia.

Incisional hernia is the most frequent surgical complication after laparotomy. Up to 30% of all patients undergoing laparotomy develop an incisional hernia. This is associated with discomfort, pain, respiratory restriction, and dissatisfactory cosmetic results.¹⁻⁶ The associated morbidity of ten results in subsequent hernia repair.^{7,8}

Although significant improvements have been achieved in the field of incisional hernia concerning operative technique and the use of prosthetic materials, recurrence rates remain high at 32% to 63%.⁹ Risk factors associated with recurrence, such as hernia size, unfortunately cannot be influenced.¹⁰ The quest for more effective and less invasive techniques continues.

The introduction of minimally invasive surgery in the early 1990s enabled the possibility of laparoscopic incisional hernia repair.¹¹ Laparoscopy has proved to be a safe, effective, efficient, and less painful technique for many types of surgery and has become the current “gold standard” for cholecystectomy, for example.¹² Laparoscopic incisional hernia repair is a widely used and accepted operative technique, assuming general advances of laparoscopy are also valid for this group. Recent studies have shown that in the short term laparoscopic repair is superior to open repair in terms of less blood loss, fewer perioperative complications, and shorter hospital stay.^{13,14} Long-term outcomes such as recurrence rates are yet unknown. So far, level 1 randomized clinical trials for benefits or disadvantages of laparoscopic incisional hernia repair are scarce.¹⁵

The ongoing debate about the expected merits of laparoscopic vs open incisional hernia repair prompted the need for a level 1 randomized controlled trial. The aim of this study was to compare laparoscopic vs open ventral incisional hernia repair with regard to postoperative pain and nausea, operative time, blood loss, perioperative and postoperative complications, length of hospital stay, and recurrence rates.

METHODS

Approval was obtained from the Erasmus Medical Center ethical committee and the local ethical committees of all 9 participating centers prior to enrollment of patients in this study. Informed consent was obtained for all patients. The consent form and consent process were carefully evaluated by the Erasmus Medical Center ethical committee and data monitoring committee on a continual basis. All participating centers provided experienced and dedicated hernia surgeons. Inclusion criteria were hernia diameter between 3 and 15 cm, location at the ventral abdominal wall at least 5 cm from the costae and inguinal area, indication for elective repair, age 18 years or older, and written informed consent. Exclusion criteria included a contraindication for pneumoperitoneum, an absolute contraindication for general anesthesia, and a history of an open abdomen treatment. Patients participating in other trials were also excluded.

After obtaining informed consent, patients were randomized by computer-generated lists stratified by center and primary or recurrent incisional hernia. Patients and medical staff were not blinded to the allocated procedure.

Laparoscopic incisional hernia repair

Laparoscopic incisional hernia repair was performed through 3 to 5 abdominal trocars (one 10 mm and 2 to four 5 mm). Pneumo-peritoneum was achieved by Veress needle or open introduction of a blunt-tip trocar for inflation with carbon dioxide to achieve intra-abdominal pressure up to 15 mm Hg. A 0 or 30 laparoscope was used to provide a view of the inner surface of the abdominal wall. The additional 5-mm trocars were positioned at the opposite site of the hernia. The hernia port size was measured. Extensive adhesiolysis was performed if necessary using diathermy. The omentum and bowel were detached from the abdominal wall to expose the hernial defect. The hernia sac was not dissected. The mesh was introduced into the abdominal cavity through the 10-mm trocar. The mesh was then placed over the defect with at least 5-cm overlap at all sides. Fixation of the mesh was achieved by 5-mm nonabsorbable tackers (Protack AutoSuture; Tyco Healthcare). A concentric ring of tackers was placed in the peripheral margin of the mesh. Transfascial sutures were often used for mesh positioning and supplementary fixation. Hemostasis was achieved before removal of the trocars. All 10-mm trocar fascial defects were closed. Skin defects were closed with absorbable monofilament sutures.

Open incisional hernia repair

Incisions were made in the old scar depending on the localization and size of the hernia. The subcutaneous layer and scar tissue were dissected from the abdominal wall to identify and expose the hernia sac. The hernia port size was measured. Dissection of the hernia sac from beneath the rectus muscles was performed if possible.

Opening and resection of the hernia sac was avoided. Whenever possible, the posterior rectus sheath or peritoneum was dissected from the rectus muscles. After closing of the peritoneum or posterior rectus sheath, a mesh was positioned preperitoneally or in the sublay position, respectively, with at least 5-cm overlap at all sides. The mesh was fixated to the rectus muscle at each corner and side with nonabsorbable (polypropylene) sutures. The anterior rectus sheath was closed only if tension-free repair was possible. The use of wound drainage was not protocolized for the study. Subcutaneous drains with low-vacuum closed systems were placed in case of large dissection areas. The skin was closed with mono-filament absorbable sutures or staples.

Postoperative care

After the operation, patients were transported to the surgical ward. Patients in whom extubation was not possible were admitted to the intensive care unit for observation and ventilatory support. Postoperative analgesia consisted of paracetamol and nonsteroidal anti-inflammatory drugs or intravenous analgesics if necessary. Patients were discharged from the hospital when they mobilized autonomously.

Primary and secondary outcomes

The primary outcome of the trial was postoperative pain. Secondary outcomes were use of analgesics, perioperative and post-operative complications, operative time, postoperative nausea, length of hospital stay, recurrence, morbidity, and mortality.

Follow-up evaluation

Preoperatively, patients were asked to complete visual analog scales for pain and nausea. Follow-up visual analog scales were completed at 3 days, 1 week, and 4 weeks postoperatively. After discharge from the hospital, patients were invited for follow-up visits at outpatient clinics at 1 week, 6 weeks, 1 year, and 5 years.

Statistical analyses

All patient data were analyzed on an intention-to-treat basis. Patients who did not undergo incisional hernia repair or withdrew consent were excluded from analysis.

Since there were no data available in this field at the time, prior power calculation could not be performed. It was thought that relevant differences could be detected with 200 patients.

Time until recurrence was evaluated using Kaplan-Meier curves and the log-rank test. Pain and nausea visual analog scale scores were compared with repeated-measures analysis of variance. Other continuous variables were compared using an independent-samples *t* test or Mann-Whitney test in cases of nonnormal distribution.

Statistical analysis was performed using SPSS (IBM). *P* .05 (2-tailed) was considered significant.

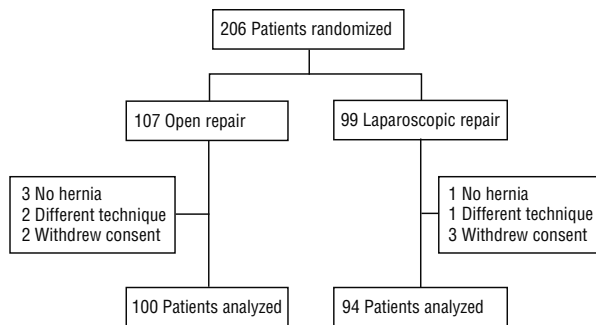
RESULTS

Between May 1999 and December 2006, 206 patients were randomly assigned to undergo either laparoscopic (*n* = 99) or open (*n* = 107) incisional hernia repair. The 2 groups were similar in age, sex ratio, mean body mass index, American Society of Anesthesiologists score, hernia size, and preoperative comorbidity (Table 1). Twelve patients withdrew consent or underwent no incisional hernia repair after randomization. In total, 194 patients were included for analysis (Figure 1).

Table 1. Patient Characteristics

Characteristics	Open (n=100)	Laparoscopic (n=94)	P value
Male – (%)	59 (59)	56 (60)	0.94
Age, years – mean (SD)	56.7 (12.8)	59.1 (12.8)	0.80
Pre-operative Body Mass Index (kg/m ²) – mean (SD)	29.3 (4.6)	28.3 (4.7)	0.81
Primary incisional hernia – (%)	82 (82)	71 (76)	0.27
Recurrent incisional hernia – (%)	18 (18)	23 (24)	
Hernia diameter size, cm – median (IQR)	5 (4-10)	5 (4-8)	0.44
ASA class – no (%)			0.43
I	25 (25)	21 (22)	
II	52 (52)	56 (60)	
III	19 (19)	12 (13)	
IV	1 (1)	0	
Missing data	3 (3)	5 (5)	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); IQR, interquartile range.

**Figure 1.** Flowchart of patients in the study.

Operative results

Operative data for both groups are shown in Table 2. The mean operative time in the laparoscopic group was significantly longer than in the open group (76 minutes vs 100 minutes; $P = .001$). In the laparoscopic group, 8 of the 94 patients (8.5%) required conversion to open repair because of technical reasons. The estimated blood loss was significantly higher in the open group compared with the laparoscopic group (median, 50 mL vs 10 mL; $P = .05$). None of the patients required blood transfusion. Closed suction drains were placed subcutaneously in 45 patients in the open group and in the abdominal cavity in 3 patients in the laparoscopic group ($P < .001$).

Table 2. Perioperative Outcomes

Results	Open (n=100)	Laparoscopic (n=94)	P value
Operative time, minutes – mean (SD)	76 (33)	100 (49)	0.001
Estimated blood loss, ml – median (IQR)	50 (10-100)	10 (1-40)	0.05
Conversion – no. (%)	-	8 (8.5)	0.003
Wound drain – no. (%)	45 (45)	3 (3)	<0.001
Length of hospital stay, days – median (IQR)	3 (2-5)	3 (2-4)	0.50

Abbreviations: ellipses, not applicable; IQR, interquartile range.

The overall perioperative complication rate for laparoscopic repair (10%) was significantly higher than open repair (2%) ($P = .049$). The operative complications included enterotomy, serosal bowel injury, and bladder perforation. Postoperative complications occurred more often in the laparoscopic group; however, the difference in postoperative complications was not significant (35% vs 26%; $P = .13$). Important postoperative complications in both groups were hematomas, wound infections, airway infections, and urinary tract infections (Table 3). The median duration of hospital stay was similar in the laparoscopic and open groups (3 days [interquartile range (IQR), 2-4 days] and 3 days [IQR, 2-5 days] days, respectively; $P = .50$). Preoperative measured hernia size was equal in both groups (median, 5 cm [IQR, 4-10 cm] in the open group vs 5 cm [IQR, 4-8 cm] in the laparoscopic group; $P = .44$).

Postoperative pain and nausea

There were no significant differences in preoperative and postoperative pain scores (Figure 2). During 4 weeks of follow-up, pain scores were similar. At the 4-week follow-up, 23 patients (25%) in the laparoscopic group and 24 patients (24%) in the open group reported persisting pain, requiring prolonged analgesia use ($P = .54$). Visual analog scale scores for nausea were also comparable for both groups.

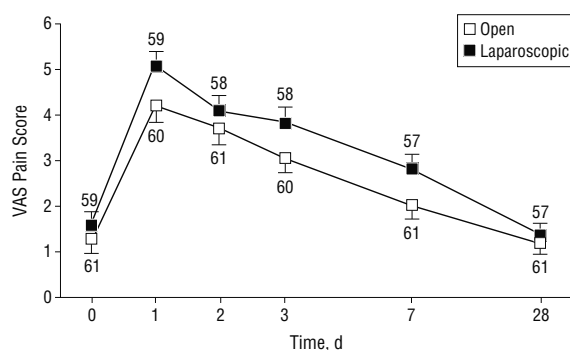


Figure 2. Visual analog scale (VAS) scores for postoperative pain. The numbers that are reported in the Figure indicate the number of patients evaluated at the different times. The error bars represent standard errors.

Table 3. Intraoperative and postoperative complications

No. of patients (No. of complications)

	Open (n=100)	Laparoscopic (n=94)	P value
Intraoperative complications	2 (2)	9 (9)	0.049
Serosal bowel injury (%)	-	1 (1)	
Enterotomy (%)	1 (1)	5 (5)	
Urinary bladder perforation (%)	-	1 (1)	
Other	1 (1)	2 (2)	
Postoperative complications	26 (35)	35 (51)	0.13
Wound infection (%)	5 (5)	4 (4)	
Wound dehiscence (%)	3 (3)	-	
Fascia dehiscence (%)	1 (1)	-	
Hematoma (%)	11 (11)	10 (11)	
Seroma (%)	4 (4)	7 (7)	
Severe pain (%)	-	12 (13)	
Airway infection (%)	3 (3)	3 (3)	
Urinary tract infection (%)	1 (1)	4 (4)	
Flebitis (%)	2 (2)	-	
Ileus (%)	-	2 (2)	
Postoperative bleeding (%)	1 (1)	2 (2)	
Relaparotomy (%)	1 (1)	2 (2)	
Other (%)	3 (3)	5 (5)	

Follow-up/recurrence

At a mean (SD) follow-up of 35 (33.3) months after index surgery, 146 of 194 patients (75%) completed follow-up (Figure 3). Patients were examined at the outpatient clinic for the presence of incisional hernia in standing and decubitus positions. In case of doubt, ultra-sonography or computed tomography scan was performed. Cumulative recurrence rates were 18% (n = 17) in the laparoscopic group vs 14% (n = 14) in the open group ($P = .30$) (Table 4). Recurrence rates in the different hospitals ranged from 0% to 33%. There were no significant differences between centers regarding recurrence rates.

Table 4. Follow-up

	Open (n=100)	Laparoscopic (n=94)	P value
Mean follow up – mean months (SD)	36.5 (33.1)	34.2 (33.5)	0.40
Recurrence rate – no. (%)	14 (14)	17 (18)	0.30a

^a Calculated using the log-rank test.

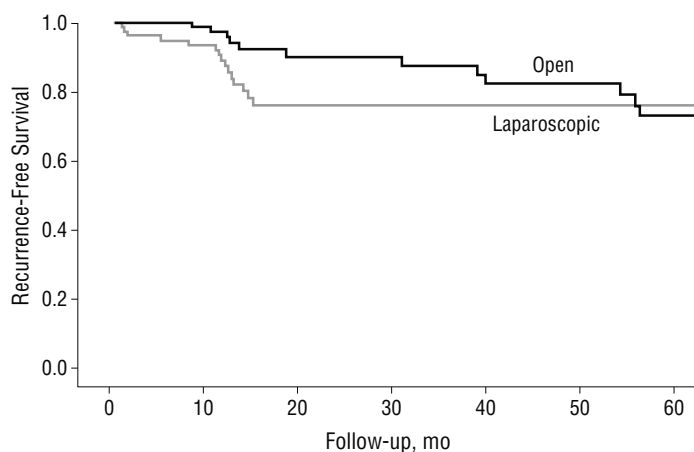


Figure 3. Follow-up for recurrence.

COMMENT

The underlying study is not the first evaluation of the value of laparoscopic incisional hernia repair. Earlier trials were either not randomized, enrolled small numbers of patients, or included varied study populations. To our knowledge, this multicenter study is the largest randomized controlled trial comparing laparoscopic and open incisional hernia repair.

In our study, laparoscopic incisional hernia repair was not associated with less postoperative pain and nausea compared with open incisional hernia repair. The operative time was significantly longer for laparoscopic repair. Also, perioperative complications were significantly higher in the laparoscopic group. During a median follow-up period of 14 months, recurrence rates were comparable. Hernia size was, as previously reported, positively correlated with recurrence rates ($P = .01$).¹⁰

The basic techniques of laparoscopic incisional hernia repair have not been subject to major changes since their introduction in the early 1990s.¹¹ Prospective studies on operative and long-term results have led to improvement of techniques and implant materials. For example, after Halm et al¹⁶ reported high rates of adhesions and bowel resection associated with intraperitoneal use of polypropylene mesh, use of this technique became obsolete. Meanwhile, significant improvements have been achieved in research and development of less adhesive prosthetic materials.

For open incisional hernia repair, sufficient evidence exists to support the superiority of mesh repair over suture repair in terms of recurrences.^{9,17} Polypropylene is the most widely used material for open mesh repair and is most often placed in the sublay (retromuscular) position.¹⁸

A recent Cochrane review, however, yielded insufficient evidence as to which type of mesh or which mesh position (onlay or sublay) should be used.¹⁹ In the underlying trial, the use of mesh was mandatory for all incisional hernia repairs, frequently using polypropylene material in the sublay or intraperitoneal position.

Shorter operative time for laparoscopic incisional hernia repair was reported by a number of recently published studies,^{13,14,20,21} while other studies show no differences or longer operative times in the laparoscopic group.^{22,23} In small incisional hernia, introduction of trocars and positioning of instruments can be time-consuming. In the open technique, the hernia is often already reduced within this time. In the laparoscopic technique, the positioning and fixation of the mesh to the ventral abdominal wall can be time-consuming. A major factor that might have affected the operative time in the laparoscopic group was the extensive adhesiolysis in the midline of the abdominal wall. Adhesiolysis was necessary for positioning the mesh but also for observing any other small hernia or "Swiss-cheese" defects. A combination of these factors could possibly explain the significantly longer operative time in the laparoscopic group. One hundred minutes to perform a laparoscopic ventral incisional hernia repair, however, is reasonable and conforms to data from previous studies.

Several small randomized studies reported no differences in postoperative pain after laparoscopic and open incisional hernia repair.^{13,14,20} One trial reported reduced use of analgesics after laparoscopic repair.²¹ Postoperative pain after incisional hernia repair often originates not from the hernia itself, but from the surrounding tissues. Mesh fixation materials, eg, tackers or transfascial sutures, are believed to be responsible for postoperative pain.²⁴ The advantages of laparoscopy regarding surgical wounds and wound pain could possibly be offset by mesh fixation materials such as tackers and transfascial sutures.

Several studies have shown a shorter length of hospital stay after laparoscopic incisional hernia repair (1.5 vs 3 days).^{13,14,20-22} After laparoscopic surgery, patients are expected to mobilize and recover faster. This, however, could not be confirmed by our data since length of hospital stay was comparable for both groups.

Previous studies have not shown significant differences in recurrence rates for laparoscopic and open incisional hernia repair.^{13,14,20-22} Contrary to previous studies that reported recurrence rates up to 20% with mesh repair, there are some studies showing exceptionally low recurrence rates varying between 0% and 5%.^{9,13,14} In this study, recurrence rates were found to be similar for both groups at an overall rate of 17% (14% vs 18%; $P = .30$). These relatively high recurrence rates, compared with recent studies, could possibly be explained by obligatory clinical examination of all patients included in our study. Likewise, patients who did not report any complaints or symptoms of possible recurrence by questionnaire were also invited to the outpatient clinics.

Another explanation could possibly be the smaller numbers of included patients in previously conducted studies, resulting in exceptionally low recurrence rates due to chance.

Based on this large randomized clinical trial, laparoscopic incisional hernia repair is an effective technique with recurrence rates comparable with open repair. Peri-operative complications, however, were significantly higher after laparoscopic repair. Common advantages of laparoscopic surgery, such as reduced amount of blood loss and less wound drainage, also applied for this study. Despite the statistical difference in blood loss between the 2 techniques, the clinical significance is negligible. Short-term benefits of laparoscopic incisional repair described in previous studies, eg, perioperative complications, operative time, and length of hospital stay, could not be confirmed. Long-term results and data on cost-effectiveness are necessary to make a more complete comparison between the 2 operative techniques.

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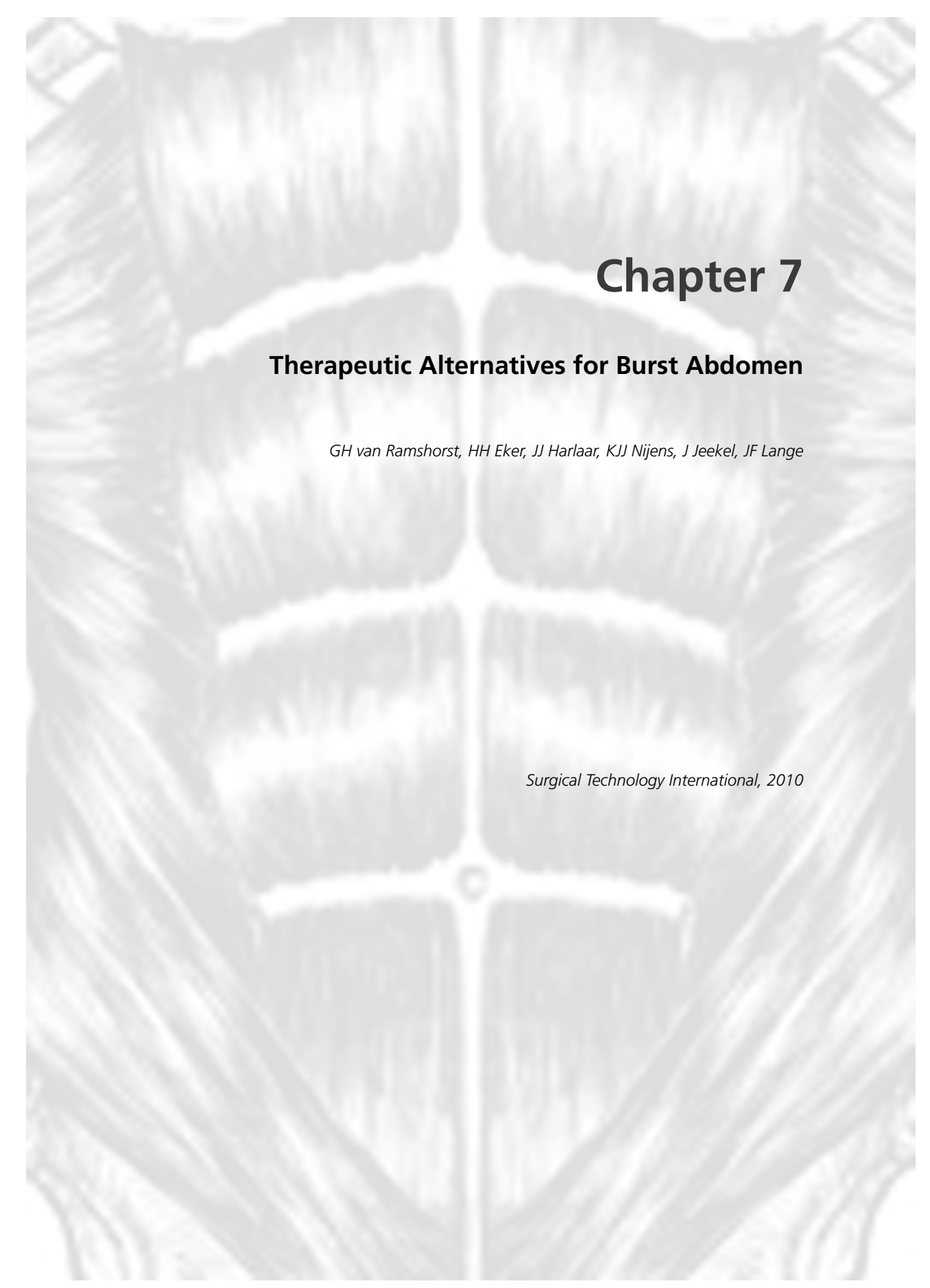
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Chapter 7

Therapeutic Alternatives for Burst Abdomen

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ABSTRACT

Burst abdomen is a postoperative complication associated with significant morbidity and mortality. The risk factors for burst abdomen are patient- and surgery-related. The management of this complication is a relatively unexplored area within the field of surgery. Relevant surgical outcomes include recurrence, mortality, and incisional hernia. A total number of 27 studies are identified that reported on at least one surgical outcome (recurrence, mortality, or incisional hernia rate) of at least 10 patients with burst abdomen. None of the identified studies were designed prospectively, and only a minority of studies reported surgical outcomes of considerable numbers of patients with burst abdomen. Reported conservative management options included use of saline-soaked gauze dressings and negative pressure wound therapy. Operative management options included temporary closure options (open abdomen treatment), primary closure with various suture techniques, closure with application of relaxing incisions, use of synthetic (non-absorbable and absorbable) and biological meshes, and the use of tissue flaps. The treatment of burst abdomen is associated with unsatisfactory surgical outcome. Randomized controlled clinical trials are needed to provide the surgical community with a greater level of evidence for the optimal treatment strategy for burst abdomen and the various subtypes.

INTRODUCTION

Burst abdomen is a serious complication of abdominal surgery and could be considered as an acute postoperative hernia. Reported incidence rates vary between 0.4% and 3.5%.^{1–15} Despite advances in perioperative care, surgical techniques, and materials, the incidence of burst abdomen has remained unchanged over the past few decades.¹⁶ In contrast to the large number of published articles to date on risk factors associated with burst abdomen, few reports exist on the surgical outcome of treated burst abdomen. In this chapter, the treatment options for burst abdomen and the surgical outcome will be discussed.

Etiology of Burst Abdomen

Burst abdomen usually occurs during the first two weeks after surgery.^{2,17–21} In 23% to 84% of wounds, leakage of serosanguineous fluid is observed before dehiscence occurs.^{9,12,19,22–24} Patient- and surgery-related factors may put a patient at increased risk of developing abdominal wound dehiscence. Patient-related variables that have frequently been reported as risk factors include age, male gender, anemia, chronic pulmonary disease, poor nutritional status, emergency surgery, and wound infection.^{1–11,14,25} Infections of the operation site have been reported to be present in as many as 18% to 72% of patients with burst abdomen.^{2,6,9,11,12,23–28} Tillou et al. reported a trauma series with a 71% intra-abdominal infection rate in patients with fascial dehiscence compared to 4.6% in patients without.²⁹ All fascial dehiscence patients with intra-abdominal infections required laparotomy (31%) or computed tomography (CT)-guided percutaneous drainage supporting routine evaluation for intra-abdominal infection in this patient group.²⁹ Graham et al. diagnosed intra-abdominal infections in 47 out of 90 patients (52%) operated upon for fascial dehiscence (32 patients with abscess, 15 with anastomotic leakage).²⁴ Fever and leucocytosis did not distinguish between patients with intra-abdominal infections compared to those without. The presence of intra-abdominal infection was associated with a significantly greater mortality rate of 44% versus 20% in patients without intra-abdominal infection.²⁴ Surgical risk factors include the type of suture material and surgical technique.¹⁷ Brown and Goodfellow found a trend toward a lower incidence of wound dehiscence with or without evisceration in transverse incisions compared to midline incisions in a systematic review.³⁰ Several studies have shown that absorbable fascial sutures are associated with an increased risk of developing an incisional hernia but found no association with burst abdomen.^{31–34} One meta-analysis by Weiland et al. found a greater incidence of wound dehiscence if continuous absorbable closures or interrupted nonabsorbable closures were used, but these findings were not confirmed by two other meta-analyses by Rucinski et al. and van 't Riet et al.^{35–37} Weiland et

al. also reported lower incidences of dehiscence and hernia if mass closures were used compared to layered closures.³⁵ A suture length to wound length (SL:WL) ratio of less than 4:1 has been associated with an increased incidence of incisional hernia, and may also expose patients to an increased risk of burst abdomen.^{38–41} A definitive answer to the question of whether the SL:WL ratio is a relevant risk factor for burst abdomen can only be provided if these ratios are documented as part of the standard abdominal closure procedure.

SURGICAL OUTCOME

100

The most frequent complications of burst abdomen include recurrence, mortality, and incisional hernia. Another complication is the occurrence of enterocutaneous fistula. Enterocutaneous fistula formation has only been reported incidentally after burst abdomen and will not be discussed in this chapter.^{42,43}

Recurrence

The technical failure of surgical repair results in recurrences. Published recurrence rates vary between 0% and 35%.^{2,18–20,22,42,44,45,50} The fascia, which has already been damaged during the initial (suture) repair and dehiscence thereafter, may be more prone to tearing after subsequent operative repair, especially in the presence of increased intra-abdominal pressure. Increases in intra-abdominal pressure can occur in the presence of abdominal distension as a result of bowel edema, mechanical obstruction, coughing, vomiting, or urinary retention.⁴² Tensile and bursting strengths of fascia, subcutis, and skin are impaired in cases of infection, tissue necrosis, and poor nutritional status. A mesh repair can also result in recurrence: Our prospective data include four observations of patients with burst abdomen who underwent polyglactin mesh repair and developed recurrences due to tearing of the mesh (Fig. 1).

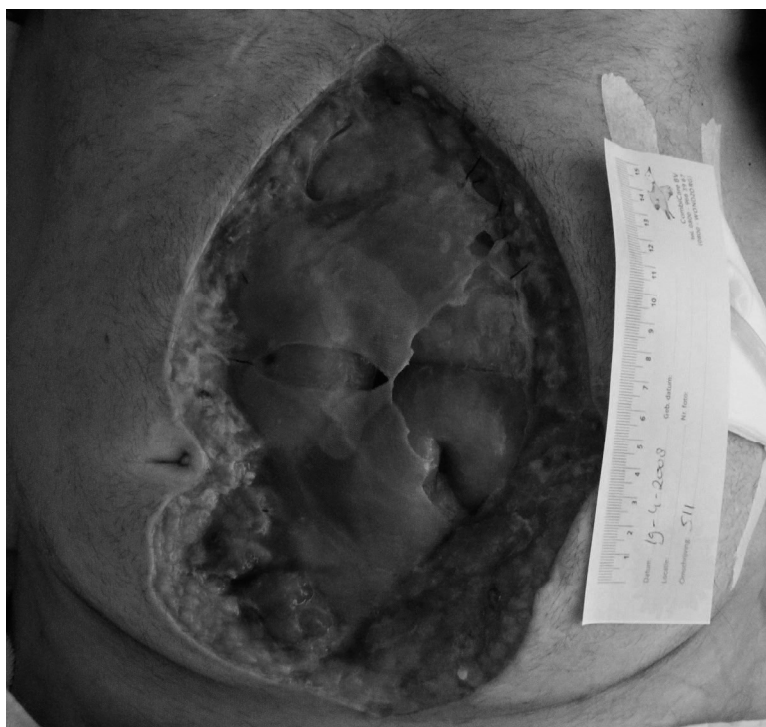


Figure 1. Example of repeat dehiscence by tearing of polyglactin mesh.

Mortality

Reported mortality rates of burst abdomen vary between 4% and 85% (Table 1). Cöl et al. reported a relation between the number of risk factors present for burst abdomen and the mortality rate.¹¹ Variables assigned as risk factors in this study included hypoproteinemia, nausea/vomiting, abdominal distension, wound infection, two or more drains, fever, an operation not performed by a senior surgeon, and wound closure of all layers with interrupted silk sutures. Mortality was found to be 30% for patients with seven risk factors and 58% for patients with eight risk factors. Madsen et al. reported the causes of death for 48 patients with burst abdomen, in order of frequency: cardiorespiratory insufficiency ($n = 28$), peritoneal sepsis ($n = 7$), primary disease ($n = 5$), complicating illness ($n = 3$), hemorrhage ($n = 2$), and unknown cause ($n = 3$).²² White et al. reported the causes of death of 40 patients: malignant disease ($n = 12$), respiratory failure and pneumonia ($n = 5$), coronary occlusion ($n = 4$), renal failure ($n = 3$), pulmonary embolism ($n = 3$), peritonitis ($n = 1$), cardiovascular accident ($n = 1$), and hematemesis ($n = 1$).²⁰ Cardiac and respiratory complications were the most frequently reported causes of death in burst abdomen patients.

Table 1: Studies with reports of 10 or more patients with burst abdomen and surgical outcome

Author	Year	Type of study	No pt	Technique (number of patients and specific aspects)	Recurrence rate %	Mortality rate %	Incisional hernia rate %	Follow-up (range)
Reitamo ²³	1972	Retrospective	49	NR	10%	35%	10%	NR
Keill ⁹	1973	Retrospective	47	21 through-and-through retention sutures 12 one-layer fascial closure with wire 10 wire fascial closure with retention sutures 2 conservative treatment 2 NR	11%	30%	NR	NR
Grace ⁴⁸	1976	Retrospective	103	96 resuture with or without tension sutures 7 conservative treatment	2.1%	20%	48%	NR
Sanders ²⁵	1977	Retrospective	11	NR	NR	18%	60%	NR (max 3 years)
Helmkamp ¹⁹	1977	Retrospective	70	Single-layer through-and-through stainless steel or silver wire retention sutures	0%	3%	NR	NR
White ²⁰	1977	Retrospective	123	Resuture with deep tension sutures and a two-layer closure when possible	1.1%	24%	19%	NR
Haddad ²⁶	1980	Retrospective	70	NR	NR	5.7%	NR	NR
Stone ⁴⁶	1981	Retrospective	13	NR	NR	85%	NR	NR
Tohne ⁷⁷	1991	Retrospective	14	7 retention sutures 2 polyglactine mesh 5 conservative treatment	22%	29%	NR	NR
Riou ¹²	1992	Retrospective	31	30 retention sutures 1 conservative treatment	NR	29%	NR	NR
Paye ⁷⁷	1992	Retrospective	17	9 repair 8 conservative treatment	22%	53%	NR	NR
Madsen ²²	1992	Retrospective	198	198 resuture with mass or retention sutures with non-absorbable braided or monofil sutures, often using a plastic bridge or polyvinylchloride tube	5.6%	24%	23%	NR
Wahl ¹²	1992	Retrospective	30	27 resuture with interrupted sutures and two or three traction sutures 3 adapted wound edges, planned relaparotomies	11%	20%	NR	NR
Mäkelä ⁸	1995	Retrospective	48	40 continuous sutures 8 interrupted sutures Type of suture: 39 polyglycolic acid 5 polyglyconate 4 polyglactin 910 28 cases additional steel-wire retention sutures	4%	10%	15%	NR
Gislaason ³	1995	Retrospective	14	11 resuture 3 conservative treatment	NR	14%	NR	NR
Graham ²⁴	1998	Retrospective	107	90 repair 17 conservative management	NR	35%	NR	NR
Cöli ¹¹	1998	Retrospective	40	30 repair 10 conservative treatment	0%	30%	NR	NR

McNeeley ⁴³	1998	Retrospective	36	11 polypropylene mesh 7 polyglactin mesh 18 NR	NR	5.6%	8%	6 months NR
Gislason ⁵⁰	1999	Retrospective	78	Type of suture: 18 polyglactin 17 polyglycolic acid 10 polyglyconate 2 polydioxanone 2 polyamide 29 NR Type of technique: 29 interrupted with retention sutures 8 continuous with retention sutures 9 interrupted 2 continuous 5 retention sutures alone 25 NR	1%	14%	43%	23 months (1-8 years)
Dare ⁵⁵	2000	Retrospective	14	13 interrupted nylon 1 sutures with tension sutures 1 conservative treatment	NR	14%	NR	NR
Hendrix ⁷⁸	2000	Retrospective	48	NR	NR	4%	NR	NR
Fleischer ¹⁸	2000	Retrospective	38	Polyglyconate 1 sutures. Retention sutures or laparostoma with mesh on indication	8%	NR	27%	NR
Pavlidis ⁶	2001	Retrospective	89	89 single layer closure Sterile tapes	NR	16%	NR	NR
Fackeldey ⁷⁹	2004	Retrospective	54	13 primary closure with nonresorbable suture (Prolene)	NR	31.5%	NR	NR
Van 't Riet ⁴⁴	2004	Retrospective	168	41 polyglactin mesh Type of suture: 79 polyglactin 42 polydioxanone 9 polypropylene 9 polyglactin mesh 16 polypropylene mesh 1 polyester mesh 12 NR Type of technique: 70 interrupted 62 continuous 36 NR	9.5%	25%	44% [†]	37 months (3-146 months)
Heller ⁴²	2006	Retrospective	13	4 NPWT followed by no closure 4 NPWT followed by component separation 5 NPWT followed by delayed primary closure (including 3 polypropylene mesh repairs)	0%	NR	NR	6 months NR
Abbott ⁴⁵	2007	Retrospective	37	27 primary closure 7 polyglactin mesh 3 conservative treatment	35%	NR	19%	NR (3 months-8 years)

NR: not reported, * Including incisional hernia patients, [†] one-year incidence, NPWT: negative pressure wound therapy

Incisional Hernia

The development of an incisional hernia is a frequent, late complication of burst abdomen.^{18,44,46,47} If burst abdomen is treated conservatively, an incisional hernia will develop in all cases. Reported incidences of incisional hernia vary between 6% and 48%, with a cumulative incidence of 69% after 10 years.^{18,20,22,44,45,48–50} The high incidence of incisional hernia suggests that patients who develop burst abdomen are more prone to develop this late type of wound failure than the average patient population.

SEARCH STRATEGY

PubMed-Medline, EMBASE, and the Cochrane Library were searched for relevant publications and their references up to November 2009 using the keywords “abdominal wound dehiscence,” “fascial dehiscence,” “evisceration,” and “burst abdomen.” Searches were limited to studies in adults and elderly patients. Studies that reported on at least one surgical outcome (recurrence, mortality, incisional hernia) on 10 or more patients with burst abdomen are included in Table 1.

RESULTS

A total number of 27 studies were identified. Data on applied techniques and the associated surgical outcomes were extracted (see Table 1). Treatment techniques for burst abdomen and the surgical outcomes associated with the applied techniques were incomplete in the majority of these reports. No prospective case series or randomized studies were found.

Conservative Management

Nonoperative management is a viable option for patients with small defects, in cases of a high risk of iatrogenic intestinal perforation due to vast adhesions, massive bowel edema, or if the general status of the patient does not allow for immediate surgery.¹⁷ Wounds can be covered with saline-soaked gauze dressings. Regular gauze dressings are inexpensive in terms of direct material costs but will require frequent dressing changes.

The use of negative pressure wound therapy (NPWT) has been reported in 13 patients with fascial dehiscence by Heller et al. and resulted in definitive fascial closure in 9 out of these 13 patients.⁴² Subramonia et al. applied NPWT in 9 patients with fascial dehiscence and 42 patients with either a laparostomy ($n = 10$) or more superficial types of abdominal wound dehiscences ($n = 32$).⁴³ The total group of patients showed a 29% mortality rate and 29% incisional hernia rate at a median follow-up of 8 months. No separate percentages were reported for patients with fascial

dehiscence. NPWT has been reported to promote the production of granulation tissue and the reduction of wound volume, and can be used if direct contact with intra-abdominal organs is prevented.⁴² Adequate wound debridement usually precedes the placement of NPWT dressings. Granulated exposed bowel can heal either by secondary intention or by covering with split-thickness skin grafts, for instance, as part of a two-staged procedure or tissue flaps.^{42,51} Virtually every conservatively managed patient who is denied operative repair will develop an incisional hernia.

Operative Management

A number of authors advocate debridement of necrotic and infected tissue, and exploration of the abdomen for the presence of intra-abdominal abscess formation, (infected) hematomas, intestinal (anastomotic) leakage, and obstruction.^{17,18} It is unknown whether a local exploration of the dehiscence suffices in cases of small defects in the absence of clinical symptoms of infection or whether the entire fascia needs to be opened (and re-closed).

Primary Suture Closure

Primary closure can be performed using a mass closure technique with a slowly absorbable running monofilament suture. Generally, a SL:WL ratio of at least 4:1 is advised.⁵² It is not known whether traditional tissue bites and suture distances of 1 cm should be used or small tissue bites with small suture distances of 0.5 cm, although use of the latter technique is supported by several clinical and experimental studies.^{38,39,53,54} Primary closure without additional measures is possible in half of patients with abdominal wall rupture according to Fleischer et al.¹⁸ Abbott et al. reported a 56% success rate associated with the primary closure of fascial dehiscence with or without retention sutures in 27 patients.⁴⁵ In selected patients, such as patients in whom technical failure has resulted in dehiscence rather than patient-related risk factors (e.g., slipped knots), primary suture repair may be successful.^{17,45}

If the fascia is easily torn during initial re-suturing, alternative closure methods can be considered. In cases of extensive debridement with the loss of abdominal wall tissue, primary closure has been reported to result in a 50% dehiscence rate.⁴⁷

The use of retention sutures or modifications thereof has been reported in many studies with high rates of recurrence and incisional hernia (see Table 1).^{2,8,9,12,19,20,22,48,50,55–57}

Retention sutures are reported to be very painful for patients and have frequently been associated with local complications and a need for early removal.⁵⁸ The available evidence is in disfavor of the use of retention sutures.^{3,58,59}

Relaxing Incisions

Esmat reported the use of relaxing incisions in the transversus abdominis and internal oblique muscles (TI incision), an additional incision in the external oblique muscle (TIE incision), or also involving Scarpa's fascia (TIES incision).²¹ Eight patients with burst abdomen underwent a total of 15 incisions (2 TI, 9 TIE, 4 TIES) in this study. The mortality rate was 12.5%, no recurrences occurred, and incisional hernias occurred at sites of TIES incisions only. Dietz et al. performed an inverting bilateral interrupted figure-of-eight suture (0 USP polypropylene) of the anterior and posterior rectus sheath in one patient, combined with relaxing incisions in the aponeuroses of the external oblique muscles and placement of a polypropylene mesh in sublay position.⁶⁰ No incisional hernia was diagnosed after 1 year of follow-up but numbness of the skin in the right lower abdomen was reported, which was possibly due to a lesion of (part of) the ilio-hypogastric nerve.⁶⁰ Relaxing incisions in the transversus abdominis and internal and external oblique muscles can be considered if primary closure cannot be performed tension-free.

Temporary Closure

Open abdomen treatment is an alternative option if tension-free closure cannot be performed. One study reported the temporary closure of the abdomen with a Bogota bag in one patient with burst abdomen, which enabled primary closure one month after placement.⁶¹ There are no studies found to date that have compared the surgical outcomes of temporary closure with other methods of treatment for burst abdomen.

Synthetic Mesh

Synthetic mesh is often placed in inlay position fixated to both fascial edges. There is no evidence to support a preference for either an inlay, onlay, or sublay position in the repair of burst abdomen. Material options included absorbable meshes such as polyglactin and nonabsorbable meshes such as polypropylene. Polypropylene meshes have been associated with high complication rates in infected environments, especially in cases of placement in direct contact with intestines, leading to enterocutaneous fistula formation and intestinal adhesions.⁶²⁻⁶⁴ Van 't Riet et al. reviewed a group of 18 patients who had undergone abdominal wound dehiscence repair in the presence of intra-abdominal infection. All patients developed complications such as mesh infection (77%), enterocutaneous fistula formation (17%), or migration of mesh through the bowel (17%). Complications had led to mesh removal in 8 out of 18 patients (44%) and at a mean follow-up of 49 months, incisional hernia had developed in 63% of patients.⁶³

Other complications of nonabsorbable meshes include bulging of the mesh, which can mimic the clinical presentation of incisional hernia, and mesh rejection. McNeeley et al. reported the use of nonabsorbable polypropylene mesh in 11 patients with fascial dehiscence (7 Marlex®, CR Bard, Murray Hill, NJ; 4 Prolene®, Ethicon, Somerville, NJ). In three out of seven patients who underwent Marlex® repair, grafts were removed and abdominal scars were revised. There were no reported observations of enterocutaneous fistula formation.⁴⁹ We are not aware of any reports to date on the use of composite nonabsorbable meshes in the acute treatment of abdominal burst. From a theoretical point of view, the use of this type of anti-adhesive meshes could be beneficial in terms of less adhesion formation than polypropylene mesh and lead to a lower incidence of incisional hernia compared to absorbable mesh.

Polyglactin mesh is 100% absorbable and can be used in the presence of infection. Repeated access to the abdomen is easily acquired by opening and subsequent closure of the mesh. However, the material can tear and thereby result in repeat evisceration and an indication for reoperation.⁶⁵ Covering the mesh with saline-soaked gauzes or NPWT is often used until granulation tissue is formed on the bowel and can be covered with split-thickness skin grafts. Removal of mesh due to rejection may be necessary at an outpatient clinic during the months following mesh repair. McNeeley et al. used polyglactin mesh in seven patients with fascial dehiscence, one of whom required mesh removal.⁴⁹ Moreover, the use of polyglactin mesh without direct contact between fascial edges inevitably resulted in incisional hernia over time. Abbott et al. reported a 100% success rate for primary polyglactin mesh repair in 7 out of 37 patients. Closure with polyglactin mesh required 12 subsequent operations (1.71 operations per case), compared to 39 operations in 27 patients (1.56 operations per case) for primary fascial repair.⁴⁵ Buck et al. reported the use of polyglycolic acid mesh (Dexon™, Mansfield, MA) in seven patients with wound dehiscence, all of whom developed incisional hernias.⁶⁶

Biological Mesh

In recent years, various types of biological meshes have been developed and become commercially available. Biological meshes consist of cross-linked or non-cross-linked extracellular matrix without cellular components, derived from porcine dermis collagen, porcine small intestine submucosa, or cadaveric human dermis.⁶⁷ The high biological compatibility is generally seen as a great advantage in comparison with synthetic materials, especially in infected surgical fields.⁶⁸ Tissue ingrowth in the mesh will eventually create a new abdominal fascia, thereby preventing incisional hernia formation unless the mesh is degraded by collagenases in cases of (severe) infection. Few publications are available on the use of biological mesh in burst abdomen patients.

Bounovas reported the implantation of porcine dermal collagen under local anesthesia in one case of infected abdominal wound dehiscence after hysterectomy. After a follow-up period of 9 months, no incisional hernia occurred.⁶⁹ Chuo et al. described the use of a biological mesh, derived from porcine dermis, in combination with NPWT in a patient with abdominal dehiscence and exposed bowel.⁷⁰ One report has been published by Wotton et al. who described a case of a patient with burst abdomen in whom severe rejection of a biological mesh, derived from porcine dermis, occurred.⁷¹ The limited number of studies published to date on this topic inhibits any substantiated advice on the use of a specific type of biological mesh (cross-linked versus non-cross-linked, human versus porcine) or on optimal mesh position.

Tissue Flaps

Tissue flaps have been used most frequently for delayed repair of abdominal wall defects, for instance, after abdominal wound dehiscence. However, Jeon et al. reported the use of a pedicled rectus femoris muscle flap for a completely eviscerated renal allograft in a 66-year-old man after development of a perigraft hematoma. The rectus femoris flap became dehiscent. After additional local tissue rearrangement and a perforator-based cutaneous advancement flap reconstruction, no incisional hernia occurred within the first two years after surgery.⁷²

Closure of the Skin and Subcutaneous Tissue

Subcutaneous (multifilament) sutures initiate a foreign-body reaction and potential bacterial colonization. In a relatively clean environment, the skin can be closed with monofilament interrupted sutures or staples. If drainage of infected material through the wound is expected, the skin should be left open or approximated at intervals with staples or interrupted monofilament sutures to allow for sufficient drainage. Chendrasakhar described the bedside stapling of Vicryl mesh to the skin as a sole preventive measure against evisceration in two patients with abdominal wound dehiscence. Skin grafts were placed after ingrowth of the mesh with granulation tissue, thereby avoiding major surgery and accepting incisional hernia formation.⁷³

Postoperative Period

Wound healing should be promoted by achieving adequate tissue perfusion and oxygenation and by creating an optimal wound environment. The nutritional status should be checked and optimized by resuming enteral feeding as soon as possible, preceded by administering total parenteral nutrition if necessary. Postoperative intestinal paralysis should be minimized to prevent abdominal hypertension and thereby stress on the wound. Pulmonary inhalers and respiratory exercises under the guidance of a physiotherapist may assist in the prevention of pulmonary

infection and frequent coughing, which can result in sudden peaks in intra-abdominal pressure. There is no evidence to support the use of restraining cotton sheets or abdominal binders to prevent burst abdomen, a further increase in the gap between both fascial edges, recurrences, or incisional hernia.

Treatment of Recurrence

Abbott et al. reported the largest series of treated recurrence patients ($n = 12$). Polyglactin mesh was used in two patients, both resulting in subsequent incisional hernia repair. Repeat fascial closure was performed in the remaining 10 patients, 3 of whom required additional operative interventions (70% success rate). Recurrence is often combined with additional damage to the fascia and adjacent tissues and is a relative contraindication for suture repair. Torn mesh can be repaired by sutures with or without bridging of the mesh or by applying two sheets of mesh in a double layer for extra support.

DISCUSSION

The evidence regarding the management of burst abdomen is extremely poor. Our review of management options has revealed that none of the studies found in the literature to date were designed prospectively, and only a minority of studies have reported surgical outcomes of considerable numbers of patients. The level of evidence therefore does not exceed 2b (individual cohort studies). Any advice on the management of burst abdomen should therefore be interpreted with caution.

Based on the available evidence from case series, conservative management may be reserved for patients whose general health status does not allow for immediate surgery. In clean and clean-contaminated wounds, primary suture closure could be attempted (e.g., in case of failed suture technique), although this repair has been associated with considerable recurrence rates and the development of incisional hernia in a number of studies.^{2,8,9,20,22,44,48,50} If intra-abdominal pressure (IAP) levels are high, primary suture repair will presumably be associated with an even worse surgical outcome. The high recurrence and incisional hernia rates following treatment of burst abdomen could be considered as a support of mesh repair, especially in these patients. In clean wounds, polypropylene or composite meshes could be used, depending on whether or not contact with abdominal contents can be avoided; intraperitoneal placement of polypropylene is associated with high complication rates after subsequent surgical interventions.⁷⁴ A biological mesh repair could be considered in clean-contaminated wounds as an alternative for a two-staged repair with temporary closure of the abdomen (with or without NPWT) or open abdomen treatment.

In contaminated-dirty wounds, treatment should be aimed at identifying the source of infection, for example, intra-abdominal abscess or anastomotic leakage. This type of patient is illustrated in Figure 2: Progressive necrosis of the fascia resulted in exposure of the abdominal content, and intra-abdominal infection was found at relaparotomy. We discourage primary suture repair in patients with obvious tissue (fascial) necrosis and considerable loss of the abdominal wall due to high reported rates of treatment failure.⁴⁷ Surgeons can choose open abdomen treatment (with or without NPWT) or closure of the abdomen with absorbable polyglactin or biological mesh repair. Due to lack of evidence, none of these techniques can be considered the method of first choice. Absorbable polyglactin meshes can be used to bridge abdominal wall defects but will eventually lead to incisional hernia formation.^{44,45,66} Tension-free application allows for a certain safety window in cases of expansion of abdominal contents during the postoperative phase. Biological meshes have demonstrated high biocompatibility in infected fields and should be considered a closure option for burst abdomen. Closure with biological mesh may be associated with a lower incidence of incisional hernia, but there are no case series of patients with burst abdomen available with long-term follow-up. Until evidence is available that the use of biological mesh results in improved surgical outcome in this patient group, its widespread use will be restrained by greater material costs.

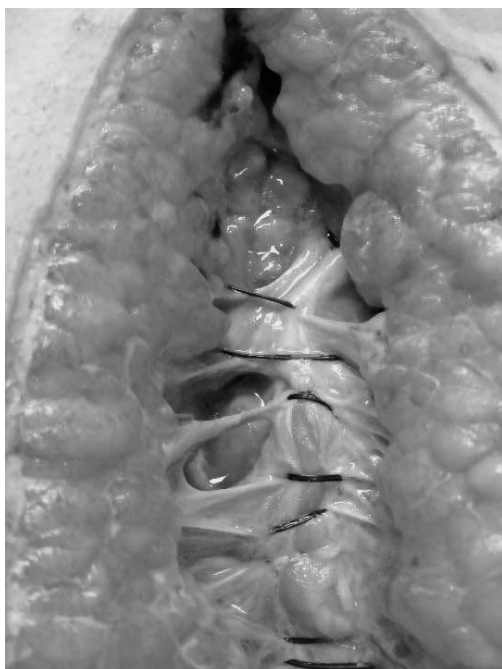


Figure 2: Example of patient with fascial necrosis, exposed abdominal content and concurrent intra abdominal infection

CONCLUSIONS

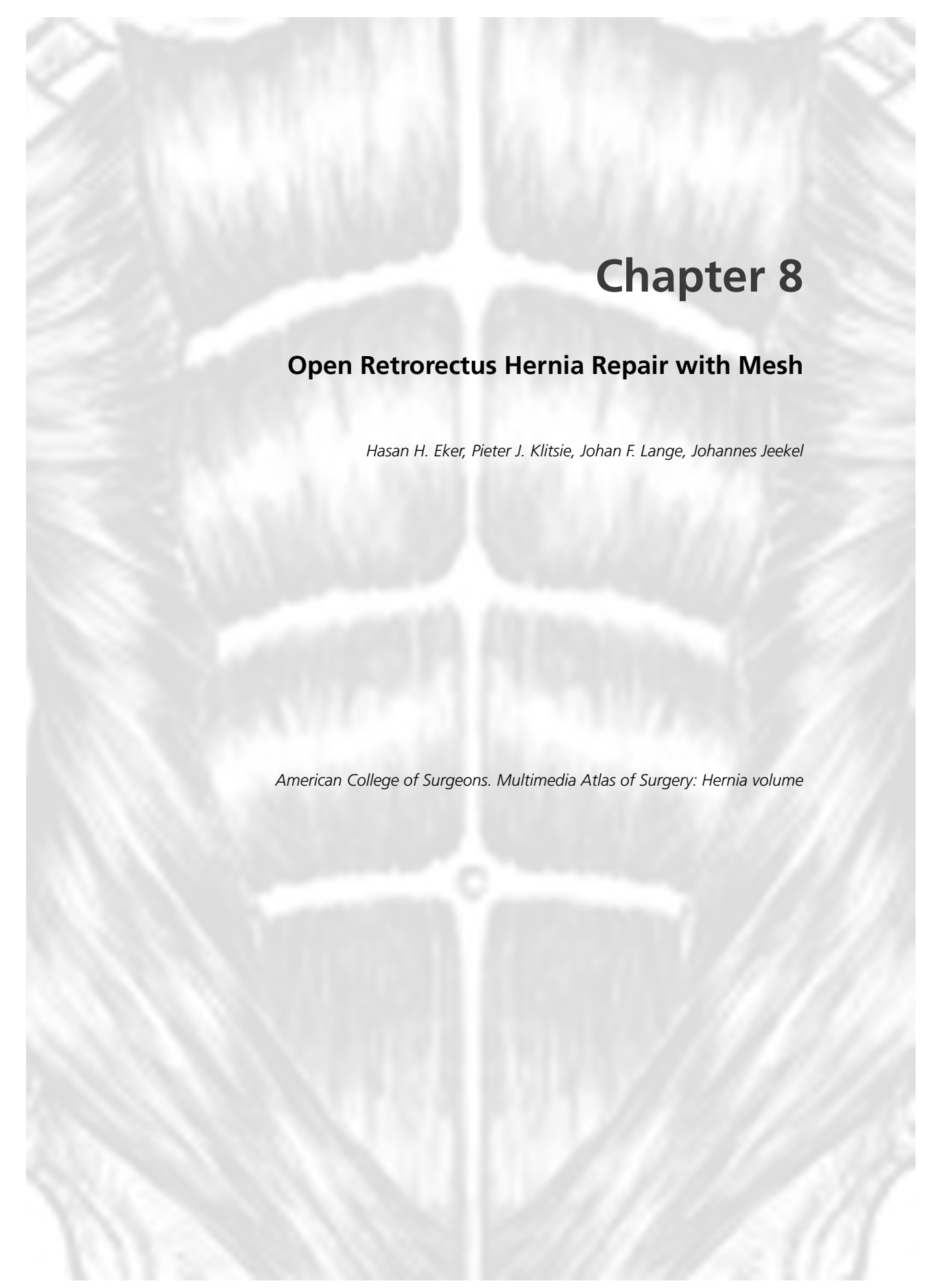
Current surgical closure techniques are associated with unacceptably high rates of recurrences and incisional hernia. The overall lack of evidence to date on this topic mandates well-designed randomized controlled trials. Conservative and operative management options should be compared for short-term and long-term surgical outcomes to provide surgeons with a greater level of evidence regarding the optimal treatment strategy for burst abdomen. We propose that distinctions are made between treatment options for patients with clean and clean-contaminated wounds on one hand and patients with contaminated-dirty surgical sites on the other, and between patients with normal versus raised intra-abdominal pressure. A possibly relevant characteristic of affected patients in view of surgical outcome is the initial calculated risk of developing burst abdomen. The size of the defect and presence of evisceration should also be taken into consideration as presumed risk factors for the development of an incisional hernia.

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Chapter 8

Open Retrorectus Hernia Repair with Mesh

Hasan H. Eker, Pieter J. Klitsie, Johan F. Lange, Johannes Jeekel

American College of Surgeons. Multimedia Atlas of Surgery: Hernia volume

INTRODUCTION

The repair of ventral hernia is one of the most common operation general surgeons perform. Excellent ventral hernia repair requires meticulous dissection, gentle tissue handling, and strict attention to the detail of the forces that the repair will be subject to upon reconstruction.

The contours of the abdominal wall hernia are drawn before starting with the operation.



Figure 1. Preoperative view of the abdominal wall hernia



Figure 2. The abdomen of a patient with the hernia site illustrated on the skin

INCISION-EXCISION OF SCAR TISSUE

The first step is to excise the scar tissue. While the wound edges are pulled upright, the hernial sac is identified and dissected sharply from the surrounding tissue. The dissection is continued until healthy skin and subcutaneous tissue is reached. We then repeat this procedure on the other side.

An incision around the complete old scar is made and the scar tissue is excised.



Figure 3.

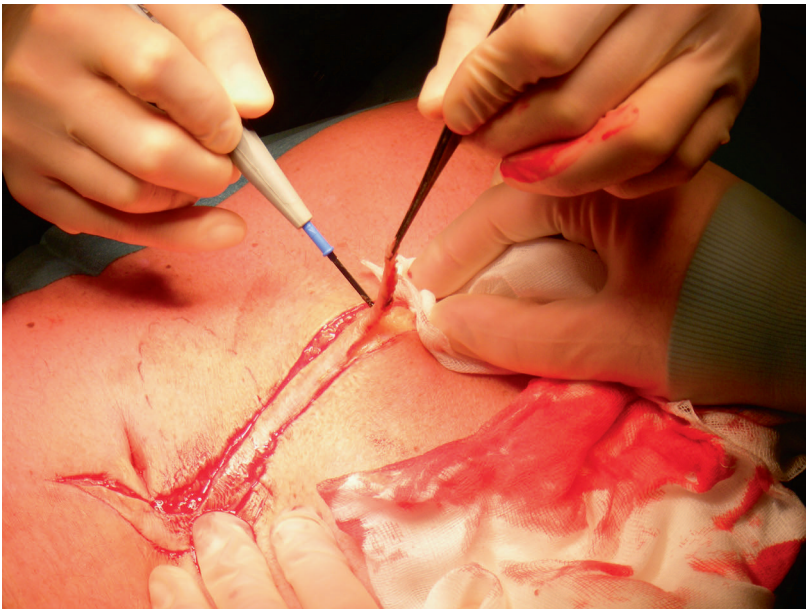


Figure 4.



Figure 5.

HERNIA SAC IDENTIFICATION AND DISSECTION

The hernia sac is opened. To ensure the safety of the intestines and omentum, the sac is opened over a finger or between two fingers. The abdominal wall is checked to make sure the abdominal wall and fascia are intact in the surrounding areas. In case of multiple defects, the so-called "Swiss cheese" defect, the hernial defect is enlarged to include all defects and until all edges are debrided to healthy tissue.

The hernial sac is identified and dissected sharply from the surrounding tissue. The dissection is continued until "healthy" abdominal wall is reached at all sides.

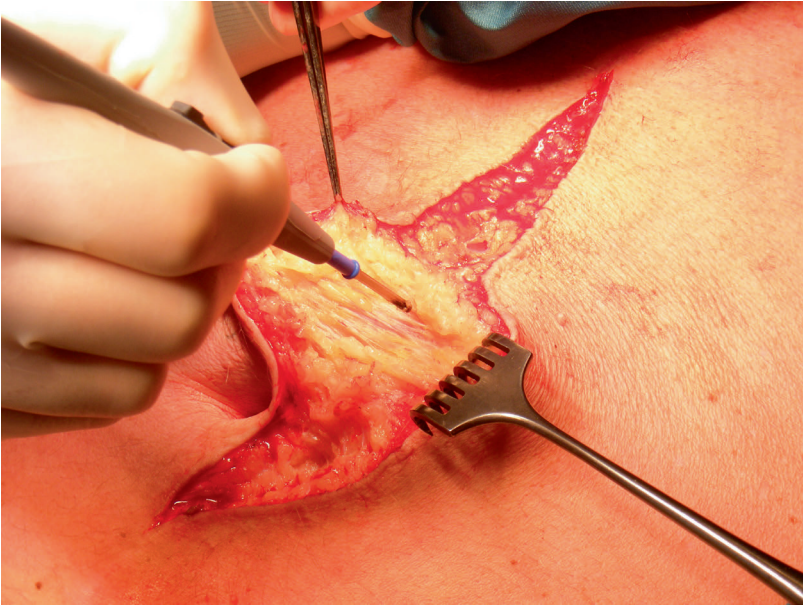


Figure 6.

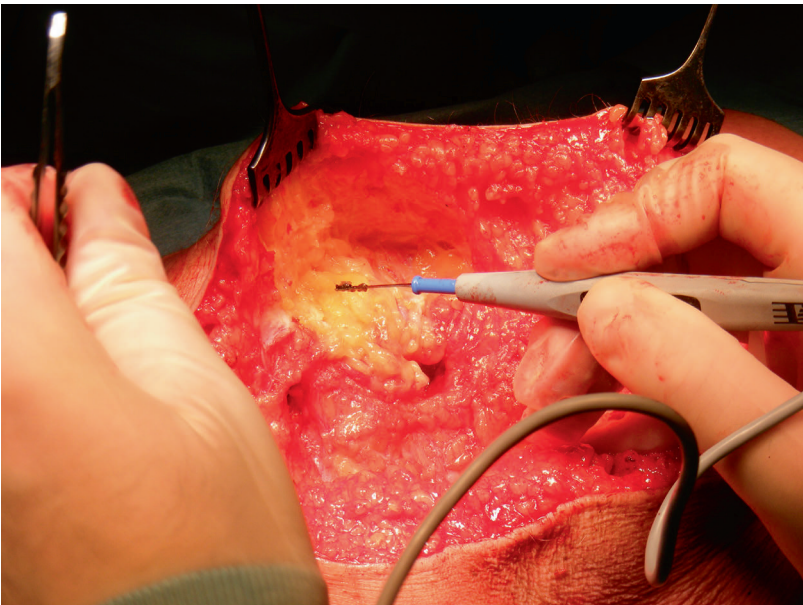


Figure 7.

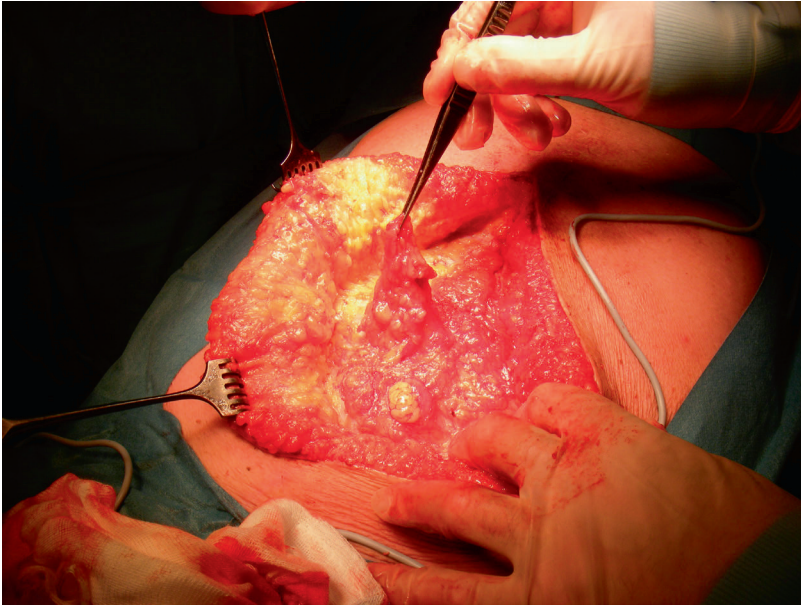


Figure 8.

The hernia sac is opened over a finger to ensure safety of the intestines and omentum.

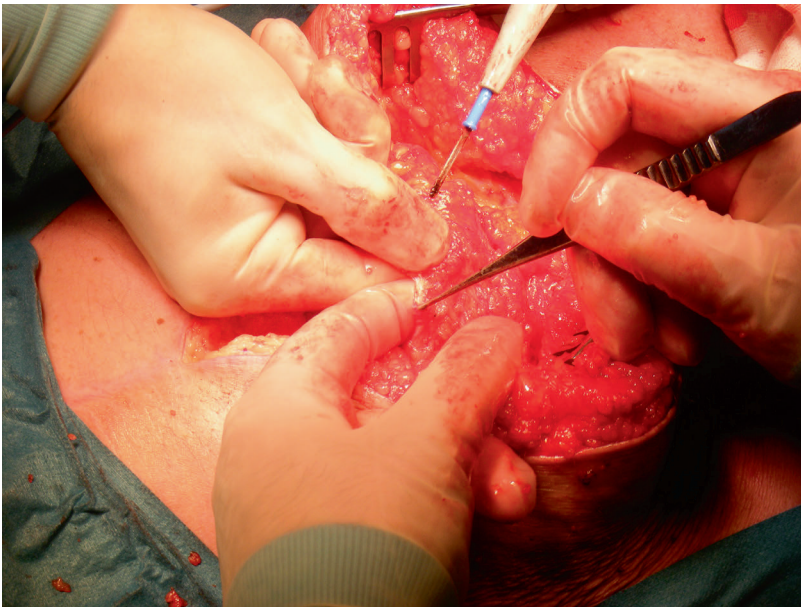


Figure 9.

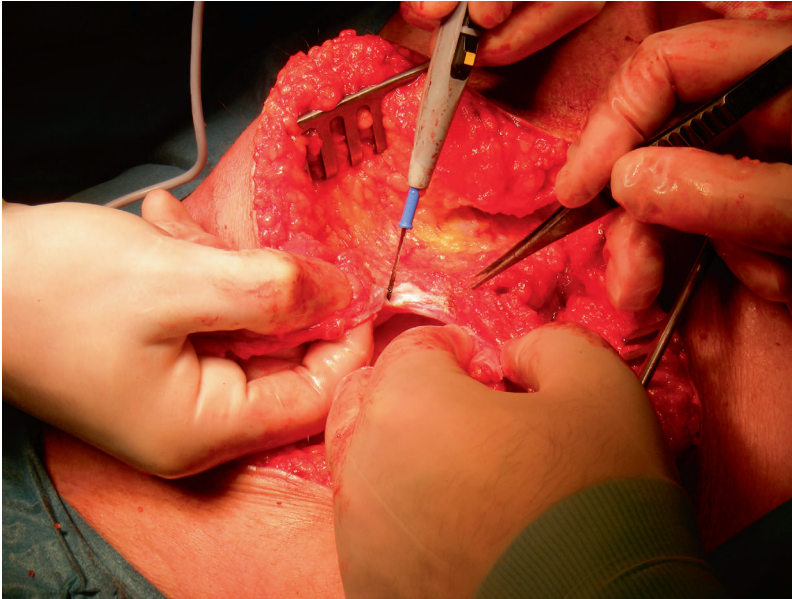


Figure 10.

In case of multiple defects, the hernial defect is enlarged until all edges are debrided to healthy tissue.

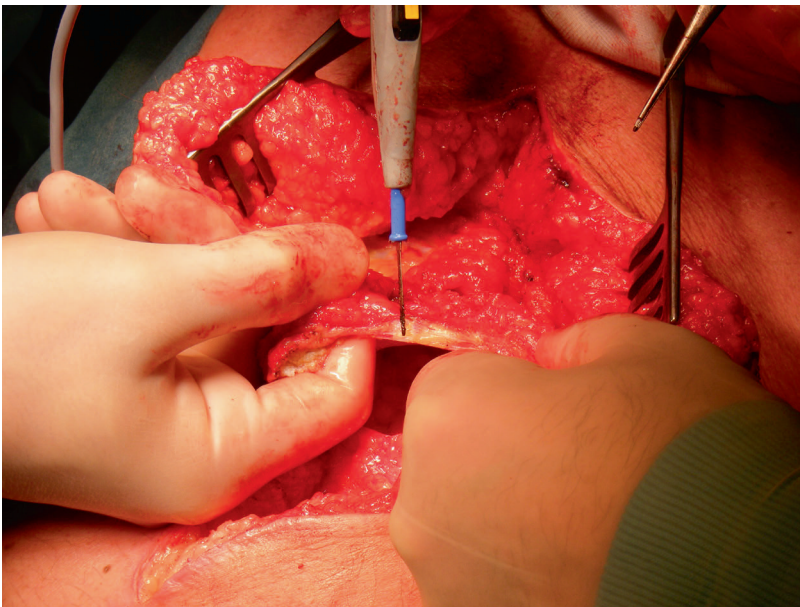


Figure 11.

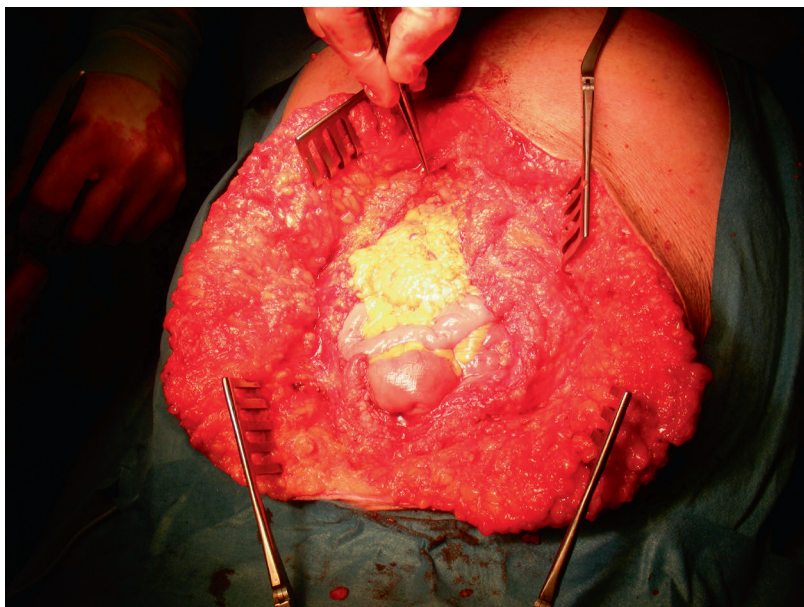


Figure 12.

ADHESIOLYSIS OF OMENTUM AND VISCERA

The next step is the adhesiolysis of omental and intestinal adhesions to the abdominal wall. Intestinal or omental adhesions are dissected sharply. Afterward the edges are trimmed to make sure that all tissue margins are of sufficient quality for the repair

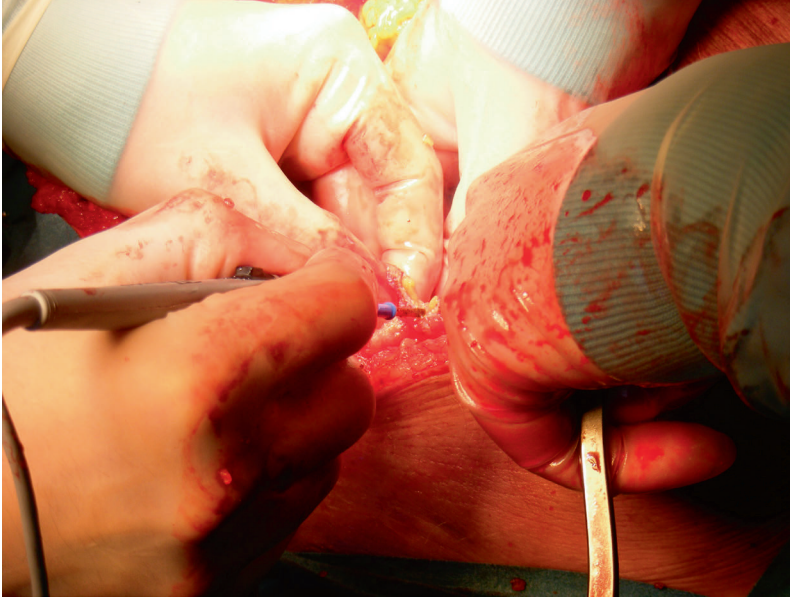


Figure 13.

DEVELOPING THE TISSUE PLANES

With an opening much larger than the original site, the plane for the mesh is prepared. The mesh will be placed over the closed posterior fascia, but underneath the abdominal rectus muscle.

The rectus sheath is opened at both sides and the plane between the posterior fascia and rectus muscle is dissected.

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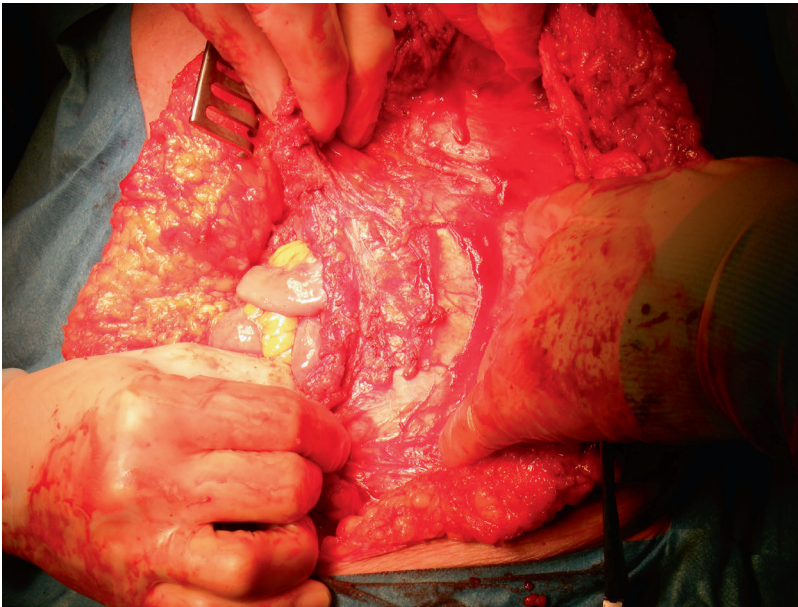


Figure 14.

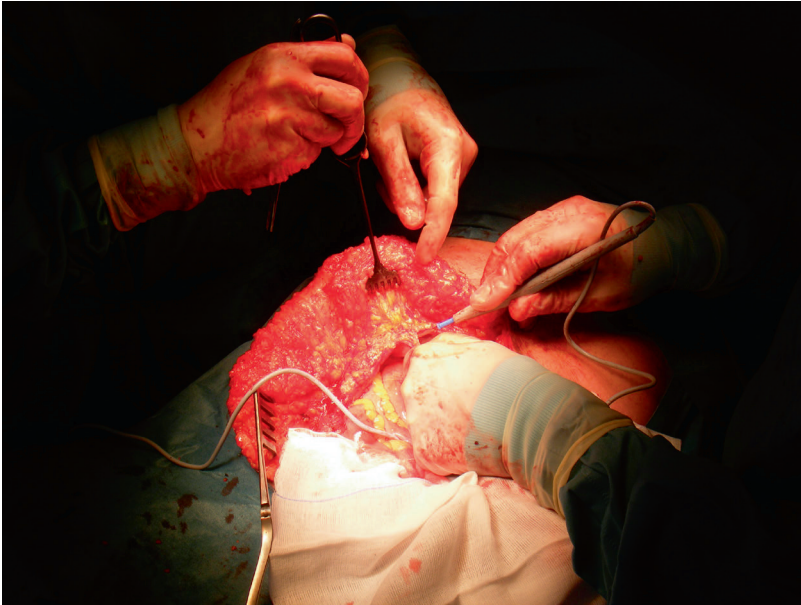


Figure 15.

The right plane is clearly visible here, and the fingers are used to dissect the tissue between the abdominal fascia and the rectus muscle.

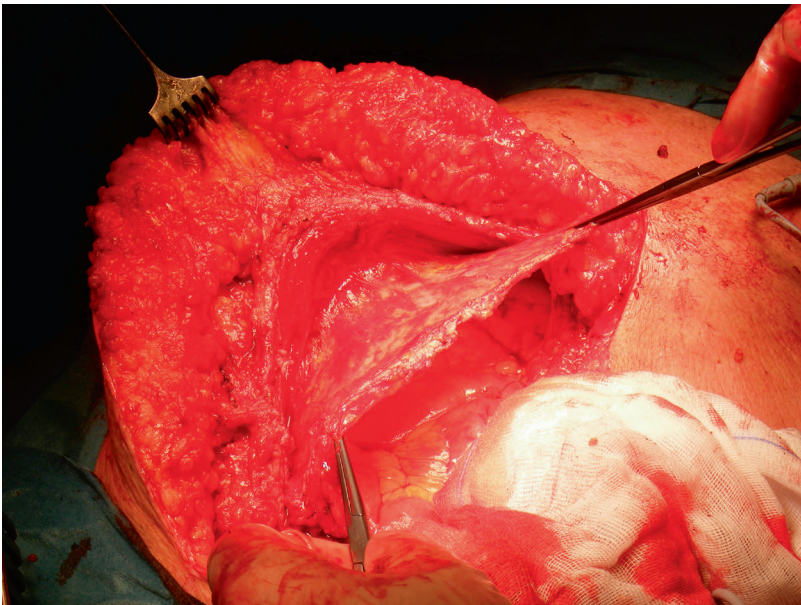


Figure 16.

The plane is opened using the dorsal approach in order to secure sufficient blood supply to the wound edges. The plane can be extended quite far; care must be taken to preserve the perforating inferior epigastric vessels. An easy technique for this dissection is to use the coagulating knife over one or two fingers. The rectus muscle is pulled up as the posterior fascia remains flat, creating the space for the mesh in between.

CLOSURE AND MESH PLACEMENT

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The last step is the dissection to trim the edges, making sure all tissue margins are of good quality and that the vascularization is intact.

The posterior fascia is closed. On top of this layer, a mesh is placed and secured. Then the anterior fascia is closed to medialize the rectus muscles. Before the posterior fascia with peritoneum is closed the mesh is sutured through the posterior fascia and peritoneum.

In the original Rives-Stoppa, the sutures are placed up through the rectus muscle, frequently resulting in chronic pain. Therefore, the authors recommend suturing the mesh posterior, on top of the posterior fascia.

A nonabsorbable mesh (polypropylene or polyester) is sutured through the posterior fascia. Nonabsorbable sutures are applied 4cm from the wound edges. The sutures are placed in full sight to avoid damage to the intraperitoneal organs.

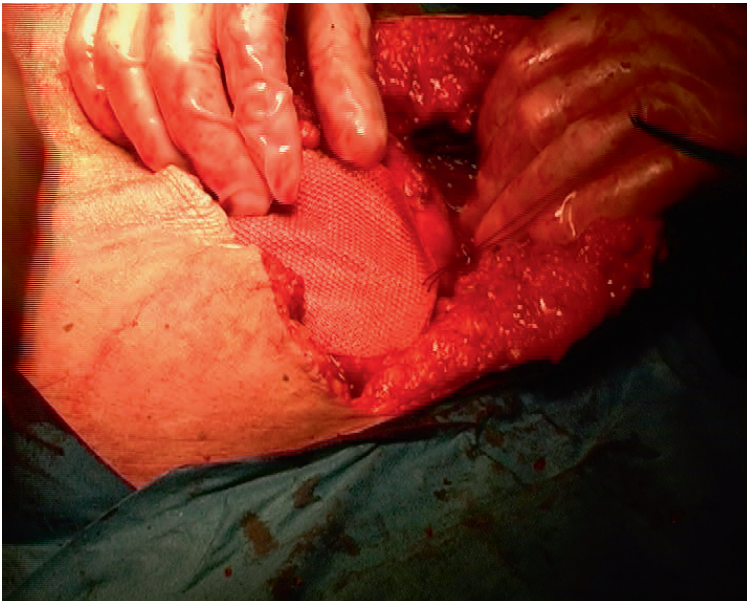


Figure 17.

A crucial step that may prevent damage to the bowel is to place interrupted sutures on the contralateral side before stitching the mesh. This enabled a good view of the intestines before positioning the mesh.

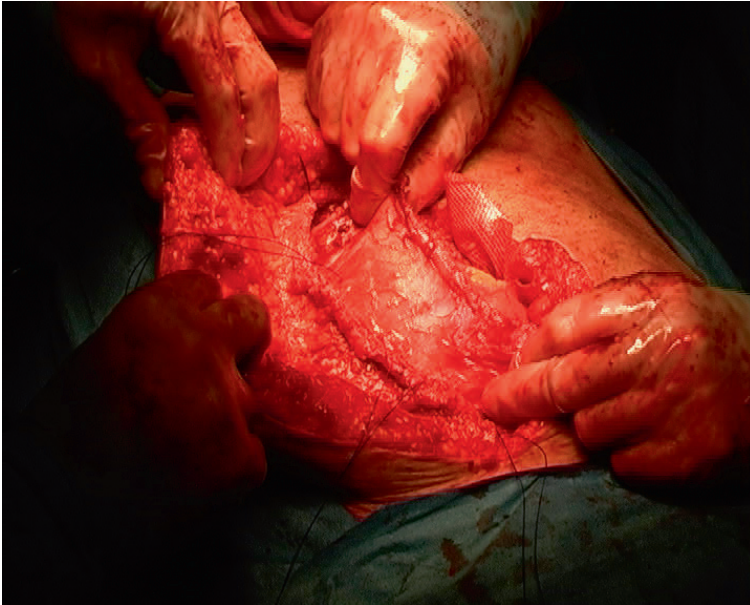


Figure 18.

The posterior fascia is closed using an absorbable suture with an extended absorption profile.

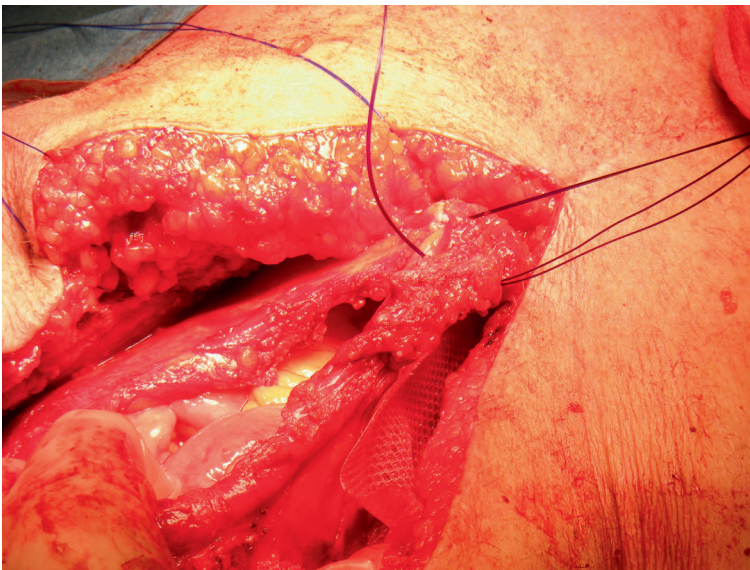


Figure 19.

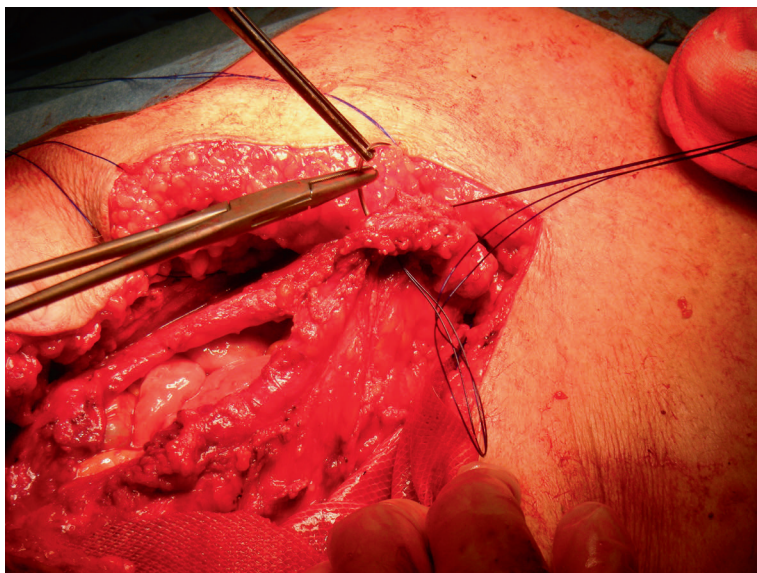


Figure 20.

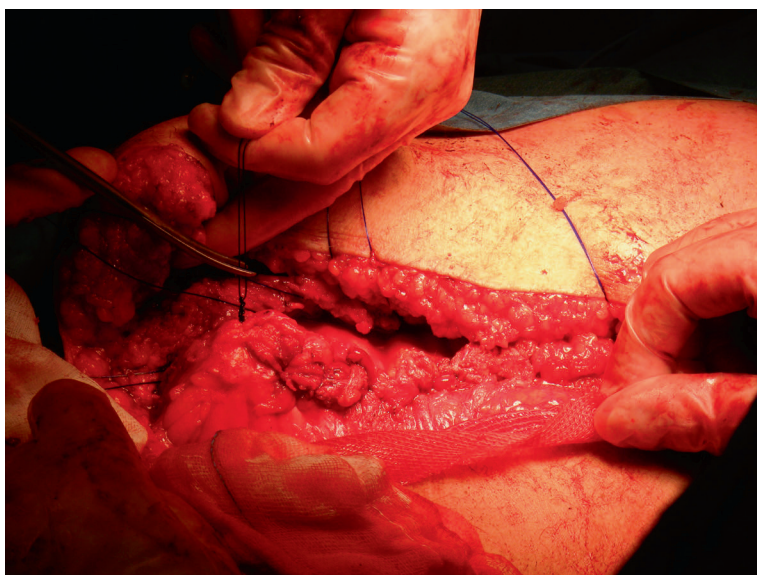


Figure 21.

The previously applied sutures are used to secure the mesh.

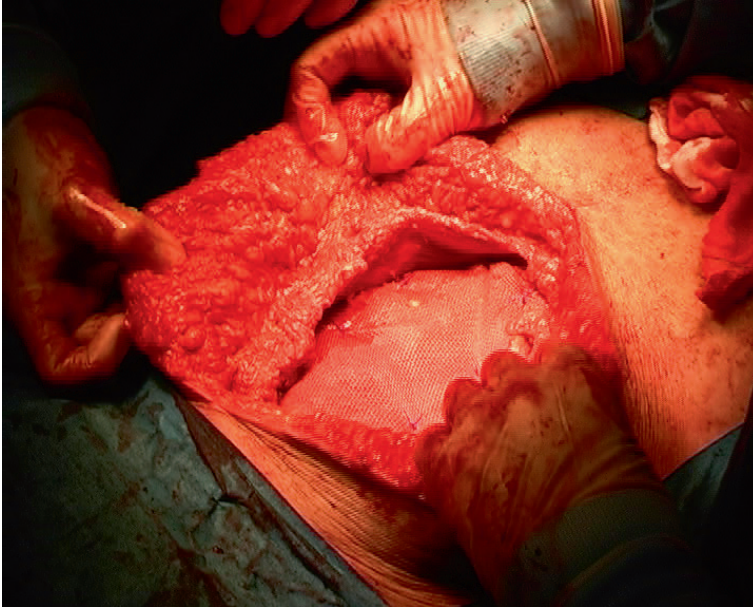


Figure 22.

The anterior fascia with the rectus muscle is closed over the mesh with a slowly absorbable suture.

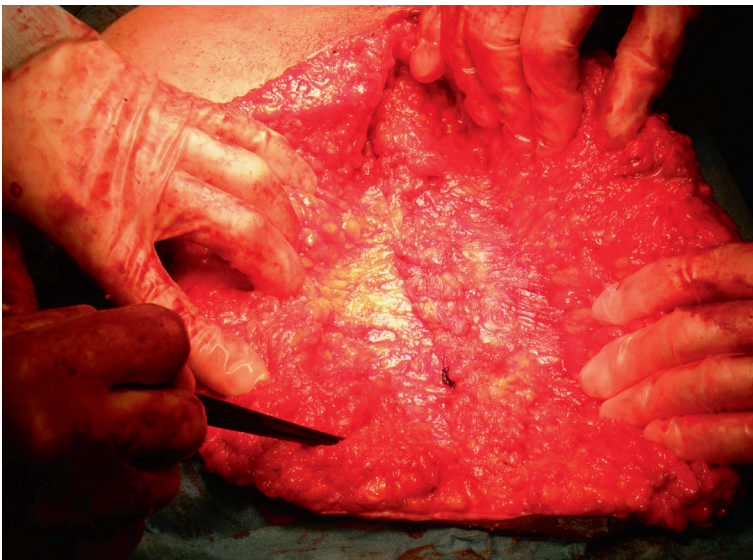


Figure 23.

Place two drains subcutaneously and close the skin in a subcuticular fashion. Drains are placed subcutaneously to prevent seroma. To prevent postoperative pain, a local anaesthetic may be used.

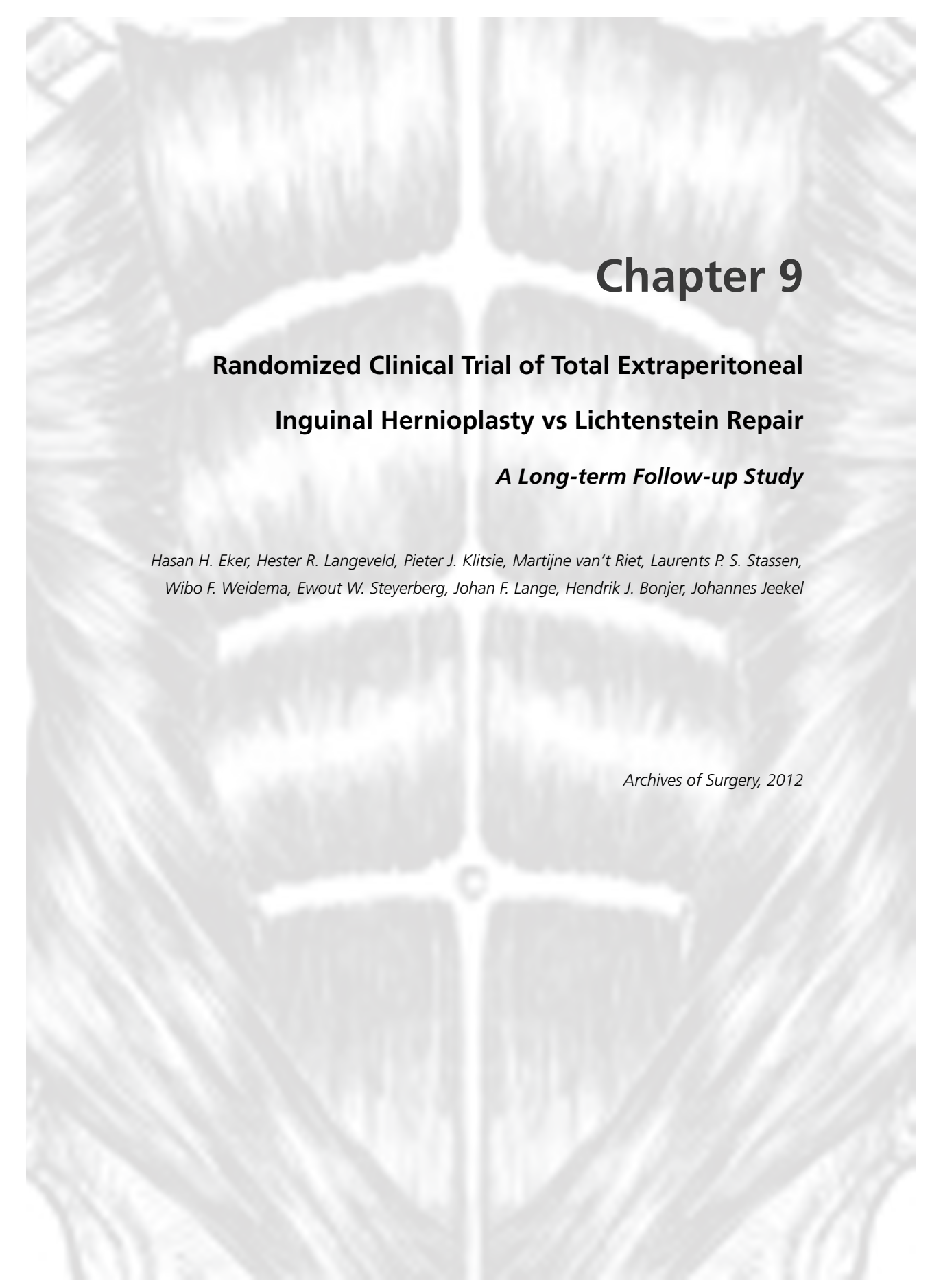
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Figure 24.



Figure 25.



Chapter 9

Randomized Clinical Trial of Total Extraperitoneal Inguinal Hernioplasty vs Lichtenstein Repair

A Long-term Follow-up Study

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Archives of Surgery, 2012

Hypothesis: Mesh repair is generally preferred for surgical correction of inguinal hernia, although the merits of endoscopic techniques over open surgery are still debated. Herein, minimally invasive total extraperitoneal inguinal hernioplasty (TEP) was compared with Lichtenstein repair to determine if one is associated with less postoperative pain, hypoesthesia, and hernia recurrence.

Design: Prospective multicenter randomized clinical trial.

Setting: Academic research.

Patients: Six hundred sixty patients were randomized to TEP or Lichtenstein repair.

Main Outcome Measures: The primary outcome was postoperative pain. Secondary end points were hernia recurrence, operative complications, operating time, length of hospital stay, time to complete recovery, quality of life, chronic pain, and operative costs.

Results: At 5 years after surgery, TEP was associated with less chronic pain ($P = .004$). Impairment of inguinal sensibility was less frequently seen after TEP vs Lichtenstein repair (1% vs 22%, $P < .001$). Operative complications were more frequent after TEP vs Lichtenstein repair (6% vs 2%, $P < .001$), while no difference was noted in length of hospital stay. After TEP, patients had faster time to return to daily activities ($P < .002$) and less absence from work ($P = .001$). Although operative costs were higher for TEP, total costs were comparable for the 2 procedures, as were overall hernia recurrences at 5 years after surgery. However, among experienced surgeons, significantly lower hernia recurrence rates were seen after TEP ($P < .001$).

Conclusions: In the short term, TEP was associated with more operative complications, longer operating time, and higher operative costs; however, total costs were comparable for the 2 procedures. Chronic pain and impairment of inguinal sensibility were more frequent after Lichtenstein repair. Although overall hernia recurrence rates were comparable for both procedures, hernia recurrence rates among experienced surgeons were significantly lower after TEP. Patient satisfaction was also significantly higher after TEP. Therefore, TEP should be recommended in experienced hands.

Trial Registration: clinicaltrials.gov Identifier: NCT00788554

Chronic pain and hypoesthesia after inguinal hernia repair are increasingly gauged, and hernia recurrence rates have decreased as a result of the use of prosthetic mesh.¹⁻⁶ Incidence rates of chronic pain up to 37% have been reported after open inguinal hernia repair.⁷ Surgical technique may have a significant role in the occurrence and reduction of chronic pain, with some studies^{8,9} demonstrating less pain and hypoesthesia after endoscopic repair. Large randomized clinical trials having long-term follow-up periods that compare chronic pain and hypoesthesia associated with open vs endoscopic inguinal hernia repair are rare.^{10,11} Particularly scarce are randomized clinical trials comparing minimally invasive total extraperitoneal inguinal hernioplasty (TEP) with Lichtenstein repair. We report results of a longterm follow-up study of a prospective multicenter randomized clinical trial comparing TEP vs Lichtenstein repair for post-operative pain, hypoesthesia, and hernia recurrence rates among 660 patients.

METHODS

Study design

Between July 18, 2000, and April 28, 2004, adult patients with a primary or recurrent inguinal hernia were eligible for inclusion in the study and were randomly assigned to TEP or Lichtenstein repair. Only patients scheduled for elective repair were included. Patients were excluded if they were pregnant, had a scrotal hernia, or had communicative or cognitive limitations to give informed consent. Other exclusion criteria were a medical history of prostatectomy, Pfannenstiel incision, previous preperitoneal operation, or abdominal bladder operation. The study protocol was approved by the ethics committees of 6 participating centers.

Primary end points were postoperative groin pain, length of hospital stay, and time to complete recovery. Secondary end points were hypoesthesia, hernia recurrence, operative complications, operating time, time to return to daily activities and work, and operative costs.

Randomization was achieved at the ward by telephone call or fax from the central study coordinators (H.R.L. and M.v.R.) using a stratified and balanced computer-generated list. Patients were stratified by center, hernia recurrence (primary, first recurrence, or second recurrence or more), unilateral or bilateral hernia, and inpatient or outpatient treatment. All participating centers were experienced in both hernia repair procedures. The experience of the operating surgeon was registered as level 1 (<10 procedures), level 2 (10-25 procedures), or level 3 (>25 procedures). During each TEP, an experienced surgeon who previously had performed a minimum of 30 TEP procedures was present in the operating room.

Both procedures were standardized and well documented in the study protocol. Polypropylene prosthetic meshes were used for both procedures. Whether the ilioinguinal and iliohypogastric

nerves were identified and spared was reported. More detailed descriptions of the procedures have been published previously.¹¹

Long-term follow-up visits occurred at 1 year and 5 years after surgery. All the patients were invited to visit the ward to undergo physical examination, performed by 2 independent physicians (H.H.E. and P.J.K.) who were unaware of each other's findings or of data from the medical records. The inguinal region was examined for any symptomatic or asymptomatic hernia recurrences on the operated or contralateral side. All the patients were asked about symptoms of chronic pain, sensibility disorders, sexual dysfunction, other hernia occurrences, and hernia recurrences. Postoperative pain and chronic pain in the inguinal and scrotal region were measured using a 10-cm visual analog scale, ranging from no pain (0 cm) to unbearable pain (10 cm). Reoperations during the follow-up period for a recurrent inguinal hernia were recorded. Ultrasonographic examination was performed when findings on physical examination were inconclusive. Patient satisfaction with the surgical procedure and with cosmetic results was assessed using a numeric rating scale, ranging from worst outcome (0 points) to best outcome (10 points).

Statistical analysis

A 2-tailed test was performed with 80% power and an $\alpha = .05$ to determine a difference of 0.7 cm on the visual analog scale for pain. A minimum sample size of 300 patients in each group (TEP vs Lichtenstein repair) was required to detect this difference, resulting in a total number of 600 patients. Considering an estimated dropout rate of 10%, we aimed to include 660 patients. Continuous variables were compared using Mann-Whitney test. Categorical variables were compared using 2 test or Fisher exact test. Cumulative hernia recurrences were calculated using Kaplan-Meier method and were compared using the log-rank test. All the statistical tests were 2-sided; $P .05$ was considered statistically significant. The primary analysis was performed on an intent-to-treat principle; that is, patients remained in their assigned group even if during the procedure the surgeon judged a patient to be unsuitable for the technique to which he or she was allocated. All the analyses were performed using commercially available software (SPSS for Windows, version 15; SPSS, Inc).

RESULTS

Between July 18, 2000, and April 28, 2004, a total of 722 patients consented to randomization, of whom 62 patients (8.6%) were excluded. Among these, 9 patients withdrew consent, and 53 patients did not meet the inclusion criteria. The remaining 660 patients were randomized and analyzed within the groups to which they were allocated to based on the intent-to-treat principle. Of 660 patients, 336 were randomized to TEP and 324 to Lichtenstein repair.

Twenty-one conversions (6.3%) occurred in the TEP group, 19 to Lichtenstein repair and 2 to a transabdominal preperitoneal procedure. Two conversions (6.6%) occurred in the Lichtenstein group, one to Shouldice repair and another to Bassini-McVay repair.

The mean (SD) age of patients at the time of study inclusion was 55 (16) years, with no significant difference between the 2 study groups. No differences were found between the 2 study groups in sex, body mass index, American Society of Anesthesiologists score, comorbidities, or primary vs recurrent hernias. Baseline characteristics of the patients are given in Table 1.

Table 1. Patient Characteristics

	TEP (n=336)	Lichtenstein (n=324)
Age (yrs)	55	56
Male (%)	99	98
Weight (kg)	80	78
Height (cm)	179	178
BMI (kg/m ²)	25	25
DM n (%)	6 (1.8)	9 (2.8)
COPD n (%)	27 (8.0)	14 (4.3)
Sensibility abnormality n (%)	2 (0.6)	2 (0.6)
Testis abnormality n (%)	7 (2.1)	9 (2.7)
ASA (%)		
I	252 (75)	225 (69)
II	77 (23)	91 (28)
III	7 (2)	8 (3)
IV	-	-
Primary hernia (%)	293 (91)	295 (93)
First recurrence (%)	23 (6.8)	18 (5.5)
≥ Second recurrence (%)	6 (1.8)	3 (0.9)
Unilateral (%)	284 (88)	292 (92)
Bilateral (%)	39 (12)	25 (7.7)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); TEP, minimally invasive total extraperitoneal inguinal hernioplasty.

During the long-term follow-up period, 44 patients died, 21 in the TEP group and 23 in the Lichtenstein group (Figure 1). No death was related to inguinal hernia repair. At a median follow-up time of 5.0 years (interquartile range, 2.3-5.8 years), 482 of the 640 patients (75.3%) completed their long-term follow-up visit. The median follow-up periods were comparable for both groups. The cumulative hernia recurrence rates were 4.9% (12 of 247) after TEP and 8.1% (19 of 235) after Lichtenstein repair ($P = .10$) (Figure 2). During the follow-up period, 15 patients underwent reoperation for hernia recurrence, 6 after initial TEP and 9 after initial Lichtenstein repair.

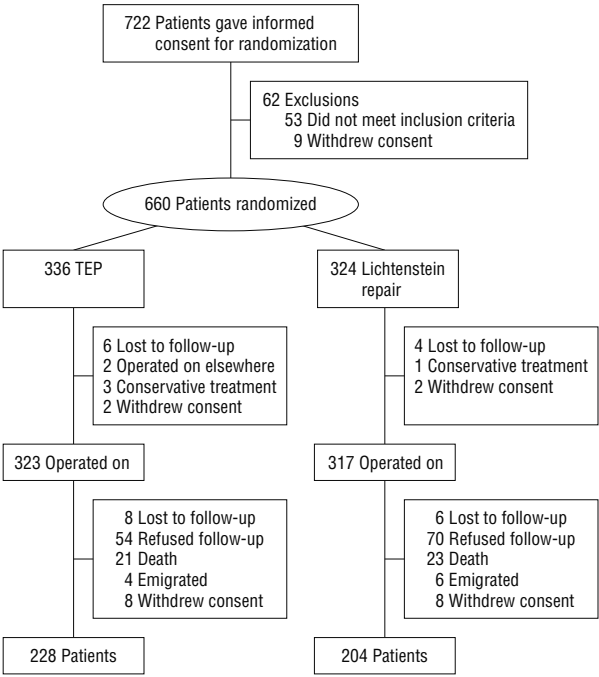


Figure 1. Patients screened for participation in the study. TEP indicates minimally invasive total extraperitoneal inguinal hernioplasty.

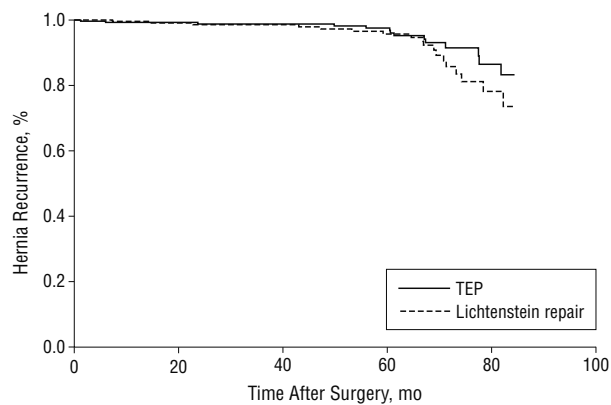


Figure 2. Kaplan-Meier curves for hernia recurrence based on physical examination findings at the outpatient clinic. TEP indicates minimally invasive total extraperitoneal inguinal hernioplasty.

The experience level of the operating surgeon was reported by 457 operating surgeons (71.4%; 457 of 640). Twenty-eight operating surgeons were classified as level 1 surgeons, 27 as level 2 surgeons, and 402 as level 3 surgeons. The overall hernia recurrence rate after 5 years for both procedures performed by experienced residents or surgeons (level 3) was significantly lower than that for inexperienced residents or surgeons (level 1) (2.4% vs 14.3%, $P = .001$). When only TEP procedures were analyzed, the differences in hernia recurrence rates between experienced residents or surgeons (level 3) and inexperienced residents or surgeons (level 1) were more obvious (0.5% vs 25.0%, $P = .001$) (Table 2). The hernia recurrence rates varied between 4.1% and 9.1% among centers but were not statistically different ($P = .67$).

Table 2. Effect of Surgeons' experience on recurrence

	Level 1 (n=28) <10 procedures	Level 2 (n=27) 10-25 procedures	Level 3 (n=402) >25 procedures	p-value
TEP	25%	6.7%	0.5%	<0.001
Lichtenstein	-	10%	4.2%	0.55
Total	16%	8.0%	2.4%	0.001

When only procedures performed by experienced residents or surgeons (level 3) were evaluated, significantly lower hernia recurrence rates were seen after TEP than after Lichtenstein repair (0.5% vs 4.2%, $P = .04$) (Table 3). The number of patients operated on by level 1 and level 2 residents or surgeons was too small to discern any differences between the 2 study groups.

Table 3. Recurrence rates for experienced and inexperienced surgeons

	TEP (n=235)	Lichtenstein (n=222)	p-value
Level 1-% (n=28)	25% (4)	- (0)	0.26
Level 2-% (n=27)	6.7% (1)	10% (1)	>0.99
Level 3-% (n=402)	0.5% (1)	4.2% (8)	0.04

Abbreviation: TEP, minimally invasive total extraperitoneal inguinal hernioplasty.

Experience level 1 is fewer than 10 procedures; level 2, 10 to 25 procedures; and level 3, more than 25 procedures.

At 5 years after surgery, the incidence of chronic pain was significantly higher in the Lichtenstein group (28.0%) compared with the TEP group (14.9%) ($P = .004$). The visual analog scale scores for pain were significantly higher in the Lichtenstein group (1.5 cm) compared with the TEP group (0.9 cm) ($P = .03$) (Figure 3). No significant differences were found in testicular pain between the study groups ($P = .09$). Identification and preservation of the ilioinguinal and iliohypogastric nerves had no influence on the incidences of inguinal pain and sensibility disorders ($P = .10$ and

$P = .07$, respectively). Whether inguinal nerves were identified was reported for 339 patients: both inguinal nerves were recognized in 199 patients (58.7%), the ilioinguinal nerve in 33 patients (9.7%), the iliohypogastric nerve in 4 patients (1.2%), and no nerves in 103 patients (30.4%). Whether inguinal nerves were preserved was reported for 293 patients: both inguinal nerves were preserved in 163 patients (55.6%), the ilioinguinal nerve in 20 patients (6.8%), the iliohypogastric nerve in 7 patients (2.4%), and no nerves in 103 patients (35.2%).

Sensibility disorders and numbness were more frequently reported in the Lichtenstein group. At 5 years after surgery, 21.7% of patients in the Lichtenstein group reported sensibility disorders compared with 1.2% of patients in the TEP group ($P < .001$).

On a scale of 0 to 10, patient satisfaction with the surgical procedure was significantly higher after TEP compared with Lichtenstein repair (8.5 vs 8.0 points, $P = .004$).

Patients were also more satisfied with their operative scars after TEP (8.8 vs 8.4 points, $P = .02$).

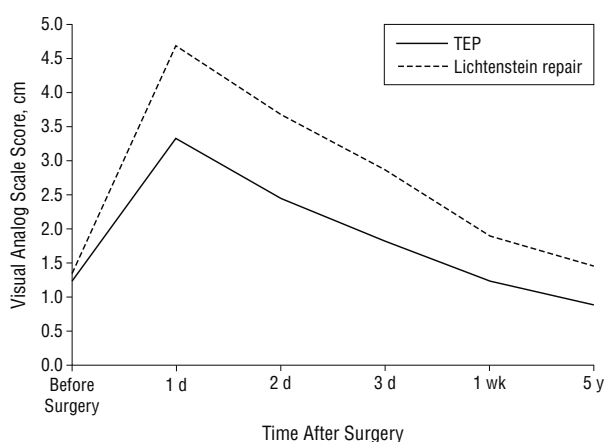


Figure 3. Visual analog scale scores for postoperative pain. TEP indicates minimally invasive total extraperitoneal inguinal hernioplasty.

COMMENT

For many decades, inguinal hernia repair has been based on “the radical cure of inguinal hernia” according to Bassini¹² and subsequent other herniorrhaphy techniques based on suture repair developed during the 20th century, such as the McVay and Shouldice techniques. However, these procedures were often associated with severe postoperative pain and high inguinal hernia recurrence rates. The introduction of tension-free repair using prosthetic mesh represented a new era in inguinal hernia repair.¹³ By reducing hernia recurrence rates, other long-term complications, such as postoperative pain and chronic pain, were addressed.

Our study is not the first evaluation of recurrence rates and chronic pain after open or endoscopic inguinal hernia repair.^{10,14-19} Several randomized trials^{10,14-19} comparing open and laparoscopic repair have been published, but most enrolled few patients or compared various open techniques with endoscopic techniques. Some studies^{14,18} had short follow-up periods or did not report chronic pain and sensibility impairment. The follow-up methods of previous investigations have been variable or even suboptimal because hernia recurrences were often determined using questionnaires. Vos et al²⁰ compared follow-up results using questionnaires and physical examination and found that at least half of the hernia recurrences were missed using questionnaires only. The accuracy of hernia recurrence rates in our study is ensured because every patient in our study had a clinical follow-up visit with physical examination performed by 2 independent physicians.

Our long-term follow-up data after inguinal hernia repair show that overall recurrence rates seem to be comparable after TEP and Lichtenstein repair. However, the experience level of the surgeon was found to be an independent risk factor for hernia recurrence. Significantly lower hernia recurrence rates were found among experienced surgeons (level 3) after TEP vs after Lichtenstein repair (0.5% vs 4.2%, $P = .04$).

In our study design, we tried to eliminate learning curve bias by assuring that during every endoscopic procedure in this study a surgeon with substantial experience in laparoscopic surgery participated by supervising or operating. In retrospect, we wonder if the requirement of 30 procedures was sufficient. Since the beginning of our study, some authors^{14,15,21-23} have reported 80 to 250 procedures before notable improvements occur in surgical outcomes after TEP.

Hernia recurrence rates are expected to increase with longer follow-up periods because recurrences may occur up to 10 years after initial repair.⁴ Some earlier investigations comparing open vs endoscopic repair found lower hernia recurrence rates after TEP.¹⁵ Other researchers have reported that hernia recurrence rates were significantly lower after Lichtenstein repair.¹⁸ A Cochrane review²⁴ and a meta-analysis²⁵ comparing open vs laparoscopic herniorrhaphy showed no difference in recurrence rates. Meta-analyses comparing TEP alone with Lichtenstein repair are needed to determine which technique is associated with the lowest hernia recurrence rate.

Chronic pain seems to be the most frequent longterm complication after open inguinal hernia repair. Particularly, if inguinal nerves are not recognized and preserved, the incidence of chronic pain increases considerably.²⁶ However, an advantage of recognition and preservation of inguinal nerves could not be confirmed in our study. In the present study,¹¹ postoperative pain was significantly less after TEP (23%) than after Lichtenstein repair (32%) ($P = .01$), measured at intervals of 1, 2, or 3 days and 1 week and 4 weeks after surgery. Post-operative pain was

evaluated as pain vs no pain. Earlier results demonstrated that return to work was quicker and recovery of daily activities was faster after TEP than after Lichtenstein repair.¹¹ Another important finding herein was that impairment of inguinal sensibility in the groin region seemed to be less frequently observed after TEP than after Lichtenstein repair (1% vs 22%, $P < .001$).

These positive outcomes for TEP are counterbalanced by its association with a significantly higher incidence of operative complications.¹¹ However, none of these operative complications affected the long-term outcomes of patients. During long-term follow-up periods, the incidence of chronic pain, severity of chronic pain, and impairment of inguinal sensibility seemed high in the Lichtenstein group (28%, 1.5 cm, and 22%, respectively) and were significantly lower in the TEP group (15%, 0.9 cm, and 1%, respectively) ($P = .004$, $P = .03$, and $P < .001$, respectively).

A strength of our study is that it was a multicenter randomized clinical trial that included many patients, randomizing between only Lichtenstein repair for open surgery and TEP for endoscopic repair. The fact that physical examination of each patient was performed by 2 independent physicians increases the reliability of our hernia recurrence rates.

In summary, this randomized controlled trial shows in a long-term follow-up study that the overall incidences of hernia recurrence after TEP and Lichtenstein repair are comparable at 5 years after surgery. Among experienced surgeons, the hernia recurrence rates were significantly lower after TEP than after Lichtenstein repair. Experience level of the surgeon was found to be an independent risk factor for hernia recurrence after inguinal hernia repair. Postoperative pain in the short term and chronic pain at 5 years after surgery were significantly greater after Lichtenstein repair vs TEP (32% vs 23% and 28% vs 15%, respectively), as was impairment of inguinal sensibility (22% vs 1%). Patients are more satisfied after TEP with the surgical procedure and with their operative scars. Therefore, TEP should be recommended in experienced hands.

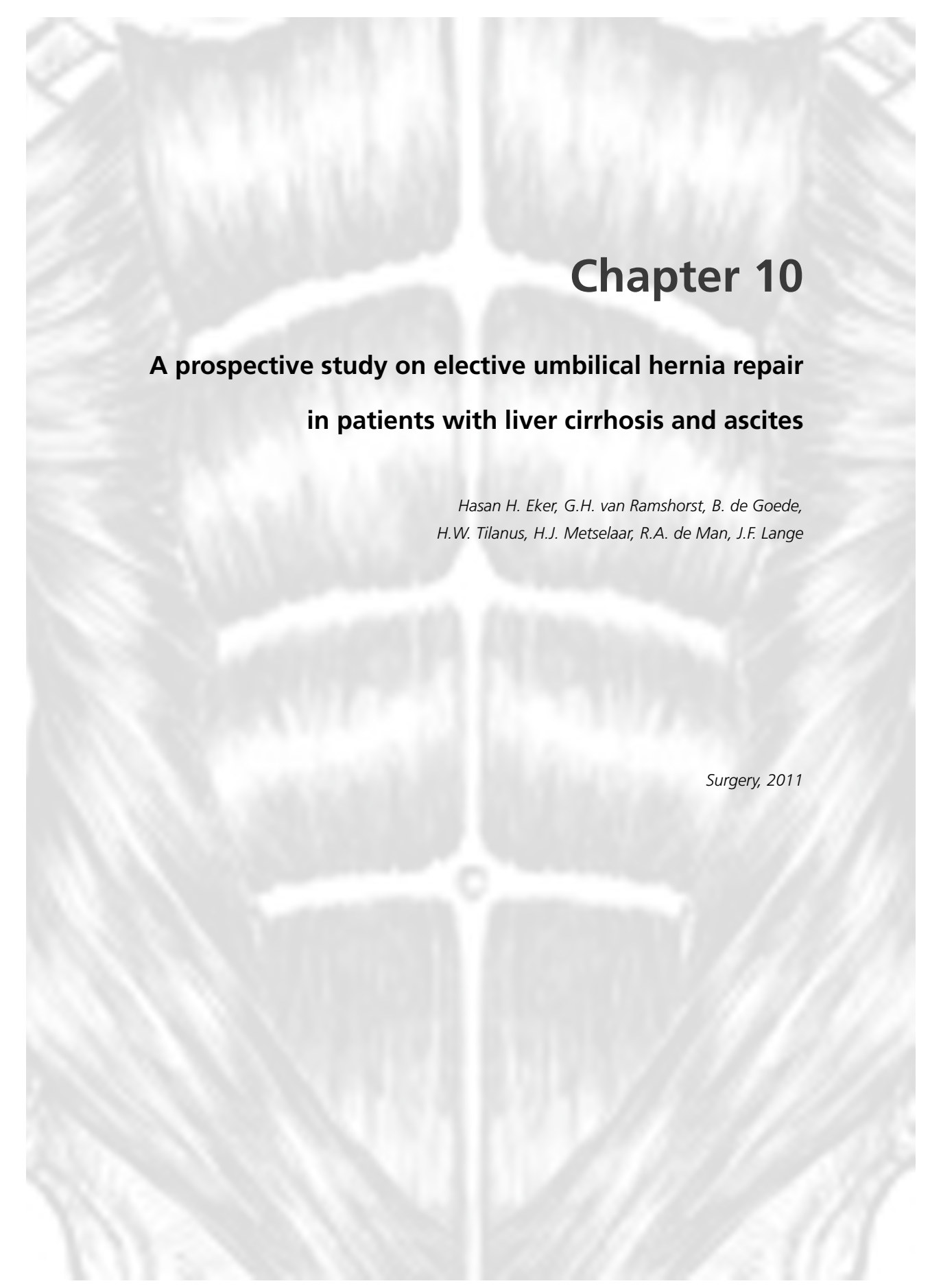
Accepted for Publication: November 4, 2011. **Correspondence:** Hasan H. Eker, MD, Department of Surgery, Erasmus Medical Center, PO Box 2040, 3000 CA Rotterdam, the Netherlands (h.eker@erasmusmc.nl). **Author Contributions:** *Study concept and design:* Eker, Langeveld, van't Riet, Lange, Bonjer, and Jeekel. *Acquisition of data:* Eker, Langeveld, Klitsie, van't Riet, Stassen, and Weidema. *Analysis and interpretation of data:* Eker, Klitsie, van't Riet, Steyerberg, Lange, Bonjer, and Jeekel. *Drafting of the manuscript:* Eker, Langeveld, Klitsie, and Jeekel. *Critical revision of the manuscript for important intellectual content:* Langeveld, Klitsie, van't Riet, Stassen, Weidema, Steyerberg, Lange, Bonjer, and Jeekel. *Statistical analysis:* Eker and Steyerberg. *Administrative, technical, and material support:* Klitsie, van't Riet, and Weidema. *Study supervision:* Langeveld, Stassen, Lange, Bonjer, and Jeekel.

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Chapter 10

A prospective study on elective umbilical hernia repair in patients with liver cirrhosis and ascites

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Surgery, 2011

ABSTRACT

Background Patients with both cirrhosis and ascites have a 20% risk of developing umbilical hernia. A retrospective study from our center comparing conservative management of umbilical hernia with elective repair in these patients showed a significant risk of mortality as a result of hernia incarceration in conservatively treated patients. The goal of this study was to assess the safety and efficacy of elective umbilical hernia repair in these patients prospectively.

Methods Patients with liver cirrhosis and ascites presenting with an umbilical hernia were included in this study. For all patients, the expected time to liver transplantation was more than 3 months, and they did not have a patent umbilical vein in the hernia sac. The following data were collected prospectively for all patients: Child-Pugh-Turcotte (CPT) classification, model for endstage liver disease (MELD) score, kidney failure, cardiovascular comorbidity, operation-related complications, and duration of hospital stay. Mortality rates were registered in hospital records and verified in government records during follow-up. Mortality rates were registered in hospital records and verified in government records during follow-up. On completion of the study, a retrospective survey was performed to search for any patients who met the study inclusion criteria but were left out of the study cohort.

Results In total, 30 patients (25 males) underwent operation at a mean age of 58 years (standard deviation [SD] $\pm$ 9 years). Of these 30 patients, 6 were classified as CPT grade A (20%), 19 (63%) as grade B, and 5 (17%) as grade C. The patients' median MELD score was 12 (interquartile range [IQR], 8–16). In 10 (33%) of the 30 patients hernia repair was performed with mesh. The median duration of hospital stay was 3 days (IQR, 2–4). None of the patients were admitted to the intensive care unit. Postoperative complications included pneumonia and decompensation of cirrhosis (1 case each,) resulting in prolonged hospital stay for those 2 patients. After a median follow-up period of 25 months (IQR, 14–34), 2 (7%) of the 30 patients died; neither of the deaths were attributable to the umbilical hernia repair. A total of 2 patients suffered recurrence.

Conclusion Elective umbilical hernia repair is safe and the preferred approach in cirrhotic patients with ascites.

INTRODUCTION

Patients with liver cirrhosis and ascites have a risk of 20% of developing an umbilical hernia in the course of their disease.¹ Possible factors that contribute to the development of umbilical hernia in these patients include increased intra-abdominal pressure due to ascites, weakening of the abdominal fascia and muscle wasting as a result of poor nutritional status, and dilation of the umbilical vein that enlarges the preexistent supraumbilical fascial opening in patients with portal hypertension.²

Although the incidence of umbilical hernia is high in cirrhotic patients, an optimal treatment strategy is unclear. For many years, surgical dogma dictated a “wait and see” approach, and surgical repair of umbilical hernia was limited to patients who developed complications.^{3, 4, 5, 6 and 7} Conservative management, however, can be complicated by bowel incarceration or spontaneous rupture from necrosis of overlying skin and subsequent peritonitis. Such conditions force emergency repair in patients who are then at a greater risk of developing complications in an emergency setting than after elective surgery.^{8, 9, 10 and 11}

This scenario appears to be particularly true in circumstances of acute removal of large amounts of ascites, such as large-volume paracentesis after transjugular intrahepatic portosystemic shunt (TIPS) or liver transplantation. Both of these procedures result in an acute decrease in the diameter of the fascial defect. In these instances, abdominal contents inside the hernia sac can become incarcerated.⁶

Currently, the natural course of umbilical hernia in patients with ascites is largely unknown, particularly in patients waiting liver transplantation, and prospective studies in this field are lacking.^{7, 8 and 12} A recent retrospective study from our center comparing conservative management of umbilical hernia in these patients with elective repair showed a significant risk of mortality resulting from hernia incarceration in conservatively treated patients.⁸

After this study was completed, the treatment strategy of patients with liver cirrhosis and ascites with an umbilical hernia was changed at our center from “wait and see” to an elective repair protocol. The objective of this study was to evaluate the results of this protocol of elective umbilical hernia repair in patients with concurrent ascites and liver cirrhosis prospectively.

METHODS

Between July 2004 and May 2010, all patients in the Erasmus University Medical Center with umbilical hernia, cirrhosis, and ascites were included in this study and followed prospectively. Liver failure with cirrhosis was diagnosed on clinical, biochemical, or histologic findings. Ascites was

diagnosed with ultrasonography or computed tomography, and umbilical hernia was diagnosed on clinical examination.

All patients included in the study were scheduled for elective hernia repair unless their expected waiting time for a liver transplantation was less than 3 months or a patent umbilical vein was present in the wall of their hernia sac. Patients with an expected waiting time for transplantation of less than 3 months or in whom a patent umbilical vein was found on ultrasonography or computed tomography were excluded from the study.

Elective hernia correction was carried out after optimal management of ascites with 2 diuretics (spironolactone [Aldactone; GD Searle/Pfizer, New York, NY] and furosemide [Lasix; Sanofi-Aventis, Paris, France]), early nutritional support, and intravenous albumin to increase patients' serum albumin to greater than 30 g/L. No large-volume paracentesis was performed preoperatively.

All patients who underwent elective and acute umbilical hernia repair within the study period at our institution were identified retrospectively to ensure that no patients who met the inclusion criteria were excluded from the final study cohort. The primary goal of the study was to investigate safety of elective umbilical hernia repair in cirrhotic patients.

The following data were collected prospectively for all patients: age, sex, nicotine and alcohol use, malignancy, chronic obstructive pulmonary disease, diabetes mellitus, chronic steroid use, primary or recurrent umbilical hernia, hernia size, serum bilirubin ($\mu\text{mol/L}$), serum albumin (g/L), serum creatinine ($\mu\text{mol/L}$), international normalized ratio, hepatic encephalopathy, Child-Pugh-Turcotte (CPT) classification, model for end-stage liver disease (MELD) score at the time of surgery, cardiovascular comorbidity, American Society of Anesthesiologists (ASA) score, presence of hernia strangulation or incarceration, use of mesh in hernia repair, mesh positioning, simultaneous liver transplantation, perioperative and postoperative complications, admission to the intensive care unit, and duration of hospital stay.

Mortality rates were registered in hospital records and verified in government records during follow-up. All patients were invited for clinical examination by 1 of the authors at the outpatient clinic to diagnose recurrence after a minimum follow-up of 6 months. Statistical analyses were carried out with the SPSS statistical software package (SPSS Inc, Chicago, IL). The chi-square test and the Mann-Whitney U test were used for categorical and continuous variables, respectively. Values were considered statistically significant at 2-sided P values less than .05. Data were described as median and interquartile range (IQR).

RESULTS

Patient characteristics (Table I). A total of 30 consecutive patients (25 males, 5 females) at a median age of 58.3 years (IQR, 51–65) were included in the elective repair protocol. Of these 30 patients, 7 (23%) were classified as CPT grade A, 18 (60%) as grade B, and 5 (17%) as grade C. The median MELD score was 12 (IQR, 8–16). Of the 30 patients, 6 (20%) had an ASA score of class II, 20 (67%) were class III, and 4 (13%) were class IV. A total of 53% of the patients were on the waiting list for liver transplantation.

Table 1. Patient Characteristics

	N = 30
Male, n (%)	5 (83)
Median age, y	58.3 (51–65)*
Primary umbilical hernia, n (%)	28 (93)
Recurrent umbilical hernia, n (%)	2 (7)
CPT classification, n (%)	
A	7 (23)
B	18 (60)
C	5 (17)
MELD score, median	12 (8–16)*
ASA class, n (%)	
I	0 (0)
II	6 (20)
III	20 (67)
IV	4 (13)

* Data in parentheses represent the interquartile range.

IQR, Interquartile range; CPT, Child-Pugh-Turcotte; MELD, model for end-stage liver disease; ASA, American Society of Anesthesiologists.

Comorbidities of patients in the protocol (Table II). At the time of hernia repair, 6 (20%) of the 30 patients in the protocol reported smoking, and 7 (23%) had alcohol abuse noted in their medical history. Only 1 (3%) patients had a malignancy related to the liver. Of the 30 patients, 6 (20%) reported chronic steroid use, and 6 (20%) suffered from type 2 diabetes mellitus.

Table 2. Comorbidities of patients included in the protocol

	Elective repair (N = 30)
Smoking, n (%)	6 (20)
Alcohol abuse, n (%)	7 (23)
Malignancy, n (%)	1 (3)
Chronic steroid use, n (%)	6 (20)
Diabetes, n (%)	6 (20)

Operation characteristics and postoperative course (Table III). All hernia repairs were performed in an elective setting with an open technique and under general anesthesia. In all patients, the presence of ascites was confirmed. In 10 (33%) of the 30 patients hernia repair was performed with a flat heavy weight polypropylene mesh. The use of mesh for hernia repair was at surgeon's discretion. Of these 10 repairs, 5 meshes were placed using the intraperitoneal (onlay) technique and 5 were placed with the preperitoneal (inlay) technique. Peritoneal tears that occurred during dissection of the hernial sac were closed with absorbable sutures.

Postoperatively, 2 patients experienced complications that necessitated prolonged hospital stay: 1 developed pneumonia and the other patient underwent decompensation of cirrhosis. The median hospital stay was 3 days (IQR, 2–4). None of the patients were admitted to the intensive care unit. At a median follow-up of 10 months, 2 (7%) of the 30 patients died: 1 died from bacteremia associated with cholangitis and hepatorenal syndrome, and the other patient committed suicide during follow-up. None of the deaths were assumed attributable to the umbilical hernia repair. After a median follow-up of 25 months (IQR, 14–34), 2 (7%) of the 30 patients suffered a recurrence. Both underwent the primary hernia repair without the use of mesh.

No notable correlations could be found between either CPT classifications or MELD scores with postoperative complications and recurrences ($P = .06$ and $P = .17$, respectively).

Table 3. Perioperative outcomes

	Elective repair (N = 30)
Operative time, min	79 (66–94)*
Defect size, mm	15 (9)†
Mesh repair, n (%)	10 (33)
Duration of hospital stay, d	3 (24)*
ICU admission, n (%)	0 (0)

* Data are presented as median (interquartile range).

†Data are presented as mean (standard deviation).

ICU, Intensive care unit.

Retrospective review

In the retrospective review, 163 patients were identified who underwent umbilical hernia repair at our institution during the study period. Of these 163 patients, 30 were in the protocol and are described above. Of the 133 patients not included in the protocol, 127 were not eligible for the study, but 6 of these patients had ascites and liver cirrhosis and should have been considered for inclusion in the protocol.

Of these 6 patients, 4 were not included in the study even though they met the inclusion criteria; they later underwent elective correction and did not experience any negative sequelae. The

remaining 2 patients were excluded from the study because they were diagnosed with a patent umbilical vein and planned to undergo hernia correction during liver transplantation.

Unfortunately, the hernia correction proved to be unsuccessful for both patients. One of the patients developed an incarcerated umbilical hernia 3 months after transplantation, which was corrected successfully without negative sequelae, but the other patient was readmitted to the hospital 2 months after liver transplantation, also with an incarcerated umbilical hernia. In this case, the complication resulted in multiple organ failure and the patient's death.

DISCUSSION

In this prospective single-center study, the safety of umbilical hernia repair in cirrhotic patients with ascites was investigated in a series of 30 consecutive patients. All patients underwent operations in an elective setting. Previous retrospective studies⁵ and ⁸ have demonstrated that conservative treatment of umbilical hernia in cirrhotic patients is associated with considerable morbidity and mortality. Hence, prospective series, such as this one, are needed to assess the safety and efficacy of elective umbilical hernia repair in this specific group of patients.

Patients with an expected waiting time to liver transplantation of less than 3 months were excluded from this study. The risk of an additional operation for these patients who typically have high MELD scores was considered greater than the risk of waiting 3 months until transplantation, because the hernia would be corrected during the transplantation procedure.

Furthermore, patients with a patent umbilical vein were also excluded from the study. The repair of an umbilical hernia necessitates the complete freeing of the umbilical ring and the ligation of a possibly reopened umbilical vein. This reopened umbilical vein can be an important outflow for the portal circulation in patients with severe portal hypertension. If the vein is ligated during umbilical hernia repair, the outflow of the portal circulation is hampered, which can lead to acute portal vein thrombosis, subsequent acute failure of the liver necessitating emergency liver transplantation.⁹ and ¹³

In our study group, the incidence of complications after elective repair was low (7%) compared to complication rates reported in the literature (43%).⁸ Other studies also have demonstrated that postoperative outcome in cirrhotic patients is correlated with the patient's CPT classification and, especially, with their MELD score.^{12, 14} and ¹⁵ In our series, however, no significant correlations were found between either a patient's CPT classification or MELD score and their postoperative outcome, but this finding could be due to the relatively low number of patients in our study.

In this study, elective hernia correction was carried out after optimal management of ascites by the use of diuretics, early nutritional support, and intravenous albumin to increase the patient's

serum albumin to greater than 30 g/L. More invasive interventions to optimize the condition of the patient are possible, such as staged and concomitant portovenous shunting in combination with hernia repair, preoperative placement of TIPS to control portal hypertension, or mechanical ascites management by temporary placement of peritoneal dialysis catheters to allow drainage of postoperative ascites.^{16, 17 and 18} None of these more invasive therapeutic modalities, however, were used preoperatively in this study.

At long-term follow-up, recurrences were found in 2 patients, both of whom had undergone primary hernia repair without the use of prosthetic mesh. The incidence of recurrences after umbilical hernia repair can be diminished markedly by using mesh, as demonstrated in this patient group and other studies.^{19, 20 and 21}

With the use of mesh, the chance of leakage of ascites is increased in cirrhotic patients; such leakage can lead to infection of the mesh and, more rarely, bacterial peritonitis. As a result, many surgeons may be reluctant to use mesh for umbilical hernia repair in this patient group. In most cases, bacterial infection of meshes made of polypropylene or polyester can be treated with antibiotics, and removal of the mesh is rarely required.^{22 and 23} Infection of the mesh was not observed in our series, nor are we aware of any studies in the literature in which an increased risk of mesh infection was observed in cirrhotic patients.

Of the 6 patients identified from the retrospective check for missed patients at our institution, 2 were considered for inclusion but excluded because of they had a patent umbilical vein. Both patients should have undergone elective umbilical hernia repair during the liver transplantation procedure, but this was mistakenly not performed with devastating results in 1 of the 2 patients. Performing umbilical hernia repair simultaneously with liver transplantation appears to be the optimal setting by avoiding complications associated with an extra admission and the use of general anesthesia. Due to organ shortages, however, the waiting time for transplantation has increased considerably, exposing patients on the waiting list to a greater risk of developing incarceration of the hernia. This situation leads to an increase in the need for emergency – rather than elective – repairs.

Considering this fact, one could argue that elective repair of symptomatic umbilical hernia even in patients on the waiting list for transplantation is the safer strategy. Randomized studies, however, must be performed to create sufficient evidence for such a policy. Our results of elective umbilical hernia repair in cirrhotic patients are very encouraging and provide sufficient evidence to set up a randomized, controlled trial on this topic.

Before such trials are undertaken, however, one needs to consider that the repairs carried out in our study were performed at a liver transplantation center with considerable experience with this patient group. The multidisciplinary approach of preoperative, perioperative, and postoperative

care may be responsible for the positive results of our study. For this reason, implementation of umbilical hernia repair in cirrhotic patients in other centers should also focus on the overall management of care.

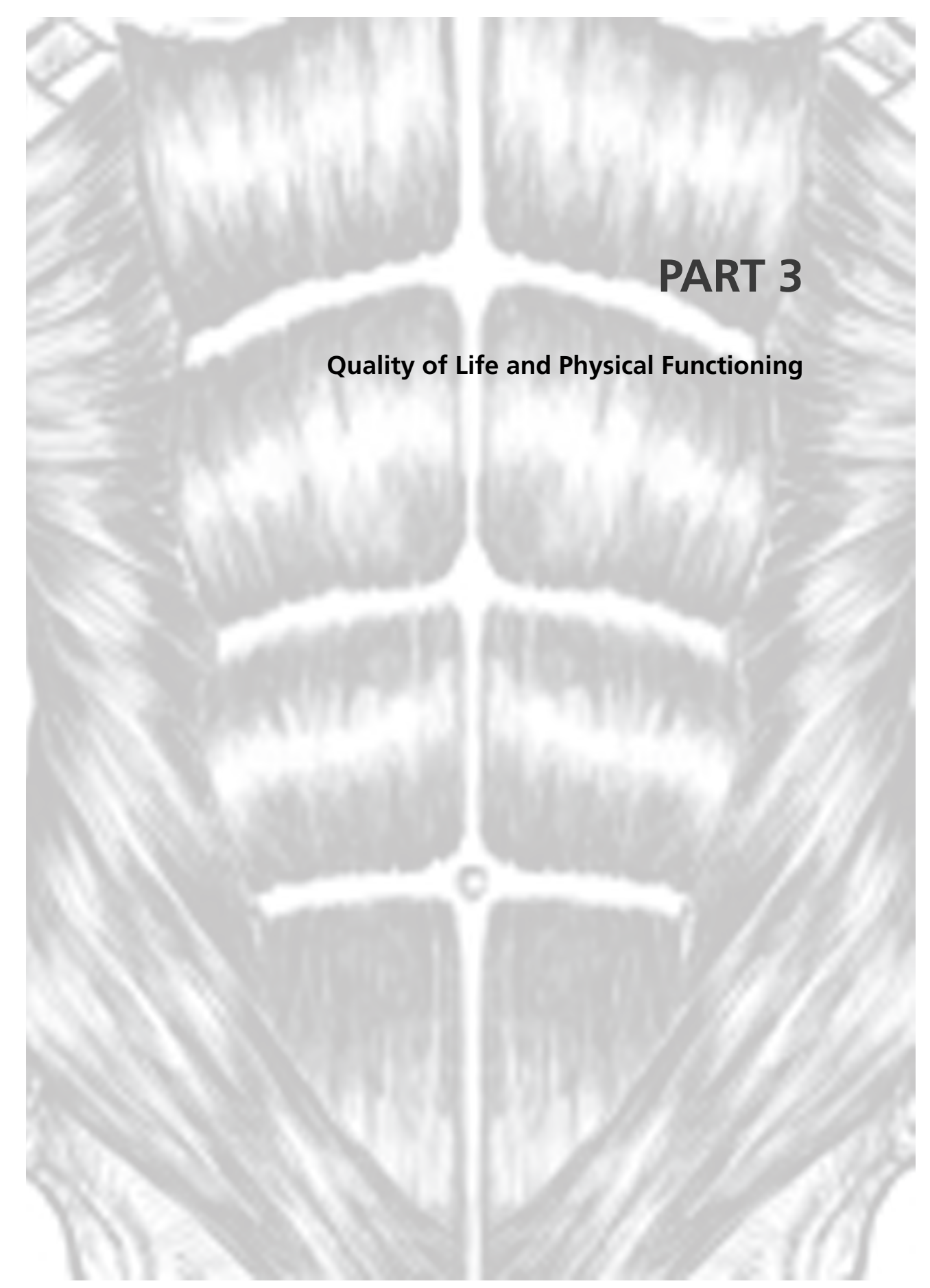
In conclusion, elective umbilical hernia repair is a safe approach and seems preferable over conservative treatment in selected cirrhotic patients. We have reported the first prospective data that advocate elective umbilical hernia repair in cirrhotic patients. A prospective, randomized clinical trial is needed to support our findings, and thereby reach a greater level of evidence to encourage implementation of this treatment strategy in other liver transplantation centers.

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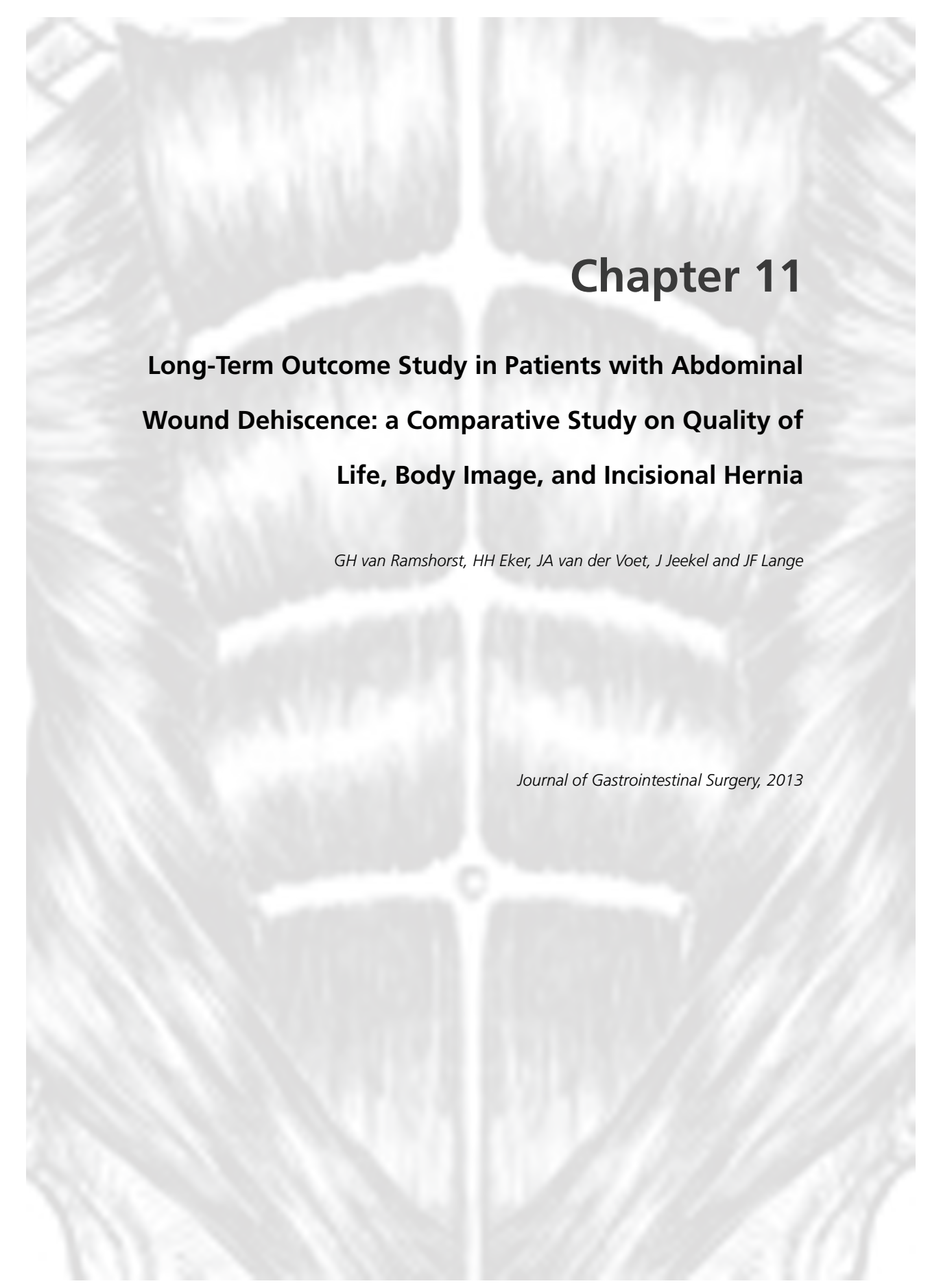




PART 3

Quality of Life and Physical Functioning





Chapter 11

Long-Term Outcome Study in Patients with Abdominal Wound Dehiscence: a Comparative Study on Quality of Life, Body Image, and Incisional Hernia

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ABSTRACT

Objective: Long-term quality of life and body image of patients with abdominal wound dehiscence were assessed.

Methods: Thirty-seven patients with abdominal wound dehiscence from a prospectively followed cohort of 967 patients (2007–2009) were reviewed. Patients completed the Short Form 36 quality of life questionnaire and Body Image Questionnaire and participated in semi-structured telephone interviews. For each patient, four controls were matched by age and gender. Analyses were adjusted for age, gender, comorbidity, and follow-up length.

Results: Of the 37 patients with abdominal wound dehiscence, 23 were alive after a mean follow-up of 40 months (range 33–49 months). Nineteen patients developed incisional hernias (83 %). Patients with abdominal wound dehiscence reported significantly lower scores for physical and mental component summaries ($p=0.038$, $p=0.013$), general health ($p=0.003$), mental health ($p=0.011$), social functioning ($p=0.002$), and change ($p=0.034$). No differences were found for physical functioning ($p=0.072$), role physical ($p=0.361$), bodily pain ($p=0.133$), vitality ($p=0.150$), and role emotional ($p=0.138$). Patients with abdominal wound dehiscence reported lower body image scores (median 16.5 vs. 18, $p=0.087$), cosmetic scores (median 13 vs. 16, $p=0.047$), and total body image scores (median 30 vs. 34, $p=0.042$).

Conclusions: At long-term follow-up, patients with abdominal wound dehiscence demonstrated a high incidence of incisional hernia, low body image, and low quality of life.

Keywords: Surgical wound dehiscence Hernia Quality of life

INTRODUCTION

Abdominal wound dehiscence, or burst abdomen, is an acute hernia, a defect of the fascia occurring in the early postoperative period. It is a severe complication of open abdominal surgery, associated with high morbidity and mortality rates varying between 3 and 35 % in most studies.^{1–10} No previous studies have investigated quality of life, body image, or costs in patients with abdominal wound dehiscence. Both conservative and operative management of abdominal wound dehiscence have been associated with a very high incidence of incisional hernia.² Van 't Riet et al. found an incidence of incisional hernia of 44 % at 1 year and a 10-year cumulative incidence of 69 % after various types of wound dehiscence repair, with abdominal aortic aneurysm and evisceration as significant independent risk factors for incisional hernia.¹ Also, the use of mesh in abdominal wound dehiscence repair can be complicated by mesh infection, enterocutaneous fistula formation, and mesh migration, especially in the presence of intra-abdominal infection.^{3,11} Although various studies have studied the long-term impact of incisional hernia on quality of life and/or body image, no studies have focussed specifically on quality of life in patients with abdominal wound dehiscence.^{12–14} Therefore, this study was intended to prospectively determine and compare the long-term health-related quality of life and body image between patients with abdominal wound dehiscence and a group of control patients from the original study cohort. In addition, rates of recurrence (reburst), incisional hernia, and costs were studied.

MATERIALS AND METHODS

Between May 2007 and January 2009, 967 eligible patients who underwent open abdominal surgery at a university hospital were included in a prospective observational study which involved daily protocolled abdominal wound assessment.^{14,15} Primary outcomes for this study included surgical site infection and abdominal wound dehiscence. Abdominal wound dehiscence was defined as a defect of the fascia of the abdominal wall incision during the postoperative period. The pre-estimated incidence of abdominal wound dehiscence in this cohort was 3 %. Type of management (conservative or operative repair, with or without mesh) of abdominal wound dehiscence was left to the surgeon in charge. Inclusion criteria were age 18 years and over, open abdominal surgery, and converted laparoscopic abdominal surgery. Exclusion criteria were laparoscopic abdominal surgery and umbilical, inguinal, and day surgery. These patients were excluded due to the low incidence of abdominal wound dehiscence and the generally short hospital admission, which would have resulted in too few in-hospital observations. Study approval

was obtained from the Institutional Review Board, and all patients had given written informed consent.

From August to September 2011, all patients from the original study cohort who had developed abdominal wound dehiscence were reviewed for long-term follow-up. All in- and out-patient records, operation notes, and patient correspondence were reviewed for operation details, type of repair, in- and out-patient complications, incisional hernia, enterocutaneous fistula formation, mesh infection, and type of hernia repair. Presence of incisional hernia was obligatory verified by physical examination, either during follow-up by the authors or through patients' doctors. Deceased patients were identified through national administrative data and, thereafter, excluded from further follow-up. All remaining patients were subjected to semi-structured telephone interviews; questions included in this interview are shown in Table 1. Inquiries were made for surgical and general health issues, and collected data were verified.

Table 1: Telephone interview questions

No.	Question
1	Do you now have an incisional hernia?
2	Do you wear any type of supportive clothing, such as a corset, abdominal binder, or anything else?
3	Do you have any complaints, such as swelling or pain?
4	How did you experience the reoperation?
5	How was the cause of the abdominal wound dehiscence explained to you?
6	Did you consider the abdominal wound dehiscence a medical error or a complication?
7	Did you feel more insecure about the future due to the wound complications?
8	Did you receive wound care after discharge, and if so, how long/frequently?

All patients were requested to complete the Body Image Questionnaire (BIQ) and Short Form 36 (SF-36) questionnaire. The BIQ consists of a body image score and a cosmetic score and has been used in several studies.^{16,17} The body image score and cosmetic score are awarded 5–20 points and 3–24 points, respectively. Adding both scores results in a total body image score, which can vary between 8 and 44 points, with higher scores signifying higher patient satisfaction. The SF-36 questionnaire consists of 36 items that comprise eight health domains including physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health. Component summary scores are calculated for mental and physical health. Calculated scores range between 0 and 100 points, with higher scores signifying higher quality of life. Charlson Comorbidity Index (CCI) scores, as described by Charlson et al., were calculated for all patients to indicate severity of patients' health condition.¹⁸ For this comorbidity score, one point is awarded for myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary

disease, connective tissue disease, ulcer disease, stroke or transient ischemic attack, and diabetes. Two points are awarded for hemiplegia, moderate or severe renal disease, diabetes with end-organ damage, any tumor, leukemia, and lymphoma. Three points are awarded for moderate to severe liver disease, and six points are awarded for metastatic solid tumor and AIDS.

Recurrence of dehiscence (reburst) was defined as division of all layers of the abdominal wall after previous repair for abdominal wound dehiscence. This included tearing of mesh after mesh repair, with resultant evisceration and need for subsequent (mesh) repair.

For each patient, four controls matched by age and gender were randomly selected from the original study cohort to compare the SF-36 questionnaire and Body Image Questionnaire responses. The assessor was not blinded as to whether patients were cases or controls. Thus, 92 patients were selected from a group of patients from the original study cohort, who were clinically evaluated for presence of incisional hernia. Of the 967 included patients, 374 patients gave informed consent and were examined at a separate follow-up, the results of which have been published previously.¹⁴ The remaining 593 patients were deceased ($n=176$), incompetent ($n=1$), emigrated/untraceable ($n=11$), nonresponders despite repeated attempts ($n=244$), or refused participation ($n=161$). Incisional hernia was defined as a palpable defect in the abdominal wall of the incision used for the operation performed during the initial study period, resulting in herniation of abdominal contents. All patients had completed the SF-36 questionnaire and Body Image Questionnaire after a median follow-up of 16 months after surgery (range 10–24 months). Abdominal wound dehiscence was an exclusion criterium for selection of controls.

Further, it was attempted to estimate abdominal wound dehiscence-related costs by calculating median hospital costs based on admission period (measured in days) and wound nurse care costs (measured in number of visits) by using standardized reference data for economic evaluations of the Dutch health-care system as described by Hakkaart-van Roijen et al.¹⁹ Costs associated with the surgical procedure were based on published calculated costs of on-demand second look laparotomies in patients with peritonitis in The Netherlands, at €1,139 per procedure.²⁰

Statistical Analyses

Differences between the patients with abdominal wound dehiscence and controls were analyzed in univariate analysis using the chi-square test or Mann–Whitney *U* test for categorical or continuous data, respectively. Multiple linear regression was used to evaluate the impact of abdominal wound dehiscence on questionnaire responses. Adjustments were made for the putative effects of age, gender, length of follow-up, and patient comorbidity (indicated by CCI) by using these factors as covariates in statistical analyses. *P* values <0.05 were considered statistically significant.

RESULTS

In total, 37/967 patients developed abdominal wound dehiscence (3.8 %) and 6/37 patients with abdominal wound dehiscence died in hospital (16 %). At baseline, there was no significant difference in comorbidity (CCI) between patients with conservative treatment ($n=19$, CCI mean 3.0 ± 2.1) and operative treatment ($n=18$, CCI mean 2.9 ± 2.7 ; $p=0.535$). All patients with evisceration ($n=10$) were operated; mortality was high with four in-hospital deaths (and two deaths during follow-up). After a mean follow-up of 40 months (range 33–49 months), eight patients had died and were lost to follow-up. The remaining 23 patients all participated in this study (see Fig. 1). In total, 8/23 patients included (35 %) were operated for abdominal wound dehiscence (four polydioxanone loop, two polyglactin mesh, one composite mesh inlay, one component separation technique with bridging composite mesh) and 15 patients were treated conservatively (65 %).

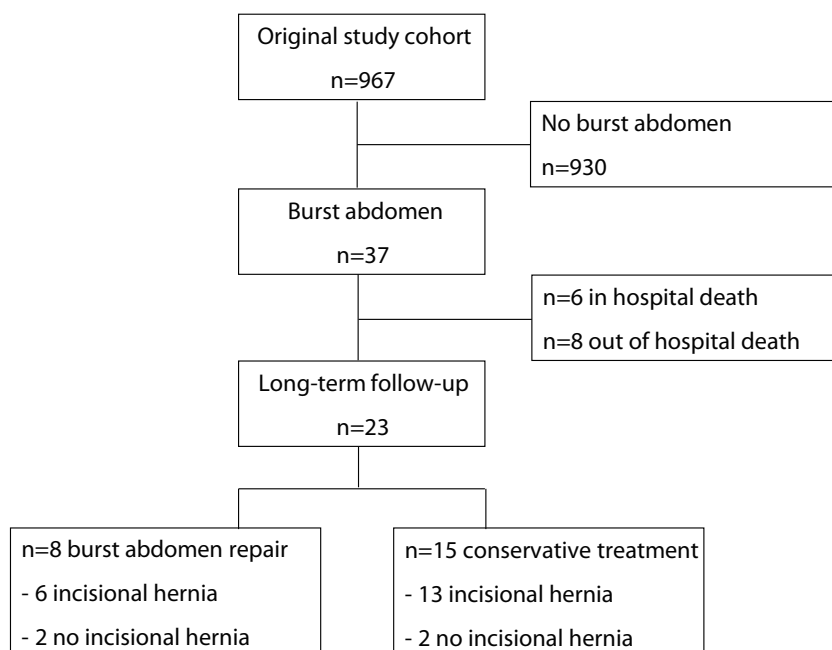


Fig. 1: Flow chart

All patients completed the questionnaires and telephone interviews. Baseline characteristics of patients with abdominal wound dehiscence and of the control group are displayed in Table 2.

Incisional hernias were found in 19 of 23 patients (83 %) at 40 months, 13/15 of whom had been treated conservatively for abdominal wound dehiscence and 6/8 had been operated for abdominal wound dehiscence (2/4 polydioxanone loop, 4/4 mesh repairs). All 19 cases of incisional hernia were objectified by physical examination. Eight patients had undergone incisional hernia repair (42 %), and during follow-up, two of the eight patients were operated again for incisional hernia recurrences.

Table 2: Baseline of patients with abdominal wound dehiscence and of the control group

Variable	Abdominal wound dehiscence (n=23)	Control group (n=92)	pvalue
Age in years (mean $\pm$ SD)	62 $\pm$ 15.2	61 $\pm$ 14.4	0.817
Gender: male/female	16/7	64/28	1.000
CCI score (mean $\pm$ SD)	3.3 $\pm$ 2.7	2.7 $\pm$ 2.7	0.230
BMI ^a (mean $\pm$ SD)	26.3 $\pm$ 3.6	25.3 $\pm$ 4.0	0.271
ASA class (n) ^a			0.189
I	4 % (1)	12 % (11)	
II	48 % (11)	42 % (39)	
III	40 % (9)	45 % (41)	
IV	9 % (2)	1 % (1)	
V	—	—	
Incisional hernia	83 % (19)	20 % (18)	<0.001
Follow-up in months (mean $\pm$ SD)	40 $\pm$ 5	17 $\pm$ 3	<0.001

BMI body mass index (in kilograms per square meter), CCI Charlson Comorbidity Index, ASA American Society of Anesthesiologists

^aAt time of initial surgery

In Table 3, the differences in the SF-36 questionnaire and BIQ results are shown for patients with and without abdominal wound dehiscence after adjustments for age, gender, CCI, and length of follow-up. The median length of follow-up was 17 months in the control group vs. 40 months in the abdominal wound dehiscence group ($p < 0.001$). Patients with abdominal wound dehiscence did not report significantly lower body image scores than control patients (median 16.5 vs. 18, $p = 0.087$). Patients with abdominal wound dehiscence reported significantly lower cosmetic scores (median 13 vs. 16, $p = 0.047$) and total body image scores (median 30 vs. 34, $p = 0.042$) compared with controls. Patients with abdominal wound dehiscence also reported significantly lower scores for SF-36 physical component summary ($p = 0.038$) and mental component summary ($p = 0.013$), as for subscores general health ($p = 0.003$), mental health ($p = 0.011$), social functioning ($p = 0.002$), and change score ($p = 0.034$). No significant differences were found for physical functioning ($p = 0.072$), role physical ($p = 0.361$), bodily pain ($p = 0.133$), vitality ($p = 0.150$), and role emotional score ($p = 0.138$) (see also Fig. 2).

Table 3: Mean and standard deviation (SD) scores for Short Form 36 questionnaire and Body Image Questionnaire for patients with abdominal wound dehiscence and for the control group. Results have been adjusted for age, gender, length of follow-up, and Charlson Comorbidity Index (CCI) score

Questionnaire	Abdominal wound dehiscence (n=23)	Control group (n=92)	Mean difference (95 % CI) ^a	pvalue
Body Image Questionnaire				
Body image score	15.2 (4.6)	16.5 (3.8)	-1.7 (-3.7 to 0.3)	0.087
Cosmetic score	12.4 (5.1)	15.0 (5.0)	-2.5 (-5.0 to -0.0)	0.047
Total body image score	27.6 (9.1)	31.5 (8.3)	-4.4 (-8.6 to -0.2)	0.042
Short Form 36 questionnaire				
Physical functioning	58.4 (33.3)	71.4 (22.0)	-11.0 (-22.9 to 1.0)	0.072
Role physical ^b	49.6 (43.5)	59.8 (42.1)	-9.9 (-31.4 to 11.5)	0.361
Bodily pain	67.9 (28.1)	75.9 (24.3)	-9.3 (-21.5 to 2.9)	0.133
General health	46.9 (26.6)	59.8 (23.0)	-11.6 (-23.1 to -0.6)	0.003
Vitality	54.7 (21.7)	62.4 (18.8)	-7.1 (-16.7 to 2.6)	0.150
Social functioning	64.9 (27.6)	82.3 (20.5)	-17.6 (-28.4 to -6.8)	0.002
Role emotional	74.7 (36.9)	75.7 (37.0)	-13.6 (-31.6 to 4.4)	0.138
Mental health	68.3 (25.5)	78.1 (15.3)	-11.6 (-20.5 to -2.7)	0.011
Change score	57.6 (35.0)	71.7 (25.7)	-14.4 (-27.7 to -1.1)	0.034
Physical component summary ^b	55.3 (22.9)	67.1 (19.2)	-10.6 (-20.7 to -0.6)	0.038
Mental component summary	62.9 (22.6)	73.0 (15.4)	-10.7 (-19.3 to -2.3)	0.013

^aMean difference between patients with abdominal wound dehiscence compared to the control group

^b n=22 available for abdominal wound dehiscence group

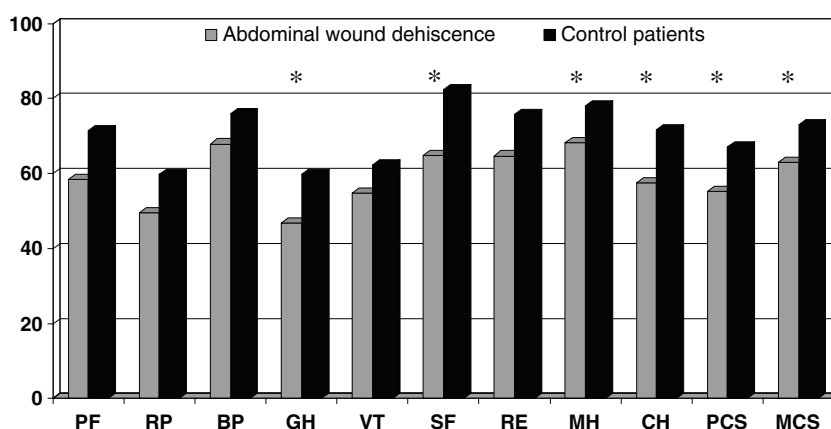


Fig. 2: Mean scores for Short Form 36 questionnaire for patients with abdominal wound dehiscence and for the control group. *p<0.05, significant difference after adjustments for age, gender, length of follow-up, and Charlson Comorbidity Index score. PF physical functioning, RP role physical, BP bodily pain, GH general health, VT vitality score, SF social functioning, RE role emotional, MH mental health, CH change score, PCS physical component summary, MCS mental component summary

Telephone Interviews

All patients participated in the telephone interviews and responded to all the questions. Of the 19 patients with confirmed incisional hernia, 15 self-reported swelling at the incisional site at the time of the interview. The other four patients had undergone incisional hernia repair and did not report any swelling. Four patients with incisional hernia reported use of custom-made corsets at the time of the interview. Six patients reported use of abdominal binders in the past; they had discontinued the use of binders after hernia repair ($n=3$) or due to binder-related discomfort ($n=3$). Out of 23 patients, nine (39 %) reported abdominal wall pain and two patients reported back pain (9 %). Enterocutaneous fistulas were present in two patients; one patient had undergone multiple excisions in the presence of polypropylene mesh, and the other patient was treated conservatively. Four out of eight patients who were reoperated for abdominal wound dehiscence had few or no recollections due to illness. The other four patients remembered feeling terrible, disappointed, ill-fated, or unprepared (all $n=1$). Out of 23 patients, 12 (52 %) stated that no explanation was ever given for the abdominal wound dehiscence; three patients stated that they had been too ill to remember whether or not any explanation was given, and eight patients were satisfied with explanations provided at the time (35 %). A total of seven patients (30 %) did not consider themselves competent enough to determine whether abdominal wound dehiscence was a complication or medical error. Sixteen patients stated that they considered abdominal wound dehiscence a complication of surgery, and not a medical error (70 %). One patient, however, considered the resulting incisional hernia as a medical error. Six patients felt more insecure about their future due to the wound complications (26 %); other patients did not report wound-related feelings of insecurity.

Median hospital stay was 11 days for control patients and 24.5 days for patients with abdominal wound dehiscence ($p<0.001$). There was no significant difference in length of admission postdehiscence between patients with abdominal wound dehiscence who were treated conservatively and patients who were treated operatively (median 15 vs. 18 days, $p=0.429$). Hospital care costs (€575 per day for academic hospitals) were €6.325 for control patients and €14.088 for patients with abdominal wound dehiscence, in case of conservative treatment (additional costs €7.763).¹⁹ In total, 10 repairs for abdominal wound dehiscence and/or recurrent dehiscence (rebursts) were performed in eight patients. The additional costs for abdominal wound dehiscence associated with relaparotomy procedures were €11,390 ($10 \times €1,139$); an average of €1,424 per operated patient.²⁰

Of all patients with abdominal wound dehiscence, five patients did not need specialized wound care. Four patients were discharged to a care hotel ($n=1$), nursing home ($n=2$), or to another hospital ($n=1$). Fourteen patients had received home (wound) care over a median period of

7.5 weeks (range 2–52 weeks), with a median of 67 visits (range 14–730). Application of the standard personal care nursing tariffs (€44 per visit) resulted in a median nurse cost of €2.948 per patient in this group of 14 patients. Most health insurance companies reimburse up to €200 for abdominal binders ($n=6$) and up to €500 for custom-made corsets ($n=4$), which results in a mean expense of €139 for abdominal support per patient (calculated as $[6 \times €200 + 4 \times €500]/23$ patients). Direct wound costs (e.g., gauzes) and indirect costs (e.g., return to work) could not be calculated. In conclusion, health-care costs were €10.850 higher (€7.763 for hospital care, €2.948 for nurse wound care, and €139 for abdominal support) in patients with conservatively treated abdominal wound dehiscence compared to uncomplicated control patients. In addition, €1,424 was spent on surgical repairs in operated patients.

DISCUSSION

This is one of few studies to report on long-term results in patients with abdominal wound dehiscence and the first to report on health-related quality of life in this vulnerable patient group. As mortality in this group of usually elderly patients is very high, especially in patients with evisceration, data have remained scarce.^{15,21} The study was designed as a prospective single-center study, in which quality of life, body image, and incidence of incisional hernia were measured in patients with abdominal wound dehiscence.

The incidence of incisional hernia after abdominal wound dehiscence was extremely high at 83 %, which is considerably higher than the 10–48 % incidence of incisional hernia reported in the literature.^{5,7,10,22} In two patients who were treated conservatively for abdominal wound dehiscence, no incisional hernias were found at physical examination. The fascial defects in these patients were small at original presentation and did not lead to clinically detectable incisional hernias. It cannot be excluded that these defects would have been detectable using ultrasonography or computed tomography. It would have been preferable if one of these methods had been used in these patients. The high incidence of incisional hernia could partly be explained by the high proportion of conservatively treated patients in our study. Also, length of follow-up in our study was longer than ever reported at a median follow-up of 40 months (range 33–49 months). Van 't Riet et al. concluded that a follow-up of at least 2 years appeared important because they diagnosed 31 % of incisional hernias in patients with burst abdomen repair after more than 2 years postoperatively.¹ The incidence of incisional hernia in the group of control patients was 20 % at a median period of follow-up of 17 months, which is consistent with the data reported in the literature.

New study findings included data on health-related quality of life and body image of patients with abdominal wound dehiscence, which to our knowledge have not been reported previously. In this study, health-related quality of life was investigated with the SF-36 questionnaire and BIQ, submitted by all patients. Ninety-two patients from the original study cohort, who were matched by age and gender and had not developed abdominal wound dehiscence after open abdominal surgery, were randomly selected to serve as controls. In these analyses, adjustments were made for important confounders such as age, gender, comorbidity, and length of follow-up. Ideally, control patients would also have been matched on comorbidity and length of follow-up too to minimize the risk of bias, but the former was not possible in the chosen study setup because the number of cases with significant comorbidity was too low in the control group. SF-36 questionnaire results illustrated the frailty of the patient group with regard to both physical and mental elements. Patients with abdominal wound dehiscence reported significantly lower scores for cosmesis and total body image. Scores for physical component summary were significantly lower and physical functioning reached borderline significance, which could be explained by the negative effects on abdominal wall function caused by the high incidence of incisional hernia of 83 % in patients with abdominal wound dehiscence.²³ Also, scores were significantly lower for the components mental health and mental component summary. These effects are not easily explained as adjustments were made for patient comorbidity and, therefore, may be based on the modest number of patients included in our study. As social functioning and change scores were also significantly lower in patients with abdominal wound dehiscence, it appeared that patients with abdominal wound dehiscence had become more socially incapacitated and isolated than control patients.

It was attempted to make an estimation of the direct costs associated with abdominal wound dehiscence by calculating costs for in-hospital stay and out-of-hospital wound nurse care. Health-care costs were €10,850 higher in patients with conservatively treated abdominal wound dehiscence compared to uncomplicated control patients, and for operated patients, an average of €1,424 per patient was spent on surgical repairs. Unfortunately, direct wound costs could not be calculated as wound gauze use was not recorded prospectively. Indirect costs related to return to work or loss of informal care provided by our patients could not be calculated. However, in view of the fact that many patients were already retired at the time of surgery, return to normal daily activities might have been a more relevant variable for this study. Also, it ought to be considered to include costs for incisional hernia repair as costs directly associated with abdominal wound dehiscence, as the incidence of incisional hernia was very high at 83 %.

Interestingly, interviewed patients did not consider abdominal wound dehiscence a medical error but a complication of surgery. Besides many patient-related risk factors for abdominal wound

dehiscence, technical risk factors may also include the suture length-to-wound length ratio, which has proven to be strongly associated with the occurrence of incisional hernia.^{21,24–27} Use of small bites (short stitch lengths) with small intersuture distances and a suture length-to-wound length ratio of at least 4 is thought to be associated with a better division of pressure across the suture line, which would lead to a lower incidence of incisional hernia. Since at the time of this study, the suture length-to-wound length ratio was not standardly measured, it remains unsure whether this technical aspect was associated with cases of abdominal wound dehiscence. Application of the optimal suture technique might lead to a reduction of abdominal wound dehiscence, especially in high-risk patients. Harlaar et al. performed an experimental study in which tensile strengths were compared between long and short stitch lengths in porcine abdominal walls.²⁸ In the long stitch length group only, a slacking effect was observed with separation of fascia edges at suture intervals as tensile forces were increased. This effect, *in vivo*, might represent the incipient dehiscence. Use of small bites with small inter suture distances was compared with regular large bites with large intersuture distances in the “Suture Techniques to reduce the Incidence of The inCisional Hernia” trial (clinical trial identification no. NCT01132209), the inclusion of which was recently completed.²⁹ The trial was powered for occurrence of incisional hernia after 1 year and may also give an answer as to which of the two investigated techniques is more effective in preventing burst abdomen. The previously published randomized controlled trial by Millbourn et al. showed no significant difference between small and large bites in the occurrence of burst abdomen (secondary outcome, 1/381 long stitch length and 0/356 short stitch length, $p=0.99$).²⁷ Preventive use of mesh is a concept that has not been studied extensively in patients at risk for abdominal wound dehiscence. Three French studies have compared the use of preventive polyglactin 910 mesh with other methods. Paye et al. published a series of patients in which two consecutive groups were compared: treatment with polyamide mesh glued to the skin vs. intraperitoneal polyglactin 910 mesh.³⁰ The latter was associated with a reduced rate of wound dehiscence (4 vs. 13 %, $p=0.02$), but the study was not randomized and no adjustments were made for possible confounders. Gainant et al. performed a comparable randomized study in which 8/50 patients with polyamide mesh glued to the skin developed burst abdomen requiring surgery vs. 0/50 patients with intraperitoneal polyglactin 910 mesh ($p<0.01$).³¹ Tohme et al. published a retrospective study on patients who were treated with extraperitoneal retention sutures ($n=226$) or intraperitoneal polyglactin 910 mesh ($n=66$).³² The incidence of burst abdomen was significantly lower in the polyglactin 910 mesh group (0/66 vs. 14/226 patients, $p=0.02$), but the patient groups were not comparable. In none of the aforementioned studies, stratification was performed for the estimated risk of burst abdomen. Risk estimation and stratification will be essential for future trials focussing on prevention of burst abdomen. Our previously published

risk score will be helpful for this purpose by allowing calculation of individuals' probability of developing burst abdomen.²¹ Variables included in the risk score are age, gender, chronic pulmonary disease, ascites, jaundice, anemia, emergency surgery, type of surgery, coughing, and wound infection.

The use of biological mesh could form a viable alternative for the use of polyglactin 910 mesh, which is completely absorbed in 90 days. Although more costly, biological mesh can be used in a contaminated environment and could offer support for a longer period of time compared to polyglactin 910 mesh. Reabsorption time also depends on the subtype of biological mesh (cross-linked or non-cross-linked). Although not yet studied as prevention of abdominal wound dehiscence, it was attempted to investigate the use of a cross-linked biological mesh for prevention of incisional hernia in patients with abdominal wound dehiscence. The international multicenter, randomized controlled trial "Repair of Challenging Abdominal Wall Defects: Strattice™ in Abdominal Wall Repair trial (StAR)" was terminated due to inclusion problems (clinical trial identification no. NCT01083472).³³ The termination of this trial illustrated that inclusion of ill patients with complications such as abdominal wound dehiscence in the acute setting remains challenging. Studies like these, however, are warranted to provide the surgical community with more evidence regarding the treatment of abdominal wound dehiscence. Future (randomized) studies should focus on determining short- and long-term benefits of operative treatment (primary suture, biological and synthetic mesh) compared to conservative approach.

CONCLUSION

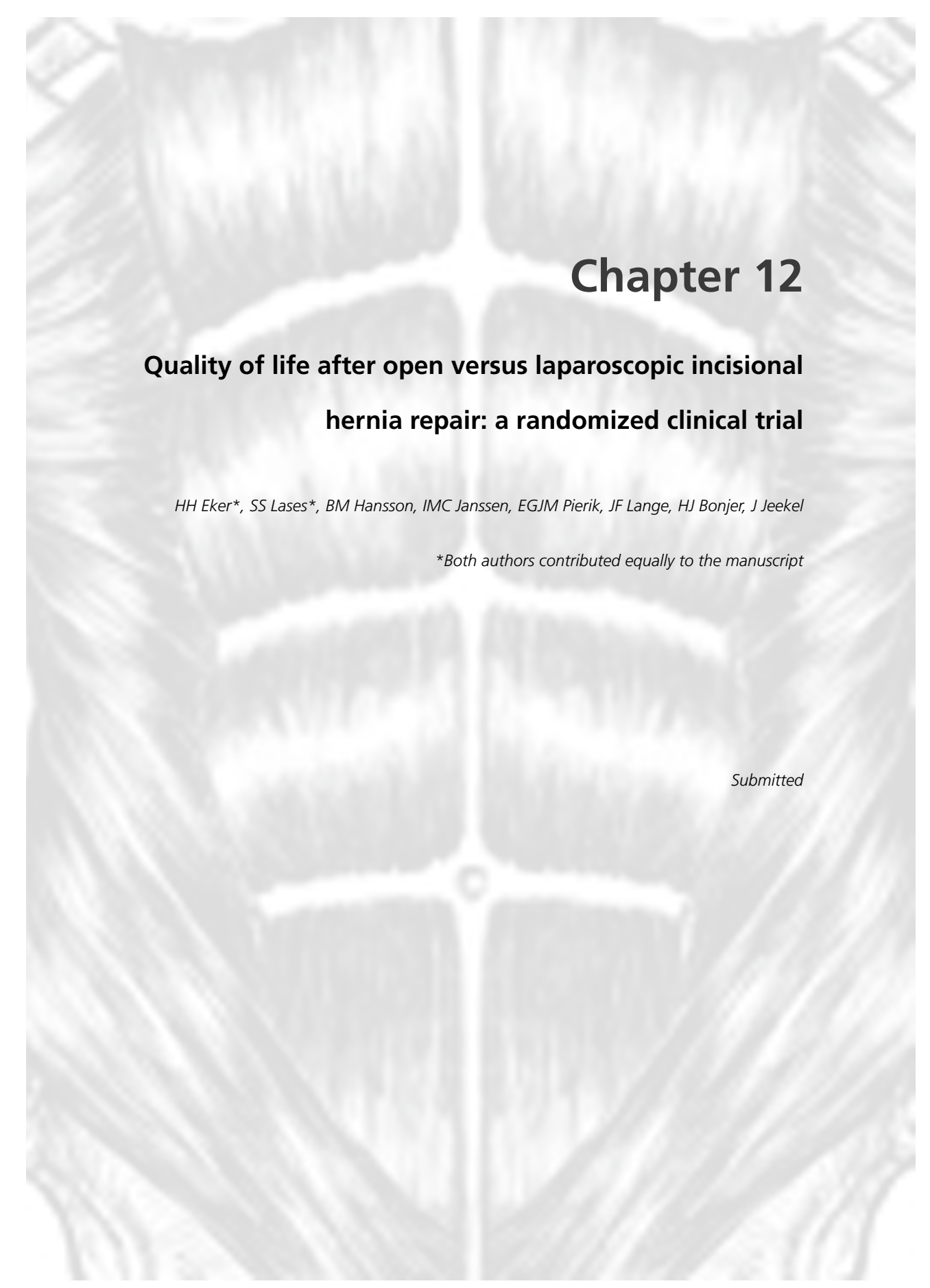
Patients with abdominal wound dehiscence constitute a vulnerable patient group with high short- and long-term mortality rates. In this group of predominantly conservatively treated patients, the incidence of incisional hernia was high at 83 % after a median follow-up of 40 months. Eight patients with incisional hernia (42 %) underwent reoperations. Patients with abdominal wound dehiscence reported significantly lower body image and lower scores for both physical and mental quality of life components, compared to control patients. Conservative treatment of abdominal wound dehiscence is associated with disappointing results. Future studies should investigate success rates of mesh repair for abdominal wound dehiscence, compared to conservative approach.

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Chapter 12

Quality of life after open versus laparoscopic incisional hernia repair: a randomized clinical trial

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Submitted

ABSTRACT

Introduction: The discussion upon the preferred approach for incisional hernia repair is still actual and continuing. Postoperative pain and recurrence were primary endpoints for the majority of the current literature and also for this randomized clinical trial. Health related Quality of Life, however, is becoming increasingly important since patient satisfaction rather than surgical outcomes are becoming the primary goal of hernia repair. In this randomized clinical trial, postoperative Quality of Life was compared between open and laparoscopic incisional hernia repair.

Methods: Two-hundred-and-six patients were randomly assigned to either open or laparoscopic incisional hernia repair. The primary endpoint of the randomized clinical trial was postoperative pain. One of the secondary endpoints was postoperative health related Quality of Life. All patient were invited to fill out a SF-36 questionnaire preoperatively and 1 week and 4 weeks postoperatively.

Results: Twelve of the 206 patients were excluded; 5 patients withdrew consent, 4 patients appeared to have no incisional hernia and 3 patients were operated with a different operation technique. 100 patients were randomized to open repair and 94 to laparoscopic incisional hernia repair. One week postoperatively the SF-36 questionnaire showed favourable outcomes for open incisional hernia repair on Role Emotional ($p < 0.001$) and the Mental Component Summary ($p = 0.03$). After 4 weeks follow-up, no differences could be measured in health related Quality of Life.

Conclusion: Overall health related Quality of Life was relatively high in both groups. One week postoperatively, open incisional hernia repair was superior to laparoscopic repair. After 4 weeks no differences could be measured between the two groups.

INTRODUCTION

Incisional hernia continues to keep surgeons' interest since it is the most frequent postoperative complication after abdominal surgery. Incisional hernia, which is in fact a failure of abdominal wall closure or abdominal fascia healing, has an incidence rate up to 30%¹⁻³. Pain, discomfort and cosmetic dissatisfaction often accompany incisional hernia and represent an indication for surgical repair.^{4,5} Despite surgical techniques for hernia repair have been improved and the use of prosthetic mesh reduced recurrence rates, morbidity and recurrence rates are still too high.^{6,7}

Two recent meta-analyses comparing open and laparoscopic incisional hernia repair reported shorter length of hospital stay and less postoperative complications in favour of laparoscopy.^{8,9} Previous studies have also described significantly less blood loss, shorter operative time and faster return to work after laparoscopic incisional repair.¹⁰⁻¹²

In literature, morbidity and recurrence are often described as primary outcomes after laparoscopic and open incisional hernia repair. Patient satisfaction may not always be equally corresponding to good practice. Another important outcome of hernia repair could therefore be represented by improvement of patient well-being, evaluated by health related Quality of Life questionnaires.¹³⁻¹⁶ It is unclear whether available Quality of Life questionnaires are useful to evaluate health related quality of life in patients after incisional hernia repair, since literature on this issue is scarce.^{6,17,18} Snyder reported the repair technique, with mesh versus suture, to have no independent effect on health related quality of life. Recurrence however appeared to have a substantial negative effect on patient outcomes.¹⁸ A small retrospective study comparing laparoscopic and open ventral hernia repair described significantly improvement in several health related quality of life domains in the laparoscopic group, compared to the open group.¹⁹

The evaluation of health related quality of life is most reliable using information reported by patients themselves. A valid instrument that is widely used is the Medical Outcomes Study Short Form-36 (SF-36).²⁰⁻²²

To our knowledge, there is no randomized clinical trial evaluating the health related quality of life after open and laparoscopic incisional hernia repair using the SF-36 questionnaire.

As previous literature describes better results after laparoscopic hernia repair in terms of hospitalization, return to work and postoperative complications⁸⁻¹², it is expected that laparoscopic repair will also result in better health related quality of life. However, possible benefits in terms of quality of life outcomes following laparoscopic incisional hernia repair are not widely available.

The objective of this study was a randomized evaluation of health related quality of life after open and laparoscopic incisional hernia repair.

METHODS

Study design

This study was designed as a multicenter randomized clinical trial to compare the health related quality of life of laparoscopic and open incisional hernia repair.

From May 1999 to December 2006, 206 patients were included in the study. Patients were eligible for enrolment in the study if they met the following criteria: 18 years or older, a hernia diameter between 3 and 15 cm, hernia location at the ventral abdominal wall at least 5 cm from costae and inguinal area and an indication for elective hernia repair. Exclusion criteria were an absolute contraindication for general anaesthesia, a contraindication for pneumo-peritoneum, a history of an open abdomen treatment or participation in other trials.

Informed consent was obtained from all patients before they were randomized into one of the two groups. One group was randomized for laparoscopic incisional hernia repair and the other for open incisional hernia repair. Randomization was done by computer generated lists and patients were stratified for center and primary or recurrent incisional hernia. Patients and the medical staff could not be blinded for the allocated procedure.

Operation procedures

Laparoscopic procedure

In the laparoscopic group pneumo-peritoneum was established up to an intra-abdominal pressure of 15 mmHg. Three to five abdominal trocars (one 10 mm and two to four 5 mm) and a 0-degree or 30-degree laparoscope were used. After exposure of the incisional hernia and reduction of any hernia contents the mesh was introduced into the abdominal cavity and placed over the hernia with at least 5 cm overlap at all sides and fixated with 5 mm nonabsorbable tackers (Protack, AutoSuture, Tyco healthcare, USA). Transfascial sutures for mesh positioning and additional fixation were often used. All 10 mm trocar fascial defects and the skin were closed.

Open procedure

The incision was made in the old scar depending on the localization and size of the hernia. The hernia sac was identified and the mesh was placed preperitoneally or in sublay position, with at least 5 cm overlap in all directions. The mesh was fixated to the rectus muscle with non-

absorbable (prolene) sutures at each corner and side. Whenever tensionfree repair was possible the anterior rectus sheath and subsequently the skin defect were closed. Subcutaneous drains were used in case of large dissection areas.

Outcomes of the study

The primary outcome of this study was pain and recurrence; health related quality of life based on the eight scaled scores of SF-36 was a secondary endpoint.

Data collection and follow-up

The SF-36 was used to investigate the health related quality of life. The SF-36 questionnaire assesses health related quality of life in terms of eight different dimensions: physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and mental health (MH). The scores range from 0 to 100, with higher scores representing better quality of life. The SF-36 Physical Component Summary (PCS) and the Mental Component Summary (MCS) scales, also ranging from 0 to 100, were additionally calculated.

The patients were asked to complete the SF-36 questionnaire preoperatively, one week after intervention and after discharge from the hospital at four weeks.

Statistical analysis

All statistical calculations were performed using the statistical programme Statistical Package for the Social Sciences (SPSS) 17.0 for Windows.

Statistical significance between the SF-36 scores before and after surgery was determined using the independent sample t-test.

RESULTS

Patient characteristics

In the period from May 1999 to December 2006 206 patients were eligible and consented to participate in the trial. Twelve of these 206 patients were finally excluded: 4 patients appeared to have no incisional hernia, in 3 patients a different technique was used and 5 patients withdrew consent after randomisation. The remaining 194 patients were randomly assigned into two groups; the first group underwent laparoscopic incisional hernia repair ($n = 94$) and the second group open repair ($n = 100$).

The patient demographics in terms of age, sex ratio, mean BMI (Body Mass Index), ASA (American Society of Anesthesiology) score, hernia size and pre-operative comorbidity were comparable. (Table 1)

Table 1 Patient characteristics

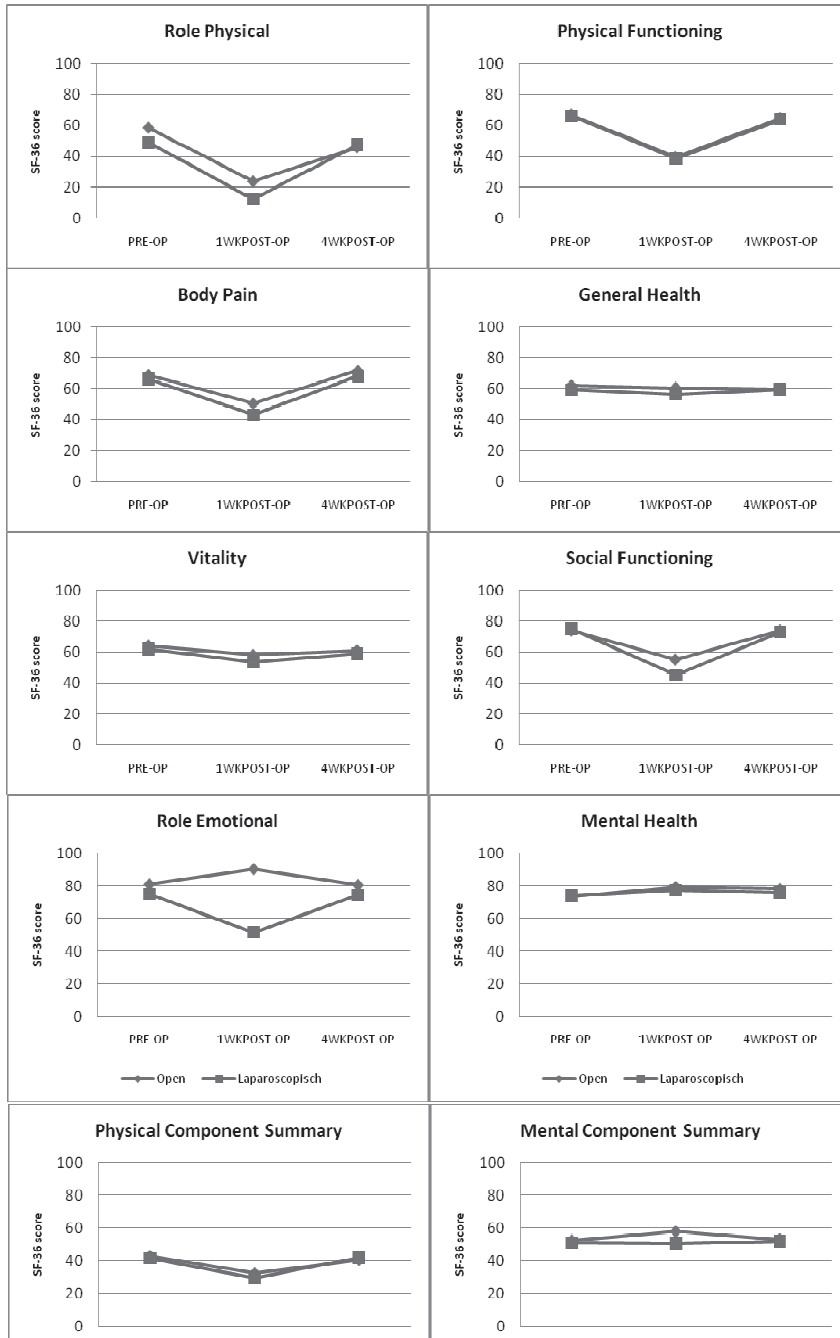
Characteristics	Open (n=100)	Laparoscopic (n=94)	P value
Gender, male – (%)	59 (59)	56 (60)	0.94
Age, years – mean (SD)	56.7 (12.8)	59.1 (12.8)	0.80
Pre-operative Body Mass Index (kg/m ²) – mean (SD)	29.3 (4.6)	28.3 (4.7)	0.81
Primary incisional hernia – (%)	82 (82)	71 (76)	0.27
Recurrent incisional hernia – (%)	18 (18)	23 (24)	
Hernia diameter size, cm – median (IQR)	5 (4-10)	5 (4-8)	0.44
ASA class – no (%)			0.43
I	25 (25)	21 (22)	
II	52 (52)	56 (60)	
III	19 (19)	12 (13)	
IV	1 (1)	0	
Missing data	3 (3)	5 (5)	

Health related quality of life (SF-36) (Figure 1)

Preoperatively, 62 (62%) and 58 (61,7%) patients completed the SF-36 questionnaire in the open and laparoscopic group, respectively. One week after surgery 21 (21%) patients completed the SF-36 in the open group and 21 (22,3%) patients in the laparoscopic group. Four weeks postoperatively, the SF-36 was completed in the open and laparoscopic group by 59 (59%) and 58 (61,7%) patients respectively.

Laparoscopic versus open repair

There were no significant differences in all 8 different domains of the SF-36 and the PCS and MCS between the two groups preoperatively. (Table 2) One week postoperatively there was a significant difference between the two groups in the RE and the MCS score in favour of the open procedure. (Table 3) The other domains of the SF-36 and the PCS were comparable. Four weeks after surgery no significant differences between the two groups could be detected. (Table 4)

Figure 1. 8 dimensions and summary scales of SF-36 before and after surgery

Role Physical; Physical Functioning; Body Pain; General Health; Vitality; Social Functioning; Role Emotional; Mental Health; Physical Component Summary; Mental Component Summary

Table 2 SF-36 scores before surgery

	Open – mean (SD)	Laparoscopic – mean (SD)	P value
PF	66.9 (21.0)	66.1 (23.7)	0.86
RP	58.5 (44.2)	49.0 (44.0)	0.26
BP	69.0 (24.9)	66.4 (27.3)	0.59
GH	62.0 (21.1)	59.2 (22.7)	0.51
VI	64.1 (19.3)	62.1 (21.3)	0.60
SF	74.0 (27.6)	75.0 (27.1)	0.84
RE	81.0 (37.5)	74.8 (41.3)	0.41
MH	73.6 (20.9)	73.8 (20.0)	0.96
PCS	42.9 (9.3)	41.4 (11.1)	0.45
MCS	52.4 (11.1)	51.0 (12.4)	0.55

Table 3 SF-36 1 week after surgery

	Open - mean (SD)	Laparoscopic - mean (SD)	P value
PF	39.7 (23.8)	38.7 (22.6)	0.89
RP	23.7 (33.8)	12.5 (27.5)	0.26
BP	50.4 (21.8)	43.1 (23.5)	0.31
GH	60.6 (21.5)	56.5 (20.8)	0.54
VI	58.2 (19.4)	53.5 (19.0)	0.44
SF	55.4 (31.0)	45.2 (31.5)	0.30
RE	90.2 (28.3)	51.7 (45.2)	0.00*
MH	79.4 (20.2)	77.4 (18.4)	0.75
PCS	31.3 (6.2)	29.7 (8.9)	0.54
MCS	57.7 (8.8)	50.4 (10.0)	0.03*

* Significant

Table 4 SF-36 4 weeks after surgery

	Open – mean (SD)	Laparoscopic – mean (SD)	P value
PF	64.5 (22.6)	63.9 (20.8)	0.89
RP	46.0 (44.2)	47.5 (40.6)	0.86
BP	71.8 (22.2)	68.1 (23.8)	0.39
GH	59.4 (24.9)	59.4 (20.4)	0.99
VI	61.9 (20.5)	58.9 (20.7)	0.44
SF	73.9 (26.1)	73.3 (25.8)	0.89
RE	80.6 (36.1)	74.5 (38.8)	0.40
MH	78.2 (20.9)	75.8 (19.6)	0.54
PCS	40.4 (10.1)	41.6 (9.0)	0.54
MCS	53.1 (11.8)	51.9 (9.2)	0.58

Primary versus recurrent incisional hernia (Figure 2)

Preoperatively, patients with a primary incisional hernia scored significantly higher on the "Bodily Pain" scale (70,9 versus 59,7). One week and 4 weeks postoperatively no differences could be detected between patients with a primary or recurrent incisional hernia.

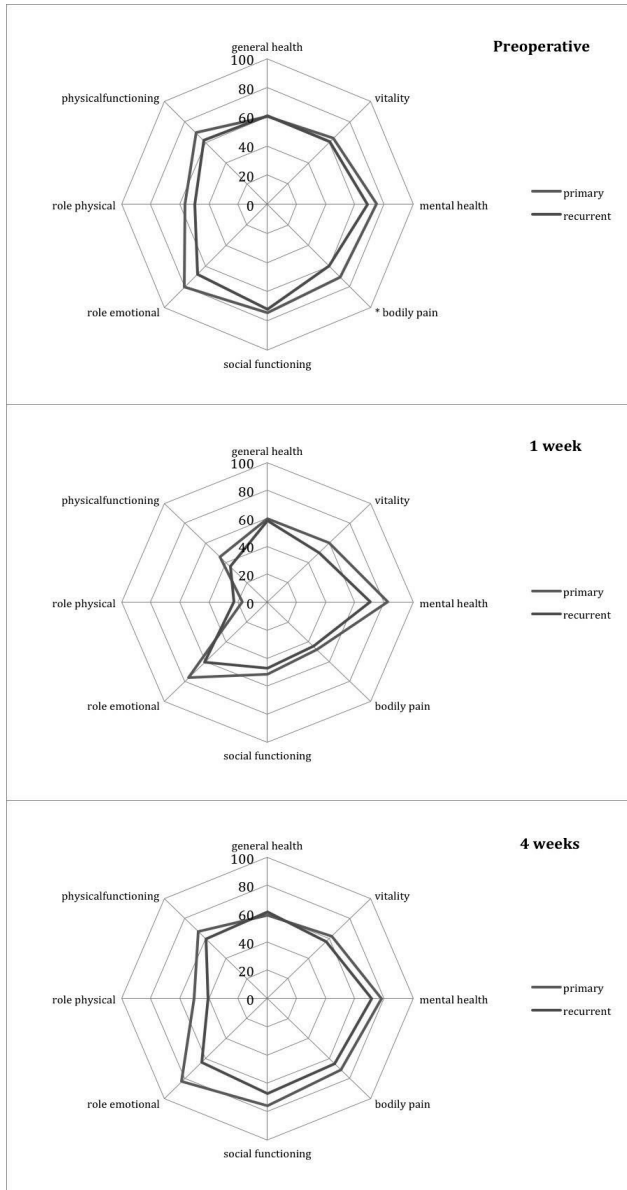


Figure 2. Primary versus recurrent incisional hernia

BMI <30 versus BMI ≥30 (Figure 3)

No differences could be detected preoperatively between patients with a BMI <30 and patients with a BMI ≥30. One week postoperatively morbid obese patients scored significantly better on the “Role Emotional” (86,7 versus 60,3), “Role Physical” (31,7 versus 10,2) and “Mental Component Summary” (75,1 versus 63,6) scales. Four weeks postoperatively the health related Quality of Life for the two groups was comparable.

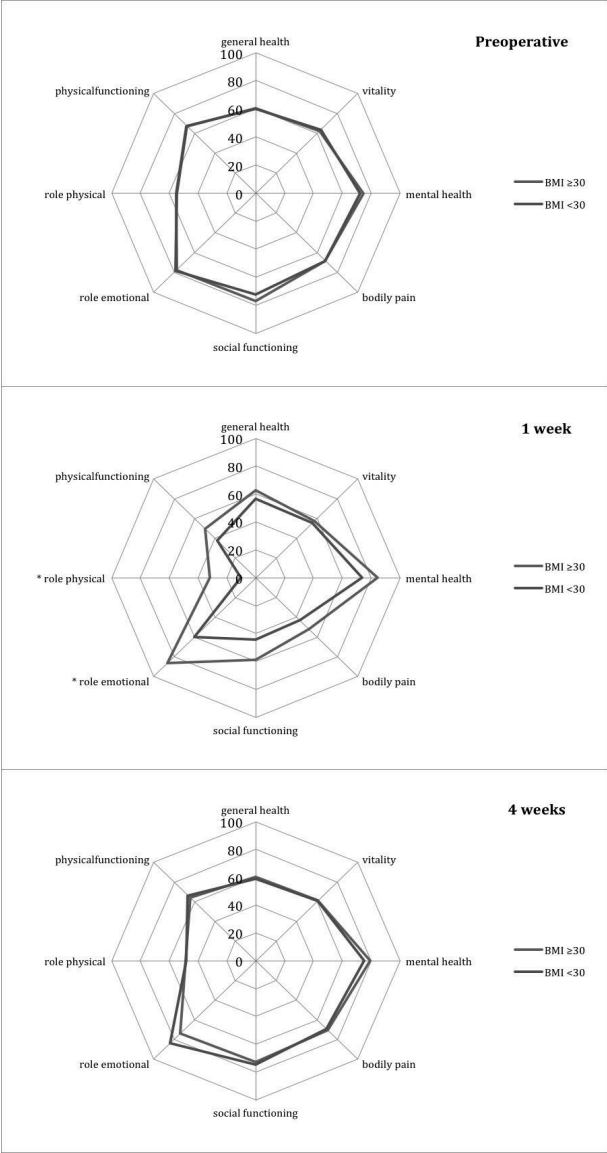


Figure 3. BMI <30 versus BMI ≥30

DISCUSSION

In this multicenter randomized clinical trial, the “Role Emotional” and “Mental Component Summary” scores of the SF-36 were significantly higher in the open repair group 1 week postoperatively. Overall, we observed higher quality of life scores than we have expected in both groups. However, no significant increase of quality of life could be measured 4 weeks after surgery compared to preoperative scores.

Asencio et al.²³ evaluated the health related quality of life after open and laparoscopic incisional hernia repair in a randomized clinical trial using the EQ5D. No significant differences in EQ5D scores could be found. The EQ5D-VAS score, a measurement of the overall health state rated by the patient was worse in the laparoscopic group during the first 2 days. However, not differences could be measured in the following days.

A matched control study evaluating health related quality of life changes using the SF-36 also could not find a difference between open and laparoscopic incisional hernia repair.²⁴ Contrary to our study results, Mussack et al. found a significant increase in all of the 8 SF-36 domain scores. Despite the significant increase of health related Quality of Life Mussack measured postoperatively, the SF-36 scores were significantly lower than age-stratified healthy control patients.

A possible explanation for the higher scores we have measured in the open repair group on the “Role Emotional” and “Mental Component Summary” domains could be due to higher expectations of patients who undergo a laparoscopic procedure. Possibly patients are not aware of the surgical procedure, the postoperative course and do not expect much pain and discomfort from “only 3 to 5 little scars”. Four weeks postoperatively no differences could be measured between the two groups. This possibly can be explained by reduction of postoperative pain and better understanding of the surgical procedure and postoperative course.

One could also hypothesize that during open incisional hernia repair often the old scar and when it is the case, the skin surplus is resected. Patients that underwent laparoscopic repair remained to have their old scar and got at least three new ones. Especially when seroma occurs after laparoscopic repair, patients can also be inconvenient about bulging of their abdominal wall.

The high overall quality of life scores we have found in both groups is consistent with high satisfaction rates Langer reported earlier.²⁵ Mussack et al, however, described significantly lower scores in both patient groups compared to the scores of the age-stratified healthy population.

The relatively high quality of life scores we have measured preoperatively could be explained by a satisfied patient population that expects their “problem” to be solved within a short period.

The Short Form 36 is a validated questionnaire to evaluate health related quality of life in a general patient population, for multiple conditions.²⁰⁻²² The SF-36 questionnaire is not a specific instrument for patients with an abdominal wall hernia. A specific quality of life questionnaire directed to patients with an abdominal wall hernia could have generated different and more detailed results. A limitation of this multi-center randomized clinical trial is the poor follow-up 1 week postoperatively. Many patients were still admitted to the hospital or had other priorities at the time of follow-up.

Postoperative pain and recurrence rates are often described as primary outcomes of hernia repair studies as objective results. The importance of quality of life studies, however, must not be underestimated. Improvement of health related quality of life after incisional hernia repair is probably the most important result considering the patients point of view.

CONCLUSION

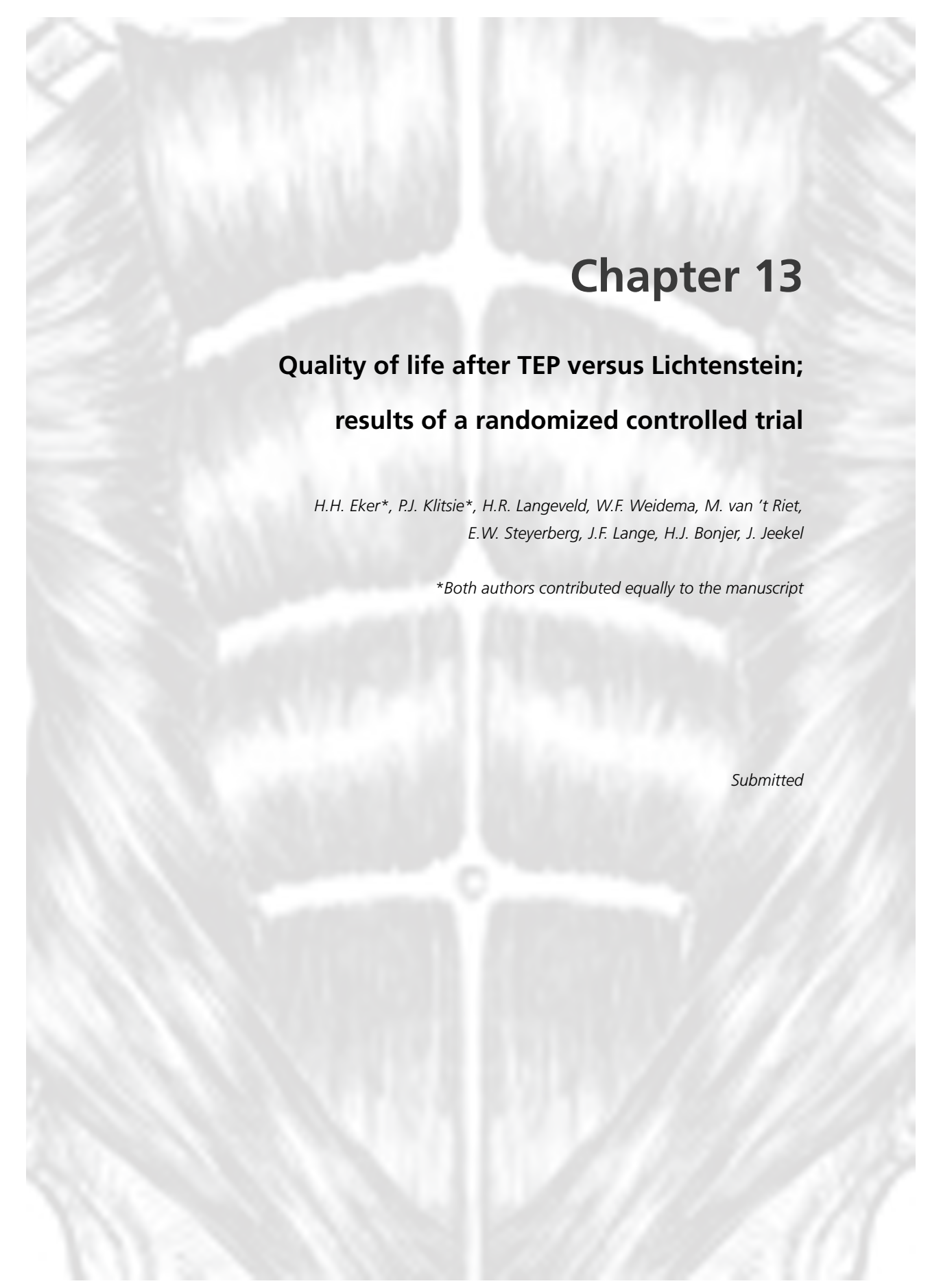
Our results suggest that health related quality of life after open incisional hernia repair is superior to laparoscopic repair in the Role Emotional and Mental Component Summary domains one week postoperatively. The overall quality of life scores in both groups were relatively high. Four weeks postoperatively no differences in health related Quality of life could be detected between the two groups. Long-term data is necessary to further evaluate the health related quality of life after open and laparoscopic incisional hernia repair.

None of the authors have conflicts of interest or financial ties to disclose.

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The background of the page is a grayscale, high-contrast image of a human larynx, showing the vocal folds and surrounding cartilages. The image is centered and occupies the entire background.

Chapter 13

Quality of life after TEP versus Lichtenstein; results of a randomized controlled trial

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Submitted

ABSTRACT

Background The Lichtenstein technique is the most commonly used technique in inguinal hernia repair. TEP is associated with less postoperative pain and less chronic pain. However recurrence rates have been reported to be comparable or higher after TEP. Quality of life (QoL) questionnaires are an objective tool to measure patient wellbeing and might help in the decision, which technique surgeons should prefer.

Methods In a multicenter clinical trial, 660 patients were randomized to either Lichtenstein or TEP repair with a follow up of 5 years. The primary outcomes were health related quality of life, postoperative pain, length of hospital stay and time to complete recovery. Quality of life was assessed using the Short Form 36 (SF-36) QoL questionnaire.

Results TEP repair was associated with better scores on three out of four physical dimensions of QoL up to 6 weeks after surgery. Postoperative pain was found to have a negative correlation to all dimensions of QoL. Hernia recurrence had no influence on QoL outcomes.

Conclusion Quality of life was superior for TEP on the short term on physical dimensions. Pain was found to be an independent factor influencing Health related Quality of life. For patient's wellbeing, TEP should be the preferred approach.

INTRODUCTION

Since the introduction of prosthetic mesh, tension-free mesh repair of inguinal hernia is preferred over non-mesh techniques because of reduced recurrence and pain rates.¹⁻⁷ A mesh can be placed with either an open or endoscopic approach. Hernia repair according to Lichtenstein is currently the most commonly used open mesh technique and the total extra peritoneal procedure (TEP) the preferred endoscopic approach.^{8,9} Consensus on the preferred approach, however, is still not reached.

The focus in current literature is on recurrence and postoperative pain.¹⁰⁻¹² Recurrence rates are equal or higher for TEP compared to Lichtenstein.¹⁰⁻¹² Conclusions of these articles, however, were drawn regardless of learning curve effects.^{11, 12} When the effect of the learning curve is taken into account, recurrence rates for TEP are comparable or superior to Lichtenstein.¹¹⁻¹³ Regarding postoperative and chronic pain, results are clear. There is significantly less pain after TEP compared with Lichtenstein. Pain is a secondary outcome measure in most TEP vs. Lichtenstein trials.^{11, 12}

Every surgeon should consider the indication for surgical repair of an inguinal hernia because this might be relevant for the choice of surgical technique. A frequently mentioned argument to perform surgical repair is prevention of strangulation. Two randomized clinical trials comparing watchful waiting with surgical repair on selected inguinal hernia patients, however, prove watchful waiting to be safe.^{14, 15} Therefore, besides strangulation, reduction of pain and discomfort are increasingly important arguments whether to perform surgery or not. Quality of life questionnaires can be used as objective instruments to evaluate patient wellbeing, which is influenced by pain and discomfort.

The focus in this article is on health related quality of life (QoL) after open or endoscopic inguinal hernia repair. The outcomes on postoperative quality of life could help us further in making a decision on the preferred surgical approach. Possibly influencing factors affecting QoL are analyzed. Operative technique, postoperative pain, hernia recurrence, experience of the surgeon and age are considered as factors that might influence health related quality of life.

METHODS

The LEVEL trial was designed to compare TEP with Lichtenstein. In a multicenter trial 660 patients were randomized. In our previous articles Langeveld et al. and Eker et al. reported on postoperative pain, chronic pain, recovery and return to work, recurrence and the effect of experience on recurrence rates.^{10, 13}

Adult men and women with a primary or recurrent, uni- or bilateral inguinal hernia with an indication for elective correction were eligible for the study. Exclusion criteria were scrotal hernia, pregnancy and communicative or cognitive limitations preventing informed consent. Medical histories of prostatectomy, pfannenstiel incision, preperitoneal procedure or abdominal bladder operation were also exclusion criteria for the study to avoid risk of serious complications during the TEP procedure. The procedures for Lichtenstein and TEP repair were standardized.¹⁰ Primary outcomes were health related quality of life, postoperative pain, length of hospital stay, and time to complete recovery.

Follow-up and Data Collection

Medical history and physical examination were recorded during the preoperative intake at the outpatient clinic. Pain was measured using a 10 cm Visual Analogue Scale (VAS). The patient filled out the VAS preoperative and postoperative after 24, 48, 72 hours and after 1 and 4 weeks.

All patients were physically examined at the outpatient clinic after 1 week, 6 weeks, 1 year and 5 years. Recurrences, reoperations and chronic pain were documented. Physical examination at 5 years was performed by two independent physicians for inspection of the incision site and recurrences.

Quality of Life (QoL) was measured with the Medical Outcomes Study Short Form 36 or SF-36 questionnaire (acute version of SF 36™ Health Survey, Medical Outcomes Trust, Boston, Massachusetts 02116, USA). The SF-36 forms were filled out preoperatively and 1 week, 4 weeks and 5 years postoperatively.

Statistical analysis

Primary analysis was performed on an intention to treat basis. Categorical outcomes were analyzed with Chi-square tests. Continuous outcomes were analyzed with a Mann-Whitney-U test. The SF-36 consists of eight components: four physical (physical functioning, role physical, bodily pain and general health) and four mental (vitality, social functioning, role emotional, mental health) components. The physical and mental components can be summarized in the

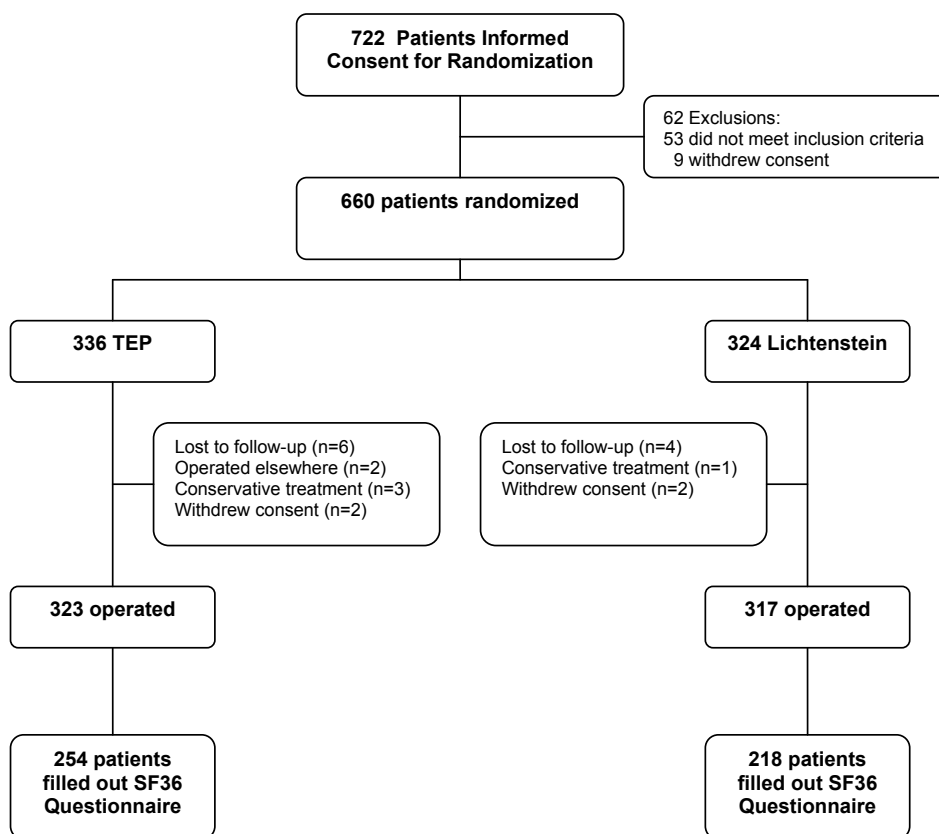
physical component summary (PCS) and the mental component summary subsequently (MCS). Primary quality of life analysis was performed comparing TEP versus Lichtenstein. Secondary the influence of postoperative technique, hernia recurrence, age and experience of the surgeon were assessed. Analysis was performed using independent samples T-test. All analyses were made using SPSS version 18 (Chicago, ILL).

RESULTS

Between August 2000 and March 2004, 336 patients were randomized for TEP and 324 for Lichtenstein. After randomization 20 patients were not operated on and therefore excluded from analysis. The follow-up case record forms were completed by 74% of the patients (n=472). Regarding baseline characteristics, no differences could be found for age, gender, ASA classification, comorbidities, medication use and hernia characteristics between the two study groups.¹⁰ (Table 1)

Table 1 Baseline characteristics

Baseline characteristics	TEP (336)	Lichtenstein (324)
GENERAL CHARACTERISTICS		
Age (yr, median)	55	56
Gender (% male)	99	98
Body Mass Index (mean)	25	25
ASA (mean)	1	1
MEDICAL HISTORY		
COPD (%)	27 (8)	14 (4)
Diabetes (%)	6 (2)	9 (3)
Abdominal surgery (%)	71 (22)	81 (26)
Corticosteroid use (%)	24 (7)	13 (4)
Preoperative analgesic use (%)	16 (5)	11 (3)
Sensibility abnormality (%)	2 (1)	2 (1)
Testis abnormality (%)	7 (2)	9 (3)
HERNIA CHARACTERISTICS		
Primary hernia (%)	293 (91)	295 (93)
First recurrence (%)	23 (7)	18 (6)
≥ Second recurrence (%)	6 (2)	3 (1)
Unilateral (%)	284 (88)	292 (92)
Bilateral (%)	39 (12)	25 (8)
FOLLOW UP		
Pain at 6 weeks	23%	32%
Hernia recurrence long term	4.9%	8.1%

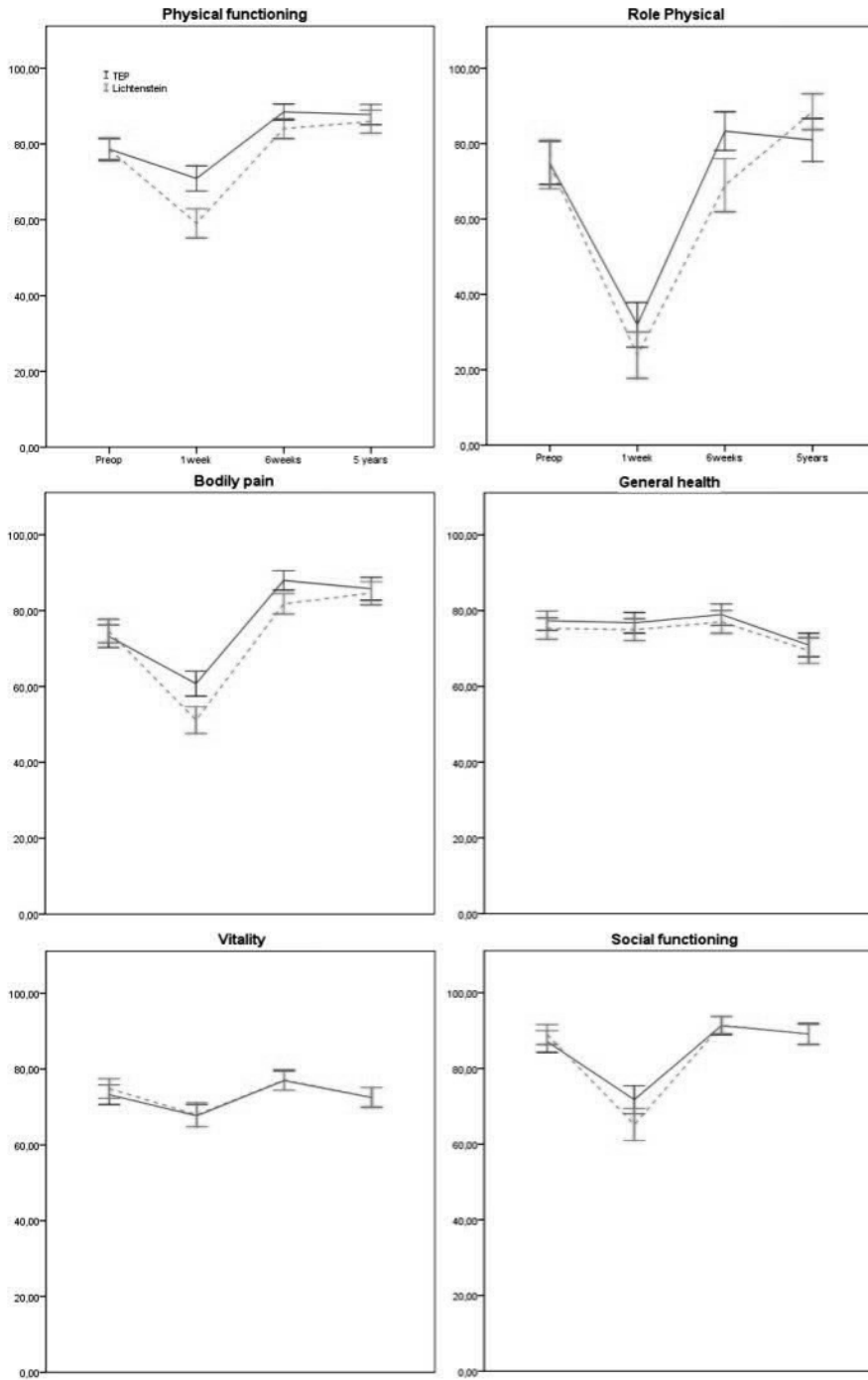


CONSORT-diagram. Flowchart of patients screened for participation in the study.

Quality of life

One week postoperatively, TEP patients reported better scores on three out of four physical dimensions and on the physical component summary (PCS) of the SF-36 questionnaire; physical functioning, role physical, bodily pain and PCS ($p < 0.001$, $p = 0.045$, $p < 0.001$, $p < 0.001$). One out of four mental dimensions was significantly better after TEP; social functioning ($p = 0.004$). The other four physical and mental dimensions showed comparable results.

Six weeks postoperatively, the TEP group still performed better on the same physical scores; physical functioning, role physical, bodily pain and PCS ($p = 0.002$, $p = 0.009$, $p = 0.001$, $p < 0.001$). The mental component summary, however, was in favor of the Lichtenstein group ($p = 0.015$). The other physical and mental dimensions showed comparable results. After five years follow-up, no significant differences could be detected for QoL between the TEP ($n = 199$) and the Lichtenstein ($n = 169$) groups. (Figure 1)



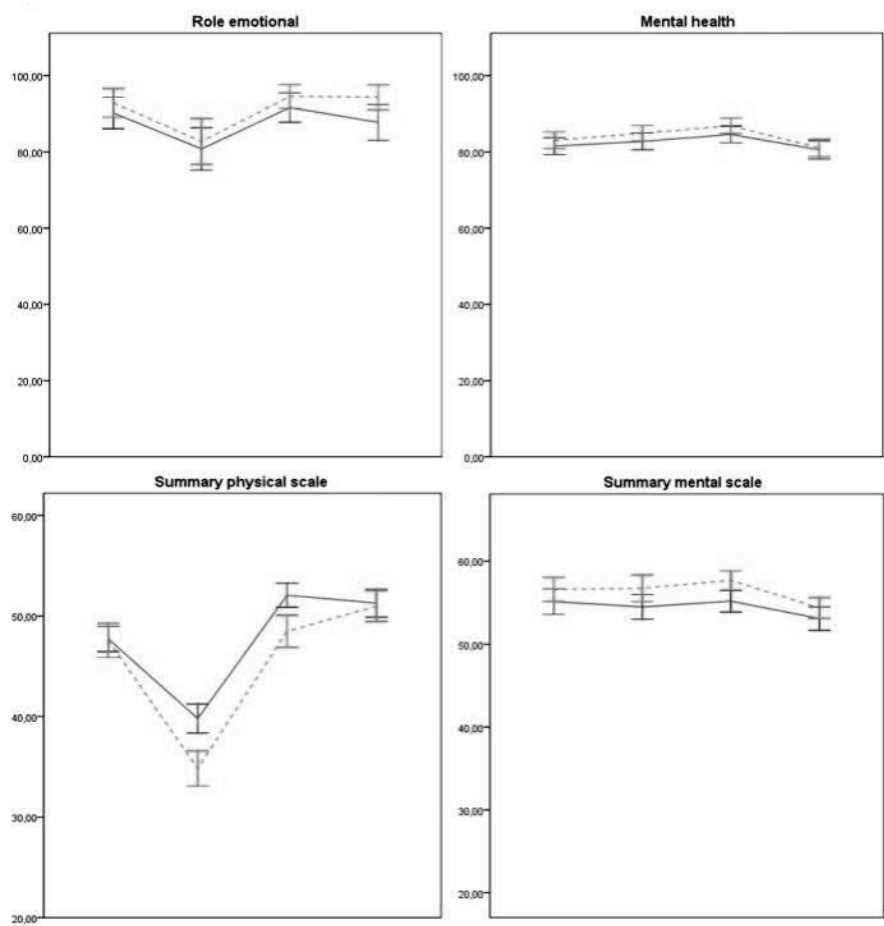


Figure 1 SF36 Dimensions TEP versus Lichtenstein
TEP versus Lichtenstein, 8 Dimensions of quality of life and 2 component summary scores. Each outcome preoperatively, postoperatively after 1 week, 4 weeks and 5 years.

Pain

Postoperative VAS pain scores on day 1, 2, 3 and after 1 week were in favor of TEP repair ($p=0.001$). Twenty-three percent of the TEP patients had pain 6 weeks postoperatively, compared to 32% after Lichtenstein repair ($p=0.01$). After 5 years, TEP patients reported significantly less chronic pain (15% vs. 28% $p=0.004$).^{10, 13}

Postoperative pain at 6 weeks postoperatively had a strong negative correlation with QoL on all measured points in time. Patients with postoperative pain had significantly lower scores on all eight dimensions, as well as the twocomponent summary scales of the SF-36 QoL questionnaire. Even after 60 months of follow-up, bodily pain and physical component summary scales were significantly lower for the group of patients with postoperative pain ($p=0.001$, $p=0.017$) (Figure 2).

Recurrence of the hernia resulted in impaired social functioning at five years ($p=0.031$). All other dimensions including the physical and mental component summary scales showed comparable results. (Figure 3) Experience of the surgeon resulted in comparable physical component summary and mental component summary scores. (Figure 4) Patients older than 65 years had better results on the physical component summary on the short term ($p<0.001$). After 5 years follow up, patients older than 65 years had lower results on the physical component summary compared to the younger group ($p<0.001$) (Table 2).

Table 2. Comparisons

Comparison/ time	Preoperatively	1 week	6 weeks	5 years
TEP vs <u>Lichtenstein</u>		Physical	Physical	
No pain vs <u>pain</u> at 6 weeks	Physical, Mental	Physical, Mental	Physical, Mental	Physical
Recurrence vs <u>no recurrence</u>				
TEP: Experienced vs <u>novice</u> surgeon				
Lichtenstein: Experienced vs <u>novice</u> surgeon				
Age <65 vs <u>≥65</u> years		Physical		Physical

Impact on physical and mental component summary

Physical = difference in physical component score ($p<0.05$)

Mental = difference in mental component score ($p<0.05$)

The superior outcome is related to the variable with equal lay-out recognizable with underscore

Non relevant comparisons are not shown (1 week and 6 weeks outcomes for recurrence comparison)



Figure 2 SF36 Influence of pain at six weeks
Eight dimensions of QoL, each on a separate axis on a scale of 0 to 100, 0 = minimum, 100 = maximum.

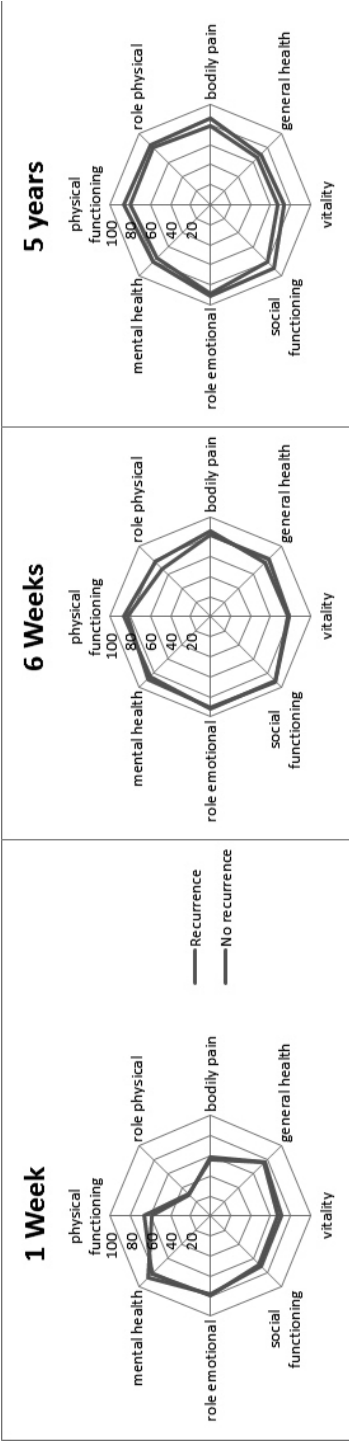


Figure 3. SF36 Influence of recurrence
Eight dimensions of QoL, each on a separate axis on a scale of 0 to 100, 0 = minimum, 100 = maximum.

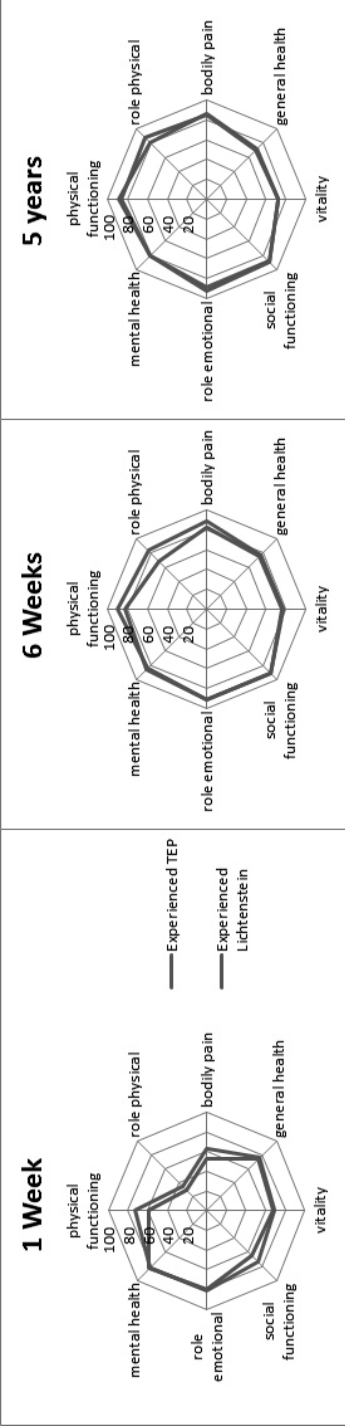


Figure 4 SF-36 Influence of experience of surgeon
Eight dimensions of QoL, each on a separate axis on a scale of 0 to 100, 0 = minimum, 100 = maximum.

DISCUSSION

Quality of life was significantly better after TEP repair compared with Lichtenstein. Three out of four physical dimensions; were significantly better after the TEP procedure at one and six weeks. These results are in agreement with current literature on quicker recovery to activities of daily life and quicker recovery to work.^{11, 13, 16-18} After five years follow-up no significant differences could be detected between the TEP and Lichtenstein procedures regarding health related quality of life.

TEP repair resulted in significantly less postoperative and chronic pain.^{10,13} These results are in accordance with previously performed randomized clinical trials comparing TEP with open hernia repair.^{11, 12, 17, 19} Pain reveals to be an independent factor influencing QoL negatively. Even after five years of follow-up the physical component summary scale was lower for patients with postoperative pain.

Other trials chose hernia recurrence as their primary outcome.^{11, 12} Quality of Life results, however, showed no differences between patients with or without a recurrence. Hernia recurrence seems to be from inferior importance on QoL.

In recent literature, experience has been shown to be important to prevent early recurrences, especially for the TEP procedure.¹¹⁻¹³ However, overall outcomes on QoL for TEP repair and Lichtenstein were comparable in experienced hands compared with novice surgeons. When Lichtenstein and TEP procedures were analyzed separately, still no differences could be detected regarding experience. The positive effect of experience on recurrence rates did not apply for QoL.

Interestingly age had a different influence on QoL during the short- and long-term follow-up. In the short term, patients older than 65 years reported better QoL on physical dimensions. A possible explanation could be that older patients had lower levels of physical activity beforehand; therefore bothered less from the effect of postoperative inactivity. In contrast with the short term findings the older patients had lower QoL scores during long-term follow-up on the physical dimensions. This result can possibly be explained by the deterioration of general health during aging of the human body, which obviously is more significant in seniors.

Although our article reports on a large multicenter randomized trial, there are some limitations. At the time of designing the current study, the TEP procedure was not the “golden standard” in The Netherlands. Experience with endoscopic inguinal hernia repair was limited when compared

to the current knowledge hernia surgeons have. Twenty-five procedures was chosen as cut-off point for experience, since data on learning curve was not yet available. Nowadays, a higher number of procedures would be chosen. Another drawback of this study could be the use of a general QoL questionnaire, which provides us data on the overall health status of the study population. The exact influence of the inguinal hernia or it's repair technique could be masked by other factors. Therefore evaluation of QoL between two surgical techniques with only a general QoL questionnaire is not ideal. A specialized hernia questionnaire in addition to the SF-36 questionnaire could provide more information. QoL measured with SF-36 is analysed in eight dimensions and two component summary scores, which means that ten p-values are calculated for each point in time, for each comparison.

In contemplation, literature is in agreement on several items. Postoperative and chronic pain is superior after TEP compared with Lichtenstein repair. Recurrence rates and total costs are comparable for TEP procedure and Lichtenstein in experienced hands.^{10-13, 19} Health related quality of life is superior after the TEP procedure in the short term. In our opinion TEP procedure should be preferred if experience is at hand. A note of caution to avoid complications is, of course, proper patient selection regarding invasive medical history in groin or bladder region to avoid serious complications during endoscopic inguinal hernia repair.

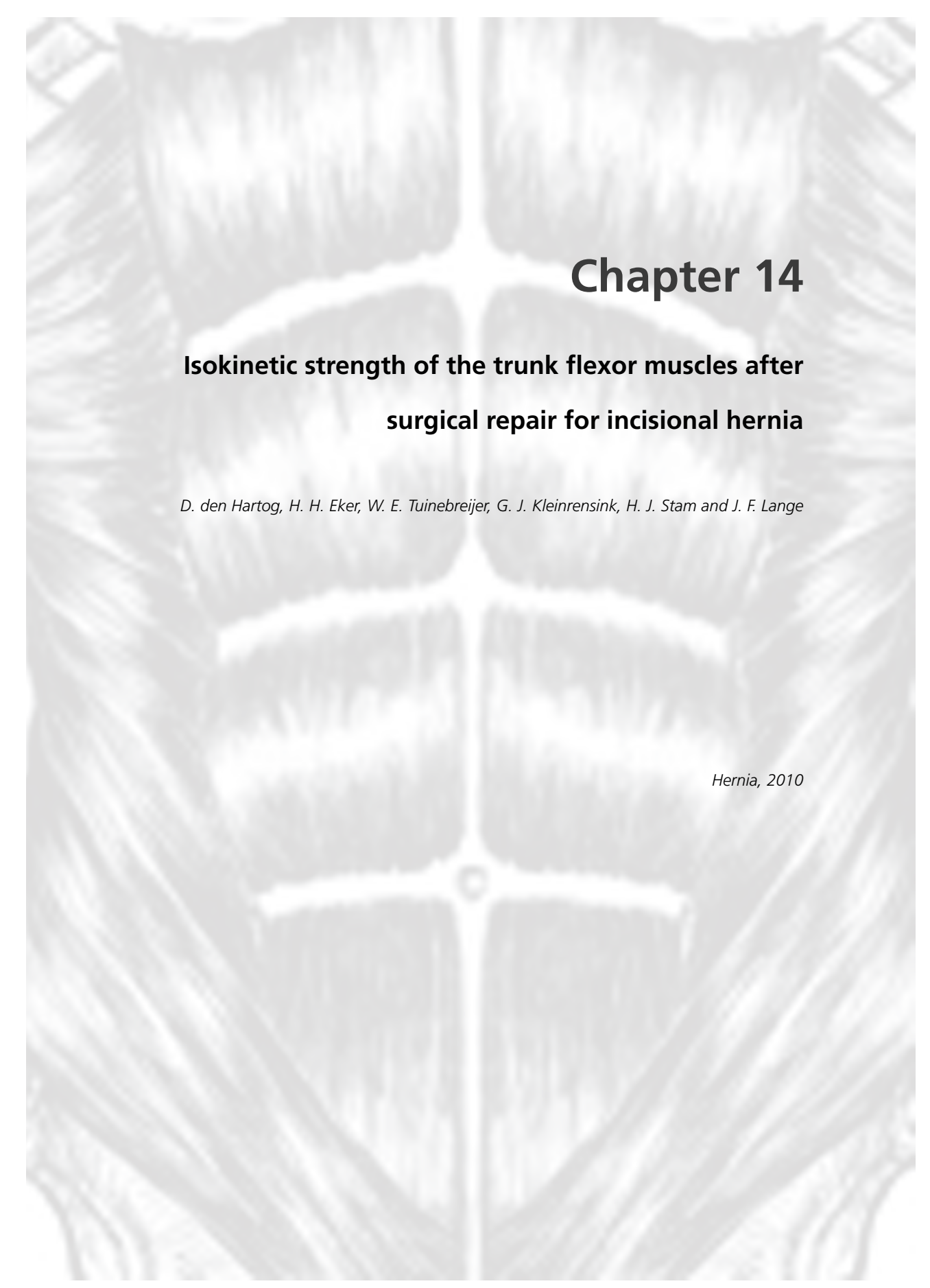
CONCLUSION

Health related Quality of Life gives an additional perspective on the debate on endoscopic versus open inguinal hernia repair. Health related Quality of Life was better after TEP repair compared to Lichtenstein in the short term. Postoperative pain is found to be an important factor correlating negatively to health related QoL. Regarding postoperative and chronic pain, TEP repair has been shown to be superior to Lichtenstein. In selected patients and in experienced hands TEP inguinal hernia repair should be preferred.

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Chapter 14

Isokinetic strength of the trunk flexor muscles after surgical repair for incisional hernia

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Hernia, 2010

ABSTRACT

Purpose The repair of incisional hernias can be accomplished by open or laparoscopic techniques. The Biodex® dynamometer measures muscle strength during isokinetic movement. The objectives of this study are to compare the strength of the trunk flexors between patients who underwent repair for incisional hernia and a control group, and to compare trunk flexion after two kinds of operative techniques for incisional hernias with and without approximation of the rectus abdominis muscles.

Methods The trunk flexion of 30 patients after different operative techniques for midline incisional hernias and of 12 healthy subjects was studied with the Biodex® isokinetic dynamometer.

Results The mean torque/weight (N m/kg) for trunk flexion was significantly higher in the control group compared to the patient group after incisional hernia repair. A significantly higher peak torque/weight [coefficient 24.45, 95% confidence interval (CI) -0.05; 48.94, $P = 0.05$] was found in the two-layered suture technique without mesh compared to the laparoscopic technique after adjusting for gender.

Conclusions The isokinetic strength of the trunk flexor muscles is reduced after an operation for incisional hernia. There is some evidence that a two-layered suture repair with approximation of the rectus abdominis muscles results in higher isokinetic strength of the trunk flexor muscles compared to the laparoscopic technique.

Keywords Ventral hernia Abdominal hernia Muscle strength dynamometer Abdominal muscles Rectus abdominis

INTRODUCTION

Incisional hernias are a serious complication of abdominal surgery and they occur in 11–23% of laparotomies.¹ After abdominal aortic resection, the incidence of incisional hernia can be as high as 60%.² The hernia can be repaired by either open or laparoscopic techniques. Laparoscopic correction is always performed with a mesh. The open technique can be simple hernioplasty (Mayo duplication or fascia adaptation), component separation technique after Ramirez or a mesh repair with (Rives–Stoppa) or without approximation of the rectus abdominis muscles. The open technique can be performed using a separate-layer technique without the use of mesh.³ In this two-layered suture repair, the abdominal wall is anatomically reconstructed and the rectus muscles are placed in a normal median position. In this technique, the rectus muscles are attached to each other at the midline; as a result, they are thought to retain normal strength. However, muscle strength studies of the trunk flexors after abdominal operations are rarely performed. Zauner-Dungl et al. studied trunk flexion strength after rectus abdominis muscle flap transfer in reconstructive surgery with an isokinetic dynamometer.⁴ The same group studied trunk flexion strength comparing a laparoscopic technique with open cholecystectomy.⁵

The Biodex® dynamometer studies muscle strength during isokinetic movement, which is a movement with a constant angular velocity (given by the dynamometer) within a certain range against a changing resistance, given by the subject.^{6–8}

The object of this study is to compare the trunk flexion strength between patients who underwent surgical repair for incisional hernia and a healthy control group. The second objective is to compare the trunk flexion strength after two different kinds of operative techniques for incisional hernia.



Fig. 1 Set-up of the Biodex® isokinetic dynamometer

Patients and methods

This study consisted of 30 patients who underwent midline incisional hernia operations and 12 healthy subjects without any abdominal operation. Fifty-five percent of the subjects were male and their mean (standard deviation [SD]) age, height, body weight and body mass index were 60 (15) years, 173 (11) cm, 81 (18) kg and 27 (4) kg/m², respectively. The mean age was significantly lower in the control group than in the patient group (49 vs. 64 years, $P < 0.01$). The patients had undergone operations in either an academic ($n = 14$) or a teaching hospital ($n = 16$). Sixteen (53.3%) patients had operations with an open technique and 14 (46.7%) by laparoscopic access. In the laparoscopic technique, a mesh was used and the fascia was left open. In the open repair, the fascia was closed in a two-layered technique without using a mesh [3]. The mean follow-up time between the Biodex® examination and the operation was 5.8 (1.8) years.

Trunk flexion strength measurements were conducted on a Biodex® isokinetic dynamometer (Model 2000, Multijoint System 3, Biodex Corporation, Shirley, NY, USA). Each subject was seated on a chair with his or her body strapped to the back of the chair. The mechanical stops were positioned with an amplitude of 60° to prevent the subject from working in non-conventional zones (Fig. 1). One session of flexions and extensions was performed to get the subject accustomed to the exercise before testing. The second test session was used for collecting data measurements.

Trunk flexor muscles were assessed at 60°/s angular velocities. The subjects performed six flexions and extensions and were encouraged to generate maximal effort through the entire range of motion for all repetitions. The peak torque was expressed in Newton metres (N m) and was normalised to the body weight (N m/kg $\times$ 100%). Torque was proportional to power and the peak torque was the highest value within the range of motion (Fig. 2).

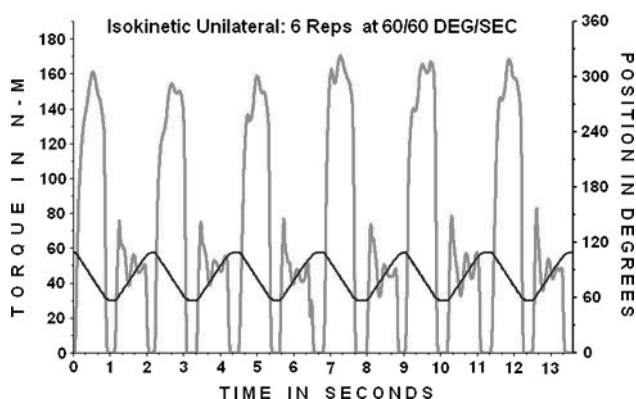


Fig. 2 Example of the torque course of six flexions and extensions as a function of time

Statistical analysis

Statistical analysis was performed with the PASW Statistics 17.0 package on a personal computer. All continuous data were given as means with SDs.

The two-sample t-test was used to compare the control and operative groups for age, weight and length. The Chi-square test was used to compare the control and operative groups for gender.

The two-sample t-test was used to compare the Biodex® measurements in the controls and the patients after operative repair for incisional hernia. This test was also used to compare the Biodex® measurements among themselves in patients after two operative techniques for incisional hernia, two-layered closure repair and laparoscopic repair with a mesh. A P-value < 0.05 was taken as the threshold of statistical significance.

The relationship between the peak torque (N m) and the operative technique (open or laparoscopic) was estimated using multiple regressions allowing for body weight, age and gender. Non-significant variables were removed one by one, removing the largest P-value first, until all of the remaining variables in the model were significant.

Because values of the Biodex® measurements with standard deviations from patients after incisional hernia operations could not be retrieved from the literature, sample size calculations could not be performed.

RESULTS

Gender, height and weight were not significantly different between the patients and controls or between the open and laparoscopic groups.

The mean torque/weight (N m/kg) for trunk flexion was significantly higher in the control group than in the total patient group after incisional hernia repair (Table 1). This difference with the

control group existed for both kinds of operative techniques, namely, the two-layered closure and the laparoscopic repair.

Table 1 Mean peak torque related to body weight in N m/kg (standard deviation [SD]) in trunk Xexion comparing two diVerent operations for incisional hernia with the control group ($n = 12$)

Peak torque/weight (N m/kg)	Operation group	Control group ($n = 12$)	Confidence interval of the difference	P-value
Total operation group ($n = 30$) versus control	84.4 (38.9)	202.4 (88.6)	60.5; 175.4	<0.01
No mesh = two-layered technique ($n = 16$) versus control	95.8 (39.7)	202.4 (88.6)	47.9; 165.3	<0.01
Laparoscopic ($n = 14$) versus control group	71.4 (34.8)	202.4 (88.6)	72.6; 189.4	<0.001

The mean torque/weight (N m/kg) for trunk flexion was not significantly different in a mutual comparison of the two operative techniques (two-layered closure repair and laparoscopic repair with a mesh) (Table 2). The post-hoc power calculation is presented in the last column of Table 2.

Table 2 Mean peak torque related to body weight in N m/kg (SD) in trunk flexion comparing the two operations for incisional hernia

Peak torque/weight (N m/kg)	Laparoscopic group ($n = 14$)	Two-layered technique ($n = 16$)	Confidence interval of the difference	P-value	Power post-hoc
Laparoscopic versus two-layered technique	71.4 (34.8)	95.8 (39.7)	−52.5; 3.6	0.086	0.41

A significantly higher peak torque/weight (coefficient 24.45, 95% confidence interval [CI] −0.05; 48.94, $P = 0.05$) was found in the two-layered suture technique compared to the laparoscopic technique after adjusting for gender (Table 3).

Table 3 Regression coefficients of peak torque related to body weight in N m/kg with respect to gender and laparoscopic access versus the two-layered suture technique

Variable	Coefficient	95% confidence interval (CI)	P-value	Standardised coefficient
Gender ^a	−37.58	−62.02; −13.14	0.004	−0.49
Laparoscopic versus two-layered suture technique ^b	24.45	−0.05; 48.94	0.050	0.32

^aMale gender is the reference category

^bLaparoscopic access is the reference category

DISCUSSION

In this study, we compared the isokinetic muscle strength of the trunk flexor muscles measured with the Biodex® isokinetic dynamometer between patients who underwent repair for incisional hernia and a control group without any abdominal operation. The mean peak torque, as a measure of the isokinetic strength of trunk flexor muscles, was significantly lower in the patients with incisional hernia operations than in the healthy controls. We also compared the trunk flexion strength after two kinds of operative techniques for incisional hernias with and without approximation of the rectus abdominis muscles. A significantly higher peak torque/weight was found in the two-layered suture technique compared to the laparoscopic technique after adjusting for gender.

Midline incisional hernias displace the rectus muscles laterally. This lateral position might be the cause of a weakened abdominal muscle strength. In a study comparing laparoscopic with open cholecystectomy, the open technique resulted in reduced muscle strength of the trunk flexor muscles compared to controls and the laparoscopic approach.⁵ The open cholecystectomy was performed subcostally with transections of the right rectus abdominis muscle. This is in contrast with the laparoscopic technique through small incisions, which leave the rectus abdominis muscles intact. So, a scarred rectus abdominis muscle lowers the muscle strength of trunk flexion measured with an isokinetic dynamometer.

In contrast to the two-layered closure repair for incisional hernia, in which the rectus muscles are medially positioned and, as such, can exert greater strength, in the laparoscopic mesh technique, the rectus muscles remain in their lateral displaced position.

Despite the considerable academic interest, the clinical relevance of a reduced isokinetic strength of the trunk flexors is not exactly known and correlations between strength, signs and symptoms have not been studied. Significantly lower mean strength values have been found in patients with chronic back pain.⁷ It will be interesting to study the relationship between the reduced muscle strength of trunk flexors in patients with incisional hernia and the patients' symptoms before and after surgical repair. Overall, incisional hernia symptoms have not been systematically studied.⁹ The reduced muscle strength of trunk flexors in patients after laparoscopic repair techniques for incisional hernia could cause a higher prevalence of back pain than in patients after the two-layered closure repair with approximation of the rectus abdominis muscles.

The statistical power for finding a significant difference between the two operative techniques was low and was caused by the small sample sizes of the groups. Because we only rented the Biodex® isokinetic dynamometer for a limited time, more patients could not be examined. The small sample size of our study is a flaw for making strong conclusions. Measuring the same patients before and after operation will increase the power of the study.

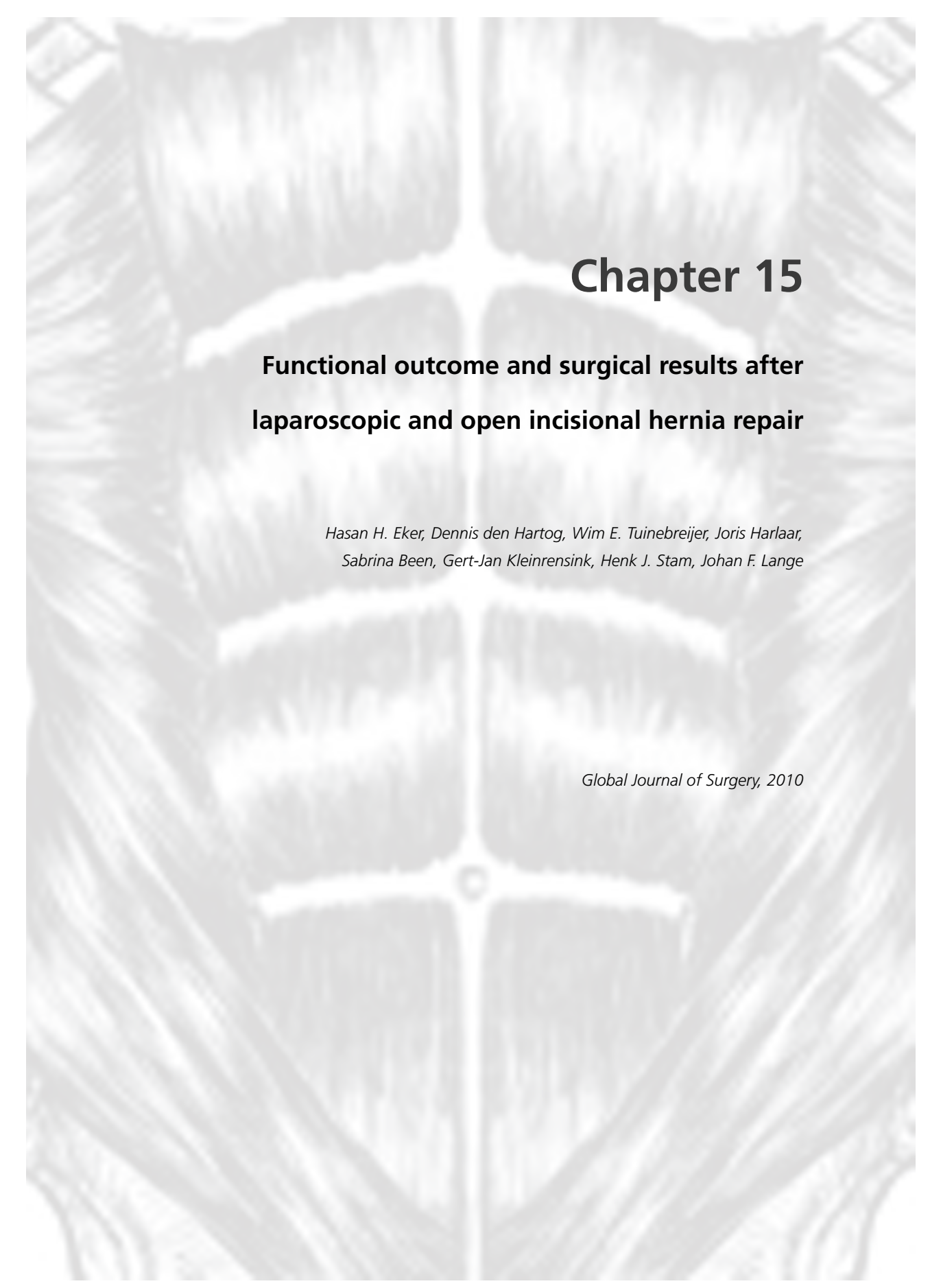
Another limitation of our study is the use of healthy controls. A better and more interesting study group for comparison would be a patient group with a well-healed scar after a median laparotomy or patients with a large primary incisional hernia. Our healthy controls were also younger than the incisional hernia patients. This could have resulted partly in the large difference between the controls and the patients. We did not examine the trunk flexor muscles in patients after a midline laparotomy and in patients with an incisional hernia. Balogh et al. studied isokinetic muscle strength of the trunk flexor muscles with the Cybex® isokinetic dynamometer 6 months to 1.5 years after open subcostal cholecystectomy and in healthy volunteers.⁵ Their controls consisted of 10 men and 12 women, but these volunteers had a mean age of 23.5 years younger than our controls. Their mean peak torque at 30°/s angular velocity was 221.7 N m/kg. Keeping account of the higher age of our controls, this is comparable with the mean peak torque at 60°/s of 202.4 N m/kg. The mean peak torque at 30°/s of the open cholecystectomy group (13 men, 12, female, mean age 58 years) of Balogh et al. was 170.7 N m/kg, which is much higher than in our incisional hernia group (84.4 N m/kg). So, having an incisional hernia and incisional hernia surgery affects the peak torque more than having a laparotomy, such as an open subcostal cholecystectomy. Moreover, it will be necessary to replicate the significant difference in peak torque between the laparoscopic group and the two-layered closure repair in larger sample sizes. It is important and interesting to establish whether the difference in trunk flexor torque also exists in other open procedures, in which the fascia is closed; this question should also be studied in larger sample sizes than those used in this study.

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Chapter 15

Functional outcome and surgical results after laparoscopic and open incisional hernia repair

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ABSTRACT

Objectives: Comparison of laparoscopic versus open ventral incisional hernia repair with regard to abdominal muscle strength and thickness of the transverse abdominal muscle.

Background data: The debate about the possible advantages of laparoscopic versus open incisional hernia repair is still ongoing. The primary outcomes of already published studies are mainly recurrence, pain or quality of life. Data upon postoperative abdominal wall function is still lacking. In this single center case control trial, muscle strength and transverse abdominal muscle thickness with regard to the open and laparoscopic techniques are analysed.

Methods: Thirty-five patients that underwent midline incisional hernia operations were included in this study. Twelve healthy subjects without any abdominal operation functioned as a control group. Trunk flexion of all patients after different operative techniques for midline incisional hernias and of 12 healthy subjects were studied with the Biodex® isokinetic dynamometer and conventional abdominal muscle trainers for the rectus and oblique abdominal muscles. All patients were examined for recurrences at the policlinical ward, where subsequently an ultrasound of the abdominal wall was performed to analyse the transverse abdominal muscle thickness.

Results: The mean torque/weight (%) for trunk flexion, measured with the Biodex®, was significantly higher in the control group compared with the patient group after incisional hernia repair. Comparing the trunk flexion of the two groups with the Biodex® after either laparoscopic or open incisional hernia repair showed a trend in favour of the open group after adjusting for gender. The muscle strength measured by the conventional abdominal muscle trainers showed no differences between the operation groups. The transverse abdominal muscle thickness difference between rest and contraction was significantly higher in the open repair group.

Conclusions: The isokinetic strength of the trunk flexor muscles is reduced after an operation for incisional hernia. There is some evidence that an open repair with approximation of the rectus abdominis muscles results in higher muscle strength of the rectus muscles and thicker Transverse Abdominis muscles, compared to the laparoscopic technique.

Key words: ventral hernia, abdominal hernia, muscle strength dynamometer, abdominal muscles, rectus abdominis, transverse abdominal muscle, ultrasound

INTRODUCTION

Despite studies on the optimal closing techniques for laparotomies, the risk for incisional hernia after midline incision still remains about 5-20 %.^{1,2} After abdominal aortic resection, the incidence of incisional hernia can be as high as 60%.² Accordingly incisional hernia is the most frequently seen long-term complication in surgery causing high morbidity rates and even mortality in patients.³⁻⁶ Complaints such as pain, discomfort and respiratory restriction subsequently is leading to surgical repair in a large number of these patients.^{7,8}

Incisional hernias can be repaired by either open or laparoscopic techniques. Laparoscopic corrections are always performed with a mesh. The open technique can be a simple hernioplasty (Mayo duplication or fascia-adaptation), component separation technique after Ramirez or a mesh repair with (Rives-Stoppa) or without approximation of the rectus abdominis muscles.

However, muscle strength studies of the trunk flexors after abdominal operations are rarely performed. Zauner-Dungl et al. studied trunk flexion strength after rectus abdominis muscle flap transfer in reconstructive surgery with an isokinetic dynamometer.⁹ The same group studied trunk flexion strength comparing a laparoscopic technique with open cholecystectomy.¹⁰

The Biodex® dynamometer studies muscle strength during isokinetic movement, which is a movement with a constant angular velocity (given by the dynamometer) within a certain range against a changing resistance given by the subject.¹¹⁻¹³

Another way to assess dynamic strength has been to determine how much weight an individual can lift for one repetition. This one repetition maximum strength can be calculated from how many repetitions a person can perform with a certain sub-maximal weight.¹⁴ Ultrasound of the abdominal wall can be used to measure the transverse abdominal muscle thickness in rest and during contraction. The change between rest and contraction can be used as a measure of abdominal wall muscle function.¹⁵⁻¹⁷

The object of this study is to compare trunk flexion strength between patients who underwent surgical repair for incisional hernia and a healthy control group. Secondary objectives are to compare trunk flexion strength and Transverse Abdominis muscle thickness after different kinds of operative techniques for incisional hernia.

PATIENTS AND METHODS

This study consisted of 35 patients who underwent midline incisional hernia operations and 12 healthy subjects without any abdominal operation. All patients had undergone operations in an academic center. Twenty-one (53.3%) patients had operations with an open technique and 14

(46.7%) by laparoscopic access. In the laparoscopic technique, a mesh was used and the hernia ring was left open. In the open repair, the fascia of the rectus abdominis muscle was closed after placement of a mesh in seven patients. The fascia was left open after placement of a mesh in fourteen patients. The mean follow-up time between the operation and the Biodex® examination was 5.8 years (1.8).

Biodex® measurements

Trunk flexion strength measurements were conducted on a Biodex® isokinetic dynamometer (Model 2000, Multijoint System 3, Biodex® Corporation, Shirley, NY, USA). The dynamometer gives a variable resistance with a fixed speed. Each subject was seated on a chair with his or her body strapped to the back of the chair. The mechanical stops were positioned with an amplitude of 60° to prevent the subject from working in non-conventional zones (figure 1). One session of flexions and extensions was performed to get the subject accustomed to the exercise before testing. The second test session was used for collecting data measurements.



Fig.1. Set-up of Biodex® isokinetic dynamometer

Trunk flexor muscles were assessed at 60°/sec angular velocities. The subjects performed six flexions and extensions and were encouraged to generate maximal effort through the entire range of motion for all repetitions. The peak torque was expressed in Newton meters (Nm) and was normalised to body weight (Nm/kg x 100%). Torque is proportional to power and the peak torque is the highest value within the range of motion (figure 3).

One repetition maximum measurements

To evaluate the maximum strength of the abdominal muscles one repetition maximum tests were performed. Two different devices were used for the exercises. One of the devices was designed to exercise the rectus abdominis (figure 2A) and the other for the oblique and transverse abdominal muscles (figure 2B). None of the patients had training experience and were instructed before doing the exercises. After measuring how many times patients could perform standardized exercises on the devices the one repetition maximum (1RM) was calculated using the formula of Brzycki.¹⁴ The formula reads: $1RM = \text{weight lifted} / (1.0278 - 0.0278 * \text{number of repetitions})$. The maximum weight a person can lift is expressed in grams. The unit of the one repetition maximum is expressed in kilogram-force or gram-force, which is the magnitude of the force exerted on 1 kilogram (or gram) of mass by a 9.81 m/s^2 gravitational field (standard gravity).

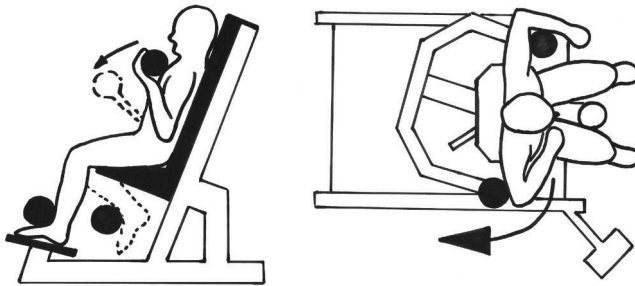


Fig.2. A and B. Set-up of abdominal muscle trainer for rectus and oblique muscles.

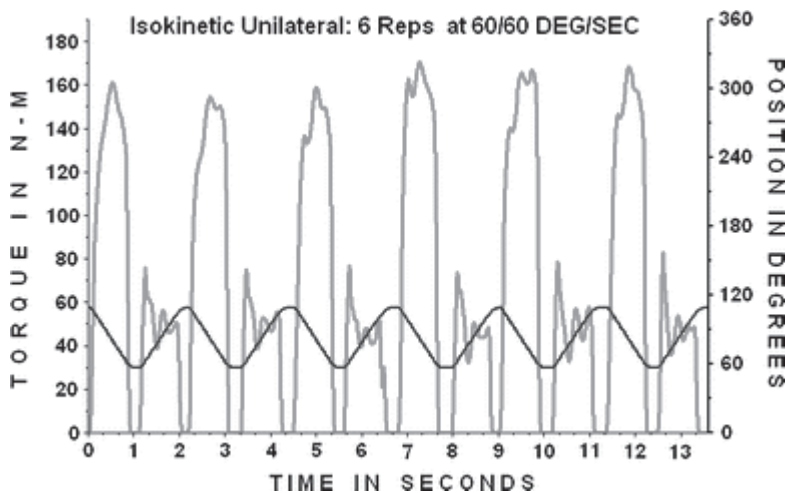


Fig 3. Example of the torque course of six flexions and extensions in function of time.

Ultrasound imaging

Changes in muscle thickness during rest and after muscle contraction were assessed with ultrasound imaging. Unilateral measurements of the transverse abdominal muscle were performed using a portable ultrasound unit (SonoSite Titan). The measurements were performed by positioning the transducer at the level of the umbilicus horizontally and hereafter moving it to lateral until the proximal edge of the transverse abdominal muscle was aligned to the left side of the onscreen display.

In resting position two images were taken from the transverse abdominal muscle to assess the rest thickness. Subsequently patients were asked to strain their abdominal wall at maximum strength. During contraction of the abdominal wall, again two images were taken after aligning the proximal edge of the transverse abdominal muscle to the left side of the onscreen display (figure 4).

The thickness of the transverse abdominal muscle was obtained using measurement software of the ultrasound device. The proximal edge of the muscle was digitally callipered, whereupon the thickness of the muscle 25 mm laterally from this calliper was measured. Every measurement is repeated two times to reduce intraobserver variability. The mean of these two measurements was calculated and used for comparison between the subjects.

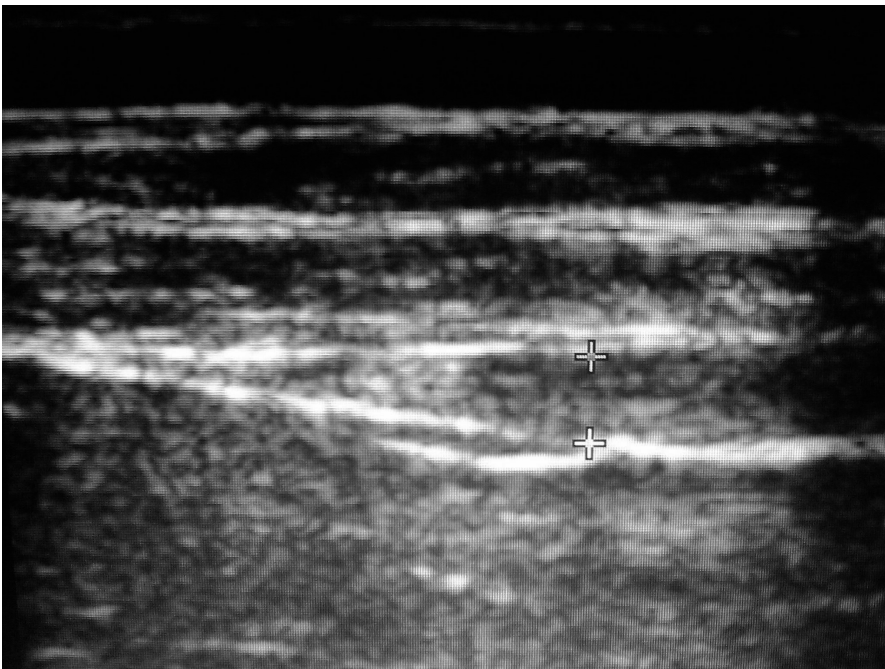


Fig.4. Example of ultrasound still frame.

Statistical analysis

Statistical analysis was performed with PASW Statistics 17.0 on a personal computer. All continuous data were given as means with standard deviations (SD).

The two-sample t-test was used to compare the control and operative groups for age, weight and length. The chi-square test was used to compare the control and operative groups for gender.

The two-sample t-test was used to compare the Biodex® measurements in the controls and patients after operative repair for incisional hernia. This test was also used to compare the measurements amongst themselves in patients after the three operative techniques for incisional hernia: open technique with fascia closure, open technique without fascia closure and laparoscopic repair. A p-value <0.05 was taken as the threshold of statistical significance.

The relationship between the one repetition maximum lift and the operative technique (open or laparoscopic) was estimated using multiple regressions allowing for body weight, age and gender. Non-significant variables were removed one by one, removing the largest p-value first, until all remaining variables in the model were significant.

The strength of relationship between the measurements of the different measurement techniques was estimated by the product-moment correlation coefficient.

RESULTS

Fifty-five percent of the subjects were male and their mean (SD) age, height, body weight and body mass index were 60 (13) years, 173 (10) cm, 83 (19) kg and 27 (5) kg/m², respectively. The mean age was significantly lower in the control group than in the patient group (50 versus 64 years, $p<0.01$). The patient groups were similar in age, sex ratio, mean BMI (Body Mass Index) and recurrence rate.

Biodex®

Significantly higher peak torque/weight were found in the control group compared to the operated group (84 versus 202 nm, $p<0.01$). After splitting up the operated group in open and laparoscopic repair the comparison with the controls remained significant ($p<0.01$, table 1). The mean torque/weight was not significantly different between the open and laparoscopic group. Comparison between patients in which the fascia is closed over the mesh with patients where the fascia is left open after open incisional hernia repair showed no difference in outcome (82 versus 97, $p=0.54$, table 2).

After adjusting for gender a trend could be seen in the mean one repetition maximum lift in favour of the open group (coefficient -136.6, [95% CI -284.9; 11.6], $p=0.07$, table 4).

Table 1. Mean peak torque/weight in % (SD) in trunk flexion comparing three different operations for incisional hernia with the control group (n=12) measured with the Biodex® isokinetic dynamometer.

Peak torque/weight (%)	Measure device	Operation group	Control group (n=12)	Confidence interval of the difference	P-value
Total operation group (n=35) versus control	Biodex®	83.7 (46.1)	202.4 (88.6)	61.0; 176.4	<.01
Laparoscopic technique (n=14) versus control group	Biodex®	71.4 (34.8)	202.4 (88.6)	72.6; 189.4	<.01
Open technique with fascia left open (n=14) versus control group	Biodex®	97.0 (59.3)	202.4 (88.6)	45.2; 165.6	<.01
Open technique with fascia closed (n=7) versus control group	Biodex®	81.9 (32.6)	202.4 (88.6)	60.1; 180.9	<.01

Abdominal muscle trainer

Analysis of the one repetition maximum strengths, measured with the abdominal muscle trainer for the rectus abdominis, showed no significant differences between the open and laparoscopic group (561 versus 424, $p=0.12$, table 2). Splitting up the open repair group in fascia closed or left open, showed comparable results between the two groups (523 versus 577, $p=0.65$). The same analyses were made for the one repetition maximum strengths measured with the abdominal muscle trainer for the oblique and transverse muscle. No significant differences were found between the open and laparoscopic groups or between the two different open techniques (table 2).

Table 2. Mean peak torque/weight in % (SD) or maximum strength (gram-force) in trunk flexion comparing the three operations for incisional hernia with three different devices.

Peak torque/weight (%) or maximum strength (gram-force)	Measure device	Operation-Group 1	Group Group 2	Confidence interval of the difference	P-value
Open group (n=21) versus laparoscopic group (n=14)	Biodex®	92.0 % (51.5)	71.4% (34.8)	-11.5; 52.6	.20
Open group fascia open (n=14) versus laparoscopic (n=14)	Biodex®	97.0%(59.3)	71.4% (34.8)	-12.1; 63.4	.18
Open group fascia closed (n=7) versus laparoscopic (n=14)	Biodex®	81.9% (32.6)	71.4% (34.8)	-22.5; 43.6	.51
Open group fascia closed (n=7) versus Open group fascia open (n=14)	Biodex®	81.9% (32.6)	97.0% (59.3)	-65.8; 35.6	.54
Open group (n=20) versus laparoscopic group (n=14)	Abdominal muscle trainer Rectus	560.5 (237.7)	423.9 (257.8)	-38.0; 311.3	.12
Open group fascia open (n=14) versus laparoscopic (n=14)	Abdominal muscle trainer Rectus	576.7 (261.0)	423.9 (257.8)	-48.7; 354.4	.13
Open group fascia closed (n=6) versus laparoscopic (n=14)	Abdominal muscle trainer Rectus	522.7 (187.5)	423.9 (257.8)	-147.6; 345.2	.41
Open group fascia closed (n=6) versus Open group fascia open (n=14)	Abdominal muscle trainer Rectus	522.7 (187.5)	576.7 (261.0)	-302.9; 194.8	.65
Open group (n=19) versus laparoscopic group (n=13)	Abdominal muscle trainer Transverse	461.6 (208.7)	375.6 (162.3)	-54.8; 226.8	.22
Open group fascia open (n=13) versus laparoscopic (n=13)	Abdominal muscle trainer Transverse	444.9 (158.3)	375.6 (162.3)	-60.5; 199.0	.28
Open group fascia closed (n=6) versus laparoscopic (n=13)	Abdominal muscle trainer Transverse	497.8 (307.3)	375.6 (162.3)	-102.0; 346.5	.27
Open group fascia closed (n=6) versus Open group fascia open (n=13)	Abdominal muscle trainer Transverse	497.8 (307.3)	444.9 (158.3)	-169.0; 275.0	.62

Ultrasound measurement transversus abdominis (TrA)

Resting thickness of the transversus abdominis (TrA) was comparable between the open and laparoscopic technique. The average thickness of the TrA was 4.4 mm for the open and 4.0 mm for the laparoscopic technique ($p=0.40$). Changes of the TrA muscle thickness after straining was significantly different between the open and laparoscopic technique ($p=0.02$, table 3). Comparing in the open technique the closed and the left open fascia groups with the laparoscopic patients

the muscle thickness difference was significantly higher for both open groups ($p=0.05$). The muscle thickness in the open group increased significantly more than the laparoscopic group after straining the TrA, 3.3mm(SD 1.8) against 1.7mm(SD 1.4) [$p=0.02$]. The increase of the transversus abdominis muscle thickness was similar, whether the fascia was closed or left open in the open repair technique (3.3mm versus 3.3mm, $p=0.98$).

The Pearson's correlations between the five different measurement techniques for abdominal muscle function are presented in table five. For the correlations the Biodex® peak torque flexion was not corrected for body weight like the other measurements.

Table 3. Ultrasound measurements of the transversus abdominis muscle comparing the three operations for incisional hernia.

Changes of mean transversus muscle thickness (mm)	Operation technique		Confidence interval of the difference	P-value
	Group 1	Group 2		
Open (n=20) versus laparoscopic (n=10)	3.3 (1.8)	1.7 (1.4)	.22; 2.9	.02
Open fascia - open technique (n=13) versus laparoscopic (n=10)	3.3 (1.9)	1.7 (1.4)	.04; 3.1	.05
Closed fascia - open technique (n=7) versus laparoscopic (n=10)	3.3 (1.6)	1.7 (1.4)	-.003; 3.1	.05
Closed fascia - open technique (n=7) versus open fascia - open technique (n=13)	3.3 (1.6)	3.3 (1.9)	-1.8; 1.8	.98

Table 4. Regression coefficients of maximum strength with respect to gender measured by one repetition maximum measurement (rectus muscle).

Variable	Coefficient	95% CI	P-value	Standardised coefficient
Gender ¹	-263.2	-409.1; -117.3	.001	-.53
Laparoscopic versus open incisional hernia repair ²	-136.6	-284.9; 11.6	.07	-.27

¹ Men is reference category.

² Open access is reference category.

Table 5. Pearson correlations (p-values) between five measurements of abdominal function.

	Biodex® (no correction for body weight)	1RM rectus	1RM oblique	Ultrasound in rest	Ultrasound during contraction
Biodex®	1.00				
1RM rectus	.86 (<.001)	1.00			
1RM oblique	.54 (.002)	.65 (<.001)	1.00		
Ultrasound in rest	.22 (.23)	.40 (.03)	.54 (.003)	1.00	
Ultrasound during contraction	.24 (.21)	.40 (.03)	.35 (.07)	.58 (<.01)	1.00

DISCUSSION

In this study we compared isokinetic muscle strength of the trunk flexor muscles measured with the Biodex® isokinetic dynamometer between patients who underwent three different repairs for incisional hernia and a control group without any abdominal operation. Mean peak torque, as a measure of the isokinetic strength of trunk flexor muscles, was significantly lower in the patients with incisional hernia operations than in the healthy controls.

We also compared the abdominal wall function after three kinds of operative techniques for incisional hernia: the laparoscopic technique, the open technique with or without closure of the fascia. No difference was found between the different kinds of operations measured with the Biodex® dynamometer. A significantly higher maximum strength measured with the abdominal rectus muscle trainer was found in the open operations compared to the laparoscopic technique after adjusting for gender. All the open operations compared with laparoscopic technique had higher thickness changes of the transversus abdominal muscle after contraction using ultrasound measurement.

Midline incisional hernias displace the rectus muscles laterally. This lateral position might be the cause of a weakened abdominal muscle strength. In a study comparing laparoscopic with open cholecystectomy, the open technique resulted in reduced muscle strength of trunk flexor muscles compared to controls and the laparoscopic approach.¹⁰ The open cholecystectomy was performed subcostally with transection of the right rectus abdominis muscle. This is in contrast with the laparoscopic technique through small incisions, which leave the rectus abdominis muscles intact. So a scarred rectus abdominis muscle lowers the muscle strength of trunk flexion measured with an isokinetic dynamometer.

In contrast to the open repair with fascia closure for incisional hernia, in which the rectus muscles are medially positioned and as such can exert greater strength, in the laparoscopic mesh technique, the rectus muscles remain in their lateral displaced position. In the open repair with the fascia left open the abdominal muscle function is probably better than in the laparoscopic technique, because the fascia is put on tension in the former technique. In the laparoscopic technique the hernia is enlarged by the pneumoperitoneum during operation. And after desufflation of the pneumoperitoneum the mesh with the fascia is even hanging floppy in the abdominal cavity.

The ultrasound measurements showed a significant increase of the transversus abdominis (TrA) muscle after contraction in the open techniques compared to the laparoscopic technique. Probably because of the better partial anatomical repair in the open technique the TrA muscle does not become atrophic or even enlarge after the repair. In the open technique the abdominal muscles remain on tension, which is necessary for a good muscle function.

The clinical relevance of a reduced isokinetic strength of the trunk flexors is not known and correlations between strength, signs and symptoms were not studied. Significantly lower mean strength values have been found in patients with chronic back pain.¹³ It will be interesting to study the relationship between the reduced muscle strength of trunk flexors in patients with incisional hernia and the patients' symptoms before and after surgical repair. Overall, incisional hernia symptoms have not been systematically studied.¹⁸ The reduced muscle strength of trunk flexors in patients after laparoscopic techniques for incisional hernia could cause a higher prevalence of back pain than in patients after open repair.

A good correlation was found between the Biodex® dynamometer and the one repetition measurement of the rectus muscles and also between the one repetition measurements of the rectus and oblique abdominal muscles. The measurements of the one repetition maximum tests and the ultrasounds in rest showed a moderate correlation. A moderate correlation showed the measurements of the one repetition and the ultrasound in rest and contraction. These correlations mean at least that these three techniques all measure abdominal function, but at a different level. The Biodex® dynamometer measures the torque or moment of force, which is the tendency of a force to rotate an object about an axis. It is expressed in Newton meter (Nm) and it was corrected for body weight in our analysis. The one repetition maximum is a measure of maximal strength, it is the maximum amount of weight a person can lift in a single repetition. This lifted weight is expressed in kilograms or grams. The good correlation between the Biodex® and the one repetition rectus muscles indicate, that the Biodex® measures more rectus muscle function than oblique abdominal muscle function. The ultrasound examination yields a measure of the thickness of the transverse abdominal muscle before and after contraction and is expressed in millimetres. It has a low correlation with the Biodex®, because the ultrasound measured the transverse muscle and the Biodex® mainly the rectus muscle function.

The statistical power for finding a significant difference between the three operative techniques was low and was caused by the small sample sizes of the groups. The small sample size of our study is a flaw for making strong conclusions. Measuring the same patients before and after the repair of their incisional hernia will increase the power of the study.

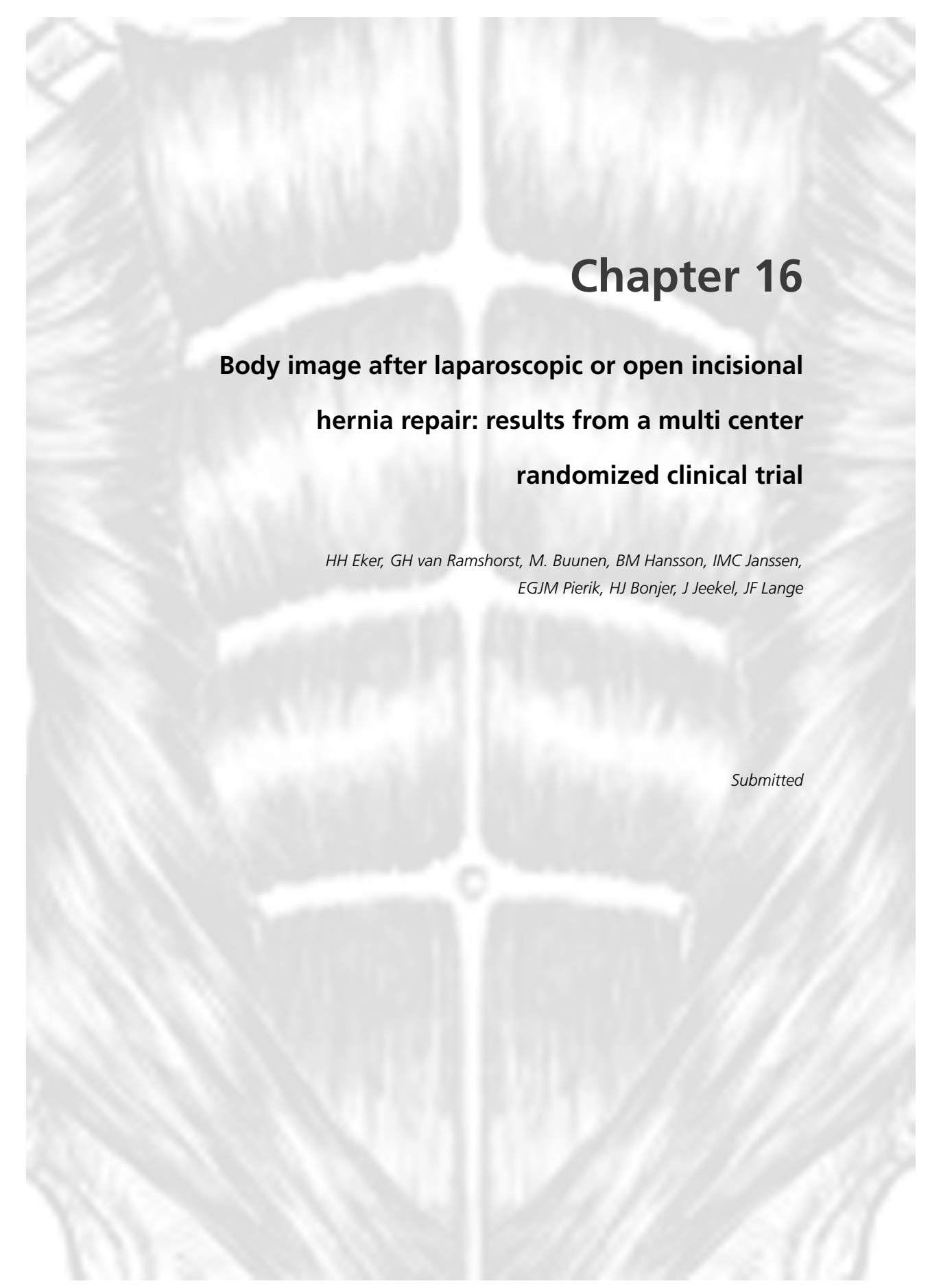
Another flaw of our study is the use of healthy controls. A better and more interesting study group for comparison would be a patient group with a well healed scar after a median laparotomy or patients with a large primary incisional hernia.

Moreover, it will be necessary to replicate the significant difference in abdominal muscle function between the laparoscopic group and the different open techniques in larger sample sizes. It is important and interesting to establish whether the difference in abdominal muscle function also exists in other open procedures, in which the fascia is closed and the rectus muscles are more or

less approximated; this question should also be studied in larger sample sizes than those used in this study.

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Chapter 16

Body image after laparoscopic or open incisional hernia repair: results from a multi center randomized clinical trial

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Submitted

ABSTRACT

Background: Incisional hernia is associated with pain, risk of incarceration and cosmetic complaints. Cosmesis sometimes can be the main objective for repair but has not previously been described as an end point of studies comparing laparoscopic and open incisional hernia repair. This study investigates the body image of incisional hernia repair patients.

Methods: A total number of 194 patients from 10 hospitals were included in a multicenter study and randomized between laparoscopic and open incisional hernia repair. After a mean follow-up of 66 months, 146 patients were invited to fill out a Body Image Questionnaire (BIQ). The questionnaire consists of 2 parts: a body image score (BIS) and cosmetic score (CS).

Results: A total number of 123 patients responded, 60 from the laparoscopic and 63 from the open repair group (response rate 84%). Age, sex and body mass index (BMI) were comparable for both groups. The BIQ scores were comparable for the laparoscopic and open group (mean scores 17.6 and 17.1 for BIS; 16.1 and 15.6 for CS). The BIS score was positively correlated to the age of the study group. No relations were found between BIS and CS scores for gender, BMI or recurrence.

Conclusions: Body image scores of patients are comparable after laparoscopic or open incisional hernia repair at long-term follow-up.

Keywords: Body image, laparoscopic hernia repair, open hernia repair, cosmesis

INTRODUCTION

Laparoscopic incisional hernia repair has been reported to be preferable over open incisional hernia repair in terms of less postoperative pain, blood loss, and infections, shorter hospital stay, and improved cosmetic result.¹⁻³ Cosmetic complaints associated with incisional hernia have been reported as a motive for incisional hernia repair.⁴ Despite the relevance of cosmesis to this patient population, none of the previously conducted studies comparing laparoscopic and open incisional hernia repair, had cosmetic outcome as endpoint.^{1,2,5-9} Patients' self-image can be investigated by means of the Body Image Questionnaire (BIQ). This questionnaire was developed by Dunker et al and has been used in several studies to evaluate patients' body image.¹⁰⁻¹²

Two studies reported improved cosmetic outcome after laparoscopic ileocolic resection compared to open ileocolic resection, and Canda et al found similar results after laparoscopic splenectomy compared to open splenectomy.^{10,12,13} Patients included in the aforementioned studies had not previously undergone abdominal surgery. In patients who undergo incisional hernia repair, preceding operations already disturbs cosmesis.^{14,15} This study is the first to report results on body image of patients randomised for laparoscopic or open incisional hernia repair.

PATIENTS AND METHODS

The aim of the trial was to compare laparoscopic and open incisional hernia repair with respect to efficacy, clinical outcome and quality of life. The primary results of this study are reported before.¹⁶ Patients with a primary or recurrent incisional hernia, larger than 3 but smaller than 15 cm, eligible for elective surgery were equally randomised to laparoscopic or open repair. Open abdomen treatment in medical history was a contraindication for inclusion. Between May 1999 and December 2006, 194 patients were randomly assigned to undergo either laparoscopic (n=94) or open (n=100) incisional hernia repair. In laparoscopic hernia repair, additional trocar wounds were created without excision of the abdominal scar. In open repair, patients were operated using the previous incision without creating additional wounds, except for wound suction drains, if necessary. Patients were scheduled to visit the out-patient clinic at 1 week, 6 weeks, 1 year and 5 years after surgery for physical examination to evaluate for recurrences and complications. Forty-eight patients were excluded; 22/48 patients died during follow-up, 26/48 patients were lost to follow-up. For this study, all remaining 146 patients were invited to fill out a Body Image Questionnaire.

Table 1 Body image questionnaire consisting of a body image score (questions 1 to 5) and a cosmetic score (questions 6 to 8)

-
1. Are you less satisfied with your body since the operation?
 - 1 = no, not at all
 - 2 = a little bit
 - 3 = quite a bit
 - 4 = yes, extremely

 2. Do you think the operation has damaged your body?
 - 1 = no, not at all
 - 2 = a little bit
 - 3 = quite a bit
 - 4 = yes, extremely

 3. Do you feel less attractive as a result of your operation?
 - 1 = no, not at all
 - 2 = a little bit
 - 3 = quite a bit
 - 4 = yes, extremely

 4. Do you feel less feminine/masculine as a result of your operation?
 - 1 = no, not at all
 - 2 = a little bit
 - 3 = quite a bit
 - 4 = yes, extremely

 5. Is it difficult to look at yourself naked?
 - 1 = no, not at all
 - 2 = a little bit
 - 3 = quite a bit
 - 4 = yes, extremely

 6. On a scale from 1 to 7, how satisfied are you with your scar?
 - 1 = very unsatisfied
 - 2 = quite unsatisfied
 - 3 = a bit unsatisfied
 - 4 = not unsatisfied/not satisfied
 - 5 = a bit satisfied
 - 6 = quite satisfied
 - 7 = very satisfied

 7. On a scale from 1 to 7, how would you describe your scar?
 - 1 = revolting
 - 2 = quite revolting
 - 3 = a bit revolting
 - 4 = not revolting/not beautiful
 - 5 = a bit beautiful
 - 6 = quite beautiful
 - 7 = very beautiful

 8. Could you score your own scar on a scale from 1 to 10?
-

The Body Image Questionnaire has been used by various authors to investigate patient opinion on body image.¹⁰⁻¹² The questionnaire, displayed in Table 1, comprises a body image scale (items 1-5) and a cosmetic scale (items 6-8). For each item of the body image scale, a score of 1-4 can be awarded, thereby resulting in a total score between 5 and 20. The total cosmetic scale score ranges between 3 and 24. Higher scores represent greater body image satisfaction.

Statistical analysis

Patients who were converted from laparoscopic to open repair were analyzed according to the intention-to-treat principle. Statistical analysis was performed with SPSS 18.0 (SPSS, Chicago, IL, USA). Continuous and categorical data were compared with the Mann-Whitney and chi-square test, respectively. Correlations between Body Image Scale score and age were assessed using the Pearson coefficient. P values less than 0.05 were considered significant.

RESULTS

Of the total group of 194 patients randomized between open or laparoscopic incisional hernia repair, 22 patients died and 26 patients were lost to follow-up. None of the mortalities were related to hernia repair. Of the remaining 146 patients, 123 patients responded to our invitation to fill out a Body Image and Cosmesis questionnaire (response rate 84%) after a follow-up period of 66 months (range 20-116), with no differences between open and laparoscopic repair. There was no difference in response between the open (n=63) and laparoscopic (n=60) repair groups. The open repair group consisted of 35 males and 28 females with a mean age of 62 years; the laparoscopic group consisted of 37 males and 23 females with a mean age of 64 years. Both groups were also comparable in terms of BMI, primary or recurrent incisional hernia, hernia size, wound complications and recurrence rate (Table 2).

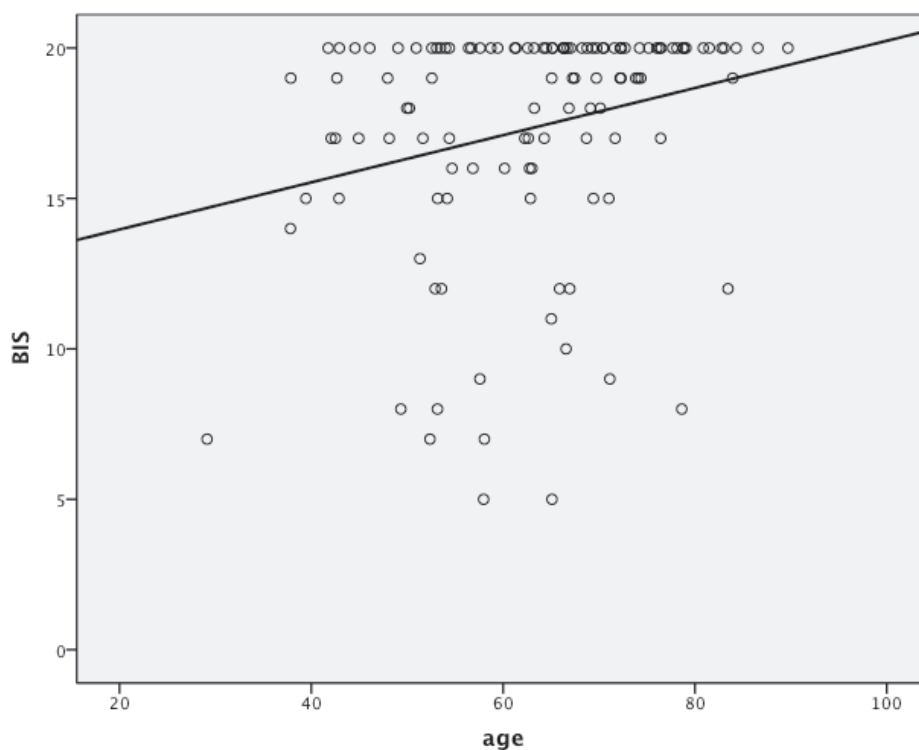
BIS scores were comparable for open and laparoscopic repair (mean scores 17.1 versus 17.6, $p=0.48$). Likewise, CS scores were comparable for open and laparoscopic repair (mean scores 15.6 versus 16.1, $p=0.59$, Table 3). A significant positive correlation was found between the BIS and CS ($p<0.001$). The BIS score was positively correlated with the age of the study population ($p=0.007$), but not with CS score ($p=0.132$). (Figure 1) No correlations were found between BIS or CS scores and gender ($p=0.866$ and $p=0.696$, respectively), primary or recurrent hernia ($p=0.945$ and $p=0.710$, respectively), hernia size ($p=0.837$ and $p=0.512$, respectively), hernia recurrence ($p=0.152$ and $p=0.470$, respectively), wound infection ($p=0.634$ and $p=0.870$, respectively), or length of follow-up ($p=0.078$ and $p=0.132$, respectively).

Table 2. Patient characteristics for the open and laparoscopic repair groups

	Open repair (n=63)	Laparoscopic repair (n=60)	P value
Male – no. (%)	35 (56)	37 (62)	0.58
Age, years – mean (SD)	62.4 (12.0)	64.4 (12.6)	0.50
Pre-operative Body Mass Index (kg/m ²)	29.8 (4.7)	28.4 (5.4)	0.14
Primary incisional hernia – no (%)	48 (76)	43 (72)	0.68
Recurrent incisional hernia – no (%)	15 (24)	17 (28)	
Hernia diameter, cm – mean (SD)	6.8 (3.5)	6.0 (2.9)	0.14
Recurrence (%)	16 (25)	15 (25)	1.00
Wound infection (%)	3 (5)	3 (5)	0.25

Table 3. Body Image and Cosmetic Scales scores for the open and laparoscopic repair groups.

	Open repair (mean, SD)		Laparoscopic repair (mean, SD)		p-value
Body Image Scale	17.1	(4.0)	17.6	(3.8)	0.48
Cosmetic Scale	15.6	(4.6)	16.1	(5.3)	0.59

**Figure 1.** Correlation between BIS (Body Image Scale) and Age.

DISCUSSION

This study is the first to show that patients who were randomised between laparoscopic and open incisional hernia repair had comparable body image scores. Besides, body image scores were relatively high for both the open and laparoscopic repair at mean scores of 17.1 and 17.6, respectively, with regard to the maximum score of 20. Both groups were comparable in terms of age and sex. No correlations were found between recurrences and wound infections and body image scores. These latter factors might have influenced body image and recurrences, but the numbers were too small to demonstrate statistical significance.

In two aforementioned studies, laparoscopic surgery was associated with better cosmesis than open surgery.^{10,12} In one study on cosmetic results after donor nephrectomy, no statistically significant difference was found for cosmetic results between patients who had undergone open or laparoscopic surgery.¹¹ Likewise, several authors found no significant differences in body image scores between laparoscopic vs. open ileal pouch-anal anastomosis; laparoscopic vs. open appendectomy; laparoscopic vs. single-incision cholecystectomy.¹⁷⁻¹⁹ Of course, the common denominator of the latter studies is the relatively small scar size used in open repair.

In laparoscopic incisional hernia repair, primary surgery's scar(s) remain in place. Moreover, additional scars are created due to trocar placement and transfascial sutures. In open incisional hernia repair scars are reentered and the appearance of the scar remains relatively unchanged after healing. Comparing these two methods, one might expect worse body image from patients who undergo laparoscopic hernia repair since additional scars are created during surgery. No statistical differences were found, however.

In view of frequently chosen primary endpoints such as recurrence, pain, costs and complications, relatively little attention has been paid to cosmesis as a study end point.²⁰ As in our study, no data are available for 'improvement in body image', i.e., patient body image after surgery compared to body image prior to surgery. It is noteworthy however, that the majority of patients reported high body image scores and satisfactory cosmetic scores, comparable to cosmetic scores associated with open appendectomy or single-incision cholecystectomy.^{18,19} This indicates that other aspects than cosmesis, such as surgeon experience and patient comorbidity, should determine the choice between laparoscopic and open surgical technique in incisional hernia repair.

CONCLUSIONS

Body image scores of patients are comparable after laparoscopic or open incisional hernia repair at a mean follow-up of 66 months. Body image scores are significantly correlated to age. Older patients are more satisfied with their Body image. In general, patients report high body image scale scores after both types of repair.

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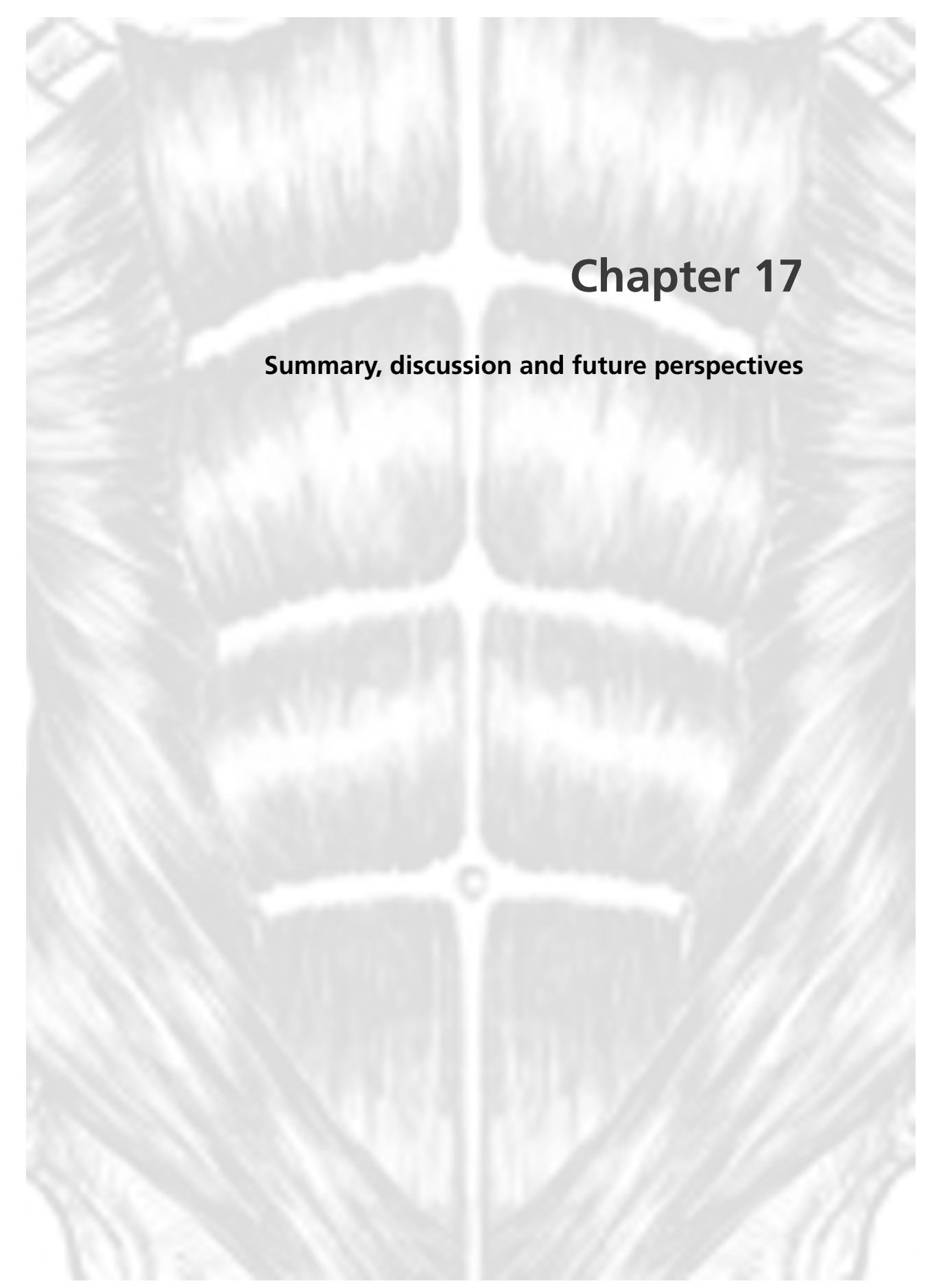
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Chapter 17

Summary, discussion and future perspectives

SUMMARY AND CONCLUSIONS

Part 1 Incidence and risk factors

The incidence of incisional hernia and the effect on health related quality of life in a prospective cohort study of 1000 consecutive patients in an academic center was investigated in **Chapter 2**. Approximately 20% of the cohort developed an incisional hernia during follow-up. The occurrence of incisional hernia had a significant negative correlation with health related quality of life and body image. In contrast with previous reports a high proportion of the patients with incisional hernia, 84% were symptomatic.¹⁻² The search for independent risk factors for incisional hernia in multivariate analyses resulted in male gender, chronic pulmonary disease, body mass index, and surgical site infection as risk factors. Male gender as an independent risk factor was reported earlier by other authors, but could not be confirmed by other publications.²⁻⁴ The negative effect of a BMI >30 that we have found in our study was reported previously by several other authors.⁵⁻⁷ Velkovic et al, reported the cut-off point for BMI as a risk factor even lower to be >24.4.⁸

Wound-related and incision-related complications such as surgical site infections and incisional hernias are common after liver transplantation and imply considerable morbidity and even mortality.⁹⁻¹⁵

In **Chapter 3** we investigated the effect of a modified incision type for liver transplantation with regard to the occurrence of incisional hernia retrospectively. Mercedes-type incisions lead to significantly more in-hospital wound related complications. In comparison with the classical Mercedes-type incision, modified J-shaped right subcostal incisions lead to significantly less incisional hernias. Two mechanism that could explain this finding are a reduced wound length and the fact that the avascular linea alba is not crossed with the J-shaped incision.

Chapter 4 reports on the modified J-shaped incision that is investigated in a prospective cohort study. Risk factors for the occurrence of incisional hernia in this specific group of patients were analyzed. Despite promising results of J-shaped incision that we had found in our retrospective study, the incidence of incisional hernia from the prospective data was surprisingly high. Compared to the 7% that we had found in the retrospective cohort, the hernia rate in the prospective cohort was as high as 43%. Explanations for this difference in incidence rates could be found in difference in length of follow-up, difference in number of patients and higher risk of bias in retrospective analyses. Also in this cohort the occurrence of incisional hernia had a significant negative impact in health related quality of life.

Part 2 Classification and repair

To make comparison of current literature on hernia possible, it is mandatory to classify incisional and primary ventral hernias first. In the last decades several authors have already published proposals for classifications, but none of them became widely used for different reasons.¹⁶⁻¹⁹ In **Chapter 5** we describe the EHS (European Hernia Society) ventral hernia classification that was initiated by Muysoms et al. From its introduction several investigators already used the classification.²⁰⁻²²

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Since the introduction of laparoscopy in the early 90's hernia surgeons more and more accepted laparoscopic hernia repair.²³ Nowadays laparoscopic incisional hernia repair is a widely used technique, and the majority of surgeons assume the general advantages of laparoscopy are also valid for this group of patients.²⁴⁻²⁶ The ongoing debate on the pro's and con's of laparoscopy prompted the need of a level one randomized clinical trial. The results of a multi-center randomized clinical trial comparing open and laparoscopic incisional hernia repair is described in **Chapter 6**. In total 206 were randomized between open and laparoscopic repair, where after 194 patients were included for analysis (100 open, 94 laparoscopic). Median blood loss during the operation was significantly less (10ml vs 50 ml; $p < 0.05$) as well as the number of patients receiving a wound drain in the laparoscopic group (3% vs 45%; $p = 0.001$). Perioperative complications and operation time, however, were significantly higher after laparoscopy (9% vs 2%) and (100 minutes vs 76 minutes; $p = 0.001$). None of the complications, however, led to re-intervention. Recurrence rates after a median follow up of 35 months were comparable after open and laparoscopic incisional hernia repair (14% vs 18%, $p = 0.30$). The relatively high recurrence rates we found in this study could possibly be explained by obligatory follow-up visits, even when patients were asymptomatic. Another explanation for the high recurrence rate in the laparoscopic group could be that some surgeons still were in their learning curve. Despite disappointing results in the short term, on the longer term, laparoscopic incisional hernia repair is an effective technique with comparable results to open repair.

Burst abdomen is a serious surgical complication after laparotomy, which often requires re-intervention. Despite the high incidence of burst abdomen, literature about the optimal treatment of burst abdomen is scarce. In **Chapter 7** we reviewed the available literature on available treatment strategies for burst abdomen. The available evidence, based on solely retrospective cohort studies, is very poor and therefore should be interpreted with caution. Nevertheless this review provides the best evidence on management strategies after burst abdomen has occurred.

Before choosing treatment strategy, distinction should be made between clean-contaminated and contaminated-dirty surgical sites. Patients' intra-abdominal pressure, as well as the size of the defect and presence of evisceration should be taken into consideration. There is a great need for randomized comparison between conservative and operative treatment of burst abdomen.

The technique for open incisional hernia repair most surgeons prefer is the modified Rives-Stoppa repair. This technique has several advantages above other open techniques when suitable for the abdominal wall defect. The mesh is positioned between the posterior fascia and rectus musculature, protecting the intra-abdominal organs from the mesh prosthesis. The rectus muscle and the anterior fascia on the other hand, protect the mesh in the unfortunate case of superficial surgical site infection. Another advantage of the technique is that the anatomy of the ventral abdominal wall is reconstructed. Besides better cosmesis reconstruction is also believed to enhance abdominal wall function.

Chapter 8 is an illustrated atlas describing the modified Rives-Stoppa technique.

Inguinal hernia is the most frequently performed general surgical procedure, which in the Netherlands only is performed over 16.000 times per year. Despite the very high volume of patients, it is still unclear whether open or laparoscopic techniques should be preferred. It is clear that the majority of surgeons prefer the Lichtenstein technique for open repair and TEP (total extra peritoneal) repair for laparoscopy. Between August 2000 and March 2004 we randomly assigned 660 patients with a primary or recurrent inguinal hernia to TEP or Lichtenstein repair. In

Chapter 9 we have reported on the outcomes of a multi-center randomized clinical trial. At long term follow-up the cumulative hernia recurrence was comparable for TEP and Lichtenstein repair (4.9% vs 8.1%; $p=0.10$). Experience level of the operating surgeon was significantly influencing recurrence rates, after both Lichtenstein and TEP repair ($p=0.001$). When only TEP procedures were analyzed, the differences in hernia recurrence rates between experienced residents or surgeons and inexperienced residents or surgeons were more obvious (0.5% vs 25.0%; $p=0.001$). When all operations performed by experienced surgeons were analyzed TEP repair resulted in significantly better results in terms of recurrences (0.5% vs 4.2%; $p=0.04$). Also results on chronic postoperative inguinal pain after five years of follow-up were in favour of TEP repair (14.9% vs 28%, $p=0.004$). Patients that underwent TEP repair were more satisfied with the surgical procedure and their operative scars ($p=0.004$ and $p=0.02$). Therefore, TEP repair should be recommended in experienced hands.

For decades the treatment strategy for patients with an umbilical hernia and liver cirrhosis has been expectative. Surgical treatment was only indicated in case of hernia related complications, e.g. incarceration, necrosis of overlying skin or evisceration.²⁷⁻²⁹ In more recent retrospective cohort studies there was some indication for superiority of primary surgical repair over a “wait and see” approach.³⁰ In **Chapter 10** we reported on the first prospective cohort study on elective umbilical hernia repair in the presence of cirrhosis and ascites. All hernias in this cohort were operated under general anesthesia and with an open technique. Notwithstanding the presence of ascites in 33% of patients prosthetic mesh was used. None of the meshes that were placed, however, led to mesh related wound complications. Only 7% of the cohort developed complications postoperatively which could be treated medicamentously. During follow-up two patients from the cohort died, none of the deaths were related to the umbilical hernia repair. In contrast with results of retrospective studies that discouraged surgeons to perform hernia repair for decades, our results show that elective repair of umbilical hernia in a controlled setting is a safe strategy.

Part 3 Quality of life and physical functioning

Recurrence, morbidity and costs are classically described as primary outcomes after both incisional and inguinal hernia repair. Patient satisfaction, however, may not always be equally corresponding to good practice. An important outcome of hernia repair should therefore be represented by improvement of patient well-being, evaluated by health related quality of life questionnaires.³¹⁻³⁴ In **Chapter 11** a randomized evaluation of health related quality of life after open and laparoscopic incisional hernia repair is described. On the short term significantly better results on quality of life (QoL) were found in favour of open repair in two of eight different domains of the SF36 questionnaire. On the longer term no differences could be measured between the two groups. A possible explanation for the difference could be that patients undergoing laparoscopic repair remained to have their old scar and got at least three new ones. The overall quality of life scores in both groups were relatively high, which also corresponds with earlier literature.³⁵

A randomized clinical trial comparing QoL between TEP and Lichtenstein repair for inguinal hernia is presented in **Chapter 12**. On the short term QoL was significantly better after TEP repair in all physical dimensions. The high levels of postoperative pain after Lichtenstein repair and the very strong correlation of pain with all dimensions of the SF36 questionnaire could possibly explain for this significant difference. On the long term no differences could be found between TEP and Lichtenstein repair. As stated before, in selected patients and in experienced hands TEP inguinal hernia repair should be preferred.

In **Chapter 13** we investigated the risk of developing an incisional hernia after enduring burst abdomen and the effect of incisional hernia on QoL and body image. A very high percentage of patients with burst abdomen developed a clinically significant incisional hernia during follow-up (83%). As we found earlier in our prospective cohort study, a great part of these hernias were symptomatic (57%). Patient with burst abdomen reported significantly worse results on the physical dimensions of the SF36 QoL questionnaire compared to control patients. Also cosmetic results and the body image that patients experienced were disappointing.

Several authors have stated that laparoscopic hernia surgery leads to better cosmetic results compared to open repair. However, none of these previous statements were supported by data and were based on expert opinion.²⁴⁻²⁶ Dunker et al developed the Body Image Questionnaire (BIQ), which measures patients' body image and satisfaction on cosmetic results.³⁶ In **Chapter 14** a randomized comparison of body image and cosmetic results is reported between laparoscopic and open incisional hernia repair. The body image score (BIS) and the cosmetic score (CS) were both found to be comparable for laparoscopic and open repair ($p=0.48$ and $p=0.59$). The BIS was correlated positively to age, which means that the older the patients were, the less inconvenience they had as a result of the operation. In general, patients reported high BIS scores after both types of repair.

Abdominal surgery causes interruption of the abdominal wall integrity temporarily. When closure of the abdominal wall fails, disruption gets permanent and incisional hernia occurs, compromising abdominal wall function. Abdominal wall reconstruction could result in functional recovery. In **Chapter 15** measurement of trunk flexor muscles are assessed between healthy volunteers and patients that underwent incisional hernia repair. The Biodex® dynamometer was used to measure isokinetic strength of the trunk flexors. The mean torque/weight (N m/kg) for trunk flexion was significantly higher in the control group than in the total patient group after incisional hernia repair (202.4 vs. 84.4, $P<0.01$).

In **Chapter 16** ultrasound measurements of the transverse rectus muscles and exercises with conventional abdominal muscle trainers were added to the Biodex® measurements. Comparison of trunk flexor muscles with the Biodex® after either laparoscopic or open repair, showed a trend in favour of the open group after adjusting for gender. Measurements by conventional abdominal muscle trainers could not confirm the difference between operative groups. Regeneration of the transverse rectus muscle was significantly better after open repair; muscle thickness difference between rest and contraction was significantly higher ($p=0.02$). The differences found between

open and laparoscopic incisional hernia repair might be the result of improved anatomical reduction hernial defects, resulting in better abdominal wall functioning.

DISCUSSION AND FUTURE PERSPECTIVES

Abdominal wall surgery should be a new subspecialty of general surgery and should be performed by dedicated surgeons. Not only incisional hernia repair should be operated on by dedicated surgeons, also closure of the abdominal wall should be. In the future, patients at high risk for developing incisional hernia will receive additional measures as hernia prophylaxis.³⁷⁻⁴⁰ Although the best techniques for open and laparoscopic hernia repair are getting more clear, in selected cases the presentation, location and size might possibly change the operative technique.

Several milestones have already been reached in the last decades. The use of mesh prosthesis and the concept of tension free repair have been true milestones in the era of hernia surgery.⁴¹⁻⁴² These gold standards, however, might not apply for all patients with incisional or other ventral hernias. Some indications will necessitate other treatment strategies.

Several meta-analyses on optimal closure techniques for abdominal wall have been published.⁴³⁻⁴⁴ Hence, since the publication of the meta-analyses, more recent literature has become available with high levels of evidence providing additional insights, e.g. suture-length-wound-length ratio 1:4, or Triclosan coated suture materials which seem to be associated with further reduction of surgical site infections and incisional hernia rates.⁴⁵⁻⁴⁶ The incidence rates of incisional hernia have remained at unacceptably high levels. There is some evidence that dedicated closure with high suture-length-wound-length ratios can lead to significant reduction of the incidence levels.⁴⁵ The closure techniques that have been advocated by those authors should be implemented more widely to assess feasibility and efficacy in surgical practice. Also, several modifications have been made by manufacturers to suture materials to reduce the incidence of incisional hernias and surgical site infections. One of those modifications is coating of suture materials with anti-septic agents like Triclosan. Several RCTs and even a meta-analysis have been published recently, in which Triclosan coating has shown to effectively reduce surgical site infections, and probably, reduction of incisional herniation.⁴⁶⁻⁴⁸ Another modification that is been made to suture materials is the use of less rigid to even elastic materials. In theory, elastic properties of suture material might cause less soft tissue tearing when intra-abdominal pressure rises. The evidence for efficacy of elastic materials is yet scarce, but more evidence is expected in the near future.⁴⁹

Despite optimal closure of the abdominal wall, some patients are at very high risk for developing an incisional hernia. There is strong evidence for two specific high risk patient groups. One of those patient groups includes patients with a BMI over 30.^{3,4,6} Moreover, some studies have indicate a lower BMI as cut-off point, at 27 or even 24.⁸ Nevertheless, it is obvious that BMI is strongly correlated with the risk of developing incisional hernia. The other patient group at high risk for developing abdominal wall hernia are patients with abdominal aneurysms. The incidence of incisional hernia is described to be up to 30% in prospective studies.⁵⁰⁻⁵⁷ A possible explanation is thought to be a compromised collagen metabolism which had also led to the formation of an aneurysm of the abdominal aorta. There is strong evidence that mesh enforced closure in these patient groups results in a significant decrease in the incidence of incisional hernias. The incidence of burst abdomen, however, seems to be equal whether closure is enforced or not. How to manage burst abdomen is currently still a point of debate, especially in these patient groups with high comorbidity.

Research performed on improvement of wound healing after laparotomy is surprisingly scarce. The use of stem cells for improvement of soft tissue healing in for example high risk patients could be considered more seriously. What could be implemented directly to surgical practice is maintaining anabolic condition in patients perioperatively. It seems obvious that a catabolic condition after surgery reduces regeneration and healing of soft tissue.

In the unfortunate case in which incisional hernia does occur, the choice for management depends on several aspects. The complaints of the patient, however, should be leading in making this choice. It is still thought and taught that a significant proportion of patients with incisional hernia are asymptomatic and the risk of complications in asymptomatic hernias is negligible. Nevertheless, there is already some literature showing that the majority of patients with incisional hernia do have symptoms.¹ After evaluation of the severity of symptoms, the choice for conservative or operative treatment should be made. Thereafter, the pattern of symptoms should determine the type of repair. None of the discussed hernia repair techniques is suitable for every indication for surgery.

To enable optimal hernia repair, the first requirement is of course a dedicated surgeon in a focused setting. In this respect the development of more specialized hernia centers, 'focused factories', should be encouraged by scientific societies and governments and implemented. The second prerequisite is a perfect mesh for all circumstances. Dozens of different mesh prostheses are currently available, all with different characteristics. Standardization is urgently needed. As yet this has been hindered by a lack of cooperation and coordination between scientific societies and

industry. The perfect mesh -without adhesions, shrinkage, infection, seroma, erosion and even rupture- is yet to be developed. Hence, surgeons must determine the most suitable mesh for every indication. In the most ideal scenario a mesh will be developed in the future without any negative side effects. As with regard to foreign body reaction individual patients react differently to the implantation of a mesh prosthesis, a tailor made approach by preoperative evaluation of mesh-patient interaction should also scientifically be explored.⁵⁸

One could hypothesize that specific indications for hernia repair, might change treatment strategy in terms of materials and technique. Notwithstanding the lack of evidence, the pattern of symptoms that patients experience could determine whether a hernia repair should be performed open or laparoscopic, tension-free or under tension, with or without reconstruction of the abdominal wall. When the primary indication for hernia repair is weakness of the abdominal wall muscles or trunk instability, reconstruction of the ventral abdominal wall could be considered.

Abdominal wall reconstruction results in significantly better isokinetic strength of the abdominal wall musculature. Despite the evidence is scarce, reconstruction of the abdominal wall anatomy could be considered when the indication for incisional hernia repair is lower backpain or failure of the abdominal wall musculature. Anatomical reconstruction can be performed open and laparoscopically. Chelala et al. published on the laparoscopic closure of the abdominal wall defect using non-absorbable sutures prior to fixation of a mesh with IPOM technique.⁵⁹ Even hybrid techniques have been described with primary closure of the abdominal wall defect prior to IPOM repair of the defect in the same session. Open techniques for anatomical reconstruction of the abdominal wall are described more frequently, like the original or modified Rives-Stoppa technique, or even (modified) Ramirez in larger defects of the abdominal wall.

In terms of cosmesis, open or laparoscopic incisional hernia repair does not make a great difference in the long term. When a patient has an ugly scar above the incisional hernia, one might choose for open repair to excise the old scar in the same session. Also, when the motive to choose for surgery is bulging of the abdominal wall, laparoscopy might be a bad choice, since seroma formation in the hernial sac or bulging of the mesh in the defect often occur. However, if the primary indication for surgery is pain and none of the abovementioned symptoms are present one might prefer laparoscopy.

In conclusion, important questions in abdominal wall hernia surgery remain to be answered. A concerted approach of dedicated surgical centers and experts from the mesh and suture industry must lead to quicker consistent solutions.

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Nederlandse Samenvatting

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Dankwoord

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NEDERLANDSE SAMENVATTING

Deel 1 Incidentie en risicofactoren

In **Hoofdstuk 2** wordt incidentie van littekenbreuken en het effect hiervan op gezondheidsgelateerde kwaliteit van leven beschreven van een prospectieve studie van 1000 patiënten in een academisch centrum. Ongeveer 20% van het cohort ontwikkelde gedurende de follow-up periode een littekenbreuk. Het optreden van een littekenbreuk had een significant negatieve invloed op gezondheidsgelateerde kwaliteit van leven. In tegenstelling tot eerdere literatuur ondervond tot 84% van de patiënten met een littekenbreuk hier, in meer of mindere mate, hinder van. De volgende variabelen bleken onafhankelijke risicofactoren te zijn voor het ontwikkelen van littekenbreuken: mannelijk geslacht, chronisch emfyseem, lichaamsgewicht en postoperatieve wondinfecties.

Wond- en incisie-gelateerde complicaties, zoals wondinfecties en littekenbreuken, komen veelvuldig voor na operaties aan de lever en in het specifiek na levertransplantaties. In **Hoofdstuk 3** wordt in een retrospectieve studie onderzocht of een aanpassing van de incisie in de buikwand effect zou hebben op het ontstaan van littekenbreuken. Vergeleken met de conventionele Mercedes-type incisie resulteerde de nieuwe J-type incisie tot significant minder littekenbreuken in deze retrospectieve studie.

Hoofdstuk 4 is een beschrijving van een prospectieve studie naar het optreden van littekenbreuken na een J-type incisie voor levertransplantatie. Risicofactoren voor het ontstaan van een littekenbreuk alsmede het effect van deze breuken op kwaliteit van leven werden onderzocht in deze studie. In tegenstelling tot de veelbelovende resultaten uit de eerdere retrospectieve studie met een incidentiepercentage van slechts 7%, was dit circa 43% in de prospectieve serie. Mogelijke oorzaken voor dit grote verschil kunnen worden gezocht in verschillen in follow-up periodes, verschillen in grootte van de studiecohorten en uiteraard het risico op bias bij retrospectieve studies. Ook in dit cohort werd de negatieve invloed van een littekenbreuk op kwaliteit van leven bevestigd.

Deel 2 Classificatie en correctie van buikwandbreuken

Om de uitkomsten van verschillende studies naar buikwandbreuken onderling te kunnen vergelijken is het noodzakelijk om deze buikwandbreuken goed te classificeren. In de laatste decennia zijn er reeds eerdere publicaties geweest met voorstellen voor een classificatiesysteem. Deze classificaties zijn echter om verschillende redenen niet in gebruik genomen. In **Hoofdstuk 5** wordt het classificatiesysteem van de EHS (European Hernia Society) voor primaire buikwandbreuken en littekenbreuken beschreven die breed wordt gedragen door de leden van deze internationale beroepsvereniging.

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Sinds de introductie van laparoscopische chirurgie in de vroege jaren '90 is ook laparoscopische herniacorrectie een steeds meer geaccepteerde behandelmethode. Tegenwoordig wordt een laparoscopische herniacorrectie veelvuldig verricht door herniachirurgen, onder de aanname dat de algemene voordelen van laparoscopische chirurgie ook gelden voor deze operatie. De voortdurende discussie omtrent de voor- en nadelen van open en laparoscopisch herstel van littekenbreuken heeft geleid tot een multi-center prospectief gerandomiseerd onderzoek waarin beide operatieve technieken met elkaar worden vergeleken. De resultaten van deze prospectief gerandomiseerde studie worden beschreven in **Hoofdstuk 6**. In totaal werden 206 patiënten gerandomiseerd tussen open en laparoscopische littekenbreukcorrectie, waarvan 194 patiënten werden geïncludeerd voor analyse (100 open, 94 laparoscopisch). Mediaan bloedverlies gedurende de operatie was significant minder (10 ml vs. 50 ml; $p < 0.05$) evenals de behoefte om een wond drain te plaatsen in de laparoscopische groep (3% vs. 45%; $p = 0.001$). Perioperatieve complicaties en operatieduur waren echter significant frequenter respectievelijk verlengd bij laparoscopische chirurgie (9% vs. 2%) en (100 minuten vs. 76 minuten; $p = 0.001$). Geen van deze complicaties heeft echter geleid tot een re-interventie. Recidiefpercentages waren na een mediane follow-up periode van 35 maanden vergelijkbaar voor open en laparoscopisch littekenbreukherstel (14% vs 18%, $p = 0.30$). Ondanks teleurstellende resultaten op de korte termijn blijkt laparoscopisch littekenbreukherstel op de middellange termijn een effectieve en veilige techniek te zijn, met resultaten die vergelijkbaar zijn met de open techniek.

Een acute dehiscentie (openscheuren) van de buikwand is een ernstige complicatie na een buikoperatie en noopt in de meeste gevallen tot een re-interventie. Ondanks het feit dat een dehiscentie van de buikwand vaak voorkomt, is de literatuur over de chirurgische behandeling hiervan schaars. In **Hoofdstuk 7** worden de meest recente inzichten over de chirurgische behandeling van een acute dehiscentie in een overzichtsartikel weergegeven. De beschikbare

literatuur, uitsluitend bestaand uit retrospectieve series, is zeer mager en dient derhalve met enige voorzichtigheid te worden geïnterpreteerd. Desalniettemin geeft het overzicht de beste evidence tot nu toe over de behandeling van een acute dehiscentie van de buikwand. Voordat een keuze gemaakt kan worden welke behandelstrategie geïndiceerd is, dient allereerst onderscheid gemaakt te worden tussen schone, gecontamineerde en vieze buikwonden. De intra-abdominale druk, de grootte van het defect en het al dan niet bestaan van evisceratie (uit de buik puilen) van darmen dient meegenomen te worden in die keuze. Er is grote behoefte aan prospectief gerandomiseerde studies die operatieve en conservatieve behandelstrategieën met elkaar vergelijken.

De open techniek die de voorkeur geniet van veel herniachirurgen om een littekenbreuk te herstellen is de gemodificeerde Rives-Stopppa techniek. Deze techniek heeft vele voordelen boven andere technieken wanneer de anatomie van de breuk het gebruik van deze techniek toestaat. De mesh (kunststof mat) wordt gepositioneerd tussen de achterste fascie en de rectusspier zodat deze geen contact maakt met de buikorganen. De rectusspier en de voorste fascie beschermen de mesh tegen eventuele oppervlakkige wondinfecties die de mesh mogelijk zouden kunnen infecteren. Een ander voordeel van de techniek is dat de anatomie van de voorste buikwand wordt gereconstrueerd. Naast betere cosmetische resultaten zou deze techniek ook kunnen leiden tot een betere functie van de voorste buikwand. **Hoofdstuk 8** is een geïllustreerde atlas die stapsgewijs de gemodificeerde Rives-Stopppa techniek beschrijft en illustreert.

Een liesbreukcorrectie is de vaakst uitgevoerde algemeen chirurgische ingreep, welke jaarlijks meer dan 16.000 maal wordt verricht in Nederland. Ondanks het zeer hoge aantal verrichtingen per jaar staan sommige punten omtrent liesbreukchirurgie nog ter discussie. Zo staat de discussie over het open of laparoscopisch herstel van een liesbreuk nog steeds open. Inmiddels is het zo dat de "Lichtenstein plastiek" de meeste voorkeur geniet onder de open technieken en de "TEP" procedure de meest gebruikte techniek is voor een kijkoperatie. Tussen augustus 2000 en maart 2004 werden 660 patiënten met een primaire danwel recidief liesbreuk gerandomiseerd tussen een "Lichtenstein plastiek" en een "TEP procedure". In **Hoofdstuk 9** beschrijven we de resultaten van deze prospectief gerandomiseerde studie. Gedurende lange termijn follow-up waren de cumulatieve recidiefpercentages vergelijkbaar voor de TEP en Lichtenstein plastiek (4.9% vs. 8.1%; $p=0.10$). Ervaring van de operator had een significant effect op het recidief percentage na een Lichtenstein plastiek en TEP ($p=0.001$). Wanneer de TEP procedures separaat werden geanalyseerd was het verschil in recidief percentages tussen ervaren en onervaren operators nog duidelijker (0.5% vs. 25.0%; $p=0.001$) Wanneer alle ingrepen die verricht werden door

ervaren operateurs met elkaar werden vergeleken bleek de TEP procedure tot significant minder recidieven te leiden (0.5% vs. 4.2%; $p=0.04$). Ook betreffende chronische pijn bleek de TEP procedure significant beter te scoren (14.9% vs. 28%, $p=0.004$). Patiënten die een TEP procedure hadden ondergaan waren meer tevreden over de ingreep en het operatielitteken dan patiënten die een Lichtenstein plastiek hadden ondergaan ($p=0.004$ and $p=0.02$). Derhalve verdient de TEP procedure de voorkeur in ervaren handen.

Decennia lang was de behandelstrategie voor patiënten met een navelbreuk en levercirrhose met ascites een afwachtend beleid. Chirurgische behandeling was strict geïndiceerd in geval van gerelateerde complicaties zoals incarceratie (beklemming van darmen), necrose (sterfte) van de huid of evisceratie (uitpuilen van darmen). In meer recente retrospectieve studies waren er aanwijzingen dat electief herstel van de breuk in deze patiëntengroep soms voordelen biedt. In **Hoofdstuk 10** beschrijven we het eerste prospectieve onderzoek op dit gebied. Alle patiënten in het prospectieve cohort werden geopereerd onder algehele anaesthesie. Ondanks de aanwezigheid van ascites bij alle patiënten werd bij 33% van de patiënten een kunststof mesh gebruikt bij het herstel. Geen van deze geplaatste protheses heeft gedurende de studie geleid tot mesh-gerelateerde wondproblemen. Van het cohort ontwikkelde slechts 7% postoperatieve complicaties welke allen medicamenteus konden worden behandeld. Gedurende de follow-up periode overleden er twee patiënten; geen van deze gevallen was gerelateerd aan de navelbreukcorrectie. In tegenstelling tot eerdere literatuur, waarin decennia-lang een afwachtend beleid werd gepropageerd, laten onze resultaten zien dat electieve navelbreukcorrectie in deze kwetsbare patiëntengroep een veilige ingreep is in gespecialiseerde centra.

Deel 3 Kwaliteit van leven en lichamelijk functioneren

Recidiefpercentages, morbiditeit en kosten van de behandeling zijn klassieke eindpunten van onderzoeken naar hernia chirurgie. Patiënttevredenheid staat echter niet altijd gelijk aan goede scores op deze eindpunten. Eindpunten die gerelateerd zijn aan het welbevinden van patiënten zijn daarom belangrijk om in ogenschouw te nemen. Een goede manier om dit welbevinden te objectiveren is het afnemen van kwaliteit van leven vragenlijsten. In **Hoofdstuk 11** wordt een gerandomiseerde studie beschreven die de kwaliteit van leven beschrijft na open en laparoscopisch herstel van littekenbreuken. Op de korte termijn leidde open herstel tot significant betere resultaten op twee van de acht dimensies van de SF36 kwaliteit van leven vragenlijst. Op de langere termijn werden geen verschillen gevonden tussen beide groepen. Een mogelijke verklaring voor het verschil op de korte termijn is waarschijnlijk te verklaren door een

ander verwachtingspatroon van patiënten die een laparoscopische ingreep ondergaan. De overal kwaliteit van leven was relatief hoog na beide ingrepen. Dit correleert met eerdere literatuur over dit onderwerp.

Een gerandomiseerde studie naar kwaliteit van leven na open (Lichtenstein) en endoscopische (TEP) liesbreukcorrectie wordt beschreven in **Hoofdstuk 12**. Op de korte termijn scoorden patiënten na een TEP procedure significant beter op alle fysieke dimensies van de SF36 kwaliteit van leven vragenlijst. Een mogelijke verklaring voor deze bevinding zou kunnen worden gezocht in hogere postoperatieve pijn niveaus na een Lichtenstein plastiek. Op de lange termijn konden geen verschillen meer worden aangetoond tussen beide groepen. Zoals eerder benoemd in dit hoofdstuk verdient de TEP procedure de voorkeur in ervaren handen.

In **Hoofdstuk 13** is de kans onderzocht om een littekenbreuk te ontwikkelen na dehiscentie van de buikwand en het mogelijke effect hiervan op kwaliteit van leven en “body image”. Een groot deel van de patiënten die postoperatief een dehiscentie van de buikwand hadden doorgemaakt ontwikkelde gedurende follow-up een littekenbreuk (83%). Zoals we ook eerder beschreven bleek een groot deel van deze patiënten ook daadwerkelijk klachten te ondervinden van de buikwand (57%). Patiënten met een dehiscentie van de buikwand scoorden significant slechter op de fysieke dimensies van de SF36 kwaliteit van leven vragenlijst. Ook de tevredenheid over cosmetiek en “body image” waren teleurstellend voor deze groep patiënten.

Verschillende auteurs hebben laparoscopische littekenbreukchirurgie betere cosmetische resultaten toegedicht. Geen van deze stellingen berustten echter op objectieve data maar op “expert opinion”.

Dunker et al heeft de “Body Image Questionnaire” (BIQ) ontwikkeld, welke het zelfbeeld van de patiënt en de tevredenheid over cosmetiek van de littekens objectiveert. In **Hoofdstuk 14** is het zelfbeeld van patiënten en cosmetische resultaten onderzocht in een gerandomiseerde studie na open en laparoscopische littekenbreuk chirurgie. De “body image score” (BIS) en de “cosmetic score” (CS) waren beiden vergelijkbaar voor de open en laparoscopische groep ($p=0.48$ and $p=0.59$). De BIS was positief gecorreleerd met leeftijd, wat betekent dat oudere patiënten over het algemeen beter scoorden op de vragenlijst. Over het algemeen scoorden beide patiëntgroepen redelijk hoog op de vragenlijst.

Abdominale chirurgie veroorzaakt een tijdelijke onderbreking van de integriteit van de buikwand. Wanneer na het sluiten van de buikwand de genezing verstoord raakt en er een littekenbreuk ontstaat, betekent dit vaak dat ook de buikwandfunctie verstoord raakt. Reconstructie van de buikwand zou in theorie kunnen leiden tot herstel van de buikwandfunctie. In **Hoofdstuk 15** wordt de buikwandfunctie vergeleken tussen gezonde vrijwilligers en patiënten die een littekenbreukcorrectie hebben ondergaan. De "Biodex® dynamometer" werd gebruikt om de isokinetische kracht te meten van de flexoren van de romp. Het gemiddelde "torque/weight" (N m/kg) voor de flexoren van de romp was significant beter in de controlegroep dan de groep patiënten na een littekenbreukcorrectie (202.4 vs. 84.4, $P < .01$).

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In **Hoofdstuk 16** werd echografisch onderzoek van de buikwand en onderzoek naar de buikwandfunctie met conventionele buikspier-trainapparaten toegevoegd aan het onderzoek. De buikwandfunctie, gemeten met de "Biodex® dynamometer", was na correctie voor geslacht significant beter na open littekenbreukchirurgie. Metingen met conventionele buikspiertrainers konden dit verschil niet reproduceren. Regeneratie van de buikwandmusculatuur bleek na open littekenbreuk herstel significant beter te zijn ($p=0.02$).

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Meta-Analysis of Primary Mesh Augmentation as Prophylactic Measure to Prevent Incisional Hernia.

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Gabrielle van Ramshorst. Beste paranimf, tot nu toe kruisen onze wegen zich voortdurend. Beiden ANIOS in het ErasmusMC, beiden onderzoeker binnen de REPAIR groep, beiden in opleiding in Regio 1 en werkzaam in het Rode Kruis ziekenhuis. We hebben elkaar al die tijd gesteund in goede maar vooral ook in moeilijke tijden. Daar zijn vrienden immers voor.

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PHD PORTFOLIO

Name: Drs. H.H. Eker

PhD period: 2008-2013

Erasmus MC

Promotor: Prof.dr. J.F. Lange

Department: Surgery

Co-promotor: Prof.dr. J. Jeekel

1. PhD training	Year	Workload	
		Hours	ECTS
General courses			
BROK	2008	40	
Seminars and workshops			
Masterclass laparoscopic parastomal hernia correction	2010	16	
Advanced suturing course	2011	8	
Presentations			
National conferences	2009-2012		5
International conferences	2009-2013		11
International conferences			
European Hernia Society	2009-2013		
European Association for Endoscopic Surgery	2008-2012		
European Society for Surgical Research	2008-2009		
European Surgical Association	2009		
American Surgical Association	2010		
European Hernia Symposium	2011-2013		
2. Teaching	Year	Workload	
		Hours	ECTS
Supervising 2 Master's theses	2006-2009		2
Supervising 1 'keuze-onderwijs' thesis	2009	14	
Teaching Emergency Service nurses	2009-2011	18	
Teaching of Medicine students	2008-2009	80	

CURRICULUM VITAE

Hasan Hüseyin Eker werd op 8 juli 1982 te Rotterdam geboren. In 2000 slaagde hij voor het eindexamen van het Voorbereidend Wetenschappelijk Onderwijs aan de Hugo de Groot scholengemeenschap te Rotterdam. In datzelfde jaar werd aangevangen met de studie Geneeskunde aan de Erasmus Universiteit te Rotterdam. Het doctoraalexamen werd behaald in het jaar 2004 waarna vervolgens in 2006 met succes het artsexamen werd afgerond. Na het behalen van het artsexamen werd hij werkzaam als arts niet in opleiding tot medisch specialist (ANIOS) op de afdeling heelkunde van het Erasmus Medisch Centrum te Rotterdam (Prof. Dr. J.N.M. IJzermans). Daarnaast was hij actief in de lokale politiek binnen de deelgemeente Charlois in Rotterdam. Na ongeveer anderhalf jaar klinische ervaring te hebben opgedaan werd hij aangenomen voor een promotie-onderzoek onder leiding van Prof. Dr. J.F. Lange en Prof. Dr. J. Jeekel. De onderzoekingen naar de incidentie en optimale behandeling van buikwandbreuken hebben geleid tot dit proefschrift. Sinds januari 2011 is hij in opleiding tot chirurg in het Rode Kruis Ziekenhuis te Beverwijk (Dr. H.A. Cense). De opleiding zal vanaf januari 2014 worden voortgezet in het VU Medisch Centrum (Hoofd: Prof.dr. H.J. Bonjer, Opleider: Dr. D. van der Peet).

NOTITIES

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